Baker McKenzie.

COVID-19: A Global Review of Healthcare and Life Sciences Industry Issues

30 November 2020

COVID-19: A Global Review of Healthcare and Life Sciences Industry Issues

The increase in legal and regulatory measures arising out of COVID-19 is truly proportional to the growth of the pandemic itself. Although the measures affect all industries, many have special relevance to the healthcare and life sciences sectors. As some industries and services are forced to shut down, players in healthcare and life sciences ambit are pushed to work even harder.

These companies are not only encouraged to assure supplies of medicines and medical devices but also incentivized to accelerate R&D Industry peers are "sharing" IP, be it through compulsory licensing or forced collaborative manufacturing arrangements. While the pandemic has put some clinical trials in jeopardy, many jurisdictions are now passing special regulations to protect patients while ensuring that ongoing trials can continue. Many countries have adopted specific measures to broaden access to telemedicine, a trend sure to survive and continue to grow well beyond the pandemic.

In this guide, our experts from 36 jurisdictions across Asia Pacific; Europe, Middle East & Africa; Latin America; and North America provide high-level answers to these questions on market access, clinical trials, IP risks and telemedicine:

Market access

(a) How has the regulator in charge been addressing the urgent needs for medicines, medical devices and medical supplies? Has the focus been faster review and grant of marketing authorization, or exceptions to or relaxation of import / use / licensing restrictions, or any other available mechanisms?
(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?
(c) Other than impact felt for clinical trials and IP risks, what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Clinical trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?
(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?
(c) Are there any general tips and recommended solutions under the local regulatory framework?

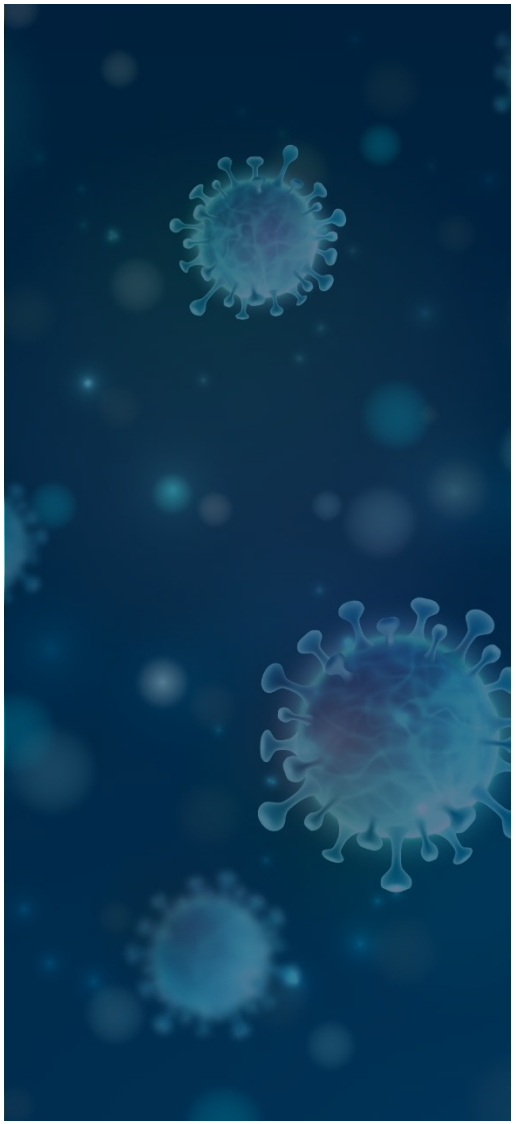
IP risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?
(b) Are there any issued or discussions on likely issuance in response to the COVID-19 outbreak in your jurisdiction?

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there interim measures or anticipated legislative changes?

In case you missed it: Our EMEA: COVID-19 Life Sciences Survey provides an overview of the measures that governments across the region have adopted in response to the outbreak. To view all our alerts and guides please visit Beyond COVID-19: Resilience, Recovery & Renewal.



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Asia Pacific

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Asia Pacific

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Click the relevant flag below for guidance on each location:

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Australia

Last updated: 26 June 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Australian regulator, the Therapeutic Goods Administration (TGA), has put in place emergency procedures to allow for:

- expedited approvals for all medical devices associated with the detection, prevention and treatment of COVID-19;
- a relaxation from the requirement to obtain marketing approval for COVID-19 diagnostic test kits imported by, supplied to or used by accredited pathology laboratories;
- a relaxation in requirements to obtain marketing approval for certain other medical devices such as face masks, disposable gowns and protective eyewear that are supplied under a contract with the Australian Government for the purposes of the national stockpile;
- a relaxation of requirements (relating to marketing approval and other technical requirements), for ventilators manufactured in Australia in accordance with minimum technical requirements prescribed by the TGA, provided that such ventilators are only supplied to Australian hospitals; and
- manufacture and supply of hand sanitisers.

The TGA is also closely monitoring the impact of the COVID-19 crisis on medicine supplies to Australian consumers, and liaising with Australian medicine sponsors, wholesalers and pharmacists. As of 6 March 2020, the TGA has not received any notifications of medicine shortages in Australia that are a direct result of COVID-19. There have been temporary local-level disruptions to supply for some medicines driven by increased demand through excessive purchasing (panic buying and stockpiling) which are currently being controlled by limits on dispensing and sales of certain high-demand medicines in community pharmacies, however, widespread national-level medicine shortages due to COVID-19 are not currently anticipated. The TGA is also part of an active international network of regulators who are meeting regularly to assess medicine shortages, with a focus on availability of medicines associated with COVID-19. In order to facilitate batch release of biological medicines and biosimilars during the COVID-19 pandemic, the TGA (temporarily) no longer requires physical samples for batch release until further notice. This only applies to biological medicines and biosimilars that are currently on batch release. This requirement will be reassessed in June 2020.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The TGA's emergency procedures create opportunities in relation to regulatory approvals for the manufacture, importation and supply of products relating to the detection, prevention and treatment of COVID-19.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

At the time of writing, the TGA is not experiencing any reported challenges or delays in processing regulatory approvals (or other business as usual processing) due to COVID-19. However, there may be some disruption to the procedures for obtaining GMP clearances associated with regulatory approvals. At the time of writing, the TGA has adopted a flexible approach to conducting domestic GMP inspections and audits - depending on risk assessment some inspections/audits may be conducted remotely/virtually or in a hybrid manner (partly virtual and partly onsite in a controlled virtual manner). However, full domestic onsite inspections will continue on sites that are considered higher risk. The TGA has put in place new arrangements to allow for remote GMP inspections of overseas manufacturers as well recognising that there will still be challenges involved and the same number of manufacturers cannot be inspected with this approach. Whilst not related to regulatory approvals, the Australian Government has imposed temporary export bans on disposable face masks, disposable gloves, disposable gowns, goggles, glasses and eye visors, alcohol wipes and hand sanitiser subject to limited exceptions.

Australia

Last updated: 26 June 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

Travel restrictions and social distancing measures have affected the conduct and management of clinical trials in various ways:

- Sponsors and investigators are encouraged to use remote technologies where possible to manage clinical trials eg. to conduct remote site monitoring visits, investigator meetings, and consultations with trial participants.
- Trial participants have been impacted due to travel restrictions and border closures which have prevented some from travelling to trial sites to receive treatment and monitoring.

Decisions to recruit new participants onto ongoing trials are now taking into account these factors, and weighing up the potential benefits and burdens on Australia's health systems and resources.

In considering new research and clinical trials, researchers, reviewers and institutions are also considering the impact of the proposed research and trials on institutional resources (including clinic and hospital capacity and availability of supporting services).

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The TGA will consider any clinical trials that relate to treatment or a vaccine for COVID-19 as a priority. Researchers are advised to consult their institutions and their State or Territory health departments for more information on expedited review processes.

The TGA has relaxed certain notification requirements in respect of some variations to clinical trial arrangements as a result of COVID-19:

- Deviations from trial protocols (under the Clinical Trial Notification (CTN) scheme) related to the supply of investigational medicinal products and resulting from potential quarantine and travel restrictions or other factors that require patients to be managed remotely do not need to be notified to the TGA.
- Variations to the trial, such as trial start/finish date change, change in PI, number of participants or the name of the trial approving authority do not need to be notified to the TGA. However, variations to the trial such as changes to existing therapeutic goods used in the trial, addition of therapeutic goods to the trial or addition of sites and those variations that are unrelated to the COVID-19 measures will continue to require notification to the TGA.

Amendments to existing protocols that are designed to limit exposure of participants, researchers or staff to infectious agents or to change methodologies, procedures or project activities to ease the burden on participants, do not need to be approved by Human Research Ethics Committees (HRECs) before being implemented, if timing does not permit.

In addition, amendments that suspend recruitment or testing of participants, or that modify research locations or staffing and other administrative matters can be implemented as necessary. If such changes are made, they should be reported to the sponsor and to the HREC, when that becomes possible, in accordance with usual processes. If there is time for an amendment of this type to be reviewed in accordance with existing administrative amendment approval processes, that will be optimal.

Australia

Last updated: 26 June 2020

Clinical Trials

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Contingency planning between institutions, principal investigators and sponsors to address the impact of COVID-19 on ongoing clinical trials is important, including an assessment of the importance and risks associated with continuing the trial as designed or with necessary modifications. Trial sponsors and investigators are also making assessments as to the resources available for continuing trials, including research staff, clinical support staff, pharmacy support, other support staff, space, equipment, supplies, etc.

Trial participants should be informed of the importance of notifying the research team in advance of attending any trial visits if:

- they are experiencing one or more symptoms suggestive of COVID-19 infection;
- they have recently (within 14 days) returned from overseas or have been in close contact with someone who is known to have contracted COVID-19 or has symptoms suggestive of COVID-19 infection; or
- they are experiencing one or more symptoms not suggestive of COVID-19 infection, but suggestive of influenza or other infectious disease or condition.

Researchers and sponsors are exploring novel approaches to the conduct of clinical trials, such as decentralised trials (i.e. teletrials) and hybrid models in which participants can be recruited, participate remotely and data can be captured remotely via available technology so as to reduce the risk for researchers and trial participants, and to adhere to the social distancing requirements and travel restrictions.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Yes. The Australian *Patents Act 1990* (Cth) includes crown use mechanisms (as well as compulsory licensing mechanisms).

Crown use is a mechanism that allows Australian Federal, State and Territory authorities (and third parties authorized by these authorities) to access and use patented technology, or technology for which a patent application is pending, without the authorization of the rightsholder if certain conditions are met. The relevant provisions are contained in Chapter 17 of the Patents Act.

Compulsory licensing provides a similar mechanism for third party entities, including private companies. An applicant may apply to the Court to access and use a patented technology, or technology for which a patent application is pending, without the authorization of the rights holder if certain conditions are met. The relevant provisions are contained in Chapter 12 of the Patents Act.

Recent amendments to Crown Use and Compulsory Licensing

On 26 February 2020, the Crown Use and Compulsory Licensing provisions in the Patents Act were updated as part of a series of amendments in the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020 (Cth).

The amendments came into force prior to any COVID-19 response measures and are unrelated to the COVID-19 pandemic: they were part of the Australian Government's ongoing reforms of Australia's IP arrangements, including as a result of reports from the Productivity Commission in 2013 and 2016. The purpose of the amendments is to provide greater clarity, accountability and transparency to the application of the Crown Use and Compulsory Licensing mechanisms in Australia.

Nevertheless, the COVID-19 pandemic provides an unexpected trial for the updated Crown Use and Compulsory Licensing mechanisms.

Australia

Last updated: 26 June 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Criteria for Crown Use

Crown Use is where an invention is exploited for "Crown purposes", meaning the invention is exploited for the services of a relevant authority, by that authority or its authorised entities. "Services" include services that are "primarily provided or funded" by Australian Federal, State and Territory authorities. This definition is likely to cover a broad range of healthcare services.

The general criteria for Crown Use requires the Minister to consider that the relevant authority has tried for a reasonable period, without success, to obtain the rights holder's authorisation to exploit an invention on reasonable terms and the exploitation of the invention is for Crown purposes.

However, COVID-19 response measures are likely to be considered an emergency trigger for Crown Use, which have a simplified criteria as follows:

- the Minister considers that the exploitation of an invention is required for an emergency;
- the Minister approves the exploitation before the exploitation starts; and
- the invention is exploited for Crown purposes and the person is authorised before the exploitation starts.

Crown Use requires the relevant authority to:

- inform the relevant rights holder of the exploitation and provide any information about the exploitation that they require, unless it is contrary to the public interest.
- remunerate the rights holder on terms that may be agreed with the authority or determined by a Court. If determined by a Court, the remuneration must be "just and reasonable" having regard to the economic value of the exploitation of the invention and any other matter that the Court considers relevant.

The Australian Courts also have powers to order a relevant entity to cease its exploitation of an invention, if circumstances demonstrate that Crown Use is no longer necessary.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

So far, no steps have been taken in Australia pursuant to the Crown Use or Compulsory Licence mechanisms in response to the COVID-19 pandemic.

A number of healthcare and life sciences companies have announced public health licences or suspension of patent enforcement activities in relation to medicines and medical devices which are required or may assist in the treatment of COVID-19. If this trend continues it may obviate the need for the Australian Government to rely upon Crown Use exemptions to patent infringement, but it will be an area which will be closely scrutinised.

Australia

Last updated: 26 June 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

- There has been increased uptake of telehealth services as a result of the COVID-19 outbreak.
- The Australian Government is encouraging and supporting the use of telemedicine services to help reduce the risk of community transmission of COVID-19 and to provide protection for patients and health care providers.
- The Australian Government has arranged for the reimbursement of medical consultations via telemedicine under the Medicare Benefits Schedule (MBS). The new temporary MBS telehealth items are available to GPs, medical practitioners, nurse practitioners, participating midwives and allied health providers. A service may only be provided by telehealth where it is safe and clinically appropriate to do so. Providers do not need to physically be in their regular practice to provide telehealth services.
- The list of telehealth services that the Government is reimbursing has continued to expand since 13 March.
- Videoconference services are the preferred approach for substituting a face-to-face consultation. However, in response to the COVID-19 pandemic, healthcare professionals will also be able to offer audio-only services via telephone if video is not available.
- No specific equipment is required to provide reimburseable telehealth services and services can be provided through video calling apps and software such as Zoom, Skype, FaceTime, Duo, GoToMeeting and others. However, healthcare providers must ensure that their telehealth solution meets their clinical requirements and satisfies applicable laws such as privacy laws.

China

Last updated: 04 August 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Emergency approvals and temporary exemption of regulatory approval have both been part of China's response to the COVID19 pandemic.

Emergency approvals

- Medical devices.
- Emergency approvals have been available under existing regulations to allow expedited market access of medical devices if: (i) they are urgently needed for public health incidents; and (ii) there are no similar products marketed in China, or that any similar products marketed in China are insufficient to meet the particular urgent needs. Guidelines issued around the granting of conditional approvals are further set out in the Guiding Principles for Conditional Approval of Medical Devices (2019) for devices used for treating severe, life-threatening diseases for which: (i) there is no existing effective treatment; but (ii) for which existing efficacy data can demonstrate foreseeable clinical value.
- Urgent approvals have been heavily utilized in response to the COVID-19 pandemic. Urgent approvals may last from three months to one year, as determined by individual provinces. Examples include the following:
  a) In vitro testing reagents for COVID-19 virus: China has approved a total of 44 COVID-19 testing reagents.
  b) Hospital beds and isolating cabins: The Guangdong Medical Product Administration (MPA) granted conditional urgent approval for an isolating hospital bed and the Jiangsu MPA granted conditional urgent approval for an isolating cabin, both for use in preventing and controlling the spread of COVID-19. In the case of Guangdong, the approval was granted within three days from filing.
  c) Medical masks and protective clothing.
- For personal protective equipment such as masks and protective clothing, the production has stabilized in China and many provincial-level MPAs have stopped accepting applications for urgent approvals.
- Pharmaceuticals
- Under existing regulations, special approval may be granted for urgent public health need. By 5 April 2020, ten drugs received clinical trial approval for potential use in treating COVID-19 and two conditional approvals were granted.

Temporary exemption of regulatory approval

- Under the Opinions on the Urgent Importation of Unregistered Medical Devices issued by the National Medical Products Administration (NMPA) on 27 January 2020, medical devices that are in compliance with relevant standards in the US, EU and Japan can be urgently imported during the COVID-19 epidemic. Some local MPAs further expanded the permitted list to include those that comply with the relevant standards in other jurisdictions, such as Australia, Korea and Canada, and may even provide exemption to selected documentation required for import. There are thus regional differences with ease of import.
- Specifically, under the Opinion on the Importation of Protective Clothing during COVID-19 epidemic issued by the Ministry of Industry and Information Technology, subject to required documentation, protective clothing in compliance with relevant standards in the US, EU and Japan can be urgently imported during the COVID-19 epidemic. The opinion made it clear that this temporary measure will be automatically abolished after the epidemic ends.
- In line with these emergency measures, the PRC Customs also set up a "green channel" under which donated medical devices that are not registered or recorded in China can be released based on local MPA's approval..

China

Last updated: 04 August 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Expedited approval for drugs and medical devices used for COVID-19 treatment

- As noted above, for drugs and medical devices that can be used for COVID-19 treatment, such as those used for treating lung damage, respiratory failure, heart failure and systematic inflammatory response, the emergency approval mechanism has been utilized to provide market authorization or conditional authorization very quickly.
- As an example, one drug -- sivelestat sodium for injection -- received approval for use in treating acute lung damage caused by systematic inflammatory response syndrome in under 10 weeks from filing. The application was first filed on 3 January 2020. On 9 February 2020 (after the COVID-19 outbreak in Wuhan in late January 2020), the NMPA decided to adopt special approval procedures for this drug, including expedited clinical trial approval on 12 February 2020 and an on-site review of the PRC manufacturer on 20 February 2020. The drug received market authorization on 10 March 2020, a mere month after the special approval procedures were initiated.
- Traditional Chinese medicines and therapy also gained popularity amid the COVID-19 epidemic. The effectiveness of Chinese medicines in treating COVID-19 patients received official recognition and was widely publicized. Traditional Chinese therapies (e.g., acupuncture, medical massage) were also recommended for the rehabilitation and recovery of COVID-19 patients.

Medical device manufacturing permits for manufacturers in non-medical field

- COVID-19 has brought a significant increase to China's manufacturing capacity for medical protective clothing and medical masks. In particular, manufacturers that were traditionally engaged in other industry sectors (e.g., textile products, electrical appliances, etc.) were encouraged to divert some of their manufacturing capacity to produce medical protective clothing and masks in order to meet urgent public health need.
- As the product stabilized in China, some local MPAs have started to re-evaluate the urgent approvals granted for compliance with applicable quality requirements. Non-compliance may result in early termination of the urgent approvals.

Business opportunities for reusable medical hygiene supplies and associated sterilization technology

- Demand for reusable medical supplies and associated sterilization technology increased amid the COVID-19 pandemic.
- Due to supply shortages, regulatory authorities in China were actively exploring the possibility of reusing disposable medical protective clothing and glasses. On 30 January 2020, disposable protective glasses were the first to be allowed to be reused. On 13 March 2020, the NMPA announced that it had urgently started the drafting of industry standard for reusable medical protective clothing.
- Previously, the sterilization of medical protective clothing heavily relied on ethylene oxide, a process that normally takes around seven to 14 days. Sterilization through irradiation received urgent approval under the Emergency Standards for the Irradiation Sterilization of Disposable Medical Protective Clothing (Tentative), which significantly shortened to one day the time required for sterilization. Companies that provide irradiation services were quickly involved to sterilize millions of medical protective clothing.

China

Last updated: 04 August 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Due to travel restrictions and quarantine requirements, the review of regulatory approval for drugs and medical devices not related to the treatment, prevention and diagnostics of COVID-19 has been slowed down or put on hold. This is likely to be a short-term challenge anticipated to ease soon as the situation in China improves.

No export control was imposed due to concern over shortage of domestic supplies caused by COVID-19. However, China issued a number of policy documents regulating the qualifications of personal protective equipment and other COVID-19 related medical devices for export in March and April, in response to quality concerns of products exported from China.

- Under existing regulations, medical devices that are manufactured for export only do not need to be registered with the NMPA. Instead, they should comply with the requirements imposed by the country or region of destination.
- On 31 March 2020, the Ministry of Commerce (MOFCOM), the PRC General Customs and the NMPA jointly issued the Notice for Orderly Implementing Medical Device Export. Under this Notice (Notice 5 of 2020, effective from 1 April 2020), certain medical devices used for personal protection or the diagnostic and treatment of COVID-19 must be "dual-compliant" in order to be exported, which means they need to: (i) have medical device registration in China; and (ii) comply with the quality standards of the country or region of destination. The products covered under the notice include COVID-19 testing reagents, medical masks, medical protective clothing, ventilators and infrared thermometers. The PRC customs would review the products' NMPA registration certificate before releasing the shipment for export.
- Taking a further step in tightening the quality supervision of personal protective equipment, the PRC General Customs issued Order 53 on April 10, 2020, requiring quality examination of export shipments concerning medical masks, protective clothing, gloves, shoe covers, goggles etc.
- The above requirements had been partially relaxed on 25 April 2020, when the MOFCOM, the PRC General Customs and the NMPA further issued a notice to regulate the export of products for dealing with the pandemic (Notice 12 of 2020), to apply in conjunction with Notice 5 of 2020. Under Notice 12, medical supplies can now be allowed for export as long as they are compliant with either Chinese or overseas quality standards. If the latter, Customs need to check against white listed entities published by the designee of the Ministry of Commerce.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The major impacts of the COVID-19 outbreak on the management of clinical trials have been as follows:

- Dispensing of trial drugs to patient subjects and follow-on monitoring and trial management have become difficult as fewer patients are visiting hospitals due to travel restrictions, home confinement requirements, or fear of infection in crowded places such as medical institutions.
- Re-allocation of medical institution resources to COVID-19 diagnosis and treatment activities have led to the reduction and postponement of non-essential and non-COVID-19 related medical activities.
- Management of multi-center trials, especially international multi-center trials, is facing challenges as coordination between sponsors, CROs, trial sites and investigators is restricted and physical meetings are limited; disruptions to logistics systems have caused delay or cancellation of trial drug transportation.
- New clinical trials are being delayed due to difficulties in patient recruitment, temporary shortage of supports from regulatory authorities, trial sites, healthcare professionals, and challenges to other preparatory work.

China

Last updated: 04 August 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Speedy approval of COVID-19 related clinical trials

- To expedite testing, the NMPA, the Centre for Drug Evaluation (CDE) and the National Health Commission (NHC) are working together to monitor the trials of various potential treatment options for COVID-19.
- Products such as the anti-HIV drug lopinavir-ritonavir, the anti-viral drug Remdesivir, the malaria drug chloroquine, the plasma of recovered COVID-19 patients, stem cell therapies, as well as a number of traditional Chinese medicines were being tested for efficacy against COVID-19 by February 2020.
- Notably, the NMPA has given the go-ahead for the Phase I trial of a potential COVID-19 vaccine in mid-March, to be conducted by China's Academy of Military Medical Sciences and the Hong Kong-listed biotech firm CanSino Biologics to test the safety of the vaccine. By June 2020, clinical trials for six vaccines had been underway in China. However, China's success in driving down COVID-19 cases has made it harder for Chinese companies to conduct Class III trials in China and companies are now seeking cooperation in other countries for the trial.

Trial measures for "expanded medical device trials"

- On 20 March 2020, the NMPA and the NHC jointly promulgated the Administrative Measures on Expanded Medical Device Clinical Trials as an initiative to provide medical device trial access to patients in life-threatening conditions without effective treatment, and who have missed the opportunity to participate in normal trials.
- To be eligible for expanded trials, the following prerequisites, amongst others, should be met:
- Expected benefits to patients should outweigh any potential risks.
- There is proper informed consent.
- The expanded trial is conducted in the same site as the ongoing or completed trials, subject to the same use and scope.
- The patients, clinical trial sponsors and investigators can all apply for the expanded trial, subject to a four-party agreement for all involved with the trial site.

Potential flexibility in drug dispensing

- As the country is concentrating on saving lives affected by COVID-19, in order to address the difficulties of chronic disease patients in accessing treatment and to reduce the risk of infection at the hospitals, the National Healthcare Security Administration released on 2 February 2020, a notice to allow patients with chronic diseases to be given up to three months' supply of prescription drugs.
- While the policy is not for clinical trials specifically, it is expected to provide a basis to allow medical institutions to run more flexible drug dispensing schemes for clinical trial patients on a case-by-case basis in order to allow timely access to medicines.
- In February 2020, the China Forums of Clinical Research Capacity Building and Human Research Participants Protection ("CCHRPP") released a Consensus on Clinical Trial Management under First-Level Response to Major Public Health Emergency, providing guidance on clinical trial management and engaging subjects during COVID-19. The Consensus suggests that trial drugs can be dispensed through qualified courier services, provided that the process is properly documented and complies with any storage conditions required for the specific drugs. Similar guidelines were also issued by local associations, e.g., Nanjing Pharmaceutical Association, guiding member institutions on the permissibility and prerequisites for dispending trial drugs through mailing/courier services.

China

Last updated: 04 August 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

CDE guideline on clinical trial management during COVID-19 pandemic

On 14 July 2020, the Centre for Drug Evaluation (CDE) issued the Guiding Principles on the Management of Clinical Trials during COVID-19 Epidemic (For Trial Implementation), providing official guidance to clinical trial management during the special period:

- For clinical trials for drugs treating COVID-19 infections, sponsors are required to report daily to CDE the progress and safety information of the trials. Sites that are newly engaged in the trials are required to be recorded with CDE.
- For other trials, safety measures should be taken, including re-arrangement of subject visits, flexible dispensing of trial drugs and possible amendment to informed consent forms.
- Alternative measures to onsite trial monitoring and inspections are allowed, such as inspections by way of teleconference or video conference, centralized monitoring and offsite monitoring. Use of digital tools are encouraged throughout the trial process subject to safety considerations.

Encouraged use of telemedicine

On 3 February 2020, the NHC issued a notice which, among other measures to utilize information technology: (i) outlines the advantages of online hospitals and online diagnosis and treatment; (ii) encourages online consultation and monitoring of COVID-19 related cases; and (iii) promotes the online management of chronic diseases, including the delivery of medications, to reduce the risk of cross-infection during offline treatment. The notice also provides a good basis for the remote management of clinical trials, including the online monitoring of trial patients. Please also see further comments on telemedicine under Section 4 below.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Pharmaceutical companies should consider alternatives and workarounds to drug dispensing to patient subjects and follow-on management of trials, such as the following, where possible:

- Making longer term prescriptions to trial patients
- Shipping and delivering trial drugs directly to patients at home from the trial sites to allow continuous access to drugs
- Monitoring drug effects remotely by using telemedicine tools and online hospitals

In doing so, sponsors are advised to liaise with the trial sites, investigators and ethics committees (ECs) to ensure full compliance with applicable Good Clinical Practice (GCP) rules and trial protocols throughout the process. Under the China GCP, for example, the investigators should ensure that the investigative products are only used on trial subjects and that any unused investigative products should be properly collected and returned to the sponsor.

Overall, it is essential to confirm, together with trial sites, investigators and ECs, that: (a) the patients agree with any workaround and provide written consent; (b) the drugs are delivered and handled properly; (c) the proposed solution does not violate any applicable laws and ethical codes (e.g., no violation of any import/export control rules, customs regulations or applicable quarantine requirements in cross-border cases; compliance with data privacy laws and regulations); and (d) the proposed solution does not pose any risks to the health of the patients.

China

Last updated: 04 August 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Donations and associated IP concerns

- Donations of medicines and medical supplies for combating COVID-19 from foreign governments as well as overseas and domestic businesses and individuals have been received in Wuhan and other places in China.
- Large-scale donations, emergency imports and possible production of generic drugs may give rise to IP protection concerns of the products.
- One example is that a domestic company, BrightGene (Borui) Biopharmaceutical (Suzhou) Co., Ltd., announced on 11 February 2020, that it had developed a generic drug of Remdesivir, the antiviral drug patented by Gilead showing promise as a potential COVID-19 treatment. BrightGene was to "mass produce" the drug for donation to patients who need it.
- The Shanghai Stock Exchange quickly censured BrightGene, and the company released a clarification that it still needs to obtain a patent license from Gilead if it were to launch the generic drug.
- Whether donation can be a legitimate defense against patent infringement has since been hotly debated. Please see our alert here.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

Compulsory licensing – none granted thus far

- Compulsory licensing is available under the PRC Patent Law in situations such as national emergency and public health need for drugs. When faced with a state emergency such as the COVID-19 outbreak, the NMPA can seek a compulsory license from the National IP Administration for the NMPA's designated, qualified manufacturer to produce a medical product to address supply shortage. The NIPA is required to notify the patentee, who in turn may respond within 15 days of receipt of the notice. A decision to grant the compulsory license, if so decided by the NIPA following the prescribed review procedures, must state clearly the conditions of grant (including scope and duration) to control its impact on the legitimate interests of a patentee.
- It is worth noting, however, that China has so far not granted any compulsory license in response to prior public health urgencies. As the situation has greatly improved locally, the risk of compulsory licensing should be low as far as China is concerned.

Possible IP infringement in contracted manufacturing arrangements

- As China is a manufacturing hub, many local manufacturers of medical protective clothing, medical masks and devices were traditionally engaged in contracted manufacturing. A potential IP concern is whether a local manufacturers' expanded manufacturing (if any) due to urgent capacity demands and/or supply to China's domestic market and other overseas buyers (other than the principal) may infringe others' IP or exceed the licensed scope of the principal's IP rights. In such cases, liabilities can arise due to IP infringement claims, in addition to any contractual claims that may be asserted by the principals.

IP concerns associated with the use of 3D printing

- 3D printing technology was used in China's response to the COVID-19 outbreak (e.g., for customized protective masks tailored to the user's facial features, and residential cabins used to isolate patients in controlling the virus spread).
- A potential concern associated with 3D printing is whether such printing may constitute IP infringement, especially if used to produce more complicated devices that are protected by patents. As the COVID-19 outbreak is largely under control in China, this issue has not advanced as only facial masks and isolating cabins have been printed. As COVID-19 is now a global pandemic, it remains to be seen how this would develop in other countries and regions (e.g., 3D printers in Europe and the US are already starting to print ventilator parts).

China

Last updated: 04 August 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Travel restrictions and the need to reduce in-person visits during the COVID-19 pandemic have led to greater use of internet-based diagnosis and treatment. While the increase may be temporary, the associated policy incentives, especially the confirmation on healthcare insurance coverage, are likely to have long-term effects in boosting the development of internet hospitals and online pharmacies.

- Under the *Administrative Measures for Internet-based Diagnosis and Treatment (Tentative)* (2018) issued by the NHC, a medical institution can provide outpatient services for certain commonly seen diseases and chronic diseases, as well as internet-based home doctor services, using its registered medical professionals and relying on internet-based information technology. Internet-based medical services were strictly prohibited for first-time diagnosis.
- The use of internet-based diagnosis and treatment increased significantly during the COVID-19 pandemic. On 6 February 2020, the NHC issued the *Notice on Internet Diagnosis and Consultancy Services for the Prevention and Control of Epidemic* to formally encourage medical institutions to build and make good use of internet-based platforms in providing treatment for chronic diseases and mental health conditions. The notice also allowed medical institutions to provide consultancy services for patients with fever, as a means to preliminarily identify suspected cases of COVID-19 infection.
- Previously, internet-based diagnosis and treatment were generally not covered under China's public health insurance regime, making it an unpopular choice of medical services for the general public. The NHC and the National Healthcare Security Administration jointly issued on 3 March 2020, the *Guiding Opinions to Encourage "Internet plus" Healthcare Services during the Prevention and Control of the COVID-19 Epidemic*, which specify that internet-based diagnosis and treatment can be covered under China's public health insurance. The guiding opinions also confirmed insurance coverage for the use of electronic prescriptions for certain common chronic diseases (e.g., diabetes, hypertension), i.e., patients can obtain electronic prescription through a medical institution's internet-based system and fill the prescription online with the medical institution or local pharmacies.

Hong Kong

Last updated: 05 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

While there is no formal change in the marketing authorization approval process, the Department of Health's (DOH) Drug Officehas provided a "fast track" for applications involving public interest, wherein the evaluation process will be expedited as far as possible.

Whether an application can go on the priority list will be determined by the DOH at its discretion, but based on the applicant's statement as to why public interest is involved. Apart from COVID-19 related medicines, medicines for measles is an example mentioned by the DOH as a candidate for prioritized review.

Under the Anti-epidemic Fund, HKD 1 billion is earmarked for the procurement of personal protective equipment (PPE). The amount is meant to secure the much-needed supplies as fast as possible in order to meet Hong Kong's operational needs in a highly competitive international market. As long as the items meet the technical specifications and are offered at the prevailing market price, the government will make an immediate direct purchase.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

For drugs that can be used to treat or prevent COVID-19, the DOH mentioned that immediate work for approval would be possible.

For urgently needed medical supplies such as masks, the government launched the "Local Mask Production Subsidy Scheme" under the Anti-epidemic Fund, facilitating local mask production as soon as possible to help address the imminent shortage, as well as to build up reserve stock. However, as of April 2020, the quota of 20 production lines has been fully allocated. The Government estimates that, when all the 20 subsidised lines are in full production, every month they will collectively supply 34.55 million masks to the Government and supply a further 8.15 million to the local market.

Also under the Anti-epidemic Fund, the government seeks to enable technology applications in relation to mask reusability to cater to the urgent needs of the community. The total expenditure is estimated to be HKD 800 million.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

In early April 2020, the Drug Office issued a special notice that while they are maintaining the services on handling applications and cases, the processing time may be lengthened. Traders and clients are therefore advised to take note of the arrangement and prepare early for submission.

The general picture is that matters can be expedited if it is in the public interest as mentioned above; otherwise, delays should be expected.

Hong Kong

Last updated: 05 April 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

General difficulties include recruiting trial participants and managing ongoing clinical trials due to quarantine measures, and the patients' reluctance to go to the trial sites.

Researchers from overseas may need to undergo 14-day quarantine before being able to join the research work.

There is the general need to provide a safe working environment.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

There have been no special measures announced by the DOH.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Collaboration with the Hospital Authority (HA) hospitals will be important, as they make up more than 70% of all hospitals in Hong Kong. The University of Hong Kong Clinical Trials Centre has joined forces with Queen Mary Hospital, Prince of Wales Hospital, Princess Margaret Hospital and the manufacturer of remdesivir, an investigational antiviral drug, in arranging for two clinical trials aiming at the treatment of moderate to severe COVID-19 patients.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Yes, for medicines, where the local Director of Health considers that the pharmaceutical industry in Hong Kong has no or insufficient capacity to manufacture a patented medicine to meet the needs in Hong Kong, it may grant an import compulsory license under the patent concerned. The prerequisite is the declaration of extreme urgency by the chief executive, having considered it to be necessary or expedient in the public interest to do so to address any public health problem in Hong Kong.

The import compulsory license covers, among other things, the importation, putting on the market, stocking, and using of a medicine. An import compulsory license is subject to terms and conditions imposed by the Director of Health, including no exportation and specific labelling, as well as certain post-termination obligations. For medical devices and general compulsory license for patents, a declaration of extreme urgency by the chief executive is not necessary. However, the patent concerned must have been granted for at least three years and an application for a compulsory license must be made to the court, based on one or more of the specified grounds.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

No declaration of extreme urgency has been declared by the chief executive, and no compulsory license has been granted or ordered to date in response to the COVID-19 outbreak (or any of the earlier outbreaks of infectious diseases, including SARS) in Hong Kong.

Hong Kong

Last updated: 05 April 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

There is currently no specific legislation on telemedicine in Hong Kong.

The Medical Council of Hong Kong has traditionally taken a cautious approach in advising medical doctors to conduct in-person examinations before providing any telemedicine services. In its 2019 "Ethical Guidelines on Practice of Telemedicine" (Guidelines), the Medical Council re-affirmed its position by stating that it is advisable to practice telemedicine only in cases in which a prior in-person relationship exists between a doctor and a patient. The Guidelines also require that all necessary information regarding the telemedicine interaction be explained fully to the patient, including how telemedicine works, its limitations and adequacy to meet the desired standard of care, other suitable alternatives available, privacy concerns, the possibility of confidentiality breaches, protocols for contact during virtual visits, and prescribing policies. Contravention of the Guidelines may render a doctor liable to disciplinary proceedings.

In practice, HA public hospitals have provided limited medical services remotely. In response to the COVID-19 outbreak causing cancellation of most non-emergency appointments, a few public hospitals adopted in March 2020 an interim measure to provide telemedicine consultation services to selected patients. Patients who require limited internal inspections or those whose wounds can be observed externally are the targeted groups.

Two private hospitals as well as many private clinics are now offering phone or video consultations to patients and services also include getting a prescription.

The COVID-19 outbreak has reignited discussion and debate on the use of telemedicine, and a request for clarity on whether telemedicine in permitted in Hong Kong has been raised. Those who are not in support believe that telemedicine is not necessary, given the sheer number of family doctors and the convenience of medical clinics in Hong Kong. No legislative changes are anticipated for the use or provision of telemedicine services in Hong Kong.

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Indonesian Government is encouraging pharmaceutical and healthcare companies (primarily, state-owned companies) to conduct research, development and import of supplies to handle the COVID-19 outbreak. This is shown through the implementation of actions and policies relating to the handling of the pandemic situation. Given the urgency of the COVID-19 situation, many of those actions are being implemented based on unwritten policies.

However, under Presidential Decree No. 9 of 2020 ("**Presidential Decree 9**"), the President has given a mandate to the Chairman of the Task Force for the Acceleration of COVID-19 Handling, i.e., the Head of the National Disaster Mitigation Body (*Badan Nasional Penanggulangan Bencana* or "**BNPB**"), to give exemptions on import requirements. Drugs, medical devices and medical supplies related to the handling of COVID-19 are covered under Presidential Decree 9.

Medical devices

As a response to the urgent need for medical devices and personal protective equipment to help with the COVID-19 situation (e.g., medical/non-medical masks, hand sanitizers, ventilators) ("**COVID-19 Equipment**"), the government has adopted several emergency procurement measures in the form of relaxation of import requirements for COVID-19 Equipment.

Despite some uncertainty, the government has finally focused its effort on relaxing the requirements for the importation of COVID-19 Equipment through the Emergency Response Licensing scheme (*Perizinan Tanggap Darurat*), which started on 30 March. To import through this channel, an applicant must obtain the BNPB's recommendation for which it can submit a request through the Indonesian National Single Window ("**INSW**"). The user manual on the submission for this application can be accessed through INSW's official website: https://www.insw.go.id/.

The Emergency Response Licensing is reserved for import, while direct local donations to hospitals do not need any recommendation from BNPB. Private companies (such as banks) are making donations to hospitals and the government is being lenient with this practice.

Before the Emergency Response Licensing regime, the government had a special access scheme ("**SAS**") for the importation of medical devices in times of pandemics. Under this scheme, importation required a special SAS license and only government/private owned healthcare companies were able to do the importation. However, in the last few weeks, the government has implemented several new schemes to meet the growing urgency to handle the pandemic situation in Indonesia. Among other things, the government tried to implement an expedited process for obtaining product registration to import COVID-19 Equipment.

At one point, there was a discussion that the Ministry of Health ("**MOH**") would issue a special marketing authorization for COVID-19 test kits. For context, there was an attempt to import COVID-19 test kits by a government-owned company, PT Rajawali Nasional Indonesia (i.e., 500,000 units). This was dubbed as an 'expedited route'.

The government is no longer pursuing the expedited route of importing those products. The expedited route is now reserved for local medical device manufacturing applications. In other words, companies that are keen to manufacture COVID-19 related medical devices can now get product registration through this expedited process. Based on the official announcement on the MOH website, the MOH will implement a one-day-service to issue product registration for locally manufactured COVID-19 related medical devices, i.e., the MOH will issue the license one day after the documents and formal requirements are considered to have been met.

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Previously, procurement of COVID-19 Equipment through Emergency Response Licensing was not viable for private use (e.g., distributing masks for employees), as products procured from the Emergency Response Licensing must be granted to the government to help them in handling the pandemic. Now, parties that want to import COVID-19 Equipment through Emergency Response Licensing may do so on a personal need basis.

Emergency Response Licensing

Currently, there is no overarching regulation on Emergency Response Licensing. Information on the process of this special importation channel is found in publications, and it is mostly driven by policies. Nevertheless, this system finds its roots in the president's mandate under Presidential Decree 9.

The following are the parties that are allowed to apply for the BNPB recommendation:

1. central/regional governments
2. public service agencies (*badan layanan umum*)
3. foundation/non-profit institutions (*lembaga non-profit*)
4. private companies/individuals for commercial purposes
5. private companies/individuals for non-commercial purposes

In general, if they obtain the BNPB recommendation from the Emergency Response Licensing, importers could receive the following facilities:

1. exemption from import requirements (including marketing authorization)
2. relaxation of fiscal facilities (i.e., in the form of exemption from import duties, excise and/or taxes)

However, based on our discussions with the BNPB officials, it seems that fiscal facilities are only applicable for COVID19 Equipment imported for non-commercial purposes (100% granted to government/public/hospitals).

Procedures to Apply for BNPB Recommendation

Applications for importation of COVID-19 test kits and personal protective equipment for personal use can be made through the following simple steps:

1. access https://www.insw.go.id/ and choose INSW Application menu, then choose Emergency Response Licensing (*Perizinan Tanggap Darurat*)
2. choose submission of BNPB Recommendation Application
3. fill in the application form and upload required documents according to the type of applicant. - Note: Applicants may monitor the application through the BNPB Recommendation Application Tracking feature in the INSW website

Once the application is submitted, the relevant authorities will analyse the recommendation application. If the application is approved, a BNPB recommendation will be issued/announced through the INSW system.
The applicant importer only needs to submit the following required documents through INSW:

1. bill of lading (i.e., Bill of Lading Number)
2. invoice (i.e., Invoice Number)
3. packing Document (i.e., Packing Number)
4. statement letter (there is no required format but the letter should stipulate the purpose of importation)

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Uncertainty on the Import Exemptions and Procedures

Most of the regulations and the MOH Guideline set out that the exemptions and/or relaxation to import COVID-19 Equipment are applicable until 30 June 2020 (as discussed below). However, the government has yet to revoke those regulations although the deadline (i.e., 30 June 2020) has already passed. There are several things that are unclear:

1. whether a BNPB recommendation is sufficient to import COVID-19 Equipment
2. whether the procedures to import COVID-19 Equipment through the BNPB are still applicable
3. whether the exemptions and/or relaxation to import COVID-19 Equipment (as discussed below) are still applicable

We have contacted the authorities to clarify the above, but we got different responses. The BNPB official we spoke to is of the view that the procedures to import COVID-19 Equipment are still applicable. The MOH official we spoke to is not sure whether those procedures are still applicable. We are still monitoring this.

Nevertheless, the MOH officials we spoke to are of the view that starting from 1 July 2020, the MOH requires a marketing authorization to import COVID-19 Equipment (previously by obtaining a recommendation from the BNPB, the applicant could import and market the COVID-19 Equipment).

Priority for Public Purposes

Currently, the government is still prioritizing importation of COVID-19 test kits and personal protective equipment for public use. In other words, there is a possibility that BNPB may overlook applications for personal use and prioritize applications for public use/procurement.

Prioritized COVID-19 Equipment

Further, the MOH, the Ministry of Trade ("**MOT**") and the Task Force COVID-19 Handling (i.e., the BNPB) have set out lists of products that are subject to the import exemptions. Considering that BNPB holds the authority to give the final approval (i.e., recommendation), other goods that might not be listed may be exempted as well if their utility is acknowledged by BNPB.

To date, the government has enacted the following regulations and guideline, which deal with relaxation of import requirements of COVID-19 Equipment:

a) MOT Regulation No. 28 of 2020 on the Eighth Amendment to MOT Regulation No. 87 of 2015 on Provisions of Import of Certain Goods ("**MOT Regulation 28**")

Based on Article 23A of MOT Regulation 28, the following goods are exempted from surveyor report (Laporan Surveyor) and unloading port requirements.

*Note: However, a Bill of Lading (or Airway Bill) is still required. These provisions are valid until 30 June 2020. The government has yet to revoke MOT Regulation 28, therefore, arguably the exemption under MOT Regulation 28 is still applicable.

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

HS Codes	Goods
3307.49.10	disinfectant/non-disinfectant air freshener
ex.3401.30.00	papers and tissues, impregnated or coated with deodorizers or cosmetics
3401.30.00	organic surface-active products and preparations for cleaning the skin, in liquid or cream form and prepared for retail sale, whether or not containing soap
6115.10.10	stocking for varicose disease, made from synthetic fibers
ex.6210.10.19	medical protective clothing
6210.20.30 6210.30.30 6210.40.20 6210.50.20 6211.33.30 6211.39.30	chemical or radiation protective clothing

HS Codes	Goods
6211.43.10	surgical clothing
ex.6211.43.90	examination gown made from synthetic materials
6307.90.40	surgical masks
ex.6307.90.90	other masks made from non-woven material
ex.8543.70.90	infrared thermometer
9619.00.19	sanitary towels

b) MOT Regulation No. 37 of 2020 on the Second Amendment of MOT Regulation No. 118 of 2018 on Import Provisions for Used Capital Goods ("**MOT Regulation 37**")

MOT Regulation 37 has similar provisions with MOT Regulation 28. Article 43A of MOT Regulation 37 sets out certain capital goods that are exempted from import approval (*Persetujuan Impor*) and surveyor report (Laporan Surveyor) requirements. Similar to MOT Regulation 28, a Bill of Lading (or Airway Bill) is still required. These provisions are also valid until 30 June 2020. *Note: The government has yet to revoke MOT Regulation 37, therefore, arguably the exemption under MOT Regulation 28 is still applicable.

The following capital goods are exempted from import administration requirements under MOT Regulation 37:

HS Codes	Goods
9019.20.00	ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus
Ex.9020.00.00	other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

c) MOH Decree No. HK.01.07/MENKES/218/2020 ("**MOH Decree 01**")

On 30 March 2020, the MOH issued MOH Decree 01. Based on MOH Decree 01, medical devices, in vitro medical devices and household supplies that are imported to handle COVID-19 (i.e., COVID-19 Equipment) are exempted from all import requirements.

MOH Decree 01 does not elaborate on the exempted requirements. Based on our discussion with the authorities, this regulation is connected with the Emergency Response Licensing, and therefore, we assume that the exempted requirements will also refer to the exempted requirements under Emergency Response Licensing channel. The list of goods is as follows:

HS Codes	Goods
3004.90.30	antiseptics
3808.94.10	ethyl alcohol having an alcoholic strength of more than 99% by its volume
3808.94.20	others that contain a mixture of coal tar acid and alkali
3808.94.90	others
3401.30.00	organic surface-active products and preparations for cleaning the skin, in liquid or cream form and prepared for retail sale, whether or not containing soap
3821.00.10	processed culture media for the development of micro-organisms
3822.00.10	plates, sheets, films, foils and strips of plastic impregnated or coated with diagnostic or laboratory reagents
3822.00.20	cardboard, cellulose wadding and tissue from cellulose fibres impregnated or coated with diagnostic or laboratory reagents
3822.00.90	others
3926.90.99	others
4015.11.00	for surgical purposes

HS Codes	Goods
4015.19.00	others
6211.43.10	surgical clothing
6307.90.40	surgical masks
9018.31.10	disposable syringes
9018.31.90	others
9018.90.30	electronic instruments and equipment
9018.90.90	others
9019.20.00	ozone therapy apparatus, oxygen therapy, aerosol therapy, artificial respiratory or other therapeutic respiratory apparatus
9020.00.00	respiratory equipment and other gas masks, not including protective masks that are not equipped with replaceable mechanical parts or filters
9022.14.00	others, for medical, surgery or veterinary use
9027.80.30	others, operated electronically

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

d) Task Force for the Acceleration of COVID-19 Handling Letter No. B-77/KA GUGAS/PD.01.02/04/2020 on the Exemption of Import Requirements for Imported Medical Devices Through Passenger's Luggage and Shipment ("**BNPB Letter 77**")

On 16 April 2020, the BNPB has issued BNPB Letter 77. BNPB exempts certain goods that are imported to Indonesia through passengers' luggage and shipment (i.e., hand-carried) from import administration requirements (subject to certain limitations). Unlike the Emergency Response Licensing, the goods listed under BNPB Letter 77 can be hand-carried from offshore without needing any recommendation from the BNPB.

No.	Classification of Products	HS Codes	Goods	Recommended Exemption Limitation
Hand Sanitizers, Raw Materials for Hand Sanitizers and Products that Contain Disinfectant				
1.	hand sanitizers	3004.90.30	antiseptics as medicines, with certain dosages	5 litres/ 5 kilograms
2.		3808.94.10	disinfectant that contains a mixture of coal tar acid and alkali	5 litres/ 5 kilograms
3.		3808.94.20	disinfectant in a package of aerosol	5 litres/ 5 kilograms
4.		3808.94.90	other disinfectant	5 litres/ 5 kilograms
5.	disinfectant substance	3808.59.60	goods or materials to create disinfectant products	5 litres/ 5 kilograms
6.	products that contain disinfectant (ready to use)	3401.30.00	preparations for cleaning the skin, in liquid or cream form and prepared for retail sale	5 pieces
Test Kits and Laboratory Reagents				
7.	rapid test	3822.00.10	plates, sheets, films, foils and strips impregnated or coated with diagnostic reagents	50 pieces
8.		3822.00.20	cardboard, cellulose wadding and web of cellulose fibres impregnated or coated with diagnostic or laboratory reagents	50 pieces
9.	PCR test	ex. 3822.00.90	reagents for PCR analysis	50 pieces

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

No.	Classification of Products	HS Codes	Goods	Recommended Exemption Limitation
Viral Medium for Transport				
10.	viral medium for transport	3821.00.10	prepared culture media for the development of micro-organisms for swab test	500 pieces
Medical Devices				
11.	Dacron Swab	ex. 9018.90.90	other swab	100 pieces
Personal Protective Equipment				
12.	masks	6307.90.40	surgical masks made from textile materials	500 pieces/ 10 boxes
13.	mask raw materials	3926.90.99	plastic nose wire	100 pieces
14.	protective clothing	6211.43.10	protective clothing made from fabric	20 pieces
15.	gloves	4015.11.00	surgical gloves made from rubber	500 pieces/ 10 boxes

Indonesia

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

e) MOH Guideline on the Licensing Procedures of Marketing Authorization ("**MA**") of Medical Devices and PKRTs ("**MOH Guideline**")

We summarize our review on the MOH Guideline, as follows:

i. The MOH further clarifies the procedures for MA registration for medical devices and PKRTs during the COVID-19 outbreak. One of the important matters is that the MOH implements one-day-service for MA registration of COVID-19 Equipment.

ii. The MOH Guideline sets out the prioritized products that are relaxed from import and product registration requirements, as follows:

- surgical apparel (masks, personal protective equipment, medical goggles)
- liquid chemical sterilants/high level disinfectant (disinfectant)
- surgeon's gloves (sterilized gloves)
- patient examination gloves (examination gloves)
- clinical electronic thermometers (thermometers)
- ventilators
- infusion pumps
- mobile x-ray
- high flow oxygen devices
- bronchoscopy portable
- power air purifying respirators
- CPAP masks
- CPAP machinery
- ECMO (extracorporeal membrane oxygenation)
- breathing circuit for ventilator and CPAP
- neonatal incubator and incubator transport
- transport culture medium (VTM/UTM)
- microbiological specimen collection and transport devices (dacron swab)
- device/reagent/rapid kits for COVID-19 test
- antiseptics (hand sanitizers)
- resuscitation bags

iii. Chapter 3 of MOH Guideline provides clarification on the legal basis of the BNPB's authority over the import of COVID-19 Equipment until 30 June 2020.

iv. The Guideline has emphasized that the SAS mechanism is not used for the import of COVID-19 Equipment. Rather, it must be conducted through the BNPB (until 30 June 2020).

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Drugs

As a general rule, Article 106.1 of Law No. 36 of 2009 on Health ("**Health Law**") requires all pharmaceutical products (including drugs) to be equipped with a marketing authorization [1] before they can be imported and sold in Indonesia. Additionally, BPOM Regulation No 30 on Supervision of the Importation of Drugs and Food provides that each importation of drugs requires an import permit ("**SKI**") to be issued by BPOM.

In the drugs sector, Indonesia also has the SAS mechanism for importing drugs for special cases, such as to address big shortfalls in the fulfilment of medical needs as can occur during an epidemic. The importation of drugs using the above exception regime is done through the SAS mechanism does not require normal marketing authorization or SKI. However, during our previous discussion with MOH officials on SAS importation of drugs, the MOH official confirmed that currently the MOH conducts SAS through policy. Further, MOH officials confirmed that the MOH would issue a special product registration for drugs, which is only effective for a limited amount of time.

Drugs imported through SAS: (i) require special marketing authorization, (ii) cannot be supplied commercially and directly to patients [2], (iii) must be imported in a very limited amount (only can be used for the reason declared during its importation), and (iv) can only be imported through designated government owned institutions. There might be some leniency from government on point (ii) and (iv), as SAS is currently regulated based on policy of the government authorities.

The government has not issued any regulation providing details of the exact process to import types of drugs other than biological drugs and vaccine through the MOH SAS channel, leaving wide discretion for the MOH as to how to handle the various cases.

According to applicable policies, the exception regime through the SAS mechanism is currently divided between the MOH and BPOM. BPOM handles the SAS mechanism for biological and vaccine products, while the SAS mechanism for other types of drugs is handled by the MOH.

The importation of drugs through the SAS mechanism is allowed for the following purposes:

- samples for registration
- research, product development and/or science (e.g., clinical trial)
- donation
- drugs for national emergency (e.g., epidemic and disaster)
- personal use
- special therapeutic treatment

[1] Marketing authorization for drugs are issued by the national BPOM and only local pharmaceutical manufacturers are eligible to hold marketing authorizations for drugs. BPOM is a government body responsible for the monitoring of drugs in Indonesia, which is under the direct supervision of MOH.

[2] Commercial sale to physicians based on their orders for special therapeutic treatment of their patients or based on personal purchase of the patient is allowed. However, the government would most likely require the drug to be dispensed and supplied through medical institutions such as hospitals, to the extent it is possible.

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Given the current COVID-19 pandemic, (d) above should be applicable for the importation of drugs. Discussions with BPOM and the MOH are needed to get more details of the procedures for point (d).

We set out in brief below the requirements for importing drugs through the SAS mechanism (i.e., through either the MOH or BPOM) based on our previous verbal confirmation with the MOH and BPOM officials:

1. The drug must be equipped with a special marketing authorization issued by the MOH/BPOM (as relevant).
2. Direct supply of the drug to patients is prohibited.
3. Drugs imported and supplied through the SAS mechanism are prohibited to be sold commercially to the public and must only be used for the intended purpose.
4. The drug must be qualified by the authority.
5. The shelf life of the imported drug must be for a reasonable period.
6. The drug can only be imported through a designated government-owned institution.

In March 2020, the Drug and Food Supervisory Agency ("**BPOM**") issued Decree No. HK.02.02.1.2.03.20.134 of 2020 on Stipulation of Guidelines on Drugs as Measures to Combat COVID-19 ("**BPOM Decree 02**").

BPOM Decree 02 sets out two important guidelines to encounter the COVID-19 outbreak in the pharmaceutical sector:

1. Information on COVID-19 Drugs ("**BPOM COVID-19 Drugs Information**")
2. Guidelines on Public Service in the Drugs Sector During the COVID-19 Outbreak ("**BPOM Public Service Guidelines**")

BPOM COVID-19 Drugs Information

There are several main issues addressed in the BPOM COVID-19 Drugs Information:

1. It compiles the research and development of drugs used to cure COVID-19 issued by international health organizations and countries (e.g., World Health Organization).
2. It lists the drugs that are preferred/prioritized to cure COVID-19.
3. It provides an analysis of the use of each COVID-19 related drug (e.g., indication, contraindication, work mechanism (*mekanisme kerja*), dosage, warning, drug interaction (*interaksi obat*), side effects).

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/ licensing restrictions, or any other available mechanisms?

We set out below the list of preferred/prioritized drugs to cure COVID-19 under BPOM COVID-19 Drugs Information:

***Note:** other drugs that are not listed might be preferred/prioritized as well if their utility is acknowledged by BPOM.*

No.	Classification of Drugs	Prioritized Drugs
1.	antivirus	• lopinavir + ritonavir • favipiravir • remdesivir • oseltamivir
2.	antivirus drugs for emergency use	• chloroquine phosphate • hydroxychloroquine sulfate
3.	antibiotics	• azithromycin • levofloxacin • meropenem • cefotaxime
4.	non opioid analgesics	• paracetamol (acetaminophen)
5.	selective beta-2 adrenoceptor agonist	• salbutamol sulfate
6.	central nerve system drugs - benzodiazepine group	• midazolam
7.	sputum thinner	• acetylcysteine
8.	vitamin	• vitamin c • vitamin e

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

BPOM Public Service Guidelines

The following are some of the licensing procedures being expedited for COVID-19 related drugs under the BPOM Public Service Guidelines:

a) *Expedited Drugs Registration Procedure*

This table summarizes the expedited drugs registration procedures.

No.	Type of Procedures	Normal Procedures	Expedited Procedures
1.	Pre-registration	Process time: 40 working days	Process time: 6 hours
2.	Evaluation registration procedure for the new drugs and biological products	Process time: 100/120/300 working days (depending on the risk assessment)	Process time: 20 working days
3.	Evaluation registration procedure for generic drugs	Process time: 150 working days	Process time: 5 working days
4.	Required quality documents (*dokumen mutu*)	Documents evidencing the batch size with a validation process report in the commercial scale (data stability in 12 months) and the complete bioequivalence (BE) report	Documents evidencing the batch size with a pilot scale (data stability in six months), and the UDT (*Uji Disolusi Terbanding*) and bioequivalence (*BE*) commitments (depending on the risk assessment)
5.	Required clinical and non-clinical documents	Must be completely submitted	May be submitted with the usage data during the COVID-19 outbreak obtained onshore (Indonesia) or offshore (depending on the risk assessment)

b) *Expedited Procedure for the Application for a Special Access Scheme ("**SAS**") Approval*

The BPOM Public Service Guidelines provide two procedures to obtain an SAS approval depending on the purpose:

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(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

SAS approval for drugs with donation purposes

The following are the steps to apply for SAS approval through the INSW system:

- The applicant accesses https://www.insw.go.id/ and chooses INSW Application menu, then chooses Emergency Response Licensing (*Perizinan Tanggap Darurat*).
- The applicant chooses the Submission of BNPB Recommendation Application sign.
- The applicant fills in the application form and uploads the required documents according to the type of applicant.

**Note: Applicants may monitor the application through the BNPB Recommendation Application Tracking feature in the INSW system.*

The required documents under this procedure are as follows:

- application letter for the recommendation letter to the head of the National Disaster Mitigation Body (*Badan Nasional Penanggulangan Bencana or "**BNPB**"*) copied to the head of BPOM and the head of Legal, Organization and Cooperation Bureau of BNPB
- packing list
- invoice
- gift certificate
- airway bill
- certificate of analysis

The estimated timeline is eight hours after all required documents are submitted.

SAS approval for drugs with non-donation purposes

The SAS approval must be obtained through https://e-bpom.pom.go.id/. This only applies for the development of COVID-19 related drugs that will be locally produced in Indonesia.

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(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The following are the steps to apply for SAS approval through this scheme:

- The applicant logs in to its e-bpom account.
- The applicant uploads the required documents for the SAS approval.
- The applicant pays the licensing fees.
- BPOM assesses the uploaded documents.
- BPOM issues the SAS Approval two working days after the licensing fees are paid.

c) *Expedited Procedure for the Application of the Bioequivalence Trial Protocol Approval (persetujuan protokol uji bioekivalensi or ("**PPUB**"))*

The following are the steps for the application for the PPUB:

- The applicant logs in to its new-aero account.
- The applicant chooses the Application sign and then chooses the PPUB sign.
- The applicant fills in the form and uploads the required documents.
- The applicant pays the licensing fees.
- BPOM assesses the uploaded documents.
- BPOM issues the assessment report or PPUB two working days after the licensing fees are paid.

The following are the required documents for the application of the PPUB:

- administrative documents
- bioequivalence trial protocol
- informed consent form
- report on the validation method of bioanalysis
- references
- information on the batch size
- statement on the equivalence of the formula

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The following are the required documents for the application of the PPUB:

- source of active ingredients
- process of the registered drugs (*proses dengan obat yang didaftarkan*)
- SAS approval (if applicable)

The estimated timeline is two working days after all required documents are submitted.

d) *Expedited Procedure for Applications for Clinical Trial Approval (persetujuan pelaksanaan uji klinik or ("**PPUK**"))*

The following are the required steps for applications for PPUK:

- The applicant submits the required documents by email to clinicaltrial@pom.go.id.
- The applicant pays the licensing fees.
- BPOM assesses the uploaded documents.
- BPOM issues the PPUK four working days after all the required documents are uploaded.

The following are the required documents for the application for PPUK:

- clinical trial protocol
- ethical commission approval (*persetujuan komisi etik*)
- informed consent form
- investigator's brochures
- drugs quality documents (certificate of analysis, GMP certificate, lot release)
- other supporting documents

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

e) *Expedited Procedure for the Certification of Good Drugs Manufacturing Practice ("**CPOB**")*

The CPOB certification process is now conducted online. The application for the CPOB certification must be submitted through https://e-sertifikasi.pom.go.id/.

For new CPOB certification, BPOM will issue a conditional approval for pharmaceutical manufacturing companies that produce COVID-19 related drugs. The estimated timeline is seven working days after all the required documents are uploaded.

For the re-certification of CPOB certificate for COVID-19 related drugs, the estimated timeline is five working days after all the required documents are uploaded.

For new CPOB certification of manufacturing facilities of imported drugs, the estimated timeline is seven working days after all the required documents are uploaded.

f) *Expedited Procedure for the Certification of Good Drugs Distribution Practice ("**CDOB**")*

The CDOB certification process is now conducted online. The application for CDOB certification must be submitted through https://sertifikasicdob.pom.go.id.

The following are the required documents for the application for a CDOB certificate:

- pharmaceutical wholesaler license or acknowledgement as the branch of a pharmaceutical wholesaler, and business identity number (*NIB*)
- pharmacist practice license (*SIPA*)
- map and layout
- list of distributed products
- organizational structure
- list of personnel and their job descriptions
- list of tools and equipment
- quality management system documents
- self-assessment documents

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

BPOM will implement the desktop inspection (without a field inspection). The estimated timeline for the CDOB certification is seven working days after all the required documents are uploaded.

*g) Expedited Procedure of the Application of the Import Certificate (Surat Keterangan Impor or ("**SKI**"))*

The application for the SKI approval must be conducted through https://e-bpom.pom.go.id/. The estimated timeline for the issuance of the SKI through this expedited procedure is two hours after all the required documents are uploaded.

The required documents for an SKI for drugs during the COVID-19 outbreak are:

- marketing authorization number
- certificate of analysis
- invoice
- power of attorney of the importer (if the import is conducted by the proxy of the marketing authorization holder)

The required documents for an SKI for drug ingredients are:

- certificate of analysis
- CPOB/CDOB certificate of the manufacturer
- statement letter on the purpose of use/distribution
- Invoice

The required documents for an SKI for vaccines are:

- marketing authorization number
- certificate of analysis
- invoice
- power of attorney of the importer (if the import is conducted by the proxy of the marketing authorization holder)

**Note: Before the vaccine is marketed, the vaccine must be certified by BPOM. BPOM will not conduct any vaccine sampling process.*

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

h) *Import of Drugs Through Shipment and Passengers' Luggage for Personal Use*

The applicant may apply by filling in the forms available at airports, ports and post offices. The following are the required documents to import hand-carried or shipped drugs:

- ID Card
- invoice
- doctor's prescription
- power of attorney (if applicable)

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Government Sets the Maximum Tariff of Rapid Antibody Tests

One of the preliminary methods to check if a person has been infected with COVID-19 is a rapid antibody test. In addition, under COVID-19 Task Force Circular Letter No. 7 of 2020 currently, a rapid antibody or PCR (*Polymerase Chain Reaction*) test result is a requirement for anyone taking public transportation for domestic (interprovincial or intercity) and international travel in Indonesia. Although the accuracy of rapid antibody tests is questionable, the rapid antibody test is the easiest and quickest way to identify COVID-19 exposure.

Because it is easy to use, there has been high demand for rapid antibody tests. To ensure a reasonable price, on 6 July, the Directorate General of Healthcare Services ("**DGHS**") (i.e., a division under the MOH issued Circular Letter No. HK.02.02/I/2875/2020 on the maximum tariff of Rapid Antibody Tests ("**DGHS Circular Letter 02**").

DGHS Circular Letter 02 is an implementing rule of MOH Decision No. HK.01.07/MENKES/247/2020 on Guidelines on Prevention and Control of Corona Virus Diseases (COVID-19).

DGHS Circular Letter 02 sets the maximum tariff of rapid antibody tests at IDR 150,000.

The maximum tariff is applicable for all citizens who want to take a rapid antibody test. Healthcare service facilities or any parties that provide rapid antibody tests must comply with the maximum tariff requirement.

There is no written sanction for noncompliance with DGHS Circular Letter 02. However, based on the recent public comment made by the Coordinating Minister for Human Development and Cultural Affairs (*Menteri Koordinator Bidang Pengembangan Manusia dan Kebudayaan*) on DGHS Circular Letter 02, the government is keen to ensure that hospitals that charge more than IDR 150,000 for rapid antibody tests will receive a severe sanction. The sanction could be a verbal warning, a reprimand or a stricter form of sanction.

Although the statement was issued by another ministry, given the subject matter, this would fall within the MOH's jurisdiction and enforcement should be mainly coming from its DGHS division.

It remains to be seen how the MOH (through DGHS) will impose the sanctions, and what exactly the sanctions would be. The MOH might try to impose sanctions on hospitals or healthcare service facilities if the maximum tariff for rapid antibody tests under DGHS Circular Letter 02 is not complied with. So, hospital business actors and relevant healthcare service providers that handle COVID-19 rapid antibody tests must remain vigilant and take a conservative approach to comply with DGHS Circular Letter 2.

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Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

As we mentioned in (a) above, the Indonesian Government has taken measures in the form of relaxation of import requirements to help accelerate the procedures and requirements for handling the COVID-19 outbreak.

The Head of the Indonesian Investment Coordinating Board (BKPM) has issued Decree No. 86 of 2020 on the Facilitation of Business Licensing for Certain Business Fields Related to the Handling of the COVID-19 Outbreak ("**BKPM Decree 86**"). BKPM Decree 86 relaxes the procedures for applying for business licenses for manufacturing of medical devices and pharmaceuticals by (i) reducing and/or simplifying the licensing requirements, (ii) accelerating the licensing process and (iii) providing a special assistance service.

The aim is to induce both new investors and existing domestic companies to manufacture COVID-19 related medical devices or pharmaceutical products. We have not seen any indication that the relaxation will be realized by liberalizing foreign ownership restrictions in the medical devices and pharmaceuticals sectors.

Other than the above, BPOM recently issued the following regulations:

- BPOM Regulation 14 of 2020 on the Amendment of BPOM Regulation No. 29 of 2017 on the Supervision of Import of Drugs and Food Materials
- BPOM Regulation 15 of 2020 on the Amendment of BPOM Regulation No. 30 of 2017 on the Supervision of Import of Drugs and Food

Other than introducing the new licensing items for general products (i.e., SKI Post-Border and SKI Border), both regulations specifically provide that the procedures for the issuance of SKIs for COVID-19 related products should be expedited. This seems to be connected with the BPOM Guidelines that provide expedited licensing procedures for COVID-19 related drugs (as discussed in section 1(a) above).

Licensing and Accreditation for Health Care Facilities and Research Hospital

On 29 July 2020, the MOH issued Circular Letter No. HK.02.01/MENKES/455/2020 TAHUN 2020 on the Licensing and Accreditation of Healthcare Facilities and Determination of Research Hospitals in the Corona Virus Disease Pandemic Period (COVID-19) ("MOH Circular Letter 02"). MOH Circular Letter 02 simplifies the administration process for healthcare facilities that were hindered because of COVID-19 such as the (i) renewal and application of operational licenses of healthcare facilities, (ii) accreditation of healthcare facilities and (iii) determination of research hospitals. MOH Circular Letter 02 was issued to help overcome any hurdles and prevent any further delay in the administration process for healthcare facilities to operate.

MOH Circular Letter 02 also aims to synchronize the cooperation between institutions, the regional governments and accreditation institutions in undergoing the licensing and accreditation process for healthcare facilities during the COVID-19 period. Another aim of MOH Circular Letter 02 is to avoid the gathering of crowds when undergoing the licensing and accreditation process.

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Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

1. Licensing of Health Care Facilities

Operational licenses of healthcare facilities (i.e., hospitals, local community health centers, clinics, healthcare laboratories and blood transfusion units) that have expired and whose extension process was hindered because of COVID-19 will remain applicable until one year after the government revokes the National Disaster or Public Health Emergency COVID-19 status ("COVID-19 Status").

Healthcare facilities that applied for an operational license for the first time before or during the COVID-19 period, but whose application process was hindered because of COVID-19, will be granted an operational license valid until one year after the government revokes the COVID-19 Status.

Healthcare facilities whose extension or application process of their operational licenses was hindered because of COVID-19 will have to submit a commitment letter to operate healthcare facilities, which is a requirement to cooperate with BPJS Health, other business entities or institutions.

The commitment letters should be submitted to the central or regional government that issued or should issue the license.

2. Accreditation of Health Care Facilities

Government revokes the COVID-19 Status. The head of each healthcare facility will have to make a letter of commitment to maintain its efforts to increase the quality of health care.

Healthcare facilities that do not yet have an accreditation certificate and were undergoing the process of accreditation before or during the COVID-19 period will have to make a letter of commitment to maintain their efforts to increase their quality of health care. The commitment letter will be valid until one year after the government revokes the COVID-19 Status.

The commitment letters should be submitted to the MOH via email to may3subdit@gmail.com not later than one month after MOH Circular Letter 02 was issued. The commitment letters are a requirement for healthcare facilities (i) to cooperate with BPJS Health, other business entities or institutions and/or (ii) for the extension of healthcare facilities' operational licenses or the upgrading of hospital class.

3. Determination of Research Hospitals

Determinations of research hospitals that have already expired and were in the process of extension, but where the extension process was hindered because of COVID-19, will remain valid until one year after the government revokes the COVID-19 Status.

If a hospital was applying for determination as a research hospital for the first time before or during the COVID-19 period, but its application process was hindered because of COVID-19, the hospital will be certified to have been determined as a research hospital, This will be valid until one year after the government revokes the COVID-19 Status.

Hospitals that (i) have an expired determination as a research hospital or (ii) have applied to be determined as a research hospital, will have to make a letter of commitment to fulfill the standards of a research hospital. The commitment letter should be submitted via Google form at the following link https://forms.gle/WmjWd1feFhwy8WGK9.

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Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Previously, the MOT issued a temporary export control regulation in respect of the COVID-19 outbreak, namely MOT Regulation No. 23 of 2020 on the Temporary Ban of Export of Antiseptics, Raw Materials for Masks, Personal Protective Equipment and Masks as amended by MOT Regulation No. 31 of 2020 ("**MOT Regulation 23**").

By revoking MOT Regulation 23, the MOT recently issued MOT Regulation No. 57 of 2020 on the Provisions of Export of Raw Materials for Masks, Masks and Personal Protective Equipment ("**MOT Regulation 57**"). MOT Regulation 57 sets out that exporters may now export raw materials for masks, masks and personal protective equipment by obtaining an Export Approval (*Persetujuan Ekspor*) from the MOT.

The following are the requirements to obtain the Export Approval (*Persetujuan Ekspor*), which it must be submitted through the INSW system:

1. industrial business license (*Izin Usaha Industri*)
2. self-assessment statement letter (stating that the applicant has reserved stocks for local needs)
3. financial statements and information on the shareholding composition of the company
4. a document showing the company's export plan in six months

However, the provisions of MOT Regulation 57 are only applicable for certain goods (Annexure I of MOT Regulation 57), as follows:

HS Codes	Goods
5603.11.00	*meltblown nonwoven* textiles
5603.91.00	*meltblown nonwoven* textiles
6307.90.40	surgical masks
ex 6307.90.90	respiratory N 95 masks
ex.6210.10.19	medical protective clothing (*coverall*)
6211.43.10	surgical clothing (*surgical gown*)

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

Procurement of COVID-19 Vaccines and COVID-19 Vaccination

On 29 July 2020, the government issued Presidential Regulation No. 99 of 2020 on the Procurement of Vaccines and Vaccination of Corona Virus Disease 2019 (COVID-19) ("Presidential Regulation 99"). Presidential Regulation 99 regulates the (i) COVID-19 vaccine procurement, (ii) COVID-19 vaccination, (iii) funding of COVID-19 vaccine procurement and COVID-19 vaccination, and (iv) support and facilities provided by the ministries, institutions and regional governments.

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Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

1. **Procurement of COVID-19 Vaccines**

The procurement of COVID-19 vaccines includes (i) the supply of COVID-19 vaccines and supporting equipment, and (ii) the distribution of COVID-19 vaccines to the receiving points determined by the Minister of Health ("MOH"). The procurement of COVID-19 may be conducted as follows:

a. Appointment of a state owned company

The MOH will appoint PT Bio Farma (Persero) to do the procurement of COVID-19 vaccines. This appointment may also include participation of subsidiaries of PT Bio Farma (Persero), i.e., PT Kimia Farma Tbk and PT Indonesia Farma Tbk. In performing its duties, PT Bio Farma (Persero) may cooperate with other onshore or offshore companies/institutions, and determine the terms and conditions of the cooperation to procure the COVID-19 vaccines.

b. Direct appointment of business entities

The MOH may directly appoint a business entity for the procurement of COVID-19 vaccines. Business entities that may be appointed by the MOH are onshore or offshore business entities that fulfill the requirements set out by the MOH. The requirements include (i) a certificate of good drug manufacturing or (ii) a certificate of good drug distribution in accordance with the business line of the business entities.

c. Cooperation with international institutions/agencies

The cooperation with international institutions for the procurement of COVID-19 vaccines should be conducted with:

- the Coalition for Epidemic Preparedness Innovations (CEPI)
- the Global Alliance for Vaccines and Immunizations (GAVI), and/or
- other international institutions/agencies

The Minister of Foreign Affairs will be performing the cooperation with CEPI, and the MOH will be performing the cooperation with GAVI and/or other international institutions/agencies.

2. **Vaccination of COVID-19**

The MOH will be conducting the vaccination of COVID-19 by (i) determining the criteria and priority list of vaccine receivers, (ii) determining the priority list of areas where vaccines will be given, (iii) preparing a schedule and procedure for providing the vaccines and (iv) issuing vaccination service standards.

The MOH will cooperate with other ministries, institutions, business entities, and other bodies/agencies to obtain support for (i) medical personnel; (ii) vaccination locations, (iii) logistics/transportation, (iv) warehousing and vaccine inventory, including stock buffer/stockpiling, (v) security and/or (vi) socialization and community service. Entities that will provide warehousing and vaccine inventory support are required to have a certificate of good drug distribution. Otherwise, the warehouse and vaccine inventory has to be a pharmaceutical installation owned by the government.

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Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The MOH and the Indonesian Food and Drug Authority (Badan Pengawas Obat dan Makanan or "**BPOM**") will continue to supervise post COVID-19 vaccination conditions.

3. Pricing and Monetary Facilities

The MOH will be determining the price for COVID-19 vaccines. The pricing will consider the type of vaccine, the source of supply and the timing of the performance of the relevant contracts.

The government will grant monetary facilities such as tax and duty facilities in relation to the importation of the vaccines,supporting equipment for the production of COVID-19 vaccines and supporting equipment for vaccination.

4. Funding

The procurement of the COVID-19 vaccines and the vaccination is funded by the state budget. The government may also have capital participation in PT Bio Farma (Persero) to support the procurement of the COVID-19 vaccines and the COVID-19 vaccination.

Based on Presidential Regulation 99, the MOH will be determining the types and quantity of the COVID-19 vaccines that will be used in Indonesia. For the acceleration of the vaccination process, the MOH will (i) accelerate the licensing process and procurement of supporting equipment forCOVID-19 vaccination, including the importation licenses and formalities, (ii) issue COVID-19 vaccine service standard, and (iii) other support as necessary.

Further to the above, other ministries, institutions and other agencies will give support for the procurement of the COVID-19 vaccines and COVID-19 vaccinations, including BPOM. BPOM will give support such as (i) granting an emergency use authorization or product registrations for the COVID-19 vaccines, (ii) granting approval for COVID-19 vaccine clinical trials, (iii) issuing certificates of good manufacturing of drugs and certificates of good distribution of drugs, (iv) other necessary support. The procurement of COVID-19 vaccines and the COVID-19 vaccinations will be conducted in the years 2020, 2021 and 2022. The MOH and the COVID-19 Handling and Recovery of the National Economy Committee may extend the period for procurement of COVID-19 vaccines and vaccinations as necessary.

National Team for Acceleration of Vaccine Development for COVID-19

On 3 September 2020, the Government issued Presidential Decree No. 18 of 2020 on National Team for Acceleration of Development of a Vaccine for Corona Virus Disease 2019 (COVID-19) ("Presidential Decree 18"). The objectives of the COVID-19 Vaccine Development Team are to (i) accelerate the development of the vaccine for COVID-19, (ii)achieve national independence to develop a COVID-19 vaccine, (iii) increase synergy in research, development and implementation of knowledge and technology as well as the innovation, production, distribution and utilization of a COVID-19 vaccine between the government and knowledge and technology institutions, and (iv) conduct preparations, and increase national capacity and capability to develop a COVID-19 vaccine.

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Market Access

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The COVID-19 Vaccine Development Team consists of:

1. Steering Committee: The Steering Committee will be responsible to provide instructions to the Person in Charge and carry out supervisory functions over the development of the COVID-19 vaccine.

- The members of the Steering Committee of the COVID-19 Vaccine Development Team are:
  - Chairman: Coordinating Minister of Economy
  - Members: (i) Coordinating Minister for Human and Cultural Development and (ii)
  - Coordinating Minister for Political, Legal and Security Affairs.

2. Person in Charge: The Person in Charge is responsible for preparing a strategic program for the acceleration of the vaccine development; coordinate and control the implementation of acceleration development activities; supervise the implementation of the acceleration development activities; and prepare periodic reports for the President and the Steering Committee of the COVID-19 Vaccine Development Team. The periodic reports are to be submitted to the President and the Steering Committee of the COVID-19 Vaccine Development Team once every six months or at any time as necessary.

In carrying out its duties and functions, the Chairperson in Charge of the COVID-19 Vaccine Development Team coordinates with the Chief Executive of the COVID-19 Management Policy Committee and National Economic Recovery as regulated in Presidential Regulation regarding the 2019 Corona Virus Disease Management Committee (COVID-19) and National Economic Recovery. The coordination is conducted once every three months.

- The members of the Person in Charge of the COVID-19 Vaccine Development Team are:
  - Chairman: Minister of Research and Technology
  - Vice Chairman I: Minister of Health
  - Vice Chairman II: Minister of State-Owned Enterprise
  - Members: (i) Minister of Foreign Affairs, (ii) Minister of Industry, (iii) Minister of Trade, (iv) Minister of Education and Culture, and (v) Head of BPOM.

3. Daily Executor: The Daily Executor will be responsible for (a) implementing the vaccine development acceleration activities in accordance with the strategic program prepared by the Person in Charge, (b) preparing and implementing the operational plan to accelerate the development of COVID-19 vaccine, (c) utilizing national resources to accelerate the development of COVID-19 vaccine, (d) conducting consolidated coordination with the government and research and technology institutions for the development of the COVID-19 vaccine, and (e) reporting the implementation of the acceleration of development of a vaccine for COVID-19.

Indonesia

Last updated: 30 October 2020

Market Access

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The COVID-19 Vaccine Development Team will be funded by the state budget and other sources of funding in accordance with the applicable laws and regulations. The COVID-19 Vaccine Development Team will be performing its duties until 31 December 2021. Afterwards, the duties of the COVID-19 Vaccine Development Team will be performed by BNBP.

BPOM also issued BPOM Public Service Guidelines set out the expedited procedures to obtain approvals for clinical trials of COVID-19 related drugs i.e., PPUK and PPUB. For further details, please refer to our response in section 1 (a) above.

Further to the above, in response to the COVID-19 outbreak, MOH has issued Decision HK.01.07/MENKES/104/2020 ("**Decree 104**") on 4 February 2020, which allows the government to take precautionary actions as well as countermeasures over the impacts of COVID-19. Decree 104 promotes several actions that may help mitigate the COVID-19 outbreak such as (a) risk communication, health education for the community to mitigate the further infections in the community (b) inspections to detect and respond to any infected persons on entry gates to the territory of Indonesia, (c) healthcare facilities and supporting facilities such as laboratories and healthcare logistics to be continually available, and (d) increase coordination amongst sectors for efficacy and efficiency on handling the COVID-19 outbreak. Furthermore, Government Regulation No. 21 of 2020 on Large-Scale Social Restriction for the Acceleration of Mitigation of Corona Virus Disease 2019 (COVID-19) ("**GR 21**") provides large scale social restrictions as one of the measures to mitigate the COVID-19 outbreak.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Other than the BPOM Guideline, BPOM and MOH have yet to issue any specific regulation or announcement in relation to clinical trials. BPOM Guideline does not indicate any deadline on the implementation of expedited licensing procedures, which also cover the expedited licensing procedures (as discussed above). Therefore, we assume those expedited procedures are implemented on an on-going basis.

In May this year, BPOM has issued another guideline on the application and implementation of clinical trials during the COVID-19 pandemic. In general, this guideline further specifies the provisions in the BPOM Public Service Guidelines, particularly for clinical trials. However, there is no mandatory change on the licensing procedures for clinical trials of COVID-19 related drugs.

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Last updated: 30 October 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

We also note that Indonesia has declared its participation in WHO's program, i.e., Solidarity Trial.[1] As you may be aware, WHO is conducting a global mega trial anticipating the COVID-19 outbreak.[2]

Indonesia's pharmaceutical holding company, Bio Farma and Sinovac (a Chinese biopharmaceutical firm) have been working together to develop a vaccine of COVID-19. According to the Foreign Minister and the Minister of State-Owned Enterprises, Indonesia had secured a commitment to be sent 20 million to 30 million doses of the potential vaccine by the end of this year, some 80 million to 130 million doses in first quarter of next year and 210 million doses for the remainder of 2021. [3] The cooperation between Bio Farma and Sinovac would give Indonesia the equivalent of 50 million doses of the potential vaccine from November to March and priority access for the rest of 2021. The vaccines will be supplied in the form of vaccine bulk, an aqueous form of the purified antigens, or vaccine, provided in a large container from which individual vials are filled. Bio Farma is currently cooperating with Sinovac in the Phase III of clinical trial for the vaccine, which involves nearly 1,600 volunteers. [4] It is anticipated that the preliminary result of Phase III clinical trial can be submitted for emergency use authorization by BPOM by the first quarter of 2021. Nevertheless, currently, the Indonesian government is being supportive on the development of the vaccine.

[1] For reference, please access the following link (in Bahasa Indonesia):
https://www.liputan6.com/health/read/4216323/bersama-who-indonesia-siap-uji-4-terapi-alternatif-untuk-corona-covid-19
[2] For reference, please access the following link:
https://www.sciencemag.org/news/2020/03/who-launches-global-megatrial-four-most-promising-coronavirus-treatments
[3] For reference, please access the following link:
https://f.datasrvr.com/fr1/520/92974/JP-1-25Aug2020.pdf
[4] For reference, please access the following link:
https://www.thejakartapost.com/news/2020/07/21/sinovac-covid-19-vaccine-to-undergo-phase-iii-clinical-trials-in-bandung.html

(c) Are there any general tips and recommended solutions under the local regulatory framework?

The preferable approach is quite similar to our response for section 1 (a) above. The Health Law requires pharmaceutical products (including drugs) to have marketing authorization before they can be imported and sold in Indonesia. Further, the BPOM also requires an SKI to be issued by the BPOM for each importation of drugs. Under this COVID-19 outbreak, we believe that the SAS mechanism is applicable. Indonesia has the SAS mechanism for importing drugs for special cases, such as for personal use or to address medical needs due to an epidemic. The importation of drugs using the above exception regime is done through the SAS mechanism, which does not require normal marketing authorization or SKI.

Further, the imported drugs cannot be used for any purposes other than for the company's own use (e.g., the company cannot distribute or resell the drugs), so it is possible that the MOH will require the company to sign a letter of undertaking on the use of the imported drugs. This should be known once the Company has connected with the DGCE.

Ethicality is a highly considered issue in Indonesia. Based on our experience of how the MOH and the BPOM usually react to ethicality issues, they would most likely want to prevent the patient from using drugs (especially prescribed ones) without proper professional supervision. Further, considering the development of the COVID-19 outbreak, it is very possible that the government will want to monitor more carefully products going in to Indonesian territory.

Indonesia

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IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Article 109 of Law No 13 of 2016 on Patent ("Patent Law") stipulates that the government may implement patents in Indonesia due to urgent public needs. The term "patents" as outlined in this article covers patents related to pharmaceutical and biotechnology products that are expensive and/or needed to overcome diseases that may cause widespread mortality or significant physical impairments, and are declared as Public Health Emergency of International Concern (*Kedaruratan Kesehatan yang Meresahkan Dunia - KKMD*). The implementation of the patents by the government should, however, be confirmed by a presidential regulation.

The patent holder is entitled to receive proper remuneration as compensation from the government to implement its patent. The government will decide the amount, but if the patent holder does not agree on the amount of remuneration, the patent holder can file a civil claim to the Commercial Court to challenge the amount of remuneration.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

We have seen the government implement pharmaceutical patents for antiviral and antiretroviral for HIV and Hepatitis B treatment, such as by issuing Presidential Regulation No. 76 of 2012. As you are aware, corona has been declared as KKMD by WHO in January this year. Hence, it would be best to monitor any public discussions regarding potential implementation by the government of patents for any drugs for the COVID-19 treatment.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Currently, the MOH cooperates with famous application providers which are (i) Go-Jek; (ii) Halodoc; (iii) Grab; (iv) Good doctor to provide services in handling the COVID-19 outbreak.[1] The integration of those services is done between the transportation application service providers (i.e., Go-Jek and Grab) and telemedicine service providers (i.e., Halodoc and Good doctor). Under the integrated services, they are encouraged to provide (i) consultation services for COVID-19 handling and (ii) drug delivery services.[2]

Other than the above, MOH also cooperates with Indonesian Telemedicine Association (*Aliansi Telemedik Indonesia*) in handling for those who need guidelines, consultation and other related matters in handling COVID-19 outbreak. MOH believes that this step is sought to encourage citizens to perform self-isolation by using the applications rather than seek healthcare advice or treatments to hospitals. Given this, the cooperation is to minimize a surge in patients in hospitals, clinics, other healthcare service providers.[3]

With the above being said, those measures by MOH are in line recent enacted regulations and policies encouraging citizens to implement social distancing as GR 21 proclaiming large scale social restriction.

The BPOM recently issued Regulation No. 8 of 2020 on Supervision of Online Distributed Drugs and Food, effective as of 7 April 2020 ("**BPOM Regulation 8**").

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

The regulation covers monitoring of online distribution of the following commodities by BPOM:

1. drugs
2. traditional drugs
3. health supplements
4. cosmetics
5. processed food (i.e., including processed food for special medical needs or "**PKMK**")

("**Commodities**")

BPOM Regulation 8 is an implementing regulation of Government Regulation No. 71 of 2019 on Electronic Systems and Transaction Operation ("**GR 71**") and Government Regulation No. 80 of 2019 on Trade through Electronic Systems ("**GR 80**").

The regulation is issued ahead of its schedule, as BPOM mentioned last year that the process of finalizing the draft was still quite long. It seems that the government has accelerated the drafting process in response to the sudden spike of online buying by consumers due to thesocial distancing policies issued by the government to combat COVID-19.

Despite the above, we do not see that the regulation poses any major roadblocks for offline players (e.g., manufacturers, distributors and retailers of the Commodities).

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Notable Provisions

We set out below the notable provisions of BPOM Regulation 8:

Highlights	Description	Reference
Marketing Authorization	All Commodities that are sold through online channels must be registered at BPOM and equipped with marketing authorization. Exemption is given to (i) ready-to-serve processed food and (ii) processed foods that are used as raw materials and not directly sold to end consumers.	Articles 3, 12, 16, 20
Electronic System	Online distribution/sale of drugs can only be done through electronic systems. Pharmaceutical manufacturers and pharmaceutical wholesalers ("**PBF**") must use their own electronic system if they want to sell drugs online (i.e., branch PBFs can only use the electronic system operated by the main PBF). Although not mentioned specifically, pharmacies can also sell drugs online, by using their own electronic system or cooperating with a third party pharmacy electronic system operator ("**PSEF**"). Only pharmaceutical manufacturers, PBFs and pharmacies can sell drugs through online channels. In other words, individual resellers (including drugstores) are not permitted to sell drugs online. For context, PSEF is defined as legal entities that provide, manage and/or operate electronic systems for their own and/or other parties' purposes. The definition is very broad and covers anyone who runs or provides an electronic system for the purpose of online sale of drugs and other Commodities. Online sale of other Commodities can be done through each selling company's electronic system or a third party's electronic system (e.g., PSEF). ***Note**: The concept of online drug distribution does not exempt sellers from the prevailing supply chains that are applicable to them for offline channels. In other words, theoretically pharmaceutical manufacturers and PBFs cannot use BPOM Regulation 8 as an excuse to sell drugs directly to patients or end consumers. For example, local pharmaceutical manufacturers can only sell drugs directly to PBFs, pharmacies, pharmaceutical installations at hospitals, healthcare facilities, clinics and drugstores.*	Articles 4-6 Articles 13 and 14
Coverage of PSEF	As mentioned above, the definition of PSEF is not limited to specific electronic system operators that operate a pharmacy-related platform. The definition arguably covers any electronic system operators, especially those that operate a platform that includes a page offering pharmaceutical goods. So the likes of e-commerce platforms can be categorized as PSEF if they host a pharmacy-related offering page. As an implication, the full force of BPOM Regulation 8 will apply to such platform operators, including the obligation to provide access to BPOM at any time if required and to provide periodical reports. PSEF that violate the provisions in BPOM Regulation 8 could be subject to administrative sanctions - see section on sanctions below.	Article 1(19), 6(2), 6(3), 6(4), 6(5), 6(6), 22(2), 22(3), 22(4), 32

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Notable Provisions

We set out below the notable provisions of BPOM Regulation 8:

Highlights	Description	Reference
Reporting Obligation	Online sellers of drugs (i.e., pharmaceutical manufacturers, PBFs, pharmacies) must submit a periodical report containing: 1. name and address of the seller (i.e., pharmaceutical manufacturers, PBFs, pharmacies) 2. date, month and year of the start of online drug distribution 3. name of the PSEF and website/Uniform Resource Locator (URL) address for pharmacies that work together with PSEF to distribute drugs online 4. list of drugs distributed online 5. data of online transactions for drugs sold online	Article 4 (4) and (5)
Delivery of Drugs	Delivery of drugs that are sold online by pharmacies may be arranged through their own electronic systems or an electronic system provided by PSEF. Drugs can be surrendered directly at the pharmacies or sent to the patient. In case of the latter, the delivery can be arranged by the pharmacies themselves or through cooperation with a third party legal entity.	Article 6
Type of Drugs	Online distribution of drugs is limited to over-the-counter drugs ("**OTC**"), limited OTC, and potent drugs (*obat keras*) / ethical drugs. Ethical drugs can only be delivered to patients based on prescription that can be written electronically or physically, and must be in the exact prescribed amount based on the patient's therapeutic needs. Physical prescriptions may be uploaded to the electronic system.	Articles 7 and 8
Data Retention	Online sellers of drugs must maintain all collected electronic transaction information related to online sale of drugs (and keep it accessible) for at least five years.	Article 11
PMKK	Online distribution of PMKK can only be done by pharmacies by using their own electronic system or cooperating with PSEF.	Article 20 and 21
Supervision	Online sales and distribution of food and drugs will be supervised by relevant BPOM officials. The supervisors can coordinate with relevant ministry or agency, regional government and/or electronic system operators association.	Article 25

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Notable Provisions

We set out below the notable provisions of BPOM Regulation 8:

Highlights	Description	Reference
Prohibited Goods	▪ Pharmacies and/or PSEF are prohibited to sell the following drugs online: 1. certain ethical drugs that are specifically prohibited based on the prevailing laws and regulations 2. drugs that contain pharmaceutical precursors 3. injections except insulin for self-use/administration 4. implants that require healthcare professional assistance to be used 5. narcotics and psychotropic ▪ Alcoholic beverages are prohibited to be distributed online. ▪ Cosmetics that are prohibited from being distributed online, as follows: 1. cosmetics that must be applied with assistance of medical professionals 2. cosmetics for skin that contain alpha hydroxyl acid (AHA) with more than 10% content 3. teeth whitening cosmetics that contain and/or release hydrogen peroxide with more than 6% content	Articles 27-29
Social Media and Promotion	Online distribution of drugs and PKMK through social media, daily deals and classified ads are not permitted. Pharmacies that sell drugs online are prohibited from doing any promotion and advertising of drugs (i.e., this is consistent with the prohibition under Article 9 of Head of BPOM Decision No. HK.00.05.3.02706 of 2002 on Promotion of Drugs). Notwithstanding the above, pharmacies are allowed to conduct promotion and advertising activities for infant/advanced formula and PKMK, but only through special healthcare printed media with the Ministry of Health's approval.	Article 31

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Notable Provisions

We set out below the notable provisions of BPOM Regulation 8:

Highlights	Description	Reference
Sanctions	Any business actors and/or electronic system operators that violate the provisions of BPOM Regulation 8 are subject to the following administrative sanctions that can be imposed by the head of BPOM: 1. warnings 2. recommendation to cut off electronic system (i.e., takedown or blockage) of the online seller (i.e., pharmacies, pharmaceutical manufacturers and PBFs), including takedown of any merchant in the PSEF's electronic system, as well as any social media account, daily deals, classified ads and other internet media used for e-commerce 3. recommendation to revoke licenses for pharmaceutical facilities 4. temporary distribution ban 5. recall order for drugs and food ***Note:*** *Although not specifically mentioned, the recommendation in point (b) above should be from BPOM to the relevant government authority that supervises electronic systems, i.e., Ministry of Communications and Informatics. The recommendation in point (c) above should be from BPOM to the MOH, as the licenses for pharmaceutical facilities are issued by the MOH.*	Article 32
Transitional Period	Pharmacies, PSEF, businesses and electronic system operators must adjust to BPOM Regulation 8 at the latest on 7 July 2020 (i.e., three months after the date the regulation became effective).	Article 34

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Indonesian Medical Council Regulation on Telemedicine Services

On 29 April this year, the Indonesian Medical Council ("**IMC**") issued IMC Regulation No. 74 of 2020 on Clinical Authorities and Medical Treatment Through Telemedicine During the COVID-19 Pandemic ("**IMC Regulation 74**").

The telemedicine sector has never been rigidly regulated in Indonesia, despite growing numbers of business players and huge potentiality. There is always a debate on the ethicality of providing healthcare services remotely, as full diagnosis or prognosis provided through electronic systems without a physical check-up may not be 100% accurate and could pose some risk from a medical perspective. Some associations are of the view that this might not be in line with medical codes of ethics.

As part of the government's agenda (i.e., Industry Revolution 4.0) the Ministry of Health ("**MOH**") also principally supports the growth of telemedicine and encourages healthcare service providers to begin adopting telemedicine models in giving services to patients. However, in reality the MOH has not reflected this attitude in a concrete written legislative document and rather leaves much of the issue to the relevant professional associations, which are encouraged to provide written protocols to clarify the views on telemedicine services.

Further, to keep the number of COVID-19 patients in healthcare facilities in check, the Indonesian government encourages patients with early symptoms of COVID-19 to self-isolate before they undergo medical treatment in healthcare facilities. Due to how COVID-19 is spread, physical contact may pose a risk not only to the medical practitioners but to patients as well. It is clear that patients have difficulties in seeking medical attention due to COVID-19 not only for early detection of COVID-19 symptoms but also for other types of disease as well. The provision of telemedicine services is also one of the solutions to treat patients with early symptoms of COVID-19 while social distancing is in effect.

Key takeaways of telemedicine services under IMC Regulation 74

The key development associated with KKI Regulation 74 is that it provides a legal basis and permission for doctors and dentists to provide healthcare services through electronic system platforms (commonly known as telemedicine).

KKI Regulation 74 came into effect on 30 April 2020, but will only remain in effect until the Indonesian government officially declares the end of the COVID-19 state of public health emergency. Business actors in the hospital or healthcare business should see KKI Regulation 74 as 'temporary permission' for doctors and dentists to provide healthcare services remotely. It should not be seen as an indication of the authorities' long term view on telemedicine.

While KKI Regulation 74 does not clearly regulate any sanctions, business actors must consider other relevant sanctions provided under the prevailing laws and regulations that could be applicable if KKI Regulation 74 is violated. We will discuss these in further detail below.

Telemedicine Services under KKI Regulation 74

Other than direct medical treatments (onsite medical treatments), KKI Regulation 74 clarifies that doctors and dentists are allowed to provide telemedicine services through applications/electronic systems. Telemedicine services under KKI Regulation 74 means consultation or teleconsultation services in the form of writing, voice and/or video to diagnose, treat and cure patients.

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Pre-Requisite to Provide Telemedicine Services

KKI Regulation 74 requires doctors and dentists who intend to provide medical treatment through telemedicine services to have a registration letter (*Surat Tanda Registrasi* or STR) and practice permit (*surat izin praktik* or SIP) at their healthcare facility.

Key Takeaways of Telemedicine Services under KKI Regulation 74

1. In emergency situations, doctors and dentists who provide medical treatment through telemedicine services must instruct their patients to undergo direct (**read**: physical) medical treatment at the relevant healthcare facility.
2. Patients must provide their general/informed consent in accordance with the prevailing laws and regulations. KKI Regulation 74 does not elaborate on the context of the general/informed consent [1]. In any case, this requirement must be read in conjunction with medical confidentiality principles. Any medical data of the patients collected through the telemedicine platform would also be subject to the prevailing personal data protection rule. Business actors need to consider gaining patients' consent for the use of their medical data along with the general/informed consent if this is intended.
3. Doctors and dentists who provide medical treatment through telemedicine services must provide a medical record for every patient and archive it at the healthcare facility in accordance with the prevailing laws and regulations. The medical record may be in written or electronic form and may be provided to patients in the form of a transcript but the original one must be kept at the healthcare facility where the doctors and dentists are registered.
4. Doctors and dentists may provide a diagnosis (through telemedicine) and subject the patient to supporting medical examination procedures in the form of:
    - laboratory
    - radio image
    - therapy
    - drugs prescription (except narcotics and psychotropic) and/or medical devices
    - explanation letter (*surat sakit*)

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

5. Telemedicine services that can be provided by doctors and dentists are subject to some limitations. Below are the actions that doctors and dentists are prohibited to do in providing healthcare services through telemedicine:

- conduct teleconsultation with patients without any involvement of a healthcare facility[2]
- provide misleading, non-ethical and inadequate information and/or explanation to patients and/or their families
- diagnose and treat patients outside of their competence
- require patients to conduct unnecessary additional medical assessments
- conduct immoral, intimidating and reprehensible actions against the patients
- conduct invasive actions through teleconsultation
- impose additional costs outside costs settled by the healthcare facility
- provide a letter of healthiness (*surat keterangan sehat*)

Doctors and dentists who provide medical treatment through telemedicine services may receive payment as determined by the healthcare facility they are registered to in accordance with the prevailing laws and regulations. This implies that any payment for the telemedicine service (through a payment platform or otherwise) must observe the internal rule of the healthcare facility where the doctors or dentists are registered, and direct payment to the doctors and dentists providing the services might not be possible.

Clinical Authority on COVID-19 Medical Treatment

Other than regulating the provision of telemedicine services, KKI Regulation 74 also sets out the clinical authority (i.e., doctor-in-charge) in the provision of COVID-19 medical treatment in healthcare facilities.

Article 6 of Regulation 74 states that doctors, specialist doctors and subspecialist doctors can be in charge of providing COVID-19 medical treatment in the healthcare facility where they are registered, based on their relevant competency. Severe cases that must be treated in an Intensive Care Unit (ICU) must be referred to specialist and/or subspecialist doctors depending on their competency. In case of overabundance of severe COVID-19 related cases, internists and/or pediatrics can take up the role as the doctor-in-charge who has the clinical authority to provide COVID-19 related care, with due observance of the prevailing clinical authority limitations in the relevant hospital.

The above implies that treatment of COVID-19 is not expected to be limited to a select few hospitals that are designated as COVID-19 hospitals.

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Relevant Sanctions

Relevant Sanctions for HCP

KKI Regulation 74 does not elaborate on the relevant sanction that could be imposed on healthcare professionals (**read**: doctors and dentists) if they violate KKI Regulation 74. However, to understand the real implications of KKI Regulation 74, we need to see the bigger picture and see whether there is any other applicable sanction under the prevailing laws and regulations that could be relevant to healthcare professionals or business actors in relation to the provision of telemedicine services that is contrary to KKI Regulation 74, i.e., other sanctions established under other laws and regulations.

As one of the basic principles in providing medical treatments for patients, Article 10 of the Medical Code of Ethics (*Kode Etik Kedokteran*) states that every doctor must be sincere and use his/her best knowledge and skills for the interests of the patients. If the doctor is not able to treat or cure his/her patients, the doctor must provide a reference to other doctors who are capable of treating the disease.

In this context, Article 66 of Law No. 36 of 2014 on Healthcare Professionals ("**HCP Law**") states that every healthcare professional must implement its compliance practice and fulfill the professional standards, professional services standards and operational procedures standards. To be more specific, KKI Regulation No. 4 of 2012 on Professional Discipline for Doctors and Dentists regulates that there are 28 forms of actions classified as non-compliance that could subject doctors and dentists to sanctions that will be imposed by KKI. The imposition of sanction is further regulated in KKI Regulation No. 43 of 2016 on the Guidelines of the Enforcement of Administrative Sanctions.

Article 49 of the HCP Law generally regulates that any noncompliance action of a healthcare professional may be subject to sanctions by KKI in the form of:

1. a written warning
2. recommendation on the revocation of a registration letter ("**STR**") or *Surat Izin Praktik* ("**SIP**")
3. requiring the healthcare professional to participate in training or a workshop at a healthcare educational institution

There are also other criminal sanctions that can be imposed on healthcare professionals in certain conditions under the laws and regulations.

The supervisory authority for the STR and SIP is different. Healthcare professional councils (e.g., KKI) administer and supervise the STRs, and regional governments administer and supervise the SIPs. The HCP Law regulates that an STR serves as the prerequisite of an SIP. So, KKI has more authority to sanction the relevant healthcare professionals in the provision of telemedicine services.

Indonesia

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Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Relevant Sanctions for Electronic System Operators

Due to its nature, telemedicine services are operated through electronic system platforms. However, it is unclear whether KKI Regulation 74 is connected with Ministry of Trade Regulation No. 50 of 2020 on the Provisions on Business Licensing, Advertisements, Development and Supervision of Business Actors in Electronic Systems Trading ("**MOT Regulation 50**"). It remains to be seen whether the government would consider the provision of telemedicine services as "trading" activity and subject to requirements set out in MOT Regulation 50.

Accordingly, it remains to be seen whether a telemedicine electronic system operator will be subject to a sanction due to vidation of KKI Regulation 74. However, as a general rule of the current licensing regime, Government Regulation No. 24 of 2018 on the Online Single Submission system ("**OSS**") regulates that the OSS agency (i.e., BKPM) may impose administrative sanctions on business actors due to, among other things, failure to comply with laws and regulations. We have seen the OSS agency sending an electronic reprimand to a company for its breach of the foreigninvestment restriction. Under that reprimand, the company was required to rectify its noncompliance within 30 days after the date of the electronic letter.

The general sanctions are:

1. electronic or written reprimand (the relevant business entity must provide its written responses and follow-up actions in relation to the letter at the latest 30 calendar days after the date of the letter)
2. restriction of business activities
3. suspension of business activities and/or investment facilities
4. revocation of business activities and/or investment permit and/or investment facilities

[1] Based on the known medical law literature, 'informed consent' refers to the process of getting the permission before conducting a healthcare intervention on a person or for disclosing personal information. It also involves educating the patients (i.e., done by healthcare providers) on the risks, benefits and alternatives of a given procedure or intervention. Then the patient can decide whether or not to undergo the procedure or intervention. General consent is a similar concept being a consent given by a patient or his/her representatives to receive physical health services to address his/her medical condition.

[2] This could mean that doctors and dentists who are independent practitioners cannot provide telemedicine services to their patients.

[1] For reference, please access the following link (in Bahasa Indonesia):
http://sehatnegeriku.kemkes.go.id/baca/rilis-media/20200323/2133493/gandeng-gojek-dan-grab-kemenkes-luncurkan-telemedicine-penanganan-covid-19/

[2] For reference, please access the following link (in Bahasa Indonesia):
https://www.gojek.com/blog/gojek/check-covid-19/

[3] For reference, please access the following link (in Bahasa Indonesia):
https://www.liputan6.com/health/read/4212624/12-layanan-telemedik-yang-beri-informasi-covid-19

Japan

Last updated: 16 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

To counter a COVID-19 outbreak in the country, the Japanese parliament passed an amendment to the Act on Special Measures to Respond to Novel Influenza and New Infectious Diseases, of which a recently amended version entered in effect on 14 March 2020 (the "**Act**") that gives the Prime Minister the authority to declare a state of emergency due to the spread of COVID-19, if deemed necessary. The Act provides an institutional framework for crisis management, which is designed to enable the implementation of various measures to cope with emergencies. In a state of emergency a prefectural governor may, among other things:

- request that people stay indoors and may also direct the use of certain establishments (e.g., schools, movie theaters) to be restricted or prohibited;
- request the sale of, or seize without the consent of the owner, certain essential supplies (e.g., medicine and food); and
- use private land, buildings and materials for temporary medical care facilities with or without the consent of the owner/occupier.

The state of emergency declared on 7 April 2020 for seven prefectures and extended subsequently to the whole of Japan was lifted on 25 May. Since the last week of June, however, the number of cases tested COVID-19 positive has been on a rapid increase particularly in Tokyo and its neighbouring prefectures and there are growing concerns again that there may be shortages of hospital beds, medical devices and diagnostics, such as test kits, ventilators and respiratory ECMO devices.

On 13 April, the Ministry of Health, Labour and Welfare ("**MHLW**") announced measures to provide manufacturers in non-medical industries with easier access to the medical devices market to promote the manufacture of medical devices for COVID-19 (such as ventilators). The measures include the following:

- If a manufacturer manufactures only parts of medical devices and supplies them to marketing authorization holders of such devices, regulatory procedures will not apply to such manufacturer.
- If a manufacturer is to be involved in assembly and other important manufacturing processes:
    - regulatory registration as a medical devices manufacturer will be handled on a priority and expedited basis; and
    - a change to the product approval resulting from the addition of manufacturing sites will also be handled on a priority and expedited basis and physical QMS inspection of the manufacturing sites will be conducted after the approval of such change.

A foreign-manufactured test kit was approved as an IVD on 27 March on an expedited basis with a small amount of support data but subject to the condition that post-approval clinical assessment be conducted.

On 7 May, MHLW approved Remdesivir only three days after application. The approval was granted through a special approval procedure under the Pharmaceuticals and Medical Devices Act. Special approval is available only if (i) there are urgent needs for the use of the drug for which approval is being sought where there is no alternative method, and (ii) the drug is already approved in a foreign country.

Japan

Last updated: 16 July 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

See (a) above for the approval of products on an expedited basis, and the section "Clinical Trials" below for the approval ofclinical trials.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

As of 16 July 2020, Japan refuses entry to visitors from 129 countries and areas in principle.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

Given that some hospitals were shut down after medical staffs and patients were found to be infected byCOVID-19, we understand that COVID-19 outbreak itself may be an obstacle to implementation of clinical trials. For example, trial subjects' visits to hospitals and sponsors' meetings with the clinical trial investigators may be affected by the outbreak.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Under the Pharmaceuticals and Medical Devices Act, a sponsor may not start a clinical trial until 30 days have elapsed sinceits submission of a clinical trial plan to MHLW. However, on 19 March 2020, MHLW issued an official letter stating that, in connection with an investigational drug for treatment of COVID-19, a sponsor may start a clinical trial without waiting for the 30-day period to elapse, if MHLW has finished review of the clinical trial plan.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

We understand that MHLW encourages clinical trials of pharmaceutical products which are expected to be used for treatment of COVID-19 and may take further regulatory measure. Accordingly, close attention should be paid to the latest regulatory framework and government support in this respect.

Japan

Last updated: 16 July 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

In the Patent Act of Japan, there is a provision for a sort of compulsory license to protect public interests. Thus, under Article 93 of the Patent Act, in the case where the patent at issue is particularly necessary for the public interests, a potential licensee may request the patentee to hold discussions toward an agreement to grant a non-exclusive license. If the parties cannot reach an agreement, the potential licensee may request the Minister of Economy, Trade and Industry to grant an award. Based on the award issued by the Minister, the applicant (the potential licensee) will own the non-exclusive license and then can exercise the patent.

In fact, this Article 93 has been rarely used here in practice. However, the situation around COVID-19 is unusual and the necessity to protect public interests must be very high. At the same time, it is our view that the patentees will be cooperative to protect the public interests by their invention and agreement will be reached outside the framework of Article 93.

In addition, under Article 69 of the Patent Act, the use of a patented invention for the purpose of research and development is not an infringement of patents in general.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

We are not aware of any of such discussions and we believe that it is unlikely.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

MHLW has issued guidelines for telemedicine ("**Telemedicine Guidelines**") to give guidance on how telemedicine may be used in compliance with the Medical Practitioners Act, which in general requires healthcare practitioners to examine patients in person. For example, the Telemedicine Guidelines provide that in principle, telemedicine may not be used for the initial examination of the patients and it may be used only where the initial face-to-face examination has been completed. Further, the Telemedicine Guidelines require physicians to establish a telemedicine plan for each patient before starting telemedicine services.

In the light of the outbreak of COVID-19, MHLW has issued an official notification to allow flexibility in certain circumstances so that patients will not need to visit hospitals/clinics and be exposed to infection risks. Specifically, the official notification provides that (i) continuing prescription of pharmaceuticals for chronic disease patients who have regularly been treated by the physician is permissible irrespective of whether the prescription has been set out in a written telemedicine plan, (ii) different pharmaceuticals may be prescribed for chronic disease patients when a new but predictable symptom is observed in the patients and (iii), when the COVID-19 infection further spreads, telemedicine for COVID-19 patients whose condition is not serious and who stays at home will be permissible.

On 10 April 2020, MHLW issued an official letter which provides that, as an emergency and temporary measure in response to the outbreak, physicians may use telemedicine even for the first examination of patients if the physicians believe that they can conduct diagnosis or prescribe drugs without examining the patients in person. The letter also provides that when physicians use telemedicine for the first examination, they should (i) give patients sufficient information about possible risks arising out of telemedicine services, actions to be taken if and when sudden changes of their conditions occur etc., (ii) immediately change telemedicine to in-person treatment when it becomes necessary and (iii) carefully verify the identity of patients etc. Based on this official letter, since 13 April 2010, telemedicine for the first examination of patients has become permissible in Japan.

Malaysia

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

For context, the Malaysian government imposed a Movement Control Order ("**MCO**") on 18 March 2020 to curb the spread of COVID-19 across Malaysia which has since been extended to 28 April 2020.

Notwithstanding this, to address the urgent needs for essential items such as medical devices and supplies, companies manufacturing these essential items are able to continue their operations during the MCO period, subject to approval of the Ministry of International Trade and Industry. To address the pressing necessity for medical equipment and supplies, the government and its agencies have provided the following:

- Allocation of RM1.5 billion (approximately USD344.7 million) to the Ministry of Health ("**MOH**") for the purchase of medical equipments and hiring of medical staff;
- Approved an emergency procurement procedure to expedite the purchase of critical medical equipment;
- Arranged a separate bank account for public donations and special line for contributions in the form of medical equipment through the MOH;
- Collaboration of MOH and the National Disaster Management Agency to channel critical medical equipment and supplies to gazetted hospitals for COVID-19 and quarantine centers;
- Indicated that companies must meet domestic demand in relation to the export of medical gloves before exporting internationally; and
- Distribution of 24.62 million free face masks to the public.

Please also refer to our responses to the next question for the special mechanisms introduced by government authorities in relation to the marketing authorizations and licensing restrictions.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

In respect of medical devices which are required to be registered under the Malaysian Medical Devices Act 2012, to bypass the typical lengthy process of regulatory approval, companies can apply for exemption from registration requirement with approval from the Malaysian Medical Device Authority ("**MDA**"). In order to safeguard an adequate supply of face masks, MDA announced that companies can apply for exemption from registration for face masks through a Notification of Medical Device for Special Access. Exempted face masks are not allowed to be advertised publicly and must be sold to authorized health premises or pharmacies only.

Since the COVID-19 outbreak, MDA has exempted COVID-19 test kit brand Wondfo from registration requirements to assist medical staff in combating COVID-19 outbreak in Malaysia. These exempted kits are limited to professional use by staff in hospitals and health laboratories. Another notable MDA exemption was for the importation, distribution and sale of personal preventive equipment used by the frontliners to prevent or reduce the risk of transmission and infection of germs.

In relation to general market access of medical devices, selected rapid test kits from United States and South Korea are pending approval and certification as they are currently being tested by the MOH. There is potential for increased market access for companies of these test kits as MOH has plans to purchase in large quantities if the results pertaining to the accuracy of these test kits are promising.

Malaysia

Last updated: 16 April 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

In respect of other medical devices and pharmaceuticals which do not fall within the exemptions above or are not related to COVID-19, market access are generally not completely prohibited as most of the healthcare related government authorities remain in operation during the MCO and are open to online submissions. That said, market access for these products may be affected by potential delays in the timeline for regulatory applications, in light of the MCO and the need to prioritize approvals which relate to COVID-19.

In the same vein, the National Pharmaceutical Regulatory Agency (NPRA) has recently decided that all domestic and overseas inspections by the NPRA scheduled for 2020 will have to be postponed to a later date. This will affect the market access for products of manufacturers who are required to comply with principles of Good Manufacturing Practice and Good Distribution Practice (GDP), as well as importers and wholesalers who are required to comply with GDP principles.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The selection of Malaysia by the World Health Organisation ("**WHO**") for the involvement of its global clinical testing to carry out the research on drugs identified as a possible treatment for COVID-19, saw clinical trials in Malaysia shifting their focus towards finding a possible treatment for COVID-19. This shift in focus is evidenced by the Medical Research & Ethics Committee ("**MREC**") prioritising new COVID-19 studies for an immediate review as research involving human subjects requires prior ethics review and approval by MREC. Separately, Malaysia have also began testing of vaccines based on previous research on vaccines for Infectious Bronchitis virus.

Since MREC's review and approval of clinical trials involving human subjects is required before the trial is allowed to start, non-COVID 19 related trials is likely to experience an administrative backseat with the postponement of full-board reviews for all non-COVID 19 related trials until MCO term has ended. The shift in priorities and postponement of full-board reviews would result in a marked delay for the start of non-COVID 19 related trials as the majority of these trials are high risk studies requiring a full-board review.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The ongoing measures to assist with clinical trial management includes online registration of research and submissions for approval through the National Medical Research Register (NMRR), which would reduce the research review time and assist investigators to track the status of their research online. The online directory on the NMRR website, which lists participating investigators, also allows for investigators to locate other potential collaborators and sponsors of clinical trials to identify suitably qualified clinical investigators to participate in their multi-center trials.

As mentioned above, the MREC will be prioritizing COVID-19 studies for an immediate review. Depending on the risks involved to the human subjects, the MREC will decide if the COVID-19 study will require either a full-board review or an expedited review that would be assessed by the chairperson.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

For people who wish to start clinical trials related to COVID-19, it is advisable to register the study in NMRR and include "COVID" in the title of the study which would allow for the study to be forwarded directly to the MREC for review.

Malaysia

Last updated: 16 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

While compulsory licensing and "government-use" licenses are recognized under the Patents Act 1983, there has not been any compulsory or government-use licenses issued for drugs in relation to COVID-19. As stated earlier, Malaysia will carry out clinical trials to test selected drugs to combat COVID-19, which could trigger the possibility of a government-use license, depending on the type and cost of the original patented drug. Meanwhile, the Malaysian government has recently approved the import of 10 million facemasks from China.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

Discussions on the likely issuance have yet to be seen as the focus has been primarily on clinical trials and testing.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

There has been more emphasis on the provision of telemedicine as seen with the collaboration of the MOH with the largest telemedicine platform in Malaysia, DoctorOnCall to launch a virtual health advisory portal to address rising number of public queries about COVID-19 and reduce congestion at medical facilities. The increased use of telemedicine services of the portal since its establishment is apparent as a growingnumber of people turn to telemedicine services as an alternative health advisory guide since the MCO started. Other telemedicine platforms such as Doc2Us have also been expanding the provision of telemedicine services by actively releasing informative guides on COVID-19 to the public at large. As of now, there are no anticipated legislative changes to the Telemedicine Act 1997 which provides for the regulation and control of the practice oftelemedicine, though the legislation is still not yet in force.

Philippines

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The government agencies that directly and primarily regulate health products, such as medicines, medical devices and medical supplies, in the Philippines are the Department of Health ("**DOH**") and the Food and Drug Administration ("**FDA**"), an office under the DOH.

In light of the Coronavirus Disease 2019 ("**COVID-19**") situation in the Philippines, the FDA has adopted and issued procedures and guidelines to ensure that medicines, medical devices and medical supplies are accorded priority for faster registration (where required), expedited release from customs authorities, or granted exemptions from certain standard regulatory permits.

The FDA also now allows online banking transfers to the FDA bank account for payment of COVID-19 related applications (discussed below), during the period of the enhanced community quarantine ("**ECQ**").

Medicines

FDA Circular No. 2020-02 entitled, "Guidelines for the Registration of Drug Products under Emergency Use ("**DEU**") for COVID-19" ("**DEU Guidelines**") provides for a streamlined set of requirements and application process for the registration of DEUs. It applies to all Marketing Authorization Holders ("MAH") intending to manufacture and import / distribute the drug products listed in the PSMID Interim Guidelines on the Clinical Management of Adult Patients with Suspected or Confirmed COVID-19 Infection. Currently, the following are considered DEU for COVID-19:

Generic name	Dosage form and strength
Tocilizumab	400 mg/ 20 mL Concentrate Solution for I.V. Infusion
Lopinavir + Ritonavir	200 mg/ 50 mg Film-Coated Tablet
Chloroquine Phosphate	250 mg Tablet; 500 mg Tablet
Hydroxychloroquine Sulfate	200 mg Film-Coated Tablet

The registration process for DEUs is faster because it is not subject to the standard scheduling requirements for registration filings of the FDA, and the applications may also be filed online. Under current regulations, applications for product registration can only be filed based on a specific schedule prescribed by the FDA. Moreover, the FDA has declared it a policy that high priority will be given to health products with functions intended for the use in the diagnosis, cure, mitigation, treatment, prevention, and PPE of COVID-19 and essential businesses. These include the DEU.

Suspension of non-essential applications

Due to the COVID-19 health emergency, the President of the Philippines has declared the entire island of Luzon, where Metro Manila is located, under ECQ from 17 March 2020 to 30 April 2020, unless otherwise further extended. During the ECQ, only specific businesses offeringessential goods and services may operate. These businesses include manufacturing and processing plants of basic food products, essential products, medicine and medical supplies, retail establishments (groceries, supermarkets, hypermarkets, convenience stores, public markets, pharmacies and drug stores), logistics service providers (cargo handling, warehousing, trucking, freight forwarding, and shipping lines), hospital and medical clinics, food preparations and water refilling stations, and banks, among others. On the part of the government, physical offices of most government agencies have also closed. For those required to open, such as the DOH and FDA (in light of the COVID-19 situation), only a skeletal workforce is assigned to man such offices.

Philippines

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

In view of the ECQ, and the need to prioritize applications which may help in the diagnosis, cure, mitigation, and treatment of COVID-19, the FDA has temporarily suspended the filing of all initial drug product registrations except for certain products, which include but are not limited to the following:

- antibiotics based on CAP Guidelines of PSMID
- biologicals and vaccines
- antivirals, specifically Oseltamivir
- antiretroviral, specifically Lopinavir, Ritonavir
- medical products used in the diagnosis cure, mitigation, treatment and prevention of COVID-19.

Medical devices; testing kits

The Center for Device Regulation, Radiation Health and Research of the FDA, through FDA Memorandum No. 2020-006, has authorized the issuance of a special certification for imported IVD kits used for diagnosis and screening of COVID-19. Without this special certification, notification or registration of IVD kits is required before it may be distributed in the Philippines.

Medical devices; ventilators

Under FDA Advisory No. 2020-449, to expedite customs release of ventilators, respirators and accessories, to be used in treating patients infected with the COVID-19, the following procedures shall be observed:

- For ventilators, respirators and their respective accessories which are imported into the Philippines for commercial purposes, importers need only to present their copies of their License to Operate ("**LTO**") to the Bureau of Customs ("**BOC**") prior customs release.
- Foreign donations of ventilators, respirators and their respective accessories to be used in the treatment of COVID-19 patients do not require FDA clearance prior customs release.

Medical supplies

Under FDA Advisory no. 2020-547, dated 6 April 2020, the FDA adopted the following measures for the expedient release of certain personal protective equipment ("PPE") from the BOC. The PPE includes:

- Face Masks including N95 masks
- Shoe Covers
- Gloves
- Head Covers, and
- Gowns

The presentation of a copy of the importer's LTO shall be sufficient compliance for customs release and for entry into the local market for commercial use.

Clearance from FDA shall not be needed for foreign donation of the same PPE,. This exemption of clearance includes companies, other than medical device establishments, with employees who use face masks in the performance of their jobs and are strictly for company use.

Philippines

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

All these PPEs will be subject to strict post-market surveillance. All companies who have imported PPEs under this Advisory and will continue to distribute PPEs for commercial purposes shall apply for a Certificate of Medical Device Notification ("**CMDN**") within three months after the lifting of Proclamation No. 922 s. 2020 declaring a State of Public Health Emergency throughout the Philippines. Necessary regulatory measures will be applied to those companies who do not comply with this requirement.

Said procedure for clearance of PPE prior to customs release shall be in effect until otherwise lifted by the FDA.

Tax and Duty Fee Importation of Healthcare Equipment and Supplies

Under Section 4(o) of Republic Act No. 11469, the President was granted the following temporary power, among others, as an immediate response to the COVID-19 pandemic:

- Liberalize the grant of incentives for the manufacture or importation of critical or needed equipment or supplies for the carrying-out of the policy declared herein, including healthcare equipment and supplies: Provided, That importation of these equipment and supplies shall be exempt from import duties, taxes and other fees. (Underscoring supplied)

RA 11469 was published and became effective on 25 March 2020. It is effective for a period of three months (or until 25 June 2020), unless extended by Congress.

To implement the above-mentioned provision of Republic Act No. 1149, the Bureau of Internal Revenue ("**BIR**") has issued Revenue Regulation No. 6-2020 ("**RR 6-2020**"), which provides that:

- The importation of critical or needed healthcare equipment and supplies intended to combat COVID-19, including PPE (i.e., gloves, gowns, masks, goggles, face shields, surgical equipment and supplies); laboratory equipment and its re-agents; medical equipment and devices; support and maintenance for laboratory and medical equipment, surgical equipment and supplies; medical supplies, tools and consumables (i.e., alcohol, sanitizers, tissue, thermometers, hand soap, detergent, sodium hydrochloride, cleaning materials, povidine iodine, common medicines (e.g., paracetamol tablet and suspension, mefenamic acid, vitamin tablet and suspension, hyoscine tablet and suspension, oral rehydration solution, and cetirizine tablet and suspension); testing kits, and such other supplies or equipment as may be determined by the DOH and other relevant government agencies, shall be exempt from value-added tax, excise tax and other fees.
- Importation of materials needed to make health equipment and supplies shall be exempt from value-added tax, excise tax and other fees, provided that the importing manufacturer is included in the Master List of the Department of Trade and Industry and other incentive granting bodies.
- The importation thereof shall not require the issuance of the Authority to Release Imported Goods ("**ATRIG**") under Revenue Memorandum Order ("**RMO**") No. 35-2002 for the release of said goods from the BOC. Importations without any ATRIG shall be subject to post investigation/audit by the BIR.
- Donations of these imported articles to or for the use of the National Government or any entity created by any of its agencies which is not conducted for profit, or to any political subdivision of the said Government are exempt from donor's tax, and subject to the ordinary rules of deductibility under existing rules and issuances.

Philippines

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

On the other hand the COB has issued Customs Administrative Order No. 7-2020 ("**CAO 7-2020**"), which provides that:

- The importation of health equipment and supplies to carry out the objective of Republic Act No. 11469 shall be exempt from duties, taxes and fees, including:
  - PPE, such as gloves, gowns, masks, goggles, face shields, surgical equipment and supplies;
  - Laboratory equipment and its re-agents;
  - Medical equipment and devices;
  - Support and maintenance for laboratory and medical equipment;
  - Surgical equipment and supplies;
  - Medical supplies, tools and consumables (i.e., alcohol, sanitizers, tissue, thermometers, hand soap, detergent, sodium hydrochloride, cleaning materials, povidine iodine, common medicines (e.g., paracetamol tablet and suspension, mefenamic acid, vitamin tabler and suspension, hyoscine tablet and suspension, oral rehydration solution, and cetirizine tablet and suspension);
  - COVID-19 testing kits; and
  - Others as may be determined by the DOH.
- Manufacturers included in the Master List of the Department of Trade and Industry and other incentive granting bodies of the National Government may avail of the tax and duty free importation under Section 4(o) of Republic Act No. 11469 for their importation of materials necessary for the production of health equipment and supplies deemed as critical or needed to carry out the objectives of Republic Act No. 11469.
- Importers of medical equipment and supplies for commercial purposes are exempt from the presentation of Certificate of Product Notification ("**CPN**") or Certificate of Product Registration ("**CPR**") issued by the FDA prior to release from the BOC provided, that they are able to provide a copy of their LTO and proof of application for product notification with the FDA. For ventilators, respirators and their respective accessories imported for commercial purposes, importers only need to present a copy of their LTO.
- Foreign donations of PPEs (face masks including N95 Masks, Shoe Covers, Gloves, Head Covers, and Gowns), imported not for commercial purposes, and foreign donations of ventilators, respirators and their respective accessories to be used in the treatment of COVID-19 patients, shall not be required clearance from the FDA prior to release.
- Importers or companies, other than medical device establishments, who use face masks in the performance of their jobs and are strictly for company use can directly import without any certification from the FDA.
- Imported health products for donation, duly certified by the regulatory agency or their accredited third party in the originating countries with established regulation, shall automatically be cleared. The certification shall not be required for health products which is not subject to clearance from FDA.
- The BOC shall not unnecessarily delay the release of donated medical equipment and supplies deemed as critical or needed to carry out the objectives of Republic Act No. 11469. Clearance for donated medical equipment and supplies shall be under informal entry process.
- The shipments entitled to exemption under Section 4(o) of the Bayanihan Act may be released under a Provisional Goods Declaration subject to the submission of a Tax Exemption Indorsement ("**TEI**") from the DOF Revenue Office ("**DOF RO**") after the lifting of the Declaration of the ECQ.

Philippines

Last updated: 16 April 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Expedited government procurement

Under RA 11469, the President is authorized undertake the expedited procurement of certain health products and supplies as exemptions from the stringent process under the Government Procurement Reform Act:

- PPE
- laboratory equipment and reagents
- medical equipment and devices
- surgical equipment and supplies
- consumables such as alcohols, sanitizers, cleaning materials
- common medicines
- testing kits
- others that the DOH may deem essential

RA 11469 also authorizes the President to direct prioritization of augmentation of the budget of the DOH for use by governmert hospitals particularly those identified for treatment of COVID-19, prevention and control of infectious diseases, emergency preparedness and response and quick response fund.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Delay in processing of non-COVID-19 applications

As mentioned above, only products identified in the FDA issuances may apply for initial product registration until the ECQ islifted or until further orders from the FDA. High priority is given to health products with functions intended for the use in the diagnosis, cure, mitigation, treatment, prevention, and PPE of COVID-19 and essential businesses. This may delay the market access of products which do not fall under the foregoing classifications, particularly during the ECQ period. To partly address the situation with respect to non-COVID-19 filings, the FDA has granted an automatic four-month renewal of product registrations which are to expire on 1 March 2020 to 31 May 2020.

Price freeze

The DOH has issued Department Memorandum No. 2020-031 entitled: Price freeze of essential emergency medicines and medical devices due to COVID-19. Under this Memorandum, the DOH has ordered a price freeze on essential emergency medicines and selected medical devices in the entire country. A list of products subject to such price freeze is attached as an annex to the Memorandum. Medicines included in thelist are analgesics and anti-infective medicines / antibiotics.

New One-Stop Shop for Securing LTO to import COVID-19 Critical Commodities for Commercial Distribution

The DOH and the BOC have issued Joint Memorandum Circular No. 1 series of 2020 entitled: Creation of Bayanihan One-Stop Shop ("**BOSS**") for Securing LTO to import COVID-19 Critical Commodities for Commercial Distribution ("**Joint MC**").

The BOSS will cover all commercial importation of PPEs and certain medical devices determined as "COVID-19 Critical Commodities" by the DOH, and which require an LTO from the FDA. A list of such PPE and medical devices is attached as Annex A to the Joint MC.

Philippines

Last updated: 16 April 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The BOSS will provide for a single window that will accept all online applications for LTOs and applications for importation for the covered items. All transactions with the FDA and BOC shall be done online through the following websites: FDA LTO application | BOC application for clearance and release of shipment.

Once an application for importation or for LTO is entered into either the BOC or FDA portal, concerned agencies will automatically be prompted through the BOSS platform and email for other information and monitoring purposes. The need for verification of the licenses between the two agencies is dispensed with because each of the agencies are notified of the applications applied with each agency.

However, when the national public health emergency is lifted, all FDA rules and regulations on registration of health products, post-LTO inspection of establishment and post-market surveillance shall apply to the establishments which were issued the provisional LTO and all their health products. Based on the wording of the Joint MC, LTOs issued under such issuance are only provisional and the LTO holders will have to comply with the standard requirements of the LTO and health products covered after the ECQ is lifted.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

On 2 April 2020, the FDA issued FDA Circular No. 2020-006-A which allows companies to apply for clinical trial approvals by filing applications by email to the FDA. Prior to this, applications for clinical trials were filed manually at the FDA Action Center. However, aside from this, there appears to be no other issuance by the FDA on the management of ongoing clinical trials in the Philippines.

Also, the DOH has recently confirmed that the Philippines will join the World Health Organization's ("**WHO**") multi-country clinical trials in connection with a rapid global search for drugs that can treat COVID-19. Among the drugs that will be included in the trial are remdesivir, lopinavir and ritonavir combined, and two drugs plus interferon beta, and chloroquine. It is proposed that 20 hospitals with COVID-19 patients in the Philippines will participate in the trial. The Philippine Department of Science and Technology is also looking into virgin coconut oil as a treatment for COVID-19.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Aside from the circular mentioned in (a), we are not aware of any formal issuance by the DOH or the FDA on management of clinical trials.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

The DOH and FDA may consider adopting guidelines, similar to what other developed countries have formulated or are in the process of formulating, to manage clinical trials at this time.

Philippines

Last updated: 16 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Yes. Republic Act No. 8293, as amended, or otherwise known as the Intellectual Property Code of the Philippines ("**IP Code**"), authorizes a government agency or third person authorized by the government to exploit a patented invention, such as medicines, medical devices and biocides, even without the agreement of the patent owner where, among others:

- The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or
- In the case of drugs and medicines, there is a national emergency or other circumstance of extreme urgency requiring the use of the invention; or
- In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the DOH.

The use by the Government or third person authorized by the Government of the patented invention shall be subject, where applicable, to the following:

- In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable;
- If the demand for the patented article in the Philippines is not being met to an adequate extent, the right holder shall be informed promptly;
- The scope and duration of such use shall be limited to the purpose for which it was authorized;
- Such use shall be non-exclusive;
- The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; and
- The existence of a national emergency or other circumstance of extreme urgency, shall be determined by the President of the Philippines for the purpose of determining the need for such use or other exploitation, which shall be immediately executory.

While all disputes arising from the foregoing may be filed with the appropriate court with jurisdiction under the law, such authorization to exploit the patented invention shall be immediately executory and no courts, except the Supreme Court of the Philippines, shall issue anytemporary restraining order or preliminary injunction or such other provisional remedies that will prevent its immediate execution.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

As mentioned, Republic Act No. 11469, otherwise known as the Bayanihan to Heal as One Act, authorizes the President to exercise certain powers, for a limited time and subject to certain conditions, to implement the policies pursuant to the declaration of a state of national emergency over the entire Philippines due to the COVID-19 pandemic.

Specific to IP rights, the enactment of RA 11469 exposes patented inventions, such as medicines, medical devices and biocides, to the possibility of government use under the applicable ground(s) enumerated above under the IP Code, in view of the declaration of a state of national emergency by the President.

Philippines

Last updated: 16 April 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

E-Prescription

On 17 March 2020, the FDA issued FDA Circular No. 2020-007 entitled "Guidelines in the implementation of the use of electronic means of prescription drugs for the benefit of individuals vulnerable to COVID-19" ("**E-Prescription Guidelines**").

The E-Prescription Guidelines cover all individuals vulnerable to COVID-19 as defined therein and all licensed physicians authorized to prescribe drugs to such individuals. Individuals vulnerable to COVID-19 refer to those, regardless of age and nationality, who are either senior citizens, persons with disability ("**PWD**"), with chronic illness or those with immuno-compromised conditions who need to take prescription medicines and maintenance drugs.

The E-Prescription Guidelines allow all licensed physicians to issue electronic prescriptions by email or any other alternative modes considered as an electronic document. Such electronic prescription shall be deemed to be equivalent to a written prescription.

Primary Care Teleconsultation

On 26 March 2020, the FDA issued an announcement expressly recognizing the role of telemedicine, particularly, primary care teleconsultation. It mentioned that the DOH is currently finalizing guidelines that will:

- further promote the use of telemedicine;
- match health professional volunteers to telehealth providers / companies;
- assure that protocols of telehealth providers / companies are aligned with the latest DOH-approved algorithms;
- link telehealth initiatives with the regional / provincial / local epidemiological surveillance teams to facilitate contact tracing and surveillance activities; and
- collect data to propose investments in future iterations of the Philippine Health Insurance Corporation's primary care benefit package.

The DOH has partnered with Globe Telehealth Inc. (KonsultaMD) and Telimed Management and Medgate, to provide telehealth services for free as of 7 April 2020.

Digitalization under the Universal Healthcare Act

The recently passed Universal Healthcare Act ("**UHC Act**") requires all health service providers and insurers to maintain a health information system consisting of enterprise resource planning, human resource information, electronic health records, and an electronic prescription log consistent with DOH standards, which shall be electronically uploaded on a regular basis through interoperable systems. The health information system shall be developed and funded by the DOH and Philippine Health Insurance Corporation ("**PHIC**").

Under the Implementing Rules and Regulations of the UHC Act, the PHIC should incentivize the incorporation of health informaton systems, automation of clinical information, improvement of data quality, integration and use of telemedicine and participation in regional or national health networks.

Considering that digitization of health information, processes and services is an important component or feature of the UHC Act, and because the necessity and benefits of telemedicine and telehealth have been made evident at this time of the COVID-19 pandemic, we expect the Philippine government to spur the implementation and enforcement of these features of the UHC Act and UHC Act IRR to help address the COVID-19 situation and post-COVID-19.

Singapore

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The regulator in charge, the Health Sciences Authority ("**HSA**"), has been addressing the need by relaxing import restrictions. From 31 January 2020, importers of the following medical devices will not require an importer's licence from HSA:

- Surgical masks;
- Particulate respirators (e.g. N95 masks);
- Thermometers for measuring human body temperature; and
- Any protective gear for medical professionals (e.g. isolation gowns and gloves).

Importers of such medical devices for commercial purposes (and not personal use) will only need to notify HSA of their intention at least 24 hours before importation, and provide information on the brand and quantity of the devices to be imported into Singapore. Notification can be done via this form. Importers must also maintain proper sales and distribution records, and may use this template provided by the HSA to do so. If necessary, HSA may require these records to be submitted for review.

The HSA has also implemented greater regulatory flexibility to manage the increase in demand for respiratory devices for COVID-19 patients. The measures, which will only remain in effect during the COVID-19 period, are as follows:

- Healthcare institutions will be permitted to use existing HSA-registered anaesthesia machines or positive airway pressure devices as emergency ventilators for COVID-19 patients, provided that device manufacturers have developed specific instructions to support the safe use of such devices for such purposes. No approval from HSA is required. Manufacturers or local dealers will need to work closely with healthcare institutions to provide clear and specific instructions and ongoing support for use of such devices to ensure successful implementation.
- HSA has created an alternative regulatory pathway where registrants will not need to undergo the standard change notification process for upgrades or modifications made to registered ventilators and accompanying accessories that do not create undue risk to users, or for registration of new models of accessories for use with the registered ventilators. Registrants may implement these changes without waiting for HSA's approval, provided that:
  - The changes do not affect the registered performance specifications; and
  - The devices, including the new accessories, continue to meet the Essential Principles of Safety and Performance as set out in the Health Products (Medical Devices) Regulations 2010.

Registrants are only required to notify HSA with minimum information on these changes on a 6-monthly basis using this template and via this form.

- Companies that wish to supply ventilators that are currently not registered with HSA to meet local clinical needs may email HSA via the online form available here with the subject 'Supply of unregistered ventilators in Singapore'. HSA will then contact the company to advise on the next steps required to do so.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

HSA has set up an interim provisional authorisation process to ensure the timely availability of diagnostic tests for COVID-19 ("**Tests Kits**") in Singapore. Provisional authorisation is based on a risk-calibrated review process that considers the design and the supporting validation data of the Test Kits. Manufacturers of authorised Test Kits will have to submit periodic reports on specific data on safety and/or performance to HSA post authorisation to assure the continued performance of these devices. If any safety or performance issues are observed, HSA will require relevant follow up actions on the manufacturer's end.

Singapore

Last updated: 16 April 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Test Kits that have received this provisional authorisation from HSA can be supplied to healthcare institutions, private hospitals, medical clinics and clinical laboratories in Singapore. However, this is only an interim measure to facilitate the timely detection of COVID-19 infections. If applicants wish to supply the Test Kit in the long-term, it will still have to be registered with HSA.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

There have not been any reported issues in terms of obtaining regulatory approvals from HSA. Further, as Singapore has pledged to keep trade lines open, no export controls have been implemented.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

As a result of the implementation of stay-home notices, travel restrictions and visit restrictions at trial sites, trial participants ("**Participants**") may be unable to visit trial sites, and sponsors may face difficulties in conducting on-site monitoring visits.

The government has also recently implemented safe-distancing measures at the workplace, such as split team arrangements and staggered work hours for job functions which cannot be conducted from home. There is a possibility that the conduct of clinical trials in Singapore may be interrupted or delayed in order to comply with such arrangements. Furthermore, failure to comply with the measures may result in stop-work orders issued under the Infectious Disease Act which may cause considerable disruption to the clinical trial, which may be time sensitive.

Furthermore, a number of countries such as Taiwan and Thailand have implemented national controls to restrict the export of certain medical devices, while India has implemented export restrictions on certain active pharmaceutical ingredients and medicines. Clinical trials in Singapore which depend on such imported products, either as equipment or as clinical research materials required during the conduct of research, may face delays in obtaining these products. This may in turn disrupt the conduct of the clinical trial.

Singapore

Last updated: 16 April 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

(c) Are there any general tips and recommended solutions under the local regulatory framework?

In light of COVID-19 and the considerations laid out in the Guidance which suggest the use of remote alternatives, we may expect to see more clinical trials being conducted virtually so as to minimise interruptions or delays that would otherwise occur.

It may indeed be an opportune time for sponsors and investigators of clinical trials to consider going "site-less" by conducting remote clinical trials through mobile applications and platforms. For example, applications such as ObvioHealth and PRA's Mobile Health Platform enable sponsors to conduct video consultations with Participants, arrange for delivery of the investigational product to Participants, and obtain and record real-time data and insights from Participants.

Ultimately, regardless of the site or platform utilised, sponsors and investigators should ensure that conduct of clinical trials during this period adheres to the requirements set out in the Guidance.

Singapore

Last updated: 16 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Yes. Singapore has in place emergency supply measures such as compulsory licensing and urgent import of patented pharmaceutical products.

Under section 56 of the Patents Act, the Singapore government may issue a compulsory licence for domestic production of patented pharmaceutical products to supply the domestic market during circumstances of extreme urgency, which include public health emergencies. Additionally, during such circumstances, the government may also import any relevant patented pharmaceutical product, and issue a compulsory licence for it, as long as the government has given the relevant notification to the Council for Trade-related Aspects of Intellectual Property Rights ("**TRIPs**").

Such use by the government or any party so authorised will not be deemed as infringement of the patent. However, safeguards have been put in place ensure products manufactured under the compulsory licence are not abused for commercial profit. For instance, under section 60 of the Patents Act, re-export of such patented pharmaceutical products imported into Singapore under the TRIPS system is prohibited. Section 62 also ensures that patent holders are remunerated by the government accordingly for use of their patent.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

There have not been any orders issued relating to state emergency supply measures, nor discussions to issue such orders as yet.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

There has been a considerable increase in the use of telemedicine services in Singapore following the COVID-19 outbreak, as more patients prefer virtual consultations over visiting a clinic so as to reduce their exposure to the virus. In response to such demand, more doctors are signing up with telemedicine service providers to offer such services.

Telemedicine service providers have also announced that their doctors will be working more shifts to handle the increase in demand. To address possible COVID-19 cases, Doctor Anywhere has launched a dedicated COVID-19 Medical Advisory Clinic available to individuals in Singapore, Thailand and Vietnam. The service connects users with a doctor for a video consultation within five minutes, where the doctor will check for symptoms, travel history and other particulars to determine if the user might be infected with the COVID-19 virus. If the patient is suspected to be infected, the Doctor Anywhere team will arrange for further assistance, including deploying an ambulance to transport the user to the National Centre for Infectious Diseases within the next hour to be tested.

In addition to the various telemedicine companies and medical clinics already operating telemedicine services prior to the outbreak, more healthcare service providers are entering the market in response to COVID-19. For instance, Alexandra Hospital has started to offer virtual consultation services for patients at home. The hospital has also begun to make use of robots in wards to remotely inspect or deliver medication to isolated COVID-19 patients so as to minimise the risk of infection and to conserve use of personal protective equipment.

There have not been any interim measures implemented following the outbreak regarding the use of telemedicine. However, prior to the outbreak, the Ministry of Health ("**MOH**") has been operating a regulatory sandbox for certain telemedicine providers operating in Singapore, so as to better understand their business and develop suitable laws and guidelines. The anticipated legislative changes intended to regulate telemedicine services will only be implemented at the end of 2022 under the new Healthcare Services Act.

Taiwan

Last updated: 24 June 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

There are mechanisms under the Pharmaceutical Affairs Act of Taiwan (PAA) for the central health authority in Taiwan to address the urgent needs for medicines, medical devices and medical supplies.

Pursuant to Article 48-2 of the PAA, the Ministry of Health and Welfare (MOHW) may grant special approvals for the manufacture or import of drugs or medical devices needed in a public health emergency, such as the COVID-19 outbreak, without following the procedures for ordinary product registration. Under such a mechanism, the regulatory review of products to be imported or manufactured, as well as the grant of approval (2 to 4 weeks), are much faster than those for ordinary product registration (4 to 18 months). Since February 2020, the MOHW has granted several special approvals for the manufacture and/or import of medical coveralls, coronavirus diagnostic test kits, thermometers, and medical masks necessary for the prevention or diagnosis of COVID-19.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Generally speaking, any drugs, treatment options or technologies that may facilitate the diagnosis or treatment of COVID-19 are being published, evaluated or approved very swiftly. In addition, on an individual case basis, domestic manufacturers may be compensated for setting up additional production lines for producing medical supplies.

For example, the application for conducting phase III clinical trial for Remdesivir, a drug that could treat patients with COVID-19, was immediately approved by the MOHW and this trial is now being performed in Taiwan. In addition, the Taiwan government has also provided domestic medical mask manufacturers with additional machines for free in exchange for a certain amount of medical masks produced by those manufacturers.

Please see (c) for the challenge(s) the COVID-19 outbreak has brought regarding market access, particularly in terms of regulatory approval.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Under Taiwan regulations, GMP certificate or the equivalent of a plant is required for the new product registration or the renewal of an existing product registration of a drug or medical device produced thereby and onsite inspection on the plant is a required step for the regulator to grant a new GMP certificate or renew an existing one designated by the regulator.

However, because of the global travel bans, all scheduled inspections on offshore plants have been cancelled. As a result, the grant of new GMP certificates or the renewal of existing ones designated by the regulator for those offshore plants and the new product registrations or renewal of existing ones for relevant products are being delayed inevitably.

Currently the regulator gives certain flexibilities to the existing GMP certificates designated by the regulator that cannot be renewed timely because of cancellation of onsite inspections, and for which the relevant existing product registrations would therefore expire. The holders of such GMP certificates may still apply for the extension of such GMP certificates and the regulator would allow the extension on an individual case basis when onsite inspection has not been conducted.

The authority anticipated to resume the inspection on offshore plants in Q4 2020 or 2021.

The export of specific types of medical mask and thermometer were banned by Taiwan government since January and March 2020, respectively. These bans have been lifted and thermometers and medical masks manufactured domestically can be exported since April and June 2020, respectively.

Taiwan

Last updated: 24 June 2020

Clinical Trials

(a)	**What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?**	As of now, we have not heard of any notable impact of the COVID-19 outbreak on patient recruitment or the management of clinical trials conducted in Taiwan.
(b)	**Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**	As of now, the influence of COVID-19 on clinical trials conducted in Taiwan is limited, and therefore the regulator has not implemented any measures to assist with clinical trial management. Nevertheless, the regulator is willing to discuss/propose solutions if the industry encounters any difficulty in clinical trial management.
(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	There are none for now.

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	Please see our response to question 1. So far we have not seen any notable IP issue (e.g., compulsory licensing) arising from the measures that Taiwan regulators have implemented.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	There are none for now.

Telemedicine

(a)	**How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**	Telemedicine in Taiwan is only permitted under very limited circumstances, and the regulator does not intend to change the regulations of telemedicine services in light of the COVID-19 outbreak. Nevertheless, the Department of Health of municipal governments is allowed by the MOHW to approve at its own discretion requests for telemedicine services made by patients, especially those in isolation/quarantine, and arrange medical treatments on a case-by-case basis.

Thailand

Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- **Medicine**

The Ministry of Public Health (the "MOPH") empowered the Government Pharmaceutical Organization (the "GPO") to be the authorized importer of Favilavir from the private manufacturer in the People's Republic of China via government-to-government (G2G) sales. Furthermore, the Food and Drug Administration (the "FDA") arranges a fast-track registration for relevant drugs for treatment of COVID-19.

- **Medical Devices**

The FDA is providing a fast-track channel for business operators who wish to apply for approval to manufacture or import 14 certain general medical devices, whereby the FDA aims to approve the applications within one day, provided that all supporting documents are in good order. Furthermore, the government of China is providing COVID-19 test kits and protective equipment (e.g. N95 mask and surgical mask).

- **Cosmetics**

The FDA has reclassified alcohol-based hand sanitizers with an alcohol concentration of 70 percent or greater as a cosmetic product to increase product circulation in the market and hasten the importation process.

The FDA allows traditional and modern drug manufacturers to temporarily manufacture alcohol-based hand sanitizers for one year or six months, provided that certain criteria are met. Additionally, the Ministry of Finance issued a notification to grant import duty exemptions to certain products, regardless of tariff code of the products, which are imported for treatment, diagnosis, or prevention of COVID-19.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The GPO, in cooperation with the Department of Traditional and Alternative Medicine and the Department of Medical Science, agreed a Memorandum of Understanding on research and development of Andrographis paniculata (a herb used in traditional Thai medicine known as fah talai jon), as laboratory tests results suggest that an extract from the herb is effective in curbing virus intrusion into human cells. Additionally, Chulalongkorn University is developing a COVID-19 vaccine and aims to start a clinical study in November or December 2020.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

There is no other critical impact at this stage.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The FDA has provided infection risk control measures for clinical trials. These measures include communicating with the official of the FDA via email, instead of face-to-face, and extending the deadline for submission of the documents and reports which are relevant to clinical trial management.

Thailand

Last updated: 30 September 2020

Clinical Trials

(b)	**Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**	The FDA announced the recommendation and guidelines in accordance with Good Clinical Practice (GCP) for conducting clinical trial during COVID-19 pandemic.
(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	We recommend discussing the details with the FDA officials on a regular basis if there are any alternates to the approved protocol.

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	No, there are no urgent import orders of any such products. While the law allows compulsory licensing, we do not foresee any practical implications with regard to IP protection.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	None.

Telemedicine

(a)	**How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**	The COVID-19 outbreak has accelerated telemedicine and telepharmacy services in Thailand. During the lock-down, many hospitals sent drugs to their patients by post or by delivery, provided certain conditions were met. The draft Notification of Public Health regarding the Standards of Telemedicine Services Provided by Medical Facilities was opened for public hearing from 19 to 30 June 2020, and the Pharmacy Council of Thailand issued the Notification No. 56/2563 regarding Specification ofStandards and Processes for Providing Telepharmacy Services, as a guideline for pharmacists to comply with. Moreover, the Medical Council of Thailand also issued the Notification No. 54/2563 regarding Guidelines with respect to Telemedicine practices.

Vietnam

Last updated: 03 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

On 11 March 2020, the Medical Examination and Treatment Department under the Ministry of Health (MOH) issued Official Letter No. 188/KCB-NV, with reference to the list of essential drugs and medical devices necessary for the prevention and treatment of COVID-19, in preparation for the event where COVID-19 cases in Vietnam surpass 10,000 cases.

Pursuant to Official Letter No. 188/KCB-NV, the Drug Administration of Vietnam (DAV), as the regulator of medicine in Vietnam, published Official Letter No. 2507/QLD-KD dated 17 March 2020, to entities producing and importing drugs. In this Official Letter No. 2507/QLD-KD, the DAV encouraged relevant entities to optimize supply sources of drugs and drug ingredients, and to formulate plans regarding drug production and the drug business to ensure timely supply of essential drugs to cope in the event COVID-19 cases in Vietnam surpass 10,000 cases.

However, in the Official Letter No. 2507/QLD-KD, the DAV does not mention anything about the fast-track approval for the marketing authorization or import licenses of such essential drugs.

In terms of medical devices, the MOH recently issued Official Letter No. 1592/BYT-TB-CT dated 25 March 2020, to facilitate the manufacture and importation of test kits for COVID-19 in order to accommodate the needs of health facilities in light of the COVID-19 outbreak.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Due to the COVID-19 outbreak, the Prime Minister issued Directive No. 16/CT-TTg on 31 March 2020 ("**Directive 16**"), which orders nationwide social distancing from 1 April to 15 April 2020. Accordingly, the implementation of "Nationwide Social Distancing" within 15 days was effective from 12 am on 1 April 2020 on a national scale. As far as we understand, some licensing authorities have temporarily closed down or are either just conducting online operations or maintaining a skeletal workforce who rotate going to the office. This impacts the regulatory approval process.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Due to the requirement of social distancing and working from home, the regulatory approval for medical devices and drugs has slowed down.

Vietnam

Last updated: 03 April 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

Vietnam Prime Minister Nguyen Xuan Phuc issued Directive 15/CT-TTg dated 27 March 2020 ("**Directive 15**"), which requests local authorities to implement strict measures to stop the spread of COVID-19, including, among others, the temporary suspension of service providers, except those relating to "essential goods and services"; restriction on social gatherings; and restriction on travel. These restrictions went into effect on 28 March 2020, and will remain effective through 15 April 2020 (please see here).

Further, the Prime Minister recently issued Directive 16/CT-TTg dated 31 March 2020 ("**Directive 16**"), which implements national quarantine for 15 days, from 12 am of 1 April 2020. Accordingly, people are advised to stay at home and only go out when absolutely necessary,such as when buying food or medicines, providing emergency treatment, going to work at facilities that are allowed to maintain operation to provide essential goods or services, and in other urgent circumstances (please see here).

As a result, many people are under self-quarantine or state-mandated quarantine, and have limited access to public places (including hospitals).

Under Guidance No. 2601/VPCP-KGVX on the implementation of Directive No. 16/CT-TTg on preventing COVID-19 dated 3 April 2020, clinical trial management is not listed as an essential service (please see here).

We note that the above mentioned restrictions will likely impact clinical trials, specifically with respect to aspects such as patient recruitment, data collection and analysis in Vietnam, as is the case in other countries.

With respect to how the government is reacting to the conduct of clinical trials to treat COVID-19, the MOH recently approved a clinical trial project to use Chroloquine for the treatment of COVID-19. Collaborating parties include the National Hospital of Tropical Diseases, Cho Ray Hospital, Cu Chi Field Hospital, Can Gio Hospital, Pasteur Institute in Ho Chi Minh City and Oxford University Clinical Research Unit (OUCRU). However, there is no information available about the participation of companies providing clinical trial services.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

We are not aware of any measures adopted by the relevant regulator to assist with clinical trial management as of date.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

None.

Vietnam

Last updated: 03 April 2020

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	The government has not yet adopted any state emergency supply measures, such as urgent import orders or compulsory licensing for these products.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	There have not been any at the time of this writing.

Vietnam

Last updated: 03 April 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Under Circular No. 49/2017/TT-BYT of the MOH dated 28 December 2017 ("**Circular No. 49**"), telemedicine is defined as "the exchange of information related to a patient's health between such patient and a health care provider or among health care providers in distant areas through the use of information technology (IT) and telecommunication." Circular No. 49's scope covers healthcare facilities and authorities, organizations and individuals related to telemedicine within the territory of Vietnam, and includes offshore organizations and individuals that connect telemedicine with healthcare facilities based in Vietnam. Circular No. 49 categorizes telemedicine activities as follows: (a) telemedicine consultation; (b) remote medical examination and treatment consultation; (c) teleradiology consultation; (d) remote anatomy consultation; (e) remote surgery consultation; and (f) training in telemedicine technology transfer.

The MOH issued Decision No. 774/QD-BYT of the MOH dated 11 March 2013, on the application of telemedicine in building satellite hospital systems to overcome the overload of medical examination and treatment needs in hospitals. In Decision No. 1303/QD-BYT of the MOH dated 08 April 2016, the MOH published a list of hospitals registering the satellite hospital project, in which more than 60 hospitals in the country registered and have provided telemedicine services.

In the context of the COVID-19 outbreak in Vietnam, the government and specialized agencies have stepped up infection prevention and control measures, including restricting visits in crowded places to avoid cross-infection. Currently, hospitals, agencies and departments have begun tightening organizational mechanisms to prevent the further spread of COVID-19. However, there is no official directive to encourage citizens to use telemedicine services.

In response to COVID-19, the MOH, with the help from third-party service providers, has launched two apps for voluntary medical declaration, which are NCOVI on iOS and Suc Khoe Vietnam on Android. Hotlines are provided to help citizens consult regarding symptoms of infection and notify the authorities to implement quarantine timely. These apps limit public exposure of suspected COVID-19 patients when seeking medical care at health facilities during patients' incubation period.

The MOH has also established the Telemedicine Centre for COVID-19 outbreak control. This Telemedicine Centre will provide online remote consultancy and assistance to healthcare facilities with regard to the collection, diagnosis and treatment of patients, as well as organizing remote training to supplement and update professional knowledge in order to help doctors at health facilities in the diagnosis and treatment of patients through the use of information technology and telecommunications.

Baker McKenzie.

Europe, Middle East & Africa

COVID-19: A Global Review of Healthcare and Life Sciences Industry Issues

Europe, Middle East and Africa

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Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

I. Since 25 March, the Minister of Health and the Federal Agency for Medicines and Health Products (FAMHP) can take special individual and/or collective measures to **address shortages of medicines** in the framework of the COVID-19 pandemic (Royal Decree of 24 March 2020 on special measures to address shortages of medicines in the framework of the SARS-CoV-2 pandemic). They have the competence to:

- restrict or prohibit the export of any medicinal product or starting material
- limit the supply of a medicine to a maximum quantity per patient
- limit the supply of a medicine or raw material to pharmacies to a fixed quantity per pharmacy
- reserve the supply of a medicine for hospital dispensaries
- order the redistribution of stocks of a medicinal product or a starting material, either by way of a return to the wholesaler or by way of direct redistribution among pharmacies
- commandeer stocks of a medicinal product or a starting material to redistribute it
- authorise and regulate the delivery of medicines by doctors or other healthcare professionals
- order that the stock of medicines at wholesalers can only be sold or delivered according to the instructions of the FAMHP.

They can only take such measures if they can demonstrate their necessity, proportionality and adequateness. Moreover, the measure taken must be limited in time. The Belgian state is obliged to compensate the damage resulting from the measures taken.

The FAMHP teams continuously monitor the availability of medicines in Belgium to avoid a shortage of medicines in case of a second wave of Covid-19.

Currently, the FAMHP has already taken the following measures to address shortages of medicines:

- To avoid over-ordering and misallocation of stocks, wholesalers must limit the quantities of medicines and raw materials on the list (see Annexes of the Decision of the Chief Executive Officer of the FAMHP, dated 23 June 2020, on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic) to those corresponding to last year's sales in the same period, plus a maximum of 50 %. Larger quantities may be supplied if this does not compromise the supply to other wholesale distributors, other persons authorised to supply medicines to the public, or other hospitals, and if this has been previously notified to the Chief Executive Officer of the FAMHP. In any case, the wholesale dealer must deliver in accordance with the specific allocation key or instructions of the Chief Executive Officer of the FAMHP;
- The FAMHP sets quotas for a range of medicines for which there are no shortages (yet) in order to avoid excessive orders or overstocking. The website of the FAMHP does not mention on which medicines exactly quotas have been set. These quotas are evaluated and assessed on a weekly basis;

In addition, the FAMHP investigates the possibility of using veterinary medicines in humans. Stocks of Proposure, a sedative containing propofol that is marketed for veterinary use, have already been supplied to hospitals.

Belgium

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

II. **The former provisions on the measures to address shortages of certain medical devices and personal equipment are no longer in force.**

The sale of rapid self tests for the measurement or detection of COVID-19 antibodies is as from September 19, 2020 no longer prohibited.

III. **The Government has temporarily relaxed certain regulatory rules:**

- In a circular, the FAMHP laid down **terms and conditions for the manufacture, outsourcing and reprocessing of medical devices and their accessories for care facilities.** The circular establishes a framework to increase opportunities for healthcare institutions to collaborate with external companies on alternative solutions to address **proven** shortages of the material necessary for patient health, on the one hand through the "in-house" production of certain medical devices and, on the other hand, through reprocessing of single use medical devices.
  - *In-house medical devices* are medical devices that may only be used in care facilities and cannot be put on the market. Care institutions can call on external companies for the design, production, packaging and labelling of these in-house devices. Under the conditions set out in the circular, no national derogation for their use has to be requested from the FAMHP.
  - *Reprocessed medical devices* are medical devices are single-use medical devices but which can be reused under certain conditions. The reprocessing of these medical devices can be carried out by the care institution itself or outsourced, provided that the conditions set out in the circular are met.

  The guidance can be found here: v1 - 9 April 2020: https://www.fagg.be/sites/default/files/content/afmps_circulaire-omzendbrief_fabricage_fabrication_meddev.pdf.
- The FAMHP has also issued **guidelines for in-house fabrication of respiratory devices accessories using 3D printing**. These guidelines must make it possible to ensure patient safety when using these products. It contains an overview of potential risks related to the undocumented use of 3D printing technologies. The hospital and its subcontractor are expected to perform a risk analysis and this overview should help them with this analysis. The criteria set out in the circular remain applicable.

  The guidance can be found here: v1 - 6 April 2020: https://www.fagg.be/sites/default/files/content/guidance_afmps_3d_printing.docx.
- Persons authorised to supply medicinal products are now, for a period of 6 months from 18 March 2020, authorised to prepare **alcohol gels** containing at least 70% alcohol and place these products on the market if these products are intended for human hygiene as part of the fight against the spread of COVID-19. However, these hand alcohol gels may only be sold to healthcare professionals (Royal Decree of 18 March on the preparation and marketing of hand alcohol gels for human hygiene as part of the fight against the spread of COVID-19).

Belgium

Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- The rules regarding the conformity requirements of face masks have been relaxed:
  - **Surgical face masks**
    - Although the original guidance indicated that it is to be ensured that surgical face masks which do not bear the CE marking are only made available during the current crisis and do not enter regular distribution channels, the updated version no longer requires that the products cannot enter regular distribution channels. There is no longer a prohibition for non-CE marked surgical masks, which have been tested and approved in accordance with (i) an equivalent standard or (ii) the ATP protocol, to enter into regular distribution channels.
    - During the COVID-19 crisis, surgical face masks without a CE mark can be accepted if the face masks comply with an equivalent international standard (such as USA: ASTM F2100 or China: YY 0469:2011 and YY/T: 0969-2013). The test certificates based on these other international standards must be able to guarantee a quality comparable to the European standard EN 14683.
    - In addition, a simplified test protocol exists for surgical face masks that are not accompanied with the necessary declarations, certificates and test reports: the "Alternative Test Protocol" (ATP). The ATPonly takes into account the test results of two important parameters: Bacterial Filtration Efficiency and Differential Pressure.
    - If the test indicates that the face masks can be released as surgical face masks, the following conditions apply:
      - the masks may only be used during the crisis period;
      - the end-user is explicitly informed that the masks are not tested in full compliance with the EN 14683 standard;
      - the end-user is informed about the ATP and its application;
      - the information about the masks released in this way is fully transparent and consultable viathe FAMHP website;
      - a warning shall be printed on the retail packaging by means of the sticker (see guidance document).
    - Surgical face masks that do not meet the requirements of the ATP may not be placed on the market. These masks can only be exported back to the supplier or destroyed at the expense of the importer with proof of destruction.
    - The FAMHP will make the test results of the masks publicly available. The list of released batches will be updated regularly.
    - The guidance can be found here: v3 - 25 May 2020: https://www.famhp.be/sites/default/files/content/20200525_en_info_aanbieden_chirurgische_maskers_clean_0.pdf

Belgium

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Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- **PPE masks**
  - Exceptionally, PPE masks that do not bear the CE marking can be accepted, provided that it is ensured that such products are only made available to health professionals during the current crisis and do not enter regular distribution channels.
  - For the evaluation of the conformity assessment certification of face masks, the Federal Public Service Economy now accepts equivalent international standards (such as European Union: EN 149+A1:2009 à FFP2 and FFP3; Australia: AS/NZS 1716:2012 à P3, P2; Brazil: ABNT/NBR 13698:2011 à PFF3, PFF2; China: GB 2626-2006 à KN100, KP100, KN95, KP95; Japan: JMHLW Notification 214, 2018 à DS/DL3, DS/DL2; Korea: KMOEL-2017-64 à Special, 1st Class; Mexico: NOM-116-2009 à N100, P100, R100, N99, P99, R99, N95, P95, R95; USA: 42 CFR 84 à N100, P100, R100, N99, P99, R99, N95, P95, R95).
  - In addition, the ATP can be used if the PPE masks are not accompanied with the necessary declarations, certificates and test reports. Only masks that meet the requirements of the ATP and have a fit that is good enough may be provided to healthcare professionals. These masks cannot be put into free circulation, can only be used during this crisis period and require special warnings, information and user instructions to be placed on the packaging.
  - FFP2 and FFP3 masks that do not meet the requirements of the ATP or which have a fit which is not good enough cannot be released.
  - The guidance can be found here: https://economie.fgov.be/sites/default/files/Files/Entreprises/Conditions-deliveries-FFP2-FFP3.pdf and https://economie.fgov.be/nl/themas/ondernemingen/coronavirus/mondmaskers-en-filters/conformiteit-voor-mondmaskers/coronavirus-niet-conforme

Belgium

Last updated: 30 September 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Any medicine containing a new active substance for the treatment of viral diseases falls within the mandatory scope of the centralised procedure, meaning that they must be assessed by the European Medicines Agency and authorised by the European Commission. EMA is ready to support medicine developers with all available regulatory tools to advance and expedite the development of effective measures to fight and prevent the spread of this virus. These include fast tracked scientific advice, PRIME scheme, accelerated assessments and conditional marketing authorisations. The EMA has also offered free scientific advice for COVID related products.

Clinical

Trials for other than COVID-19 trials have been delayed, suspended. Now lockdown measures are being eased, several non-COVID-19 related trials can be restarted or relaunched. However, when making the decision to restart or launch a new clinical trial, the risk of a new large-scale outbreak of COVID-19 should be considered. A new outbreak could affect the timeline to collect evidence necessary for a marketing authorisation application and therefore potentially affect the timelines for filing such applications.

In Belgium, the government is collaborating with the pharmaceutical industry in the fight against COVID-19. As part of the collaboration (i) the Belgian health regulator has committed to approve COVID-19 related clinical trials within four working days, (ii) with support from the Belgian government, pharmaceutical companies (including Janssen, Pfizer, GSK and UCB) are opening up their labs to significantly scale up COVID-19 testing capacity. Furthermore, the government has agreed to the establishment of a Belgian Unit to combat infectious diseases. This Unit must facilitate the start up of phase 1 clinical trials and human challenge clinical studies in optimal circumstances in order to accelerate research on COVID-19. The financing hereof will be provided by a public private partnership worth 40 million euro.

This commitment of the FAHMP to approve COVID-19 trials within four working days has now been laid down in a circular. (see: https://www.fagg.be/sites/default/files/content/omzendbrief.pdf). For clinical trials involving advanced therapies (somatic cell therapy medicinal products, tissue engineered products or gene therapy medicinal products) or medicinal products containing genetically modified organisms (GMOs), a shortened time period of ten working days shall apply.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

See comments above.

Belgium

Last updated: 30 September 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

- Clinical trials are being delayed or suspended across Europe as a consequence of the COVID-19 crisis. In Belgium, the KU Leuven (one of leading research centers in the country) said it is suspending all non-essential research and no new experiments will be set up in its labs. This is with the exception of COVID-19 related research acivities which will be prioritized.
- According to BIO which is collecting information from member companies, two significant challenges to conducting clinical trials in the current environment have emerged: Missing or delayed data collection from ongoing clinical trials, particularly at hospital sites overwhelmed by COVID-19 cases (The Belgian regulator has advised against source data verification conducted by Sponsors); and difficulties getting new clinical trials up and running because patients are reluctant to enroll or unable to visit hospitals.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

I. The FAMHP, the Clinical Trial College and the Belgian Association of Research Ethics Committees (BAREC) have issued a Belgian Guidance on the Management of Clinical Trials during the COVID-19 pandemic. This document must be read in conjunction with the European Guidance on Clinical Trials.

The Guideline indicates that priority will be given to any (new) clinical trial application related to the treatment or prevention of COVID-19 infections. For multi-country COVID-19 related trials, the guidance draws attention to the accelerated Voluntary Harmonization Procedure. For multi-country COVID-19 related trials, the guidance draws attention to the accelerated Voluntary Harmonisation Procedure. For national COVID-19 related trials, it strongly recommends the accelerated CTR Pilot because a single review by the selected evaluating EC (without possible local EC's) is sufficient.

The accessibility of healthcare facilities can be restricted due to COVID-19 measures. When the participating patient cannot go to the investigator site, home nursing and/or contact via phone may be required. Direct shipment of trial medication from sponsor to patient is still not allowed in Belgium but the medication can be directly shipped to the trial participant under the responsibility of the principal investigator. It isalso allowed to send the shipment from the distributor to the patient provided that all the conditions prescribed in the European and the national guidance arerespected. The distributor (not the courier service) is not allowed to work with the details of the clinical trial's participant. He can only work withthe trial number of each participant. The trial participant names, address and contact details may never be provided to the sponsor and the distributor. The distributor can only have access to the trial participant's trial number to track the shipment and its preparation, storage at the distributor site.

Only trial medication that is suitable for transport, storage at home and administration at home use is eligible for direct shipment. Moreover, special training must be provided to the participant, care giver, nurse or physician on the home administration of the trial medication. This training must be documented. Documentation is paramount. The responsibilities of each party in the direct shipment of trial medication have tobe documented.

Remote source data verification (e.g. providing sponsor with copies of medical records or remote access to electronic medical records) is currently not allowed in Belgium. No exceptions are made to the general prohibition in Belgium.

Furthermore, the government is collaborating with the pharmaceutical industry in the fight against COVID-19. As part of the collaboration the Belgian health regulator has committed to approve COVID related clinical trials within **four days**. The government has also agreed to the establishment of a Belgian Unit to combat infectious diseases. This Unit must facilitate the start up of phase 1 clinical trials and human challenge clinical studies in optimal circumstances in order to accelerate research on COVID-19. The financing hereof will be provided by a public private partnership worth 40 million euro.

The guidance can be found here: v2 - 29 April 2020: https://www.fagg.be/sites/default/files/content/national_guidance_corona_20200429c_clean.pdf.

Belgium

Last updated: 30 September 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

II. The European Commission has also approved a € 4 000 000 Belgian direct grant scheme for the Brussels-Capital region to support COVID-19 related research and development projects in Brussels. This scheme must provide incentives to companies to direct their activities to research and production of certain products, like vaccines, drugs or disinfectants, or treatments, which are most crucial in the current circumstances. In particular, the scheme covers industrial research and experimental development projects and supports 80% of the eligible costs for the duration of the project. Furthermore, undertakings are encouraged to cooperate with each other or with research organisations by benefitting from a 15% bonus when the R&D research project is carried out in cross-border collaboration with research organisations or other undertakings, or when the research project is supported by more than one Member State (see https://www.concurrences.com/en/bulletin/news-issues/preview/the-eu-commission-approves-eur4-million-belgian-scheme-to-support-covid-19).

III. The FAMHP has issued a national guidance on the Management of Clinical Investigations during the COVID-19 (Coronavirus) pandemic. This guidance should help sponsors of clinical trials for medical devices to manage these trials in the COVID-19 context. Due to the COVID-19 crisis, the visits to healthcare facilities are restricted.

Moreover, an increased demand for health services exists and the availability of investigation staff is often changed. In addition, patients may be required to self-isolate, which makes the maintenance of medical oversight more difficult or even impossible.

- Therefore, the guidance contains a **list of possible changes of the trial** that sponsors can implement during the COVID-19, such as the conversion of physical visits into phone or video visits or the extension of the duration of the investigation. The involved investigators must agree with these changes. The possible changes mentioned in this guidance can also be initiated by the investigator sites contacting the sponsor. Before the ongoing trial can be changed, also the overall well-being and best interests of the participant must be taken into account.
- The safety of the participant is always of primary importance. Therefore, **any changes to the ongoing trial must be based on risk assessment** performed by the sponsor in collaboration with the principal investigators. The sponsor must reassess these risks as the situation develops.
- **The competent authorities and Ethics Committees must be informed** if (i) a new event is likely to have a serious effect on the benefit-risk balance of the trial whereby it is possible that immediate actions are required by the sponsor and investigator to protect the subjects against immediate hazard and (ii) changes are likely to affect the safety or well-being of the participants and/or the scientific value of the investigation but do not require immediate action from sponsor or investigator.
- If **re-consent** of the participant is needed for the implementation of new urgent changes in the ongoing trial, alternative ways of obtaining such re-consents should be considered during the pandemic e.g. contacting the participants via phone or video-calls and obtaining oral consents supplemented with email confirmation.
- **Remote source data verification** (e.g. providing sponsor with copies of medical records or remote access to electronic medical records) is still not allowed as it might infringe trial participants' rights. In addition, provision of redacted/de-identified pdf files will not be acceptable as it puts disproportionate burden on site staff.

The guidance also indicates that absolute priority is given to any clinical investigation related to the treatment or preventon of COVID-19 infection or a COVID-19 related illness.

The guidance can be found here: v1 - 30 April 2020: https://www.fagg.be/sites/default/files/content/guidance_during_covid19_pandemic_for_ci.pdf

Belgium

Last updated: 30 September 2020

Clinical Trials

(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	None.

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	We are not aware of any actions to address drug or other shortages other than those described in section 1. Specifically, we are not aware of any compulsory licensing issues or other measures having impact on IP.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	None.

Telemedicine

(a)	**How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**	Yes, in response to the guidelines to combat the spread of the coronavirus, various telemedicine services have been created. First, only doctors were able to make use of these services but later this possibility has also been opened up to other healthcare professions, such as psychiatrists, neuropediatricians, dentists, physiotherapists, speech therapists, midwives, psychologists, occupational therapists and diabetes educators. Patients and doctors have made frequent use of this possibility during the crisis (this is illustrated in the following graph: https://www.riziv.fgov.be/SiteCollectionDocuments/evolutie_aantal_adviezen.pdf). Royal Decree Nr. 20 (of 13 May 2020 on temporary measures in the fight against the COVID-19 pandemic and to ensure continuity of care in compulsory medical care insurance) lays down the principles to be observed when providing telemedicine services. It also stipulates which healthcare services can be provided remotely together with the applicable conditions. The Royal Decree clarifies that these telemedicine services can be fully reimbursed and that it is not allowed to charge additional fees for these services. Royal Decree Nr. 21 (of 14 May 2020 containing temporary adjustments to the reimbursement conditions and administrative rules in the compulsory insurance for medical care as a result of the COVID-19 pandemic) adds that an electronic medicine prescription can be provided after a telephone or video consultation. The current provisions regarding telemedicine services are only introduced temporarily during the COVID-19 crisis. However, valuable information is collected about the use of these telemedicine services. This information will be analyzed and on the basis of this data the possibility of defining a definitive regulatory framework for telemedicine services will be discussed.

Czech Republic

Last updated: 30 November 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Please note that in the Czech Republic, the State of Emergency ended as of 17 May 2020, but was declared again as of 5 October 2020. During the first State of Emergency, the Government and the Ministry of Health adopted multiple preventive and protective measures, including restriction of export of certain medicinal products, medical devices and personal protective equipment, granting marketing authorizations to certain biocidal products and relaxing CE procedures for face masks and related equipment. Although most of the measures have already come out of effect, there is a possibility that some of them will be readopted in connection with the current second State of Emergency.

Currently, the distribution and sale of medicinal products and medical devices is controlled in the following ways:

- The Ministry of Finance set out maximum prices of FFP3-type respirators, which is CZK 175 (approx. EUR 7) if produced in the EU, or CZK 350 (approx. EUR 14) if produced outside of the EU.
- The Ministry of Health limits the possibilities of prescriptions of the medicinal product plaquenil, which could be potentially effective against COVID-19. Most HCPs are completely prohibited from prescribing the medicinal product.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The Ministry of Health has issued several extraordinary decisions to grant approvals of the introduction on the Czech market of various items that could help to eliminate the spread of COVID-19 or to treat patients, including:

- the experimental medicinal product *Remdesivir*
- the non-registered medicinal product *HYDROXYCHLOROQUINE-SULFAAT TEVA*
- medical oxygen, which may be temporarily produced from other active substances than those specified in the registration documentation, if such other active substance is specified in registration of different medicinal product approved in any member state and have certificate of good manufacturing practice; this medical oxygen may be filled in tanks that are not in compliance with the manufacturing authorization, if such tanks are prepared in compliance with good manufacturing practice and the manufacturer will ensure its traceability

Czech Republic

Last updated: 30 November 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

N/A.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

We are unaware of any specific impacts on the management of clinical trials other than described further herein.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

On 6 Nov 2020, the Czech State Institute for Drug Control (SIDC) has issued a new Opinion on Ongoing Clinical Trials and To-Be-Commenced Clinical Trials in Connection with COVID-19. It supersedes previous opinions on this matter.

In this opinion, the SIDC sets out various recommendations and extraordinary measures to ensure safe conduct of clinical trials (e.g. to asses whether the trial subjects (patients) are positive to COVID-19 or could have been exposed thereto, to properly asses risk/benefit ratio of enrolling new trial subjects (patients), to replace the physical follow-up visits of patients on site by telephone/virtual visits, to introduce conditions for the home delivery of investigational medicinal products (IMP), etc.). Majority of the measures is particularly relevant for areas with worsened epidemiological situation.

Applications for new clinical trials regarding COVID-19 are assessed by the SIDC in reduced time limits.

On 7 October, the SIDC has issued the Information on Submitted Documentation in Clinical Trials on Drugs against COVID-19. This document aims specifically at drugs containing genetically modified organisms and states that even during on-going pandemic, laws and SIDC regulations relating to the use of genetically modified organisms still apply with certain exceptions (pursuant to the EU Directive 2020/1043, the clinical trials aiming to cure COVID-19 do not need approval of the Ministry of Environment for GMO handling).

EU Measures: Please note that the European Parliament and the Council have adopted the Regulation (EU) 2020/1043 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19). In this Regulation, certain conditions of relevant COVID-19-related clinical trials have been relaxed.

Czech Republic

Last updated: 30 November 2020

Market Access

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Please refer to the State Institute for Drug Control's Opinion on Clinical Trials On Medicinal Products and Ongoing Clinical Trials and To-Be-Commenced Clinical Trials in Light of the COVID-19 Epidemiological Situation and the Information on Submitted Documentation in Clinical Trials on Drugs against COVID-19.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Generally, regarding measures concerning medicinal products, medical devices and biocides, please refer to the above. We are unaware of any specific IP protection matters.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

N/A

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

There are no specific legislative measures or anticipated legislative changes in the area of telemedicine. However, the current crisis initiated the need for a practical implementation of telemedicine procedures in various healthcare areas. As an example, during the first State of Emergency, people were encouraged to only visit physicians in urgent cases and to get in contact with physicians primarily by phone or other means of distance communication. Some health insurance companies started reimbursing medical doctors for conducting virtual patient visits. In addition, several state telephone help-links for the consultation of COVID-19 symptoms have been established. Multiple practical measures in this area continue to apply or have been re-implemented.

France

Last updated: 11 August 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

I. **Market access for medicines**.

Article L. 3131-15 of the French Public Health Code (introduced by the health emergency Law No. 2020-290 of 23 March 2020) allows the Government, for the sole purpose of guaranteeing public health, to take some emergency measures. In particular, the French Government is allowed:

"*Whenever necessary, to take any measure allowing the provision of appropriate medicines to patients for the eradication of the sanitary disaster*".
Based on the above, several measures have been implemented by the French government to ensure the availability of **medicines needed to treat patients**.

- **Derogatory uses for medicines needed to treat COVID-19 patients**
  - Off-label dispensation of the medicine Rivotril® in injectable form is authorized by retail pharmacies for the treatment of patients affected or likely to be affected by the COVID-19 upon presentation of a medical prescription mentioning "*Prescription Outside MA in the context of COVID-19*"
  - Dispensation to general public of paracetamol in injectable form is authorized by hospitals' pharmacies (PUI), upon presentation of a medical prescription mentioning "*Prescription for COVID-19*".
  - Medicines with an importation authorisation and which list is set by ANSM may be imported by the National Public Health Agency without carrying out the finished products' controls required by the French public health code.

In this context, it is to be noted that the use of medicines under derogatory conditions has not been decided by the French National Agency for Medicines and Health Products (ANSM) (the authority in charge of assessing the use and marketing of medicines) on basis of existing derogatory mechanisms (such as temporary recommendation for use (French so-called RTU) but by the French Government by way of decrees.

- **Restrictions on export, sale and dispensation of medicines needed to treat COVID-19 patients**
  - Delivery of paracetamol by pharmacies to the general public, without medical prescription, is limited (1 box per asymptomatic patient, and 2 boxes per symptomatic patient).
  - Internet sales of paracetamol, ibuprofen and aspirin to the general public are suspended.
- **Pricing and reimbursement procedures prioritizing certain medicines**
  - Due to COVID-19, the French health authorities have implemented a prioritization process for pricing and reimbursement assessment procedures. In practice, the relevant Committee will evaluate as a priority medicines indicated in the treatment of COVID-19 as well as first applications for reimbursement (first-time registration or extension of a registered indication) for medicines in oncology, pediatrics or serious diseases fields where there is an unmet medical need.
- **Fast-track procedures for COVID-19 clinical trials**
  - ANSM, the French Ministry of Health (DGS), the French ethics committees (CPPs) and the French data privacy authority (CNIL) have put in place fast-track procedures for COVID-19 clinical trials (see section 2 below).

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France

Last updated: 11 August 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

II. **Market access for medical devices and personal protective equipments**.

The French government has implemented several measures to ensure the availability of medical devices and personal protective equipments needed to combat the spread of COVID-19 and to treat patients.

- **Requisition of masks**
  - As mentioned above, Article L. 3131-15 of the French Public Health Code (introduced by the health emergency Law No. 2020-290 of 23 March 2020) allows the Government, for the sole purpose of guaranteeing public health, to take some emergency measures. In particular, the French Government is allowed to:
  - "*Order the requisition of all **goods/assets** and services necessary for the fight against the sanitary disaster (…). The compensation of these requisitions is governed by the code of defense*".
  - The provisions that allowed the French government to requisition the stocks of certain types of respiratory protection and anti-projection masks stored or produced in France have been repealed.
  - Moreover, the French Government has adopted some measures in view of setting maximum retail and wholesale prices of some surgical masks that qualify as medical devices. French agents from the Ministry of Economy (DGCCRF unit) regularly carry out controls to ensure that prices are duly monitored.
- **Derogatory imports of masks, glasses and protective visors**
  - Pursuant to an inter-ministerial instruction dated 9 June 2020 (relating to the implementation of the European Commission Recommendation (EU) 2020/403 of 13 March 2020), the French Government authorizes, under the control of the supervisory authorities, the importation in France of non CE-marked masks, glasses and protective visors under restrictive conditions (which differ depending whether the product qualifies as a personal protective equipment or a medical device and whether it is intended for healthcare professionals or not), provided that these products comply with certain foreign standards recognized as equivalent to the standards that usually apply.
- **Medical devices' substitution**
  - The substitution (under specific conditions) of a medical device by the service provider, the distributor or the dispensing pharmacist is now authorised in the event of a proven shortage of a medical devices necessary for the continuity of a patient's care.
- **Pricing and reimbursement procedures prioritizing certain medical devices**
  - As mentioned above for medicines, due to COVID-19, the French health authorities have implemented a prioritization process for pricing and reimbursement assessment procedures. In practice, the relevant Committee will review as a matter of priority the medical devices and health technologies that have no equivalent in the treatment of serious diseases or where there is no alternatives and for which an application for a first registration for reimbursement or a reimbursement for a new indication is filed. This includes COVID-19 products.
- **Fast-track procedures for COVID-19 clinical trials**
  - ANSM, the French Ministry of Health (DGS), the French ethics committees (CPPs) and the French data privacy authority (CNIL) have put in place fast-track procedures for COVID-19 clinical trials.

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France

Last updated: 11 August 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

III. **Market access for biocides**.

Two Orders, dated 13 March 2020 and 10 July 2020, authorize derogatorily and temporarily pharmacists, pharmaceutical companies, manufacturers of cosmetics or biocides products and classified installations for the protection of the environment to produce and place hydroalcoholic solutions on the market.

Moreover, the French Government has adopted some measures in view of setting maximum retail and wholesale prices of hydro alcoholic gels. Maximum prices are different depending on the gels' volume. French agents from the Ministry of Economy (DGCCRF unit) regularly carry out controls to ensure that prices are duly monitored.

IV. **Market access for in vitro diagnostic medical devices (IVDs).**

Where difficulties in the supply of IVDs prevent medical biology laboratories from carrying out examinations in sufficient numbers to face the health crisis, they may use non CE-marked IVDs, under restrictive conditions.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- All the measures described in question 1 (a) can be seen as opportunities in terms of regulatory approvals. However, they are limited to:
  - specific products (medicines, medical devices, personal protective equipment and biocides) deemed to be essential in the context of and/or for the purpose of COVID-19 crisis
  - the duration of the health crisis
- On the other hand, products others than those mentioned here above are not deemed as priorities and companies may therefore face unforeseen delays in the launch of these products (clinical trials delayed, pricing and reimbursement inscription delayed, etc.) and important decrease of the sales of these products (cancelation of non-essential surgery, etc.).
- Off-label use of products and use of imported medicines could have consequences in terms of patients' safety. Authorities and companies have to closely monitor pharmacovigilance and devices vigilance.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Please see our answers above.

France

Last updated: 11 August 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

French healthcare establishments were overcrowded with COVID-19 patients and medical staff was overloaded. Activities and medical teams in most of the French healthcare establishments were being reorganized in order to face the major sanitary crisis. In this context, clinical trial challenges were in particular as follows:

- Patient recruitment for non-COVID-19 clinical trials have been negatively impacted by the fact that patients might be reluctant to spend more time in the hospital than is required for their own medical treatment.
- Medical staff participating in non-COVID-19 clinical trials might not have had enough availability as most of the medical teams in healthcare organizations had to handle COVID-19 related issues in one way or another, even when not specializing in area related to the treatment of COVID-19.
- Ensuring optimal conditions for patients' safety might have been a challenge in particular in view of the risk of COVID-19 contamination.
- Patients' monitoring might have been jeopardized by the quarantine instructions, particularly considering that dematerialized and decentralized clinical trials were not yet commonly conducted in France.
- Recruiting patients for COVID-19 clinical trials was negatively impacted by the media coverage on the use of chloroquine (some patients refused to be included in clinical trials conducted on other medicines).
- Setting up COVID-19 clinical trials urgently was a challenge given the usual heavy regulatory requirements.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

In view of the above-mentioned challenges, in March 2020, ANSM formally requested clinical trials' sponsors to re-evaluate relevance of setting up new clinical trials, given the priority set for COVID-19 clinical trials. ANSM invited clinical trials sponsors to assess the risks associated with the interruption of treatment versus the risks associated with their continuation in a context where the teams at the research sites are heavily solicited. According to the Agency, priority must be given to patients with progressive, life-threatening pathologies. Thus, continued inclusion in a clinical trial may be considered in situations of uncovered medical need and subject to taking into account the potential risks associated with the risk of concomitant COVID-19 infection.

In May 2020, ANSM indicated that the resumption of inclusions may be considered in interrupted clinical trials, while respecting measures to protect patients and healthcare professionals.

For COVID-19 clinical trials: ANSM, the French Ministry of Health (DGS) and the French ethics committees (CPPs) have put in place fast-track procedures for the initial assessment of the applications.

Thus, as an exception to the provisions of article L. 1123-6 of the French Public Health Code and until a date to be set by decree but no later than 31 December 2021, CPPs in charge of processing COVID-19 clinical trials' applications are no longer selected randomly but are directly designated by the French Ministry of Health.

Concerning the data privacy aspects linked to clinical trials, the French Data Privacy Authority (CNIL) also indicates that its services process these requests for authorization as a matter of priority and within extremely short timeframes in the event that the planned data processing does not comply with the existing fast track procedures

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Please take into account the information in the previous question.

France

Last updated: 11 August 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Article L. 3131-15 of the French public health code (introduced by the health emergency Law No. 2020-290 of 23 March 2020) allows the Government, for the sole purpose of guaranteeing public health, to take some emergency measures and notably:

"Order the requisition of all **goods/assets** and services necessary for the fight against the sanitary disaster (…). The compensation of these requisitions is governed by the code of defense"; and

"Whenever necessary, to take any measure allowing the provision of appropriate medicines to patients for the eradication of the sanitary disaster";

It being provided that "The[se] measures (…) [shall be] strictly proportionate to the health risks incurred and appropriate to the circumstances of time and place".

These provisions are not IP oriented but as they are broadly drafted they could be used to implement compulsory license on assets such as intangible assets protected by patents and more generally IP rights and patented medicines.

Moreover, for any IP deadline before the French intellectual property office ("INPI"), Ordinance No. 2020-306 of 25 March 2020 (as modified) provides that all deadlines occurring in the period between 12 March and 24 June shall be postponed. This ordinance applies to all time limits provided for in the intellectual property code, with the exception of those resulting from international agreements or European texts (such as the priority periods for international extension trademark, the payment deadline for a patent application or the deadline for filing a supplementary protection certificate).

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

At this stage, we are not aware of any such discussions.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

The conditions for the reimbursement of remote medical consultations for COVID-19 infected patients or showing symptoms of infection have been relaxed until 31 December 2020.

Freelance midwives, speech therapists, occupational therapists, psychomotor therapists, masseur-physiotherapists, pedicure-podiatrists, orthoptists and dieticians are also derogatorily authorized to conduct remote medical consultations.

These are interim measures. The measures facilitating recourse to remote medical consultation and authorising its reimbursement under strict conditions (including compliance with the coordinated care pathway) are fairly recent in France. We therefore do not anticipate any legislative changes on this subject at this stage. However, this "forced" use of remote medical consultations may change mentalities, particularly those of French physicians and patients who, for some of them, were reluctant to use telemedicine.

Hungary

Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- Medicines: The relevant authority is the National Institute of Pharmacy and Nutrition ("OGYÉI" or the "Authority"). OGYÉI stated that the export of medicinal products manufactured with hydroxychloroqiune-sulfat active substance might cause disruption in the supply of medicinal products. Such disruption could hinder the treatment of COVID-19 and the protection of Hungarian citizens' lives. Consequently, OGYÉI prohibited the export of hydroxychloroqiune-sulfat active substance and medicinal products containing it for a period of six months from the date of this decision. In addition, we are not aware of any further measures in respect of the above.
- The Government of Hungary issued the Governmental Decree No. 282/2020 ("Decree"). The Decree constitutes the termination of the state of emergency.
  - Submission of final samples: Basically, in case of a change affecting the first marketing of the medicinal product in Hungary, as well as its packaging or the package leaflet, a final sample of the medicinal product must be submitted to the OGYÉI. However, having regard to the current state of emergency and the OGYÉI's digital work schedule, OGYÉI informed applicants that a digital photo of the final sample of the medicinal product must be sent to the OGYÉI's Office Gate (in Hungarian "Hivatali kapu") through the electronic service platform for legal persons i.e. "Cégkapu" or the electronic service platform for natural persons i.e. "Ügyfélkapu". If the size of the photo as a file to be submitted is too large and it shall not be submitted through the Cégkapu or the Ügyfélkapu, the photo shall be sent via email to a specific email address (igazgatas.iroda@ogyei.gov.hu). Finally, if it is not possible to submit the photo of the final sample in electronic form at all, the final sample shall be submitted in person at the OGYÉI's seat (1051 Budapest, Zrínyi utca 3.) every Friday from 11 AM until 11:30 AM in compliance with the applicable epidemiological rules.
- Medical devices and medical supplies:
  - On the homepage of the OGYÉI from 16 March, the OGYÉI makes it clear that rules on conformity assessment and CE-marking must continue to be applied in case of medical devices.
  - According to the European Commission's decision, Hungary obtained the customs tariff and VAT exemption for imported face masks, ventilators and other protective health care supplies imported from outside the EU due to the state of emergency. However, the exemption shall not automatically apply to all protective health care supplies as only products distributed free of charge can be exempted from taxation.

Hungary has received significant quantity of face masks and other PPE from China.

Hungary

Last updated: 30 September 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

We are not aware of any changes in connection with regulatory approval in case of market access. However, please note the information on the submission of final samples indicated above in point (a).

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

We are not aware of any further challenges regarding market access in terms of regulatory approval. However, we note that Hungary has recently received significant quantity of facemasks and other PPE from China. Nevertheless, as there is a huge need for PPE products and this need may increase in the future; we cannot exclude that restrictive measures will be introduced in Hungary, similar to other EU counties such as Germany.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The extraordinary measures already implemented to inhibit the spreading of infection may have an impact on the conduct of clinical trials and some changes may be required. However, the continuity of clinical trials must be provided especially for those patients for whom the continuation of the treatment is especially important (e.g., oncology patients).

The Clinical Trials Expert Group (CTEG), the Heads of Medicines Agencies Clinical Trials Facilitation and Coordination Group (CTFG) and the GCP Inspectors' Working Group coordinated by EMA accepted a harmonized EU-wide recommendation on the conduct of clinical trials during the COVID-19 pandemic. This recommendation has a major impact on clinical trials in Hungary as well. Related thereto, OGYÉI has published a recommendation ("Recommendation") that will be applied together with this EU harmonized recommendation.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The OGYÉI's above-mentioned recommendation contains general and specific measures related to certain issues, such as the authorization practice, the study visits and the monitoring and supply of IMP. Please see below some examples of major issues raised by the OGYÉI:

i. There are two major goals: in-depth risk assessment of ongoing trials shall be performed and measures shall be taken to prioritize the patient's safety and data validation. In case of a conflict between these two goals, the patient's safety must be the priority. If the patients' enrollment is suspended due to the COVID-19 pandemic, it is enough to notify OGYÉI on its suspension.

ii. Risk assessment shall be repeated and properly documented, depending on the evolution of the situation. Any deviation from current practice should be proportionate, verifiable and clearly documented.

iii. Protocol deviations must also be documented.

iv. If the epidemiological situation so requires, the transfer of subjects to existing or new test sites should be considered. Such a relocation may be carried out only with the agreement of the subjects and the principal investigators (transfer and host) by appropriately transferring the eCRF to ensure that the new test site has access to all information and previously collected data and to record new data. The relocation agreement should be documented in the TMF (e.g., by email).

Hungary

Last updated: 30 September 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

v. If the relocation of the site also meets with difficulties, subjects should be informed in the simplest way, via telephone. This must be documented as well and the decision should be made whether to hold or terminate the study. OGYÉI should be informed about this decision, subsequently giving the reasons and the exact time points.

vi. If any site moves to another settlement of the institute or to another healthcare institution due to the evolved crisis and there the study is continued, OGYÉI only needs to be informed subsequently giving the exact dates of the address change. There is also an opportunity for the investigator to move the patient care to a private surgery that has not been marked as a satellite-site before, but OGYÉI and the Ethics Committee needs to be informed and subsequently it needs to be submitted as an amendment.

vii. If the transfer of study drugs requiring special storage conditions must be changed, the way of the amended transfer shall be documented (e.g., in a refrigerator bag), however, OGYÉI shall not be notified of this amendment.

viii. OGYÉI currently does not support that the study drug may be provided from the sponsor directly to the patient's home, as the sponsor would not know the patient's personal data (name, address).

ix. OGYÉI suggests considering stopping the patients' enrollment during this period.

x. OGYÉI will evaluate the clinical trial requests related to the treatment or prevention of COVID-19 in expedited procedure.

The whole recommendation of OGYÉI is available in English on this link.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Please take into account the above-mentioned legislations and the OGYÉI's information.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

We are not aware of any specific Hungarian legislations regarding the above. However, in respect of the export ban for hydroxychloroquine-sulfate and products containing this substance, if a medicinal product containing hydroxychloroquine-sulfat may not protected by patent, the grant of patent may be forced due to the state of emergency.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

We are not aware of any such discussions.

Hungary

Last updated: 30 September 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

- Act LVIII of 2020 on the temporary rules related to the termination of the state of emergency and the epidemiological preparedness lists the rules remaining applicable after the termination of the state of emergency. The act also contains temporary regulations of healthcare relevance.
- The performance of certain health care services and consultations through telecommunication devices such as telephone, skype, email instead of personal interactions is encouraged.
- Rules on telemedicine services. The following activities shall be provided in the patient's absence, based on the information available through remote monitoring tools and other infocommunication technologies:
  - to assess the patient's state of health,
  - to identify diseases and their risks,
  - to identify an actual disease(s),
  - to order further examinations necessary for a more accurate assessment of the patient's condition/disease and to initiate medical treatment,
  - to identify the effectiveness of the measures included in the above points i - iv through remote consultation and
  - to monitor the patient's state of health and to make diagnosis.
- The Act specifies the several services which may be performed through telemedicine, among others:
  - patient management through teleconsultation which may serve as the basis of remote consultation between a specialist HCP and the patient;
  - receiving statements regarding patient information, consent and the patient's data processing;
  - pre-screening through remote consultation to assess the health condition of the patient and to determine whether a personal meeting may be necessary to provide healthcare service;
  - prior contacting and data collection which may make the personal consultation more efficient and faster following the remote consultation;
  - setting up diagnosis and therapeutic proposals through remote consultations, remote monitoring or with remote diagnostic tools;
  - prescription of medicine;
  - medical check-up and after-care based on the previous personal consultation;
  - organizing remote consilium;
  - issuing referral;
  - psychotherapy, crisis intervention, parental counseling, counseling, supportive psychotherapy;
  - physiotherapy with a remote consultation device;
  - breastfeeding counseling;
  - care provided by district nurses;
  - consultation by phone, online or in other forms.

Hungary

Last updated: 30 September 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

As for clinical trials, OGYÉI published a recommendation to be applied together with the EU harmonized recommendation. Non-personal interactions are also encouraged by OGYÉI in the case of clinical trials as follows:

i. If wet ink signature may only be obtained with difficulties, alternative documentation tools (such as printed email) may be applied.

ii. The new clinical trial applications and substantial amendment requests should be sent to the OGYÉI client gate. However, clinical trial materials may be uploaded through CESP as well. As not all applicants have access to CESP, the relevant documents may be submitted through other channels as well, such as eudralink or transfer.

iii. In the case of ongoing clinical trials, patients may need to be re-informed and new consents may also need to be obtained from them. Alternative ways of obtaining such consents should be considered, such as telephone or video call and the confirmation of an oral consent with email. However, all consents obtained in these ways shall be documented.

iv. The sponsor, together with the principal investigator, shall consider postponing or stopping the site visits or performing them via telephone.

v. The use of telephone or video calls may be considered in connection with monitoring.

vi. If the continuation of the study is not possible at the investigational site anymore and the relocation of the site also meets with difficulties, subjects should be informed in the simplest way, via telephone.

vii. The sharing of patient data and the remote access of the sponsor's representative to the electronic database of healthcare institutions is not acceptable due to the protection of particularly sensitive data and ethical considerations.

Italy

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

In Italy, with Decree Law No. 18 of March 17, 2020 ("Decree Law 18/2020"), as converted by Law No. 27 of 24 April 2020, the Italian Government introduced exceptional measures allowing the manufacturing, import and placing on the market of surgical masks for medical use (medical devices) and personal protection equipment in derogation from the existing legislation.

- Indeed, pursuant to Article 15 of Decree Law 18/2020, manufacturers, importers and those who place on the market surgical masks intending to make use of the above-mentioned derogation, must send to the National Health Institute (Istituto Superiore di Sanità) a specific application along with a self-certification whereby they certify, under their own exclusive responsibility, the technical characteristics of the masks and declare that the same fulfill all safety requirements established by the in-force regulations. No later than three days from the issue of the self-certification, manufacturers and importers must also provide the National Health Institute with all elements useful to validate the surgical masks which are the subject of the self-certification.
- Within 3 days from the receipt of the above-mentioned elements, the National Health Institute shall express its opinion on whether surgical masks comply with the in-force regulations. If the National Health Institute resolves that surgical masks do not comply with the applicable in-force regulations, the relevant manufacturer shall immediately cease their production and the importer shall be prevented from placing them on the market.
- The above-mentioned procedure also applies to personal protection equipment with the only difference that, for these products, the authority responsible for receiving/reviewing the self-certification and the supporting documentation and for assessing compliance with the in-force regulation is the National Institute for Insurance against Accidents at Work (Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro — INAIL).
- The possibility of making use of said derogation is limited to the duration of the state of emergency resulting from the COVID-19 outbreak (currently, six months from 31 January 2020) with the consequence that, at the end of the emergency period, companies intending to manufacture, import and place on the market surgical masks and personal protection equipment shall comply with standard rules.

With circular letter dated 22 May 2020, the Italian Medicines Agency ("AIFA") updated the rules on extraordinary and simplified procedures for the submission and approval of clinical trials of medicinal products for patients with COVID-19 in accordance with Article 40 of Decree Law No. 23 of 8 April 2020 as converted by Law No. 40 of 5 June 2020.

- With respect to clinical trials, applications for authorization must be submitted to the AIFA through registration on the website of the National Observatory on Clinical Trials on Medicinal Products or, in case of technical issues, in paper format or via certified e-mail to the AIFA and the National Ethical Committee Spallanzani. Application must be filed together with the relevant supporting documentation, amongst which, the study protocol, the notice and the form for the patient informed consent, the label of the investigational medicinal product and any manufacturing/import authorization.
- As regards the procedures for the launch of compassionate uses, applications for therapeutic use programs must be sent, in electronic format, to the AIFA and the National Ethics Committee together with a brief synopsis, the protocol and the form for the informed consent whereas methods for the collection of data can also be sent after the first submission for evaluation purposes. With regard to nominal therapeutic uses, these remain the responsibility of local Ethics Committees.
- For prospective observational pharmacological studies, which only include studies related to drugs used in the standard clinical practice according to their authorized indications, the same must be notified simultaneously to the AIFA and the National Ethics Committee in electronic format.
- The above-mentioned circular also identifies the minimum requirements that proposals for clinical trials and observational studies must comply with in order to be assessed.

Italy

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

In order to promote the development of vaccines and drugs against the COVID-19 infection, with Resolution No. 564/2020 dated May 7, 2020, the Italian Medicines Agency (hereinafter the "**AIFA**") introduced urgent provisions for the activation of sites for Phase I clinical trials in derogation from the current provisions established by the AIFA's Resolutions No. 809/2015 and No. 415/2016.

- In particular, with the above-mentioned Resolution, the AIFA identified the essential requirements under which healthcare structures authorized to conduct clinical trials can activate Experimental Units for the conduct of Phase I trials to fight the COVID-19 infection, both on patients and healthy volunteers, while ensuring the protection of the rights and safety of trial subjects.
- Among the various essential requirements set forth by Resolution No. 564/2020, we name the following:
  - The Phase I Experimental Unit must be located within a healthcare structure equipped with an intensive care unit;
  - The staff of the intensive care unit must be informed about the clinical trial protocol and the time frame with which trial subjects will access the facility for treatment;
  - The activation of the Phase I Experimental Unit must be notified to the AIFA with no need to wait for 90 days for the beginning of the trial;
  - The Phase I Experimental Unit must implement all necessary measures to avoid the spread of intra-hospital contagion and, in case of healthy volunteers, it must have treatment areas separated from those where COVID-19 patients are received or hospitalized;
  - The Phase I Experimental Unit must provide both the staff and trial subjects with the protective equipment necessary to prevent contagion;
  - The Phase I Experimental Unit must ensure the full traceability of clinical trial data;
  - The Phase I Experimental Unit must identify a person responsible for communication with the competent regulatory authorities.
- The validity of the exceptional provisions introduced by Resolution No. 564/2020 is limited to the duration of the health emergency and, in any case, until the adoption of a new resolution providing for its withdrawal.
- In light of the current trend of the SARS-COV-2 epidemic, and the consequent reduction in the number of patients that can be enrolled in clinical trials, on May 19, 2020 the Technical Scientific Committee ("**CTS**") of the Italian Medicine Agency ("**AIFA**") issued a notice addressed to sponsors of new clinical trials requesting the latter to verify in advance the actual possibility of enrolling the expected subjects.

  The CTS further informed that, in line with the recent recommendations of the World Health Organization, its current position is to encourage the aggregation of several clinical sites in order to reach a sufficient number of samples to answer the clinical question with methodological rigor and in a short time. To this end, the CTS invited sponsors to check in advance the list of authorized studies available on the AIFA website.

  Lastly, the CTS discouraged, at this stage of the epidemiological trend, the submission of applications for therapeutic use programs on medicines for which sufficiently promising results from clinical studies are not available.

On September 8, 2020, the Ministry of Health and the Italian Associations of Pharmacists agreed on the opportunity to make available in pharmacies COVID-19 serological tests validated by the Italian Institute of Health and the Technical-Scientific Committee.

Italy

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

In this respect, the Ministry of Health undertook to draw up a list of serological tests which can be performed in pharmacies according to methods to be agreed with health authorities, also with respect to the transmission of results. Said decision aims at promoting the role of pharmacies in the screening and data collection for the purposes of epidemiological studies and the monitoring of the evolution of the disease in support of public action against COVID-19.

On September 14, 2020, the State-Regions Conference also reached an agreement whereby Italian pharmacies will be allowed to distribute on behalf of Regions 1.5% of influenza vaccines purchased by latter. In this respect, several Italian Associations of Pharmacists claimed that said percentage is far below the actual needs of the population and announced their willingness to negotiate with the Ministry of Health in order to increase the same to an amount of between 3% and 10% of vaccines purchased by Regions.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

On 11 March 2020, AIFA established a Coronavirus Crisis Unit in order to combat and contain the spread of COVID-19. The Coronavirus Crisis Unit is involved, amongst others, in following activities aimed at expediting the authorization/approval process for the off-label use of certain medicines and access to investigational drugs:

- Off-label use of drugs: Considering that in the context of the emergency several Italian hospitals already apply protocols providing for the off-label use of drugs marketed in Italy, the Coronavirus Crisis Unit has the task of approving those already identified, based on their prior assessment by the AIFA's Technical and Scientific Committee.
- Research and development/access to investigational drugs: In view of evidences related to certain investigational drugs, the Coronavirus Crisis Unit is responsible for assessing and possibly approving, together with the Technical and Scientific Committee, clinical trials and compassionate use programs on drugs containing experimental molecules (e.g., *Remdevisir* and *Tocilizumab*).

With respect to countering shortages of medicines at hospital level, the Coronavirus Crisis Unit is also in charge of managing contacts with MAHs and importers with respect to the regularity of supplies of medicines used at the hospital level during the emergency and facilitating the import of critical products.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

We are not aware of any further challenges regarding market access in terms of regulatory approval.

Italy

Last updated: 30 October 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

- The difficulties of sponsors in filing paper documentation relating to applications for authorization and/or substantial amendments to clinical trials.
- The difficulties of patients in reaching trials sites due to the adoption of containment measures.
- The closure of certain trial sites.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

With notice published on 7 April 2020, AIFA updated the guidelines, first published on 12 March 2020 and addressed to pharmaceutical companies, non-profit sponsors and CROs for the management of clinical trials in light of the containment measures adopted by the Council of Ministers and the Ministry of Health preventing trial subjects from reaching the relevant clinical sites.

In view of the above-mentioned measures and in order to guarantee, where possible, the continuity of the trials while reducing contacts between medical staff and patients, the guidelines also provide for the following exceptions to/derogations from the existing rules on clinical trials:

- Regarding the submission of applications for authorization and substantial amendments to clinical trials, the postponement of deadlines for the filing of paper documentation and the introduction of specific procedures for the submission of documentation relating to clinical trials for the treatment of COVID-19;
- In light of difficulties of patients in reaching trial sites and in order to guarantee the therapeutic continuity, the possibility, subject to notification to the competent Ethics Committees, of carrying out certain clinical trial activities (e.g., delivery of investigational products, performance of medical examinations, management of adverse reactions) outside of the same sites and, therefore, directly at the patient's home or at an healthcare establishment other than the authorized trial site;
- Regarding the conduct of the trial outside of the site and the administration of investigational drugs at patients' home, the possibility of using third party providers to deliver drugs directly from the hospital pharmacy to trial subjects, in accordance with the instructions of the hospital pharmacy and the principal investigator and provided that safety conditions applicable to the transport, storage and administration of investigational products are complied with;
- The application, under the principal investigator's responsibility, of exceptional measures for the remote monitoring and clinical management of patients by the trial site's staff was introduced, as well as the possibility for the sponsor to directly enter into contracts with companies/providers specializing in services for the clinical management of patients, without prejudice to the need to obtain the specific opinion of the Data Protection Authority in the case such forms of monitoring involve sensitive data;
- Lastly, the possibility for the sponsor to reimburse directly any exceptional costs incurred by trial subjects in light of the measures aimed at protecting them

The validity of the above-mentioned measures is limited to the COVID-19 emergency period.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

N/A

Italy

Last updated: 30 October 2020

IP Risks

(a) **Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**

We are not aware of any specific Italian legislations on this point.

(b) **Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**

We are not aware of any such discussions.

Telemedicine

(a) **How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**

In light of the containment measures adopted by the Italian Government to combat the spread of COVID-19 preventing trial subject to reach the relevant clinical sites, the guidelines on the management of clinical trials adopted by the AIFA on 12 March 2020, as updated on 7 April 2020, allow principal investigators to implement, under their own responsibility, exceptional modalities (e.g., teleconference or videoconferencing with the trial staff) for data source verification provided that the activity is regulated by a Standard Operating Procedure (SOP) of the sponsor/CRO and that modalities are evaluated and approved by the trial site responsible for data protection.

Other monitoring methodologies involving more risky access to sensitive data, such as the video recording of source documents or making available to the sponsor/CRO's monitor original documents in shared digital platforms, must always be approved by the party responsible for data protection of the trial site, but it is recommended to seek the specific opinion of the Data Protection Authority.

We note, however, that the validity of the above-mentioned provisions is limited to the COVID-19 emergency period.

Kazakhstan

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The issue of the urgent need for medicines and medical devices is addressed in the Kazakhstani Rules for Import of Medicines and Medical Devices into Kazakhstan, as approved by the Order of the Minister of Healthcare and Social Development of Kazakhstan No. 668 dated 17 August 2015 ("**Rules**").

Specifically, the Rules provide, among other things, the expenditure procedure of import of medicines and medical devices both with and without market authorization in case of emergency situations.

On 2 April 2020, the Kazakhstani Ministry of Healthcare adopted new Rules for Preclinical Studies and Clinical Trials #142. According to the new rules, the National Center for Expertise of Medicines and Medical Devices should review a clinical trial dossier of medicines preverting state-emergency situations and an orphan medicine clinical trial dossier no later than 15 days calendar days once it is filed.

On 16 March 2020 the Eurasian Economic Commission adopted the list of medicines and medical devices required for the treatmert of COVID-19, which are released from customs duties. The benefit is valid until 30 September 2020. The list includes tests, vaccines, components for manufacturing antiseptics, components for manufacturing protection equipment, packages of biohazards waste, protecting medical clothing, medical masks and respirators, protective googles etc. This decision of the Eurasian Economic Commission applies to Kazakhstan as a member of the Eurasian Economic Union.

No other changes and/or relaxations have been introduced because of COVID-19.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The MoH reviews and implements extremely fast new COVID-19 treatment protocols based on WHO recommendations and the experience of China and Western Europe.

Among this, one of the local medical research centers developed the COVID-19 express-tests per request of the MoH. The studies of test have been completed in two months. As of today, the MoH acquired the first batch of that test.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Regardless the state emergency and the strict quarantine introduced in Nur-Sultan (the capital of Kazakhstan) and Almaty (the main financial and business center of Kazakhstan), the National Center for Expertise of Medicines and Medical devices continues working and accepting the documents for clinical trials and marketing authorization. We are not aware of any delays in the working of this center. However, sinceall hospitals and HOPs are working closely with treatment of COVID-19 patients, we cannot exclude that clinical trials may be delayed because of the epidemic.

Kazakhstan

Last updated: 16 April 2020

Clinical Trials

(a)	**What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?**	No changes of procedure for clinical trials have been introduced because of COVID-19 except the reduction of the period of reviewing the clinical trial dossier by the National Center for Expertise of Medicine and Medical Devices (please see our comments above).
(b)	**Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**	We believe that the MoH adopted these measures in the interim in order to allow medicines aimed at the treatment of epidemic diseases, such as COVID-19, enter the market quickly.
(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	Since the changes were adopted a few days ago, we have no general tips and recommendations at this stage.

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	No changes to the IP protection measures have been introduced.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	No.

Telemedicine

(a)	**How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**	Before the COVID-19 epidemic Kazakhstan launched the development of telemedicine for residents of rural districts having no close access to hospitals or healthcare organizations. No significant developments occurred in this sphere because of absence the sufficient finance. However, certain medical institutions announced that they are ready to provide remote medical care to patients during quarantine. As of today, all people, who arrived from outside of Kazakhstan and having first negative test on COVID-19, should have 14-days self-quarantine in their apartments. Healthcare professionals monitor these patients health via phone or video-internet communications avoiding personal visits. There is no other telemedicine development at this stage.

Netherlands

Last updated: 18 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

On 26 March 2020, the Minister for Medical Care announced several measures relating to Dutch medicine provision. By taking these measures, the Minister for Medical Care aims to prevent medicine shortages.

The measures against medicine shortages focus on two aspects of medicine provision: the availability of medicines for the treatment of COVID-19 patients and the continuity of the general medicine provision within the next weeks or months. The Minister for Medical Care took the following measures:

1. Monitoring the availability of medicines for the treatment of COVID-19 patients - From 26 March 2020, the Medicines Evaluation Board (CBG) and the Health and Youth Care Inspectorate (IGJ) will monitor the availability of all medicines used in intensive care or for the treatment of COVID-19, regardless of whether or not there is a notification of medicine shortages. Furthermore, the minister instituted a committee focusing on the availability of medicines: Coronaberaad Beschikbaarheid Geneesmiddelen (CbBG). Moreover, the Minister for Medical Care announced that there would be no export ban with regard to the export of medicines within the European Union. The export of medicines outside the European Union is, in principle, also allowed. However, due to the entry into force of the Regulation 2020/402, exports of personal protective equipment outside the European Union are subject to an authorization. Because of the current shortage of personal protective equipment, the Health and Youth Care Inspectorate will not, in principle, issue the export license.
2. Precautionary measures regarding the Medicine Prices Act - Due to the amendment of the Medicine Prices Act, Wet geneesmiddelenprijzen, the maximum prices for medicines in the Netherlands would have been lowered on 1 April 2020. However, the minister postponed the change of the maximum prices for six months. The new date is now 1 October 2020.
3. Measures regarding packaging and the examination of other possibilities - The IGJ can grant permission to license holders to deliver medicines with different (non-Dutch) packaging temporarily. According to the minister, the following requirements must be met: (i) there is a shortage and the availability of the product is necessary for the continuity of patient care; and (ii) there is no alternative medicine on the Dutch market. Furthermore, the minister is examining the possibility of giving firms and wholesalers a sales guarantee and applying more flexible rules relating to the joint procurement of sensitive medicines. Moreover, the minister spoke to several market parties regarding medicine provision. For instance, the minister asked healthcare providers to consider the changing market conditions when concluding agreements with manufacturers or pharmacies.

Addressing the need for medical devices

The IGJ announced that it temporarily gives manufactures and suppliers of medical devices the opportunity to supply medical devices without a CE mark or without completing the required assessment procedure, in order to prevent supply shortages of medical devices. The IGJ will only allow such request if the manufacture or supplier satisfy certain criteria: (i) the healthcare institution must ask explicitly for the alternative device; (ii) the healthcare institution bears the responsibility for the use of such device; and (iii) there are no approved alternatives available.

Furthermore, the IGJ can grant permission to license holders to deliver medicines with different (non-Dutch) packaging temporarily. According to the Minister for Medical Care, the following requirements must be met: (i) there is a shortage and the availability of the product is necessary for the continuity of patient care; and (ii) there is no alternative medicine available on the Dutch market.

Lastly, the Dutch government instituted a national approach regarding the distribution of medical devices for which there is(potentially) a shortage. The GGD-GHOR Nederland, in cooperation with the ROAZ (Regionaal Overleg Acute Zorg), is responsible for such distribution. The LCH purchases and distributes the medical devices.

Netherlands

Last updated: 18 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Addressing the need for medical supplies

The Inspectorate SZW (Inspectie SZW) has temporary created scope for introducing non-CE marked personal protective equipment used for the treatment and prevention of COVID-19, such as FFP1, FFP2 and FFP3 mouth and nose masks, into the Dutch market, provided that such materials meet the health and safety requirements. The Inspectorate SZW is the Dutch market surveillance authority for the products falling within the scope of Regulation (EU) 2016/425. The Inspectorate SZW works together with the LCH (*Landelijk Consortium Hulpmiddelen*) to evaluate the non-CE marked personal protective equipment. The LCH is the central procurement and distribution point for personal protective equipment and medical devices. The manufacturers of non-CE marked personal protective equipment must notify such products to the LCH.

Moreover, the Dutch government instituted a national approach regarding the distribution of personal protective equipment for which there is (potentially) a shortage. The GGD GHOR Nederland, in cooperation with ROAZ (Regionaal Overleg Acute Zorg), is responsible for such distribution. The LCH purchases and distributes the personal protective equipment.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Opportunities for market access

Reference is made to our answer under question 1. (a). In the event that a supplier or manufacturer faces a shortage, this supplier or manufacturer can bring, under certain conditions, an alternative medical device into the market without a CE mark or without completing the required assessment procedure.

Furthermore, due to the entry into force of the ministerial regulation of the Minister of Infrastructure and Water Management of 28 March 2020, with reference IENW/BSK-2020/57427, establishing the emergency measures with regard to gene therapy against COVID-19, the decision-making period for permit application relating to the clinical trials for gene therapy with regard to COVID-19 is temporarily accelerated. There is now a 28 days decision-making period, instead of 120 days.

Challenges for market access

Reference is made to our answer under question 1. (c)

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Challenges for market access

In the event of a (potential) medicine shortage and the necessity of the availability of such medicine for the continuity of patient care, the CBG processes applications for a new (parallel) marketing authorization and amendments of a marketing authorization with priority. The CGB also processes a marketing authorization application with priority, if the medicine is an import medicine for the treatment of COVID-19 patients. Such measures are important in the fight against COVID-19 and the prevention of medicine shortages. The suppliers and manufactures of medicines not falling under the aforementioned scope should be aware of a possible delay in their applications for, or amendments of, marketing authorization. Furthermore, they may face other challenges and uncertainties, such as higher costs, the timing of accessing the market or travel restrictions.

Netherlands

Last updated: 18 April 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

According to the Central Committee on Research Involving Human Subjects (CCMO), examples of problems caused by the COVID-19 outbreak are the delivery of study medication, subjects unable to come to the investigational site because of which certain study procedures cannot be carried out and the postponement of monitoring activities.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The following measures have been adopted:

- Because of the entry into force of the Temporary Regulation Gene Therapy, the decision-making period for permit application relating to the clinical trials for gene therapy with regard to COVID-19, is temporarily accelerated. There is now a 28 days decision-making period, instead of 120 days.
- The CCMO facilitates an accelerated review of research files concerning studies on COVID-19 (the so-called fast-track procedure).
- Besides the CCMO, a number of accredited MRECs have also set up a fast track procedure for the accelerated review of research files on the occurrence and/or treatment of COVID-19.
- From 20 March 2020 until further notice, all submissions to the CCMO must be submitted digitally. The obligation for accredited MREC's and CCMO to sign decrees with a so-called wet signature has been suspended.
- The research dossiers for gene therapy and medicinal products containing GMOs must be submitted to the relevant authority directly. Relevant authorities are the CCMO as review committee, the Ministry of Health, Welfare and Sport as competent authority or the Ministry of Infrastructure and Water Management (GMO Office).
- A premature termination of the study must be reported to the review committee as soon as possible, but at the latest within 15 days.
- A (partial) suspended trial for reasons of subject safety must be reported immediately to the review committee. The temporary halt for other reasons must be reported within 15 days.
- A deviation from the protocol or a protocol modification due to urgent safety measures to eliminate immediate hazards to the subject must be reported immediately to the review committee. The prior approval by the review committee is not required.
- If the subject cannot give its consent in case of an emergency situation, deferred consent is allowed under strict circumstances and subject to prior approval of the ethics committee. The CCMO published a guidance document that stipulates the criteria and process.
- The IGJ allows courier transport of medicines from hospitals to subjects or to public pharmacies, it is not allowed to transport medicines from the sponsor to the subject;
- The IGJ allows the subject's oral permission to share personal data with required for the transport of medicines. The permission has to be documented and where possible the subject needs to confirm its permission in an email.

The procedures for notifications to the Dutch competent authority both during and after the study and submitting a substantial amendment to the review committee have not be changed due to COVID-19.

Netherlands

Last updated: 18 April 2020

Clinical Trials

(c) Are there any general tips and recommended solutions under the local regulatory framework?

We recommend considering whether the clinical trials can be suspended. If not, we recommend exploring alternative ways to continue clinical trials, for example by providing materials at participant's homes. Always make a participant safety analysis when exploring alternatives.

The CCMO provides the following recommendations in addition to the EU guidance for sponsors and investigators on how to manage the conduct of clinical trials during the coronavirus disease (COVID-19) pandemic:

- Set up a risk analysis on the consequences of the coronavirus on the conduct of the clinical research, whereby the safety of the participants is paramount.
- Suspend phase 1 research because hospitals cannot provide intensive care units to phase 1 clinics.
- Record all deviations from the protocol and the standard procedure in writing; unless the subject's safety is at stake, these protocol deviations need not be submitted to the review committee.
- Study medication can be sent directly to the research subject by courier from the (hospital) pharmacy for reasons of subject safety; you need not inform the review committee about this, but do record this temporary procedure in writing.
- Please note that remote source data verification and direct accessibility to the Electronic patient file are not permitted with respect to clinical trials.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

There are no state emergency supply measures for medicines, medical devices and biocides in the Netherlands.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

No measures have been issued that may likely have impact on the scope of IP protection of the medical products concerned. However, please note that in light of a recent shortage of substances required for the fabrication of COVID-19 testing kits, the imposition of compulsory licenses has been the subject of debate in the Dutch Parliament. In this discussion, the government has confirmed that the imposition of a compulsory license is considered as a valid measure, if absolutely necessary, to ensure the sufficient supply of required medical substances/components. Although this discussion is meanwhile outdated (as the pharmaceutical company concerned has agreed to voluntarily provide the recipe of the required substance), this shows that both Parliament, as well as the government, will likely be open to consider the imposition of compulsory licenses in similar situations in the future.

Netherlands

Last updated: 18 April 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

The COVID-19 developments have led to many new initiatives, changing practices or health sector related policies or opinions regarding, among others, telemedicine.

Health care sector

The Dutch Healthcare Authority (NZa) has broadened the possibilities for providing distance-care by removing all possible obstacles or restrictive conditions in all care sectors. Examples include a contract condition in the NZa rules or the obligation of face-to-face contact. This exceptional measure has taken effect on 1 March 2020 and will last until the moment when the national guidelines and advice from the government and the National Government for Public Health and the Environment (RIVM) no longer apply. After termination, a transitional period of one week will be applied. By widening the rules, the NZa removes all obstructive conditions. This means that care can also be charged remotely without a special performance being set for this or if the conditions are not exactly met. Healthcare providers can then also charge a regular session, consultaton or treatment. Hospitals can also perform the first consultation with a patient digitally or by telephone, without this having any consequences for the reimbursement. All other possible restrictive conditions are temporarily suspended. The basic principle is that the necessary care can be provided. The NZa has asked health insurers to suspend any obstacles in contracts with healthcare providers in this area (for example, mandatory minimum scope of face-to-face contact) during this period. They have had contact with health insurers in the Netherlands about this and they are currently examining how they can deal with this.

As of 24 March 2020, the Ministry of Health, Welfare and Sport has made more digital care at home possible through an emergency regulation, which makes money available for additional digital applications for remote support and care for vulnerable elderly people living at home and people with a chronic illness or disability. The special emergency regulation is called SET COVID-19 and it has been set up within the Incentive Regulation for E-health at Home: Stimuleringsregeling E-health Thuis (SET). SET COVID-19 is a temporary extension of the SET. If the coronavirus crisis and the impediments resulting from this crisis that affect the continuity of support or care expire, this temporary extension of the SET will stop. The emergency regulation is meant for care and welfare organizations that want to invest extra in remote digital care at this moment. This concerns, for example, providers of district nurses, mental healthcare providers and hospitals. All healthcare providers can make use of the regulaton by submitting a short application. The measure provides EUR 50,000 per request. The subsidy is primarily used to pay project costs for implementing the digital applications. Moreover, help with implementation may be hired. In addition, up to 50% of the amount can be spent on technology, such as purchasing licenses or devices. No personal contribution is requested. Applications can be submitted starting at 9 am on 25 March 2020 at the Netherlands Enterprise Agency. Applicants will receive a response within a maximum of five working days. After approval, they receive the subsidy amount within five working days. To qualify for a subsidy, a number of conditions apply.

The Ministry of Health, Welfare and Sport has requested suppliers of screen care devices (beeldschermzorg) to reserve sufficient stock for the use of remote care. The suppliers have indicated that they will give priority to the healthcare sector in the worldwide allocation. To assist healthcare organizations to implement screen care the fastest way possible, the measure offers "Fasttrack Screen Care Devices" for this purpose.

Netherlands

Last updated: 18 April 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Many healthcare professionals or professional organizations have published guidance on telehealth related matters. We brieflyhighlight some of the published guidance below:

- The National Association of General Practitioners provided guidance on video calls between general practitioners and patients. They recommend using the available video call solutions especially developed for the healthcare sector and expressly discourage the use of WhatsApp and FaceTime for (data) security reasons. The Dutch Healthcare Authority endorses this explicit preference for sector-specific resources.
- The Royal Dutch Medical Association has published guidance on the online provision of medical advice, additional safeguards on the online prescription of medication and dealing with medical data. According to this guidance, it is of importance that online contact with a patient guarantees the quality of care and benefits the specific patient. Doctors should be able to ensure the confidentiality and security of electronic communications with patients. The provision of an individual online consult is only permitted if the stated cumulative conditions are met, e.g., informing the patient sufficiently about the online procedure and relying on sufficient relevant and reliable (medical) data provided by the patient to be able to give a medical individual advice.
- Furthermore, big companies providing the healthcare sector with resources are developing solutions to bring care providers and patients into contact with each other from home.

Data privacy perspective

Generally, healthcare professionals take the view that the patient care interests prevail over data protection considerations and consider the use of commercially available remote communications platforms acceptable in the current coronavirus crisis. On the other hand, the Dutch Data Protection Authority (Dutch DPA) has always been quite critical of doctors using WhatsApp or other digital communication tools. However,in the current situation at hand, the Dutch DPA allows organizations more leeway to concentrate on combatting coronavirus infections and gives free rein to initiatives to protect public health. However, in response to the opinions from the healthcare sector as mentioned above, the Dutch DPA explicitly emphasizes that healthcare professionals must be aware of the security risks they take when deploying resources as WhatsApp or FaceTime. Medical data are regarded as special categories of personal data and are therefore extra protected. The processing of medical data is in principle prohibited, unless the person responsible for processing can invoke one of the statutory exceptions.

Telemedicine via mobile apps

Health care professionals as well as the Dutch government are developing mobile apps in their fight against Coronavirus. On the one hand, the government is investigating possible apps to potentially be rolled out nationwide, which would enable identifying who an infected person has been in contact with, in order to better map and control het infections spread.

On the other hand, health care professionals and the government are developing mobile apps for health care monitoring on individuals basis. A more and more common app used by health care professionals is an app intended to monitor the symptoms of a (potential) Corona patient. The app measures symptoms, which helps individuals with an initial home diagnosis to determine whether he or she may be infected. The app tracks, for instance, a daily report of a person's body temperature or whether he or she has a sore throat, a nasal cold or to what extent the person is short of breath and coughs or not. Via the mobile app, doctors can advise the individual to contact their healthcare provider, general practitioner or hospital. Several hospitals in the Netherlands have already launched such apps, which vary in their functioning.

These mobile apps are very privacy sensitive. Historically, the Dutch DPA has always been willing to criticise the Dutch central government. The Dutch DPA responded to the above initiatives by saying that these apps can only be used if privacy is fully guaranteed; the Dutch government and health care professionals cannot just set aside the privacy compliance aspects. The Dutch DPA will pay very close attention to this.

Poland

Last updated: 02 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- Based on communication of 17 March 2020, Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("**Office for Registration**") gives priority to any documentation related to SARS-CoV-2 and any such documents should be respectively marked. The Office for Registration also encourages entities engaged in manufacturing biocidal products to use the exemption envisaged in Article 55 of the Regulation (EU) 528/2012. At the same time, it is not recommended to initiate proceedings not related to combating SARS-CoV-2 or treatment of COVID-19.
- According to the Act of 2 March 2020 on specific arrangements for the prevention, counteraction and combating of COVID-19, other infectious diseases and the resulting emergencies, the Minister of Health defines maximum prices of medicinal products of certain availability specified in the pharmaceutical law, medical devices and foodstuffs for special nutritional purposes, which can be used in connection with combating COVID-19.
- Under the Ordinance of the Minister of Health of 20 March 2020 regarding the state of epidemic in Poland, there are two main export restrictions: It is prohibited to export or sell ventilators or cardiomonitors outside of Poland. An entity is obliged to notify the relevant voivode no later than 24 hours before the intention to export or sell products outside Poland, such as: (i) safety goggles; (ii) TYVEK suits; (iii) FFP2/FFP3 masks; (iv) surgical masks; (v) shoe protectors (footwear); (vi) latex; (vii) nitrile gloves; and (viii) hand sanitizer and surface and room disinfectants. The voivode may submit a request to the prime minister to ban the export or sale of these products outside of Poland.
  - The ordinance neither provides for any procedure regarding obtaining/refusing the consent from the voivode/prime minister forexporting or selling these products nor any deadlines that the authorities should meet. Furthermore, it does not provide for any sanctions in case of breach of this obligation.
  - In practice, currently the tax and custom authorities monitor the export of the ban products outside of Poland thoroughly and withhold the shipment of the products outside of Poland.
  - As far as we are aware, the authorities are currently preparing for taking over (purchasing) the masks in Poland in order to secure their availability.
  - In addition, if the products are categorized as medical devices and are listed on the list published by the Minister of Health ("**List**"), then another legal regime applies. The products on the List are not to be exported/sold outside of Poland without notifying the Main Pharmaceutical Inspector ("**Inspector**"), who can oppose the exporting of such products or devices.
  - Since the outbreak of COVID-19, the List has been expanded by a number of products or devices. As of 1 April 2020, there are 858 products listed, the overwhelming majority being drugs. However, there are also 10 categories of medical devices (very broad, as opposed to drugs that are identified by EAN codes), for example: (i) surgical gowns; (ii) non-woven gowns; (iii) surgical masks; (iv) masks for oxygen administration; (v) medical shoe covers; (vi) surgical clothing; (vii) surgical gloves; (viii) treatment gloves; (ix) medical caps; and (x) electronic thermometers.
  - In such case, an entity notifies the Inspector of its intention to: (i) export medical devices specified in list outside the territory of Poland; or (ii) sell such devices to an entity that conducts its business activities outside the territory of Poland. The Inspector may, by means of a decision, object to the intention of the export or sale within 30 days from the date of the notification, taking into account: (i) that medical devices could be in short supply in Poland; and (ii) the importance of a given medical device included in the List for public health. Breach of the obligation results in legal act being null and void (as if it had never been done) and may result in criminal liability and/or a fine.
- The Minister of Health is authorized to issue a list of medicinal products and foodstuffs intended for particular nutritional uses that may only be sold to a pharmaceutical wholesalers (this is the current regulation). However, once the draft law of 26 March 2020 amending certain healthcare-related laws in connection with prevention and combating of COVID-19 is adopted, the abovementioned regulation will be stricter; the pharmaceutical wholesalers will need to be located in Poland (this provision is still subject to works in the Parliament).

Poland

Last updated: 02 April 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- According to a Regulation of 20 March 2020 of the Council of Ministers, the Minister of Health will be authorized to purchase personal protective equipment in order to meet the needs of healthcare personnel, including sanitary transport, in connection with preventing the spread of SARS-CoV-2 and COVID-19 caused by it.
- Such PPE may be purchased:
  - Provided that it is compliant with the guidelines of the national consultant in the field of infectious diseases published on the website of the Minister of Health.
  - Before the conformity assessment completion and without CE marking, however, no longer than 30 days after the end of the state of epidemic in connection with SARS-CoV-2.
- This applies also to PPE for which conformity assessment procedures have been initiated in accordance with the requirements of Regulation 2016/425.
- Additionally, in order to prevent the spread of SARS-CoV-2 and COVID-19, the above-mentioned PPE and medical devices shall be authorized for placing on the market and use if it is authorized outside the EU/EFTA Member States.
- PPE that the Polish Minister of Health (or unspecified entity authorized by the Minister of Health) is allowed to purchase may only be used by personnel providing healthcare, including sanitary transport, services and other persons involved in activities aimed at control of SARS-CoV-2 and COVID-19 and to avoid further spread of this virus and the disease caused by it.
- On 13 March 2020, the Minister of Health published a communication recommending hospitals to deliver drugs used in drug programs and chemotherapy to patients' homes. As this is not allowed by the Polish law, certain doubts arise about how it should be done.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- Significant changes in reimbursement procedures for medicinal products and medical devices are provided in the draft law of 26 March 2020 amending the act of 2 March 2020 on specific arrangements for the prevention, counteraction and combating of COVID-19, other infectious diseases and the resulting emergencies and certain other acts (not yet in force). The most important changes are as follows:
  - Lists of reimbursed products valid from 1 March 2020 are valid until 31 August 2020. Consequently, the validity period of reimbursement decisions, which expire before 1 July 2020, is extended until 31 August 2020.
  - Reimbursement decisions issued until the date of entry into force of the act, which were intended to enter into force on 1 May 2020, will enter into force on 1 September 2020. The time limits for proceedings initiated and not completed: (i) before 8 March 2020; and (ii) in the period from 8 March 2020 to 15 August 2020 shall be suspended by law until 31 August 2020.
- However, during the period of suspension of the proceedings, the Minister of Health may take any steps to issue new administrative decisions. It is difficult to predict what kind of actions the minister will undertake as basically no new or amended reimbursement decision may be issued before 1 September.

Poland

Last updated: 02 April 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The Office for Registration follows the Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic published by European Commission.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

- On 19 March 2020, the president of the Office for Registration issued a communication containing information and recommendations to researchers, sponsors and other persons/entities involved in conducting clinical trials.
- In the light of the dynamically changing situation in all activities related to the conduct of clinical trials in Poland, the safety of patients in the broadly understood context of both the continuation of therapy and the current epidemiological situation should be an absolute priority.
- It is recommended to take into account the current epidemiological situation and the fact that medical staff of hospitals are involved in activities related to SARS-CoV-2 infections in the supervision of clinical trials (monitoring, audit).
- It is recommended that changes resulting from the need to adapt to the epidemiological situation should be treated as immediate security measures in accordance with Article 37y of the Pharmaceutical Law: (1) When any event occurs that could affect the safety of the clinical trial subjects, the sponsor or investigator shall abandon the clinical trial in accordance with the applicable clinical trial protocol. In that case, the sponsor and the investigator shall take appropriate measures to ensure the safety of the clinical trial subjects. (2) The sponsor shall immediately inform the president of the office and the bioethics committee of this situation and the safety measures taken. In view of the current situation, it is acceptable to send this information by email. The information on immediate safety measures will include a detailed assessment of the risks resulting from the changes.
- An analogical approach has been recommended to the clinical trials of medical devices.
- In view of the above, the president of the Office for Registration recommended considering the appropriateness of submitting new applications for starting a clinical trial of a medicinal product and applications for authorization to conduct a clinical trial of a medical device in this situation.
- It has also informed that the activities of the clinical trial inspection are suspended until the end of April 2020 and the decision to resume the inspection process will be made depending on the epidemiological situation.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

It is too early yet for any practical approach.

Poland

Last updated: 02 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

We are not aware of any discussions or problems regarding this issue in practice.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

No such measures have been taken yet and we are not aware of any such discussions.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

- Telemedicine services are explicitly allowed in Poland since 2015. However, since the outbreak of COVID-19, it has been used even more broadly than before. On 10 March 2020, the chief sanitary inspector issued a communication for all medical clinics, informing and urging them to inform patients of the possibility to obtain remote medical advice (telemedicine services). There is strong inducement for the broader use of telemedicine services.
- Under the existing Polish legislation, it is not fully clear whether patients, after being examined through telemedicine means, are entitled to receive medical certificates that would allow them to go on a paid sick leave. Despite those legal doubts, Polish authorities claim that such possibility has been allowed, in order to avoid unnecessary doctor's appointments and spreading the virus. According to media reports, the government is preparing necessary law amendments to formally address this issue.

Russia

Last updated: 23 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Russia has taken a complex approach to ensuring that the urgent need for medicines and medical devices are continuously met, which includes both a faster review and the granting of registrations and other necessary paperwork and the relaxation of import rules and other permissive measures on the one hand and exportation prohibition for certain types of protective equipment and medical devices from the country on the other hand.

(1) According to recent amendments, the Government of the Russian Federation shall establish the peculiarities of circulation, including the State registration of medical devices as well as the State registration of medicines that are intended for use in military operations, emergencies, prevention of emergency situations, prevention and treatment of dangerous diseases, during diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors, etc.

Moreover, in case of an emergency situation or when there is a threat of a spread of a dangerous disease, the Russian Government has the right to restrict the wholesale and retail sale of medical devices included in the list drawn up by the Government for a period not exceeding 90 calendar days from the date of adopting the relevant decision.

The Government of the Russian Federation has established a separate, simplified, procedure for the state registration of medical devices with a low degree of potential risk of their use (gloves, shoe covers, medical overalls, masks, respirators, etc.). The registration of such medical devices will be carried out within five working days. The applicant must submit only application, technical and operational documentation and a photograph of the medical device, while the submission of the results of clinical and other trials at the time of medical device's registration is not required. However, within five months the applicant will be required to confirm the state registration of their medical device and submit the documents to Roszdravnadzor, confirming the results of:

- technical tests of medical devices
- toxicological tests of medical devices
- tests of medical devices in order to approve the type of measuring instrument, etc.

In addition, the Government of the Russian Federation has approved a special procedure for the registration of certain medical devices that are intended for use in military operations, emergencies, and the prevention and treatment of dangerous diseases. The list includes 108 items, including: ventilators, extracorporeal membrane oxygenators, surgical suits, insulating suits and disposable masks, thermometers, etc. For initial registration, the applicant must provide the Roszdravnadzor with a copy of a document confirming the applicant's credentials, technical and operational documentation, photographs of a medical device, information about quality and safety, if any. Roszdravnadzor shall investigate the documents within three days and, in the absence of remarks, shall issue a temporary registration certificate to be valid until 1 January 2021. In addition, it is allowed to put into circulation disposable medical devices, such as gloves, medical masks, gowns, respirators, shoe covers, without their registration in Russia, if there is a registration certificate in the country of their manufacture.

Decree of the Government of the Russian Federation No 441 "On the peculiarities of the circulation of medicines, which are intended for use in case of threat of an emergency, liquidation of an emergency …" as of 03 April 2020 contains a number of measures optimizing the regulatory procedures for the medicines during the period of spread of COVID-19, including:

- electronic documents review and submission without hard copies with electronic signature;
- establishment of the Working Group in the Russian Ministry of Health which will determine the volume of expertise of the medicines intended for use in emergency situation;

Russia

Last updated: 23 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- reduction of the volume of examinations when introducing changes into the registration dossier related to replacement, addition, exclusion of the manufacturing site of the manufacturer of the active pharmaceutical substance and finished dosage form, as well as change in the primary packaging;
- exclusion of the examination of the medicine's quality and the examination of the expected benefit to the possible risk of the medicine's use in relation to medicines registered in the Member States of the European Union, the United States of America, Canada or another state according to the list established by the Ministry of Health. The State registration of such medicines shall be carried out by the Ministry of Health within 5 working days;
- the State registration of medicines intended for use in emergency situation shall be carried out in the period of no more than 20 working days, etc.

(2) The Ministry of Industry and Trade of the Russian Federation and the Ministry of Economic Development of the Russian Federation together with the Federal Service for Accreditation issued the following recommendations to certification bodies and applicants for mandatory certification:

- Postpone the inspection control procedure for up to six months in relation to valid certificates of conformity for serial production if the next scheduled inspection control must be within the period related to the spread of COVID-19.
- In respect of valid certificates of conformity for serial production that expire within the period related to the spread of COVID-19, certification bodies that periodically evaluated such certified products may issue a new serial certificate taking into account the positive results of the latter periodic evaluation of such certified products, etc.

(3) A series of measures related to relaxation of regulatory rules in Russia has been adopted:

- Following the initiative of the Ministry of Economic Development of Russia, the Council of the Eurasian Economic Commission exempted the importation of goods necessary to prevent the spread of coronavirus infection from customs duties. The duty-free import regime applies to personal protective equipment, vaccines, laboratory reagents, boxes and stretchers for transporting patients, bags for transporting hazardous biological waste, blood transfusion systems, tubes for artificial lungs ventilation, syringes and catheters, materials used for the production of personal protective equipment, disinfectants. The measure applies to goods imported from 16 March 2020 to 30 September 2020.
- The Russian Government has introduced the temporary suspension of the "third one out rule" in the process of public procurement for a number of medicines and medical devices determined by the Ministry of Industry and Trade and the Ministry of Health of Russia. This rule imposes a ban on the participation of a foreign product in the public procurement tender, if there are two or more participating suppliers offering products originating from Eurasian Economic Union and manufactured by unaffiliated manufacturers. The list of medicines and medical devices to which the "third one out rule" will not temporarily apply will soon be adopted.
- Following the initiative of the Ministry of Economic Development of Russia, the Council of the Eurasian Economic Commission exempted the importation of goods necessary to prevent the spread of coronavirus infection from customs duties. The duty-free import regime applies to personal protective equipment, vaccines, laboratory reagents, boxes and stretchers for transporting patients, bags for transporting hazardous biological waste, blood transfusion systems, tubes for artificial lungs ventilation, syringes and catheters, materials used for the production of personal protective equipment, disinfectants. The measure applies to goods imported from 16 March 2020 to 30 September 2020.

Russia

Last updated: 23 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- The Russian Government has introduced the temporary suspension of the "third one out rule" in the process of public procurement for a number of medicines and medical devices determined by the Ministry of Industry and Trade and the Ministry of Health of Russia. This rule imposes a ban on the participation of a foreign product in the public procurement tender, if there are two or more participating suppliers offering products originating from Eurasian Economic Union and manufactured by unaffiliated manufacturers. The list of medicines and medical devices to which the "third one out rule" will not temporarily apply will soon be adopted.
- The president of the Russian Federation approved distance selling of over-the-counter (OTC) medicines and medical devices. Distance selling means any sale that does not entail a visit to the pharmacy by the purchaser (e.g., online sales, home deliveries) and can be carried out by pharmacy organizations licensed to engage in pharmaceutical activities and authorized by the Federal Service for Surveillance in Healthcare.
- Moreover, a new law has been passed, specifying the President's initiative, that allows the distance sale of medicines, with the exception of prescription ones, as well as medicines that are subject to strict record keeping and storage and alcohol-containing medicines with a volume fraction of ethyl alcohol of more than 25%. In case of an emergency and when there is a threat of spread of a dangerous disease, the Government of the Russian Federation is entitled to establish a temporary procedure for the distance sale of all medicines (with the exception of narcotic and psychotropic medicines, as well as alcohol-containing medicines with a volume fraction of ethyl alcohol of more than 25 %). The latter provision is valid until 31 December 2020.
- According to recent amendments, in case of an emergency situation and (or) when there is a threat of spread of a dangerous disease, the Government of the Russian Federation may, if necessary, establish a temporary procedure for the distance sale of medicines (with the exception of narcotic and psychotropic medicinal preparations, as well as alcohol-containing medicines with a volume fraction of ethyl alcohol of more than 25%). In case of an emergency, the government may also establish the procedure for issuing permits for the distance sale of medicines, requirements for pharmacy organizations that can engage in distance sale of medicines, as well as temporary rules for the delivery of medicines to the population. It is expected that this provision will be in force until 31 December 2020.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

As was mentioned in Section 1 (a) above, the procedure for the state registration of medical devices with a low degree of potential risk of their use (gloves, shoe covers, medical overalls, masks, respirators, etc.) has been simplified.

In accordance with the Decree of the Government of the Russian Federation No 440 "On the extension of validity of permits and other peculiarities of licensing activities in the year 2020" as of 03 April 2020, the state registration of medicines and the state registration of medicines for veterinary use shall be extended by twelve months, if their validity expires (has expired) in the period from 15 March 2020 to 31 December 2020.

Another development to mention is the introduction of additional supporting measures for manufacturers of pharmaceutical products, personal protective equipment and disinfectants, including special loans from the Industrial Development Fund.

Finally, according to amendments, the peculiarities of circulation, including the state registration of medical devices as well as the state registration of medicines that are intended for use in military operations, emergencies, prevention of emergency situations, prevention and treatment of dangerous diseases, during diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors, etc., shall be established by the Government of the Russian Federation.

Russia

Last updated: 23 July 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The Russian Government imposed a temporary ban on the export of a number of types of protective equipment and medical devicesfrom the country. These include medical masks, gloves and white coats, bandages, cotton wool, disposable chemical protective overalls and especially durable shoe covers. The ban on export shall be valid until 1 June 2020 and does not apply to international humanitarian assistance and the export of the disposable goods by citizens for personal use.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The main issue nowadays is how to organize the process of importing medicines and exporting biological samples within the process of clinical trials. The Association of Clinical Research Organizations requested the Russian prime minister to clarify the procedure for the airtransportation of pharmaceuticals in connection with the spread of COVID-19, namely whether the measure introduced by the Russian Government to stop regular and charter flights from 27 March 2020 applies to air cargo.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The President instructed the Government of the Russian Federation to adopt regulations simplifying the procedure and reducing time for preclinical, clinical trials and state registration of immunobiological medicines necessary for the prevention of dangerous diseases (including vaccines for the prevention of COVID-2019), as well as the possibility of conducting clinical trials in parallel with preclinical trials. This measures must be developed before 15 May 2020.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

In order to ensure the safety of participants of clinical trials in the Russian Federation and compliance with the good clinical practice (GCP) the Ministry of Health of Russia issued the following recommendations to clinical trial organizers:

- Use alternative methods for monitoring patients of a clinical trial, for example, telephone contact, virtual visit, alternative location for assessment, including local laboratories or centers.
- Expand the possibilities of interaction with patients at home, provided that the research organizer is able to ensure the proper level of quality of this process. For example, organize the delivery of medicines to the research participant at home by employees of medical centers, organize the collection of biological samples at the place of residence.
- Take measures to minimize the impact on the integrity of the clinical trial to prevent deviations from the protocol.
- Take measures aimed at providing the maximum possible protection for the personnel involved in the clinical trial.

Russia

Last updated: 23 July 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

- As of 16 April 2020, there is no state of emergency in the Russian Federation. On 30 March 2020, the President of the Russian Federation ordered to replenish the reserves of artificial lung ventilation apparatus in medical institutions in Russia, as well as to create additional stocks of medicines used to combat COVID-19 and its complications.
- Although various potential revisions to the Civil Code of Russia in relation to compulsory licensing, including for export purposes, and in relation to the right of the government to grant permission to use patents in certain critical circumstances have been discussed for a long time now, none of them are directly linked to the COVID-19 situation. Nevertheless, in the current environment we cannot exclude that these discussions may receive additional attention.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

In Russia, the government has been recently authorized to set up maximum selling prices for manufacturers of certain medicines and medical devices. The same opportunity is provided in relation to the marginal wholesale and retail mark-ups to the actual selling prices of manufacturers of these medicines and medical devices. The Russian Government will determine the list of medical devices and the list of medicines that fall under the state regulation and that are not included in the List of Vital and Essential Medicines.

The government will be able to exercise the right to set up maximum selling prices and mark-ups in cases of:

- an emergency situation
- a threat of a spread of a dangerous disease
- detection of the growth of the retail prices for medicines and medical devices by at least 30% in the regions within 30 calendar days after the government decides to track the prices

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Telemedicine has been permitted in Russia since 1 January 2018. Telemedicine allows electronic communications between medical professionals in order to consult in assessment of health of a patient, to clarify a diagnosis, to set prognosis and tactics of medical examination and treatment or to assess the desirability to transfer a patient into a specialized department within a medical organization or to rely on medical evacuation. Medicinal professionals are also be able to conduct medical consilium to discuss the same questions.

Currently, there have been discussions to speed up the adoption of amendments in connection with the spread of COVID-19, allowing doctors to remotely diagnose and prescribe treatment for their patients. This will significantly reduce the flow of patients with various diseases to medical institutions.

South Africa

Last updated: 08 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Regulator, the South African Health Products Regulatory Authority (SAHPRA), has adopted various scientific reviews of new medicines and vaccines through a priority review process. It has also sought to implement a Special Access Program for practitioners treating COVID-19 patients and ensure that a speedy review of clinical trials for new vaccines or repurposed antivirals will be implemented.

Furthermore, the National Treasury has issued an instruction note (accessible here) to government departments, municipalities and entities to help speed up the procurement of goods and commodities required to reduce and control the spread of the COVID-19 virus, which would naturally include medical-related products. This instruction note further lists prices of goods/commodities to curb any opportunistic use of the national disaster to drive profit margins. The instruction note is limited to goods required to limit the spread of the virus and will be terminated at the end of the disaster or when the National Treasury retracts the instruction note. It should be noted, however, that to date no procedural requirements have been relaxed in any sphere, including medication and devices.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

In addition to the expedited review process of new medicines and vaccines as implemented by SAHPRA, various portions of the arts of the Competition Regulations have now allowed private hospitals to coordinate their activities and share beds, medical supplies, doctors and nurses without facing charges of collusion, as contemplated under the Competition Act.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

South Africa's largest private hospital networks, Netcare, Melomed and Life Healthcare, have indicated that they are either engaged in talks or have collaborated with the National Institute for Communicable Diseases, as well as with national and provincial departments of health, to share resources with the public health sector.

South Africa

Last updated: 08 April 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

South Africa is one of 10 countries involved in an urgent global trial announced by the World Health Organization to identify the most effective treatment for COVID-19.

South African health sciences faculties are involved in this program and the work will involve many of the country's senior clinicians and researchers across specialties, such as infectious diseases and intensive care.

The Southern African Pharmaceutical Regulatory Affairs Association and ethics committees are urgently reviewing potential therapeutics so that there are no regulatory delays.

As indicated in Question 1 above, SAHPRA has taken measures, including the adoption of scientific reviews of new medicines and vaccines through a priority review process, the implementation of a Special Access Program for practitioners treating COVID-19 patients, and the speedy review of clinical trials for new vaccines or repurposed antivirals.

The University of Cape Town, the Council for Scientific and Industrial Research, and Biovac have begun to conduct research and develop a potential vaccine against COVID-19.

The Department of Science and Innovation has allotted ZAR 12 million and will redirect an additional ZAR 30 million to further the development of a vaccine for COVID-19.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The South African Pharmacy Council and Regulatory Affairs Association has not issued a statement yet as to whether they will shut down operations. They are currently working proactively with institutions in terms research to develop a vaccine as a matter of urgency. They have also approved for Austell Pharmaceuticals to donate 500,000 Chloroquine phosphate tablets for use by the Department of Health. Moreover, they are issuing updates as to the status of medicinal supplies and calling upon the public not to bulk buy purchases of essential supplies and medical items.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Right now, there are no identified solutions under the local regulatory framework. Instead, the framework has been construed in order for all health-care associated entities, including the medical associations, research facilities and pharmaceutical entities, to work in unison. This approach is to ensure that the impact of the virus in all medical spheres is being effectively and adequately responded to.

South Africa

Last updated: 08 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Although no official measures have been taken yet, SAHPRA has adopted tactics to minimize and potentially prevent shortages and stockpiling of medicines or Active Pharmaceutical Ingredients (APIs). SAHPRA is identifying alternative medicine or API suppliers and (where necessary) fast-tracking their regulatory approval, authorizing the importation of unregistered products, substituting products with equivalent clinical indications, guiding to encourage rational prescribing, and prioritizing medicine access for the most vulnerable. Pharmaceutical and medical device manufacturers and suppliers are to notify SAHPRA of any anticipated disruptions in supply as soon as possible in order for the authority to make contingency plans.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

There have been none yet.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

The COVID-19 outbreak has changed the use and provision of telemedicine services, and there are currently interim measures in place, as further outlined below.

Before the COVID-19 outbreak, the use and provision of telemedicine services were only allowed in circumstances where one healthcare practitioner remotely assessed a patient where the patient was in the physical presence of another healthcare practitioner, as outlined below:

- In terms of the Telemedicine Guidelines (issued by the Health Professions Council of South Africa (HPCSA)), "telemedicine" is defined as medical practice using electronic communications or other electronic means between an HCP in one location and an HCP in another location for purposes of facilitating, improving and enhancing clinical and scientific healthcare and research.
- The SA regulatory regime did not envisage the provision of health services from one HCP to a patient, without another healthcare practitioner being in the presence of the patient.
- In particular, all telemedicine services should involve an HCP where there is an actual face-to-face consultation and physical examination of the patient.

On 26 March 2020, and given the unique challenges of COVID-19, the HPCSA permitted the use of telemedicine for managing patients remotely, using virtual platforms, including video and telephonic links, as follows:

- The use of telehealth is restricted to already established relationships (practitioner-patient relationship).
- Telephone and/or virtual consultations for new patients are discouraged.

The HPCSA noted that the revised provisions on telemedicine are only applicable during the COVID-19 pandemic, and the revised Telemedicine Guidelines will continue to be used after the end of the pandemic.

Spain

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

On 21 June 2020, the State of Alarm ended in Spain and, as a result, several measures implemented by the Spanish government and the Ministry of Health to confront the present pandemic and linked to the State of Alarm are no longer in place. In order to ensure that the most relevant measures remained in place in the event of a second wave, the authorities issued Royal Decree 21/2020, of 9 June, on urgent prevention, containment and coordination measures to confront the health crisis caused by COVID-19. Its effects will be in place "until the Government declares in a motivated manner, according to available scientific evidence and following the issuance of a report by the Center of Coordination of Alerts and Sanitary Emergencies, the end of the situation of sanitary crisis caused by the COVID-19".

In addition, various measures have been implemented in the last three months whose effects were not linked to the State of Alarm and which also remain in force.

By virtue of this set of measures, we can identify the following established mechanisms.

Addressing the need for medicines

- Dispensing of medicines
  - According to Royal Decree 6/2020, of 10 March, adopting specific urgent measures in the economic field and for the protection of public health, the Ministry of Health may establish specific conditions for the prescription of those medicines deemed necessary to protect public health and facing supply constraints. At present, and after the end of the State of Alarm, instructions that were implemented pursuant to this provision are no longer in place.
  - The Spanish Agency for Medicines and Medical Devices (the "AEMPS") published in March different recommendations on the dispensing of critical medicines (midazolam and different neuromuscular blocking agents, among others) to Intensive Care Units (ICUs) and terminally ill patients. These recommendations propose alternative treatments in the case of medicines in most demand and promote the establishment of protocols to personalise doses and avoid misuse.
  - The AEMPS also published in August recommendations on the use and acquisition of tocilizumab. Said medicine is mainly aimed at treating patients with arthritis, but it is also being used to treat COVID patients. In order to avoid shortages, the Spanish agency asks hospitals to avoid stockpiling and reminds that COVID patients must be treated with the formulation of 20 mg/mL (400 mg).
- Supply and manufacture
  - Pursuant to the authorization provided by the Spanish government on Royal Decree 21/2020, the AEMPS has established on its Resolution of 19 June 2020 an exhaustive list of medicines that are considered essentials. This list may be updated from time to time according to the latest information available on the effectiveness of different drugs to combat the virus. Based on this Resolution, manufacturers and Marketing Authorization Holders of these medicines must comply with specific information, supply and manufacturing requirements aimed at ensuring the availability of the listed medicines in the various health care centres.
  - With regard to the information requirements, these entities must share with the AEMPS on a weekly basis information on (i) available stock, (ii) packages sold during the last week and (iii) batch delivery forecasts (quantities and date of availability on the Spanish market).
  - In terms of supply of the listed medicines, the obliged entities must adopt any necessary measures to avoid shortage in the health care centres, including on vacation periods and weekends. The Ministry of Health reserves the right to prioritise the production of the listed medicines above any other medicine, and the AEMPS may request information from manufacturers on planned manufacturing operations.

Spain

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- Centralized supply
  - According to Royal Decree 6/2020, of 10 March, adopting specific urgent measures in the economic field and for the protection of public health, the Ministry of Health may establish specific conditions for the prescription of those medicines deemed necessary to protect public health and facing supply constraints.
  - Within the first weeks of the pandemic, the AEMPS decreed the centralised supply of hydroxychloroquine/chloroquine, by virtue of its dual condition as critical medicine in the present outbreak and treatment for chronic patients against lupus or arthritis. Since 20 May 2020, the AEMPS has established that such centralised supply will only remain in place regarding applications made by hospitals to treat COVID-19 patients. Applications in such cases must be made through the centralized mechanism called Management of Medicines in Special Situations.

Addressing the need for medical devices and medical supplies

To overcome the shortage of critical medical supplies, Royal Decree 21/2020 includes various measures directed at the AEMPS and targeting the relaxation of authorisation requirements of surgical masks and medical gowns

These measures include: (i) the possibility of granting temporary operating licences to manufacturing facilities located in Spain, once their premises, quality systems and the documentation of the products to be manufactured has been evaluated, and (ii) the possibility of authorising the use of surgical masks and medical gowns that have not obtained the CE mark, after evaluation of the available documentation and assessment of the health guarantees required in each case. The Government has expressly stated that it will assume any liability derived from the relaxation of the established measures if such medical devices have been provided to the authorities to help address the present pandemic and if no commercial benefit has been obtained under any circumstances.

The Ministry of Industry, Commerce and Tourism adopted the Resolution of 23 April 2020, authorising the commercialisation of PPE equipment (masks, gloves, glasses and clothing) that do not bear the appropriate CE marking. Said authorisations expired on 30 September 2020. However, the Ministry has issued the Resolution of 28 September 2020, establishing specific conditions under which (i) PPE equipment which commercialisation was authorised by the Resolution of 23 April 2020 (ii) acquired before 1 October 2020, can temporarily be distributed. The exceptions established by the authorities and present distribution conditions are:.

- Public authorities' acquisition of PPE equipment without CE marking to supply HCPs, which cannot be made available to the general public or through normal distribution channels. HCPs may receive until 31 December 2020 PPE equipment acquired by the public authorities before 1 October 2020;
- Temporary authorization for the commercialization of said PPE equipment, when they are pending on CE marking and provided that they meet alternative technical specifications accepted by the Spanish authorities (concrete American, Korean, Japanese, Australian or Chinese specifications, as specified in the text of the Resolution). Commercialization will be permitted until 31 December 2020 only when it can be proved that, before 1 October 2020, (i) the equipment was already in the Spanish territory, and (ii) the aforementioned temporary authorization had been provided. In addition, the final recipient of such equipment must be duly informed of this situation; and

Spain

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- Temporary authorization for the commercialization of PPE equipment that also meet such alternative specifications and that bear a CE marking based on non-harmonized technical specifications. In this case, the Spanish notified bodies shall follow the provisions of the European Commission and the agreements reached by the European notified bodies' coordination groups, when issuing EU type-examination certificates, as well as for setting the date of validity of such certificates.

Additionally, the Spanish authorities have established (by means of Order SND/354/2020) specific labelling requirements for hygienic masks, including, among others: (i) a disclaimer that such masks are not medical devices nor PPEs, (ii) the recommended period for use, (iii) whether they comply with UNE or equivalent technical specifications; and (iv) whether they are reusable and washing instructions. Hygienic masks which filtration and breathability efficiency have not been verified by a laboratory must avoid including claims in their labelling that lead to the assumption that they have properties which have not been tested (e.g. "protection against viruses").

With regard to biocides, Royal Decree 21/2020 authorizes the use of bioethanol that complies with minimum specifications (asspecified on the Annex of such text) on the manufacturing of hydroalcoholic hand gels and solutions. It also establishes that the AEMPS may authorize the manufacture of antiseptics containing chlorhexidine digluconate acquired from suppliers other than those included in the list published by the European Agency for Chemical Substances and Mixtures, provided that this active substance complies with the specifications laid down in the European Pharmacopoeia.

Finally, and in view of the high number of companies that were developing their own prototypes of ventilators, the AEMPS has issued a document on the steps companies must follow to obtain AEMPS authorization to use their prototypes for investigation purposes, including security tests and elaboration of technical documentation.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Opportunities for market access

Refer to the information provided in Section 1(a) above. The Spanish authorities have increased flexibility of access to themarket of high demand products event if not bearing the CE mark, although they remain subject to strict requirements and evaluations.

Furthermore, the possibility of using bioethanol for the manufacture of hydroalcoholic hand gels and solutions may also provide market access opportunities.

Challenges for market access

Clinical trials on medicines other than those treating COVID-19 may confront timeline delays, due to the prioritisation decided by the AEMPS. The AEMPS has expressly stated that they will prioritise the evaluation of clinical trials referring to treatments for COVID-19. In addition, companies may face other hurdles, such as reluctance of patients to visit laboratories (see recommendations adopted by the AEMPS on Section 2(b) below).

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

See comments above.

Spain

Last updated: 30 October 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

During the present outbreak, the vast majority of clinical trials relating to pathologies other than COVID-19 were affected. Among the circumstances that have impacted clinical trials we can count the reduction of the staff managing the trials, the difficulties of maintaining the required live monitoring, and the impact on the patient visits and the difficulty of recruiting new patients as a result of restrictions on movements.

However, the AEMPS and Pharmaindustry (the Spanish Pharma industry association) combined their efforts to establish a set of recommendations aiming at ensuring the continuity of clinical trials while protecting professionals and patients. Pursuant to said recommendations, Pharma companies implemented different protocols focused on patient safety-such as sending medication to the patient's home or performing online interviews- and on efficiency through the digitalization of procedures (remote signing of contracts or remote monitoring).

As a result and according to Pharmaindustry, clinical trials in Spain have almost totally resumed pre-pandemic activity. In addition, more than ten pharma companies are already investigating in Spain medicines against COVID-19, with more than 120 ongoing clinical trials being conducted on the efficiency of such medicines.

To see the recommendations adopted by the AEMPS to manage this situation, please refer to Section 2.(b) below.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Recommendations adopted by the AEMPS

The AEMPS has stated that priority will be given to any new clinical trial application related to the treatment or prevention ofCOVID-19 infections.

On 16 March 2020, the regulator also published a number of recommendations aimed at guaranteeing that clinical trials are conducted in a safe manner during the COVID-19 outbreak and that the continuity of the ongoing trials is not affected. Each clinical trial sponsor must undertake a risk assessment to determine how to implement these recommendations and though approval is not required, the AEMPS requires that sponsors notify the measures adopted to the agency and to the Medicine Research Ethics Committee (CEIm). The provisions of the AEMPS are the following:

- Sponsors and investigators must consider the possibility of postponing visits of patients or conduct them over the telephone. Visits deemed critical cannot be cancelled. To this end, the government has allowed regional authorities to adopt the necessary measures to allow the dispensation of medicines to patients' homes in the context of clinical trials.
- Sponsors and investigators must decide whether to interrupt the recruitment of new patients or the ongoing treatment of the participating patients based on a benefit-risk analysis and the individual circumstances of the each trial center. If treatment is interrupted, patients must be offered an alternative treatment.
- The participants in the trials must receive their doses in the same conditions as before the outbreak. The AEMPS recommends that patients receive a higher number of medicines in their visits to cover a longer period of treatment. To allow this possibility, the restrictions on the dispensation of medicines mentioned in Section 1 above does not affect medicines used in clinical trials.
- The monitoring plans for the next four months must be updated as the centers participating in the trials may be under an extreme load of work in the current context and should not be required to monitor participants. For that purpose, centralized and remote monitoring must be prioritized. Also, remote verification of source data shall be considered only for COVID-19 clinical trials and for the final preparation of data prior to the therapies, and must be approved by the site's data protection delegate.
- If necessary, patients can be transferred between clinical trial centers. For this purpose, both centers must sign a transfer agreement, documenting the transfer and sharing all the available information of the patient (including the data collection logbook and the medical record), to ensure the continuity of treatment and the recording of the transfer.
- The measures adopted on the basis of these recommendations must be properly documented in the trial archive. However, authorization is not required from the AEMPS nor the CEIm. The adoption of specific urgent measures do not require notification to the CEIm (the dispatch of study's drugs to the patient's home, the carrying out of test in a local laboratory and transfers of patients between sites).

Spain

Last updated: 30 October 2020

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The AEMPS also recommends the implementation of fee exemptions and the simplification of contracts between sponsors and participating sites. In non-commercial clinical trials, the Spanish regulator considers that the contract may be replaced by a document of agreement issued by the management body of those sites.

Specific measures for trials on hydroxycloroquine/cloroquine

Recent studies have suggested that such active ingredients do not provide any clinical benefit against COVID-19. Consequently, the AEMPS has suspended all the related trials that have not initiated the recruiting phase and adopted different measures aimed at ensuring that trials in progress provide further evidence on this matter. The measures that promotors must implement vary depending on the phase of research reached by the different trials. The AEMPS has also established that promotors must prove that the patients of said trials have different characteristics from those recruited in the trials that suggested the lack of effectiveness of these active ingredients.

Safety protocol issued by Pharmaindustry

In the context of resumption of face-to-face scientific and technical activities (including face-to-face monitoring of clinical trials), Pharmaindustry has published a set of mandatory measures aimed at protecting the health of the professionals in the industry. Among other measures, professionals must have the adequate protective equipment, carry out diagnostic tests when indicated, and extreme the prevention and safety measures. They must also carry out training programmes regarding risk prevention and good health and hygiene practices before returning to on-site activity.

EU Measures

Please note that the European Parliament and the Council have adopted the Regulation (EU) 2020/1043 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19). In this Regulation, certain conditions of relevant COVID-19-related clinical trials have been relaxed.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Please refer to recommendations established by the AEMPS regarding clinical trials, as included in Section 2 (b).

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

The Spanish Patents Act contains two mechanisms to deal with the misuse of patents by the companies in the pharmaceutical sector:

- The compulsory license (Section 95): This entitles the government to suspend the exclusivity of a patent and to force the owning company to allow its exploitation by private or public entities when: (i) it is required for critical needs of public health; (ii) the company is not supplying a reasonable number of products to the market at a reasonable price; and (iii) following the issuance of the relevant Royal Decree. This decree must specify the scope and terms of that license and determine the pecuniary compensation that the government must grant to the owning company.
- The expropriation of patents (Section 81): This entitles the government to obtain the ownership of a patent when extraordinary circumstances of public interest require so, and in exchange of a pecuniary compensation. In this case, the government should issue a law specifying the terms of this expropriation, as it is a much more aggressive mechanism.

Spain

Last updated: 30 October 2020

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

To date the government has not issued any specific measures in response to the COVID-19 outbreak regarding the above mechanisms and we are not aware of any discussions having place on their likely issuance. As measures are being adopted on a daily basis, this possibility cannot be excluded in the future if the situation so requires.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Legal provisions

From a legislative perspective, the Spanish authorities have not promoted any legislative change during the outbreak. However, the Spanish Government has launched the program "Spain Digital 2025", which aims at fostering the digitalisation of Spain across different sectors. Among other measures, said plan states that the Government will promote the digital transformation of the health sector, empowering patients with telemedicine and self-diagnosis tools or through the improvement of accesibility.

In addition, different autonomous regions have implemented their own telemedicine programmes (e.g. eConsulta in Catalunya), which focus on primary attention and assistance to patients located in rural areas.

It must be pointed out that the possibility of providing this kind of services is not yet fully recognized in Spain. The Code of Ethics of the OMC stills forbids not face-to-face full consultations. The code is under review since the end of 2018 and this position may vary in the future. The Code of Ethics of the regional medical associations follow the same criteria. For example, the Code of Ethics of the Professional Association of Doctors of Madrid ("ICOMEM") also establishes that telemedicine services can only be used as an assistance to decision-making and a complement to face-to-face consultation, and HCPs providing consultation services exclusively via remote means may be subject to disciplinary action.

However, the National Medical Association ("OMC") published on 10 June 2020 a report called "Telemedicine in the medical practice", which recognises the need to conduct e-consultations when advisable and possible, in order to avoid unnecessary visits to hospitals and reduce risks for patients and companions in the present context. This document establishes general provisions on objectives of remote medical consultations, doctors' obligations or doctor-patient relationship.

Due to the high number of questions raised by doctors, the ICOMEM has issued a report on recommendations for HCPs willing to implement telemedicine services. The document points out that the Spanish legislation in this field is still not developed and providessome recommendations for those professionals looking to offer said services, which focus on the need to pay attention to data privacy requirements andto conduct internal audits.

Spain

Last updated: 30 October 2020

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Public approach

From the public perspective, the Spanish Government agreed with the various regional authorities the development of telephone assistance services to carry out triage regarding potential cases of coronavirus. During the State of Alarm, each region has made available their own telephone assistance numbers, in order to reduce the saturation of hospitals and allow citizens to receive initial advice without breaching the isolation requirements and to increase general awareness of the public. These regional resources are still in place.

To the same end, the Ministry of Health fostered the development of technological solutions and mobile applications for data collection in order to improve the operational efficiency and accessibility of health services. This has led to the creation of the mobile app "Asistencia COVID-19", available only in the five autonomous regions that adhered to the project (Cantabria, Canarias, Castilla-La Mancha, Extremadura and the Balearic Islands).

These technological solutions should not be considered as a substitute for face-to-face consultations, but as a complement allowing the patient to: (i) perform a preliminary self-assessment of the risk of having been infected by COVID-19 based on their medical symptoms they report, (ii) obtain information about the disease and (iii) obtain practical advice and personalized recommendations.

Private approach

Within the private sector, the offer of telemedicine services has experienced a dramatic increase in the last months, including medical consultation services, mobile apps, online chats and advice sections on well-known medical websites. The platform Top Doctors, specialised in these type of services, has reported that in the first weeks of March they received 30 times more requests from HCPs to help them implement remote medical consultation.

Different companies are exploring this new business opportunity. For example, Telefónica has recently announced the launch of its own telemedicine service, called Movistar Salud, where users will be able to solve their health problems through consultations with doctors from multiple specialties in real time.

Sweden

Last updated: 14 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- In response to the urgent needs for medicines, medical devices and medical supplies, the Swedish government has decided to reorganize the national supply scheme by appointing the National Board of Health and Welfare (Socialstyrelsen) as the national purchasing center for medical supplies to facilitate the supply of the equipment across the country.
- Sweden has not imposed any export restrictions intra-EU on personal protective equipment (PPE), as imposed by several other EU Member States. To the contrary, Sweden is working on completely lifting these restrictions. However, the EU has imposed export restrictions on PPE to a third country, i.e., country outside the EU.
- Sweden follows the recommendations provided by the EU Commission (EU 2020/403) on conformity assessment market surveillance procedures for the PPE.
- Normally, the transfer of medicines between pharmacies is not allowed. However, the Swedish Medicines Agency (MPA) has imposed reliefs in this regard by allowing pharmacies that need to be kept closed for an extended period during the ongoing pandemic to transfer medicine to another pharmacy with the same licensee.
- The MPA has granted emergency license for remdesivir (which is still under development) for patients with COVID-19 who have, or are at risk of developing, a complicated disease, i.e., life-threatening problems with breathing. The relief means that treating physicians do not need to apply for a license from the MPA for each patient to treat with remdesivir.
- Generally, the regulations on clinical trials are based on the fact that trial products are delivered to the test site and then provided to the trial participant. However, given the current circumstances with participants (and clinic staff) not being able to visit the clinics as scheduled, the MPA has imposed reliefs with delivering the trial products to the participants directly.
- The government has adopted measures to limit the purchase of prescription drugs to only cover a three-months' consumption.
- A temporary permit exemption for the construction of field hospitals is in place to enable field hospitals being built in collaboration with the Swedish Armed Forces to treat corona-patients.
- The Government has decided that the extradition of public documents in all Swedish authorities must normally be proceeded with urgency. However, the requisite to deliver urgently has been relaxed to deliver as soon as possible for some authorities.
- The Ethical Review Agency has created a procedure for the handling of requests for granting priority of authorizations of clinical trials regarding COVID-19.
- The Swedish Work Environment Authority has granted temporary authorization to use a non CE marked military grade gasmask (sw Skyddsmask 90) in certain functions outside of the armed forces such as ambulance and other emergency rescue services.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- As mentioned above, the drug remdesivir is under development but may be an alternative in the treatment of COVID-19, for which the MPA has granted an emergency license for its use.
- The MPA has banned two self-tests for COVID-19 as they are not considered compliant with the rules and requirements under the medical devices regulations. The manufacturers have failed to provide sufficient documentation on the safety and performance of the products.

Sweden

Last updated: 14 July 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- The demand for PPE is constantly increasing, within both Sweden and the EU. The majority of Swedish medical technology companies that manufacture and distribute PPE have production in other countries, including Germany and France. With the export restrictions from Germany and France, companies are prevented from fulfilling their delivery commitments.
- Due to the EU export restrictions on PPE, the Swedish companies must apply for an export license in order to fulfill their delivery commitments.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

- One major impact of the COVID-19 outbreak is trial participants (and clinic staff) not being able to visit the clinics as scheduled, resulting in the suspension of trials and a shortage of staff. In recent days there have been examples of retired staff being called in to answer questions and health care students signing up as volunteers.
- Clinical trials conducted in other jurisdictions have also been impacted as trials are suspended due to lockdowns and governmental recommendations.
- The Ethical Review Agency (*Etikprövningsmyndigheten*) conducts ethical examinations and authorizations of research on humans and on biological material. Since the COVID-19 outbreak, the agency has been getting numerous requests for granting the priority of authorizations of clinical trials regarding COVID-19, thus delaying clinical trials not related to COVID-19.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

- As mentioned above under 1 (a), MPA has imposed reliefs with delivering the trial products to the participants directly, facilitating the clinical trials to proceed as planned.
- The Ethical Review Agency has created a procedure for the handling of requests for granting priority of authorizations of clinical trials regarding COVID-19.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

No other than already mentioned above.

Sweden

Last updated: 14 July 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Not as of now.

The World Intellectual Property Organization (WIPO) has however informed that it will accept delays in correction of applicatons. In accordance with WIPO, The Swedish Intellectual Property Agency has informed that no late fees will be imposed in this regard.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

Not as of now.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Telemedicine is already commonly used in Sweden in both public and private sectors. For example, citizens are requested to call the online health care platform (Vårdguiden at 1177) when having symptoms of COVID-19. However, there are no anticipated legislative changes in this regard. Market insight tells us that there is an increasing demand, as well as an increasing willingness in the public sector to cooperate with private telemedicine companies to deliver telemedicine services.

Switzerland

Last updated: 30 November 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The focus initially has been on a faster review and the introduction of an export license for certain protective equipment (protective eyewear and visors, gloves, face shields, mouth-nose protection equipment, protective garments). Meanwhile the rules have been amended and no more export restrictions are in place. Now, apart from faster reviews, the focus is on the relaxation and even exceptions to licensing and import requirements.

The latest temporary rules are to be found in the Ordinance 3 on Measures to Combat the Coronavirus (COVID-19 Ordinance 3) of 19 June 2020, which initially was set to expire on 14 September 2020, but now has been extended until 31 December 2021. Furthermore, whilethe COVID-19 Ordinance 3 was initially only based on Article 185 Para. 3 of the Swiss Constitution, it is now primarily based on the SwissFederal Covid-19 Act, a law which was passed by the Swiss parliament on 25 September 2020 creating a legal basis allowing the Federal Council to maintain decree resolved by emergency and that are still necessary to manage the COVID-19 epidemic.

Medicinal Products

Medicinal products for the treatment of COVID-19 patients that are manufactured with certain specific active substances explicitly mentioned by law may, provided an application for marketing authorization of a medicinal product containing one of these active substances hasbeen filed, may be placed on the market without authorization pending the decision of Swissmedic (the Swiss Agency for Therapeutic Products) on the marketing authorization. When examining applications for marketing authorization, Swissmedic may permit a relaxation of the relevant legal requirements for such medicinal products based on a risk-benefit analysis. For example, on 29 June 2020 Swissmedic received an application for the temporary authorisation of remdesivir (active substance mentioned by law) and following a fast-track procedure and risk-benefit assessment on the next day, decided to allow temporary distribution of remdesivir. This means that products containing the active substance remdesivir and marketed under the brand name "Veklury" may be used in Swiss hospitals, without authorization, for the treatment of COVID-19 patients until the official authorization decision is issued or the corresponding emergency status is revoked.

In addition, amendments to the Swiss marketing authorization for a medicinal product that is used to prevent and treatCOVID-19 in Switzerland and contains a specific active substance listed by law may be made immediately after filing a corresponding amendment application Swissmedic may permit a relaxation of the relevant requirements for such amendments. Swissmedic may, based on a risk-benefit analysis, permit changes to the approved manufacturing process for medicinal products used to prevent and treat COVID-19 in Switzerland.

Swissmedic has published a guidance document on the authorization procedure forCOVID-19 medicinal products during the pandemic which was last amended on 3 November 2020, as a resource for deciding on possible authorization procedures in the exceptional situation of apandemic and to set out the specific preconditions and requirements that must be fulfilled so that procedures can be used and applications processed as quickly and efficiently as possible during a pandemic. In line with the above, the guideline applies to (1) new authorizations and (2) type II variations (i.e. additional indications used to prevent or treat COVID-19).

The relaxation on the Swiss marketing authorization for medicinal products is further combined with a relaxation on the import of medicinal products: pharmacists that have pharmaceutical responsibility in a hospital pharmacy may import non-authorized medicinal products containing specific active substance listed by law and have to notify Swissmedic of such import within 10 days of the arrival of the goods. In addition, a company with a wholesale or import license may be instructed to import such medicinal products. Furthermore, in order to prevent and treat the coronavirus in Switzerland, Swissmedic may allow the temporary placing on the market of a medicinal product as a short-term solution for the temporary non-availability of an identical medicinal product authorized in Switzerland, provided no essentially identical medicinal product is authorized and available in Switzerland. The latest updated table listing the temporary import and distribution licenses granted by Swissmedic and available on Swissmedic's website dates back to 11 November 2020.

Switzerland

Last updated: 30 November 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Medical Devices

Furthermore, Swissmedic may authorize the placing on the market and use of medical devices that have not undergone a conformity assessment procedure, provided their use for preventing and combating COVID-19 in Switzerland is in the interests of public health or patient safety or health and provided, taking account of their intended purpose, their fulfilment of the essential requirements and their effectiveness and performance are adequately proven. When assessing the risks, Swissmedic shall in particular take account of the procurement needs identified by the Federal Office for Public Health for preventing and combating COVID-19 in Switzerland. Swissmedic has established the criteria according to which the Responsible Person may grant an early market release for medicinal products used to prevent and treat COVID-19 in Switzerland.

Personal Protective Equipment

Initially, some relaxations also existed relating to respiratory masks and personal protective equipment placed on the market in Switzerland, in particular to ensure the supply to health care professionals. Given that the supply situation has improved, such requirement was no longer deemed necessary and has been removed in September 2020. However, should the situation deteriorate again in the future, the Federal Council may (re)introduce appropriate measures to ensure adequate supply of protective equipment. Personal protective equipment that was permitted before the amendment of 11 September 2020 may continue to be placed on the market until 30 June 2021. Finally, due to public demand, Swissmedic has also issued an information sheet relating to medical devices to clarify what type of face masks exist and the related requirements for use as medical device or personal protective equipment.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The focus of the Swiss regulatory body Swissmedic is now clearly on COVID-19.

In terms of opportunities, this means that Swissmedic is conducting faster reviews and that medicinal products may be placed on the market without authorization pending the decision of Swissmedic on their filed application for marketing authorization or amendment of their application in case of type II variations. Furthermore, Swissmedic has the right to issue exemptions for placing non-compliant medical devices on the market by existing law. The exemption option exists for individual patients with life-threatening conditions or permanently impaired physiological functions that cannot be treated in any other way. Swissmedic announced that owing to the current "extraordinary situation" in Switzerland, Swissmedic would guarantee that exemption applications are processed promptly and pragmatically. In the case of ventilators, the criterion of "use for individual patients" should be interpreted generously and applications for devices for which the conformity assessment procedure has not yet been completed or which are still under development may also be submitted to Swissmedic.

In addition, at the beginning of October, the first application for authorization for a COVID-19 vaccine was submitted for review to Swissmedic. As of mid-November, Swissmedic is reviewing three COVID-19 vaccine candidates undergoing a "rolling submission procedure". In a rolling review, the data can be evaluated as soon as it becomes available. The companies can then submit the latest data continuously without having to wait for the conclusive results from all studies. Swissmedic can thus obtain an initial picture of the benefit-risk profile of the vaccine candidates before the authorization studies are completed (Phase III studies). This accelerates the review process while at the same time preserving the same level of careful checking of all requirements relating to safety, efficacy and quality.

Although Swissmedic is reviewing the dossier independently, it is working closely with partner authorities abroad on the scientific evaluation. Despite the high level of urgency, Swissmedic is reviewing the scientific data in accordance with its usual standards. Drug safety and the safety of the people who receive the vaccine are paramount.

Switzerland

Last updated: 30 November 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

As regards challenges, given the focus on COVID-19, this can result in delay to the marketing authorization for other drugs. On the other side, as Swissmedic was not able to do inspections for a long time and has only been gradually resuming inspections as of June, and, more recently, only according to COVID-19 related capacity problems and while observing the recommended protective measures, establishment licenses will be granted considerably quicker than before provided the relevant inspection has already taken place.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

There are delays in normal regulatory work for products unrelated to COVID-19 or virology/infectious diseases at large (e.g., physical regulatory audits were put on hold and only resumed in full on 1 September 2020 due to travel restrictions and general restrictions on business activity).

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

During the first wave in Spring 2020 and with the first set of measure to combat the coronavirus, hospitals and medical practices were prohibited from carrying out non-urgent medical examinations, treatment and therapies. Given the high number of cases and hospitalizations during the second wave of autumn 2020, the government has again recommended to avoid non-urgent medical interventions. This prevents many clinical trials from starting or going on without major impact on the study.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The Joint Guidance of Swissmedic and swissethics on the management of clinical trials with medicinal drug products in Switzerland during the COVID-19 pandemic ("Guidance") provides guidance to the parties involved in clinical research activities during the COVID-19 pandemic. Applications for clinical trials with medicinal drug products to treat COVID-19 or substantial amendment applications to existing clinical trials necessary as a result of COVID-19 are prioritized by the authorities. During the COVID-19 pandemic period, the delivery of the study medication directly to the study patient from the trial site might be permissible provided the study drugs are suitable for use at home. Changes in the distribution of the study medication have to be notified to Swissmedic and swissethics for information. The Guidance also deals with other issues related to clinical trials such as the patient's informed consent or the conduct of study visits. Applications for new clinical trials can now be filed electronically.

Finally the latest version of the guidance from 15 June 2020 addresses aspects such as monitoring and resumption of clinical trials activities following the COVID-19 pandemic.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Consult Guidance in its most recent form and act accordingly. Guidance document is available on Swissmedic's website.

Switzerland

Last updated: 30 November 2020

IP Risks

(a) **Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**

No.

(b) **Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**

No.

Telemedicine

(a) **How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**

Telemedicine services have become more widely used. No legislative changes have been implemented or are being considered and the usual rules of medical law and professional guidelines and main principles apply.

The Swiss professional association of Swiss doctors has issued a factsheet on telemedicine during the COVID-19 outbreak, which also addresses data protection and professional secrecy, including a table listing various tech services providers and related risks.

Turkey

Last updated: 25 June 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

TİTCK Measures

- Due to the urgent need for medications used for the treatment of COVID-19, Turkish Pharmaceuticals and Medical Devices Agency (TİTCK) required hospitals to make unit dosage notifications through Pharmaceuticals Track & Trace System (İTS) for certain pharmaceuticals used for the treatment of COVID-19. In other words, the TİTCK will be tracking these pharmaceuticals and may possibly introduce restrictions for the distribution of such pharmaceuticals as a measure to combat COVID-19 effectively.
- The TİTCK also required medical device registration and pharmaceutical licensing procedures to be carried out electronically. For instance, during the medical device registration process, applicants must submit certain documents relating to the medical devices. Some of these documents (e.g., EC certificate and conformity certificate) must be apostilled and physically submitted to the TİTCK. The TİTCK announced that it will not initially require physical submission of these documents and will grant a 60-days extension period. If the documents cannot be submitted within the extension period, the TİTCK may grant 60 more days upon the applicant's extension application.
- As for the Certificate for Pharmaceutical Products (CPP) applications, the TİTCK required certain documents to be submitted physically at the end of certificate approval procedure, which is 10 days from the date of the initial CPP application. The TİTCK also noted that it will carry out all assessment procedures electronically and urged applicants to upload necessary documents to Electronic Application System (EBS).
- The TİTCK announced that the effective period of approvals for off-label or use of the pharmaceutical procured from abroad (name patient sales) are extended to 30 June 2020, if the approvals are expired between 1 March 2020 and 30 June 2020.
- National and international science, cultural, art and similar organizations or meetings held in open or closed areas are postponed until the end of April. In this regard, the TİTCK announced that it will only accept applications for online scientific meetings.
- The TİTCK suspended product promotion representatives' promotional activities of visits to doctors, dentists and pharmacists in all health organizations and institutions, including pharmacies. The TİTCK also announced that promotional activities could still be carried out electronically (such as email and video conference).

Customs Measures

- In addition, the export of medical devices such as ventilators, oxygen concentrators, intubation tubes and other respirators are now subject to the TİTCK's prior approval. Accordingly, persons wishing to export the mentioned medical devices must apply to the TİTCK electronically for approval.
- On the other hand, according to the Amending Decrees on Import Regime, the Ministry of Trade remitted additional customs tariffs applicable to the respirators (13%), disposable medical masks (20%) and ethyl alcohol used for disinfectant liquids (10%) to facilitate the supply of these materials from abroad.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- Turkey introduced limitations to the export of certain medical devices such as respirators. Accordingly, the TİTCK must issue pre-approval for the export of these materials. Given that this is a new process, there is no comprehensive guidance on the specifics of the approval procedure.
- Due the urgent need for medications used for COVID-19 treatment, market access to these medications are becoming limited. As stated above, the TİTCK is tracking these medications currently and may introduce measures to limit the distribution and sale of these medications.
- Regulatory approval procedures are carried out electronically and the TİTCK eased some of the procedures by granting additional time for the submission of certain documentation.
- That said, the TİTCK is very active in responding the needs of sector during the COVID-19 and publishes announcement and guidelines on a daily basis. Therefore, it is possible for the TİTCK to introduce changes to the regulatory approval procedures and facilitate the processes.

Turkey

Last updated: 25 June 2020

Market Access

(c) **Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?**

Please see above.

Clinical Trials

(a) **What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?**

The importance of social distancing and the workload of research centers during the COVID-19 outbreak also affected the management of clinical trials. Accordingly, the TİTCK required clinical trials to be suspended or postponed. The TİTCK also announced that all clinical trial applications will be made electronically and that it will not accept any application for increasing the number of participants or involving more research centers to the clinical trial. Therefore, patient recruitment and operation of multi-center trials have been limited.

(b) **Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**

The TİTCK announced changes to clinical trial procedures during the COVID-19 outbreak. The TİTCK's measures generally aim to reduce the workload of research centers and ensure the safety of volunteers. In that regard:

- The TİTCK requires sponsors to regularly conduct risk assessments, coordinate their clinical trial organizations and make updates when necessary. In this respect, the TİTCK states that sponsors must initially evaluate whether clinical trials should be temporarily suspended or terminated early, depending on the nature of the clinical trial.
- If an event occurs that affects the safety of volunteers, sponsors or principal investigators must take the necessary emergency safety measures to protect volunteers. Accordingly, safety measures taken against the COVID-19 pandemic can be implemented without the Ethics Committee's approval or the TİTCK's authorization.
- Sponsors or principal investigators may make changes to the monitoring activities during the clinical trials. In this regard, monitoring activities at the research center may be postponed and/or re-planned. The TİTCK also allows remote monitoring if physical monitoring at the research center is unfeasible, subject to Law No. 6698 on Protection of Personal Data and the confidentiality principles of clinical trials.
- The TİTCK allows investigational products and clinical trial supplies to be stocked for a longer period so that a sufficient amount of materials can be supplied to research centers in case of possible scenarios such as import restrictions or quarantine. The TİTCK also requires that volunteer visits to research centers are postponed when feasible, recommending telephone calls as an alternative.
- The TİTCK stated that research meetings will be held online and it will not grant approval for face-to-face trainings or meetings regarding good clinical practices and clinical trials.
- The TİTCK will not require physical documentation to be submitted for clinical trial applications and stated that the applications will be made electronically.

Turkey

Last updated: 25 June 2020

Clinical Trials

(c) Are there any general tips and recommended solutions under the local regulatory framework?

All sponsors and principal investigators must duly implement the measures required by the TİTCK, make comprehensive risk assessments and postpone/suspend their clinical trial activities if necessary. Accordingly, all pharmaceutical companies must closely follow the announcement of the TİTCK and ensure full cooperation with the authority.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

No.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

The General Assembly of the Grand National Assembly of Turkey enacted a provisional article, which suspends the time limits of trials, the mandatory administrative application periods and all periods related to the origination, exercise and termination of any rights in the legal proceedings between 13 March 2020 and 30 April 2020, both dates inclusive. This amendment also applies to the Intellectual and Industrial Property Courts and Turkish Patent and Trademark Office.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

- There are no comprehensive legislative developments for telemedicine services. However, the Ministry of Health recently launched its hotline to assist citizens during the COVID-19. Accordingly, citizens may request assistance through hotline as to whether they carry symptoms of the COVID-19 and should receive professional health services from the nearest health organization.
- In other words, telemedicine services in Turkey is currently limited to the basic consultancy services, which aims to reduce the spread of the COVID-19 and urges citizens to take immediate action in the case of COVID-19 symptoms. However, given the increase in number of COVID-19 cases, the Ministry of Health may take further measures and improve the telemedicine services.

Ukraine

Last updated: 30 October 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Parliament and the Government of Ukraine have been addressing the urgent need for medicines, medical devices and medical supplies by taking a number of actions, including the following:

- Faster regulatory approval procedures for pharmaceuticals aimed at treating COVID-19
  - Legal timelines for approving marketing authorization (variation) applications of pharmaceuticals for treating COVID-19 should be significantly reduced. Based on Law No. 3539-IX adopted on 30 March 2020, the government must ensure that marketing authorization (variation) applications for pharmaceuticals for treating COVID-19 are approved within seven calendar days. By way of example, obtaining marketing authorization under the standard procedure in practice may take one to two years.
- Relaxed conformity assessment procedures for medical devices and personal protective equipment for combatting COVID-19
  - Personal protective equipment, medical devices, in vitro diagnostics and active implantable devices for combatting COVID-19 may be placed on the market without conducting conformity assessment set forth in applicable technical regulations.
  - To place products on the market in derogation of technical regulations, the applicant must submit to the State Labor Service of Ukraine (for personal protective equipment) or to the MOH (for medical devices, in vitro diagnostics and active implantable medical devices) the application containing information on the purpose of importation, the product, its manufacturer etc. The State Labor Service of Ukraine or the MOH should issue a notification on introducing personal protective equipment and devices into circulation in derogation of relevant technical regulations.
- VAT and import duty exemption for goods, including pharmaceuticals, medical devices and personal protective equipment for treating COVID-19. The list of such goods is established by the government.
- Prohibiting export of medical devices and personal protective equipment. The list of such devices and equipment is established by the government.
- Permitting use of unapproved pharmaceuticals and off-label use of pharmaceuticals for treating COVID-19
  - The off-label use is permitted in case a pharmaceutical has proven efficiency in treating COVID-19 and/or if a pharmaceutical is recommended by the authorities of the USA, EU member countries, the UK, Switzerland, Japan, Australia, Canada, China or Israel for treatment of COVID-19. Unapproved pharmaceuticals may be used for treating COVID-19 if same pharmaceuticals are recommended by authorities of states set forth above for treatment of COVID-19. At the same time, there is no guidance as to the form in which the same authorities should recommend pharmaceuticals for treating COVID-19 or guidance on how the proven efficiency of product in treating COVID-19 should be confirmed. Apparently, these criteria remain to be clarified by the MOH.
  - The use of unapproved pharmaceuticals and off-label use of approved pharmaceuticals are only permitted subject to obtaining the patient's consent. Such pharmaceuticals must be used in compliance with clinical protocol approved by the MOH.
- Prioritizing customs clearance of goods, including pharmaceuticals, medical devices and personal protective equipment, for treating COVID-19

Ukraine

Last updated: 30 October 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Market participants may benefit from faster regulatory approvals for pharmaceuticals aimed at treating COVID-19, relaxed conformity assessment procedures for medical devices and personal protective equipment for combatting COVID-19, VAT and import duty exemption for goods required to combat COVID-19 and off-label use of certain pharmaceuticals and use of unapproved pharmaceuticals for treating COVID-19.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Regulatory approvals of products unrelated to COVID-19 are likely to be delayed.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The COVID-19 outbreak resulted in travel restrictions, causing difficulties in patient recruitment, patients' visits to clinical trial sites and monitoring clinical trials.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Yes, the regulator for clinical trials, the State Expert Center of the Ministry of Health of Ukraine ("State Expert Center") has issued recommendations regarding conducting clinical trials in view of the spread of COVID-19. Among other things, the safety measures that may need to be taken include the following:

- replacing personal meetings by phone calls, video calls, use of electronic communication devices, etc.
- remote monitoring, provided it does not create an extra burden on trial sites and the subjects' consent to sharing of their personal information outside the trial site
- withdrawal of subject from a trial
- temporary halt of a trial/recruitment of new subjects
- transfer of participants to other sites
- direct-to-patient shipment of trial products
- providing study subjects with greater quantities of investigational products
- rearranging the distribution of investigational products between different sites

Ukraine

Last updated: 30 October 2020

Market Access

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

- laboratory testing outside the trial site or at a patient's home
- visiting patients at their residential addresses by investigators for clinical and diagnostic tests
- use of telemedicine technologies
- when there is the need to re-consent, investigators may obtain oral informed consent supplemented with email confirmation
- obtaining informed consent remotely by signing separate forms by the study subject and the investigator (in case of COVID-19 study subjects)
- online safety reporting
- canceling or postponing on-site monitoring and/or using centralized, off-site monitoring and/or remote source data verification or
- postponing sponsor audits.

Clinical Trials

(c) Are there any general tips and recommended solutions under the local regulatory framework?

In addition to following recommendations provided by the State Expert Center as set forth in question 2(b) above, prior to implementing any changes, sponsors and contract research organizations should evaluate whether any such change would be considered a substantial amendment under Ukrainian laws that would require approvals by the State Expert Center and the ethics committees.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

As of 26 October 2020, no state emergency supply measures for medicines, medical devices and biocides were taken and therefore there are no implications on IP protection.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

The Parliament Committee on National Health, Medical Aid and Medical Insurance is developing the draft law whereby Ukrainian pharmaceutical manufacturers would be permitted to produce pharmaceuticals that may be used for treating patients with COVID-19, including anti-malaria products, products for treating HIV and autoimmune diseases and pharmaceuticals that are protected by patents. The text of the draft law has not been published yet.

Ukraine

Last updated: 30 October 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

- As far as we are aware, due to lack of technical infrastructure and appropriate facilities in state and municipal healthcare organizations that are treating patients with COVID-19, the use of telemedicine technologies in practice is very limited, if used at all.
- Regarding clinical trials, the State Expert Center has noted that telemedicine may be used when the trial subject is unable to visit the trial site, but using telemedicine should be an additional method for ensuring medical oversight and evaluation of adverse events.

United Kingdom

Last updated: 16 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The focus has been on a faster review for medicines and medical devices that are related to COVID-19, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) may authorise manufacturers to supply a non-CE marked device in the interest of the protection of health (see here).

UK health technology assessment bodies are prioritising COVID-19 as follows:

- The National Institute for Health and Care Excellence (NICE), the health technology assessment body in England that makes reimbursement recommendations, is prioritising all therapeutically critical topics, including all appraisals of cancer medicines, diagnosis of COVID-19 and treatment of COVID-19.
- The Scottish Medicines Committee (SMC) has cancelled all its scheduled meetings of New Drugs Committees until the end of May 2020 in response to the COVID-19 crisis, in order to release its committee members and staff to support work aligned with COVID-19 resilience. A core SMC team will continue to assess the new medicine submissions that are currently in the system and will work on urgent activities around COVID-19 as required.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Medicines

The MHRA is expediting the assessment of variations and initial applications – it is implementing priority and expedited assessment for national variations (including batch-specific variations) and initial marketing authorisation applications that impact the medicines supply chain. Guidance is in preparation on how to highlight these at the time of submission.

The focus of the MHRA is now on COVID-19, which may delay the marketing authorization for other drugs. On the other hand, as the MHRA is no longer undertaking inspections abroad, some licenses may be granted more quickly than before.

Medical Devices

The MHRA may authorise manufacturers to supply a non-CE marked device in the interest of the protection of health (see here). This will be under regulations 12(5), 26(3) and 39(2) of the Medical Devices Regulations 2002, and is likely to be relevant for manufacturers ofventilators and PPE. The Department of Health and Social Care (DHSC) can grant its approval so that manufacturers may submit applications for exemption from the regulations to the MHRA. The DHSC may grant its approval regarding ventilators as long as they comply with the necessary minimum specifications which have been set out by the UK Government for ventilators (see here). For any other relevant devices such as PPE, the application may be sent directly to the MHRA.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

There may well be delays in normal regulatory work and in reimbursement advice for products unrelated to COVID-19 with all priorities directed at the current pandemic situation.

United Kingdom

Last updated: 16 April 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The COVID-19 outbreak resulted in travel restrictions, causing difficulties in patient recruitment, patients' visits to clinical trial sites and monitoring clinical trials. In addition, the regulator is unable to inspect clinical trial sites and has rescheduled inspections that were supposed to take place in Q1 2020 to Q2 2020.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

Medicines

The UK's Health Research Authority (HRA) and MHRA have published guidance on the impact of COVID-19 on medical research in the UK (here and here). The HRA provides guidance on:

- New studies relating to COVID-19, including procedures for expedited review.
- Amendments to existing studies to address COVID-19 elements, such as adding sub-studies or components to enable epidemiological analysis of COVID-19, or to add patients with COVID-19 to an existing trial.
- Amendments to existing studies impacted by the wider COVID-19 response, such as sponsors making changes to how or when patients are seen (to avoid exposing patients or to reduce burden on clinical services), investigational medicinal product (IMP) being sent by courier direct to participants, or halting / closing studies.

The MHRA's guidance addresses a range of issues, including:

- the MHRA prioritising COVID-19 assessments.
- providing investigational medicinal products to trial participants.
- remote monitoring for trials.
- submitting paperwork for trials that have been halted.
- restarting a trial after it has been halted.
- reporting of serious adverse events (SAEs) and submission of annual safety reports (DSURs) and end-of-trial notifications.
- protocol deviations, serious breaches and waivers.

Medical Devices

For clinical investigations of medical devices, the MHRA will expedite clinical investigations as follows:

- Any amendments to existing clinical investigations as a direct result from COVID-19.
- Any new submissions for clinical investigations that will have a direct impact on the COVID-19 emergency.
- Protocol deviations as a result of COVID-19 do not need to be notified to MHRA unless there is an impact on patient safety; however good records of these deviations should be kept. However, all other protocol deviations must be reported as normal.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Yes, please see above.

United Kingdom

Last updated: 16 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Medicines

NHS England has developed a list of the most critical ITU medicines and anaesthetic drugs and is liaising with the Association of the British Pharmaceutical Industry (ABPI) to promulgate the list and calling for support from the UK pharma industry to maximise production of these essential products. Additional critical drugs may be added to the list in due course as further clinical policies are developed to support the COVID-19 response. Again, we expect the UK government to prefer that this support is voluntary but it is not inconceivable that powers under the Civil Contingencies Act could be used or the government may pass specific legislation to deal with the situation if the supply of the listed medicines to the UK market was perceived to be at risk.

The MHRA has been maintaining its list of medicines that cannot be parallel exported from the UK, which was originally developed in 2019 ahead of a possible no-deal Brexit, but now includes medicines key to the treatment of COVID-19, including morphine, paracetamol, adrenaline and insulin.

Medical Devices

The UK Government is looking for businesses that can support in the supply of ventilators, CPAP devices and related components across the UK (see here). It has produced a specification of the minimally clinically acceptable ventilator, along with some preferred options, and a CPAP device, to be used in UK hospitals. In the UK, the Civil Contingencies Act 2004 provides the UK Government with particular powers in emergencies such as loss of human life, human illness and injury. We expect the UK government to prefer that manufacturing switches are voluntary but itis not inconceivable that powers under the Civil Contingencies Act could be used or the government may pass specific legislation to deal with the situation.

IP Implications

In the short-term, IP-owners may need to share their IP with third parties to enable supply of medicines and medical devices to be met. This might be a license of know-how (for example to enable new manufacturers to start making ventilators) or as part of a collaboration (for example in the race to find a vaccine against COVID-19).

For many types of IP (in particular patents) there are existing compulsory licensing and "Crown Use" provisions that could beimplemented or might be triggered by state emergency supply measures or any specific legislation that is passed. However such measures can be complicated to implement, and for IP such as confidential trade secrets there are no existing compulsory licencing or government use exceptions. Instead, other laws that would permit requisition, new emergency legislation or a consensual approach would be required.

Once the goal of meeting the emergency supply need has been met IP owners will want to ensure that they retain their IP rights and can bring the licensing arrangement to an end and regain exclusivity promptly when appropriate, such that they can commercialise the medicine or medical device in the longer term. In addition, robust confidentiality protocols and requirements to destroy or return information after termination will be key, as will provisions regarding ownership and rights to use any IP developed as a result of any licensing or collaboration. Any licence negotiated now should seek to address those points.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

At the time of writing no compulsory licensing, Crown Use or other emergency measures relating to IP have been implemented. IP sharing in the context of the measures to date (such as those referred to above) has been consensual.

United Kingdom

Last updated: 16 April 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Telemedicine services are well used. To our knowledge, no legislative changes have been implemented or are being considered.

Baker McKenzie.

Latin America

COVID-19: A Global Review of Healthcare and Life Sciences Industry Issues

Latin America

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Last updated: 07 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

In response to the current health emergency and within the framework of the joint Resolution No. 1/2020 ("**Resolution**") of the Health Ministry and the Productive Development Ministry, which provides the list products devices that are essential to face the COVID-19 crisis ("**Key Supplies**"), the Argentine Federal Health Agency (ANMAT) published two circulars: (i) an emergency mechanism for the registration of critical medical devices of Class I and II; this mechanism and the registrations made within the mentioned framework will be valid for 180 calendar days from the circular publication (April 15, 2020); and (ii) a simplified mechanism for those companies that import or manufacture medical devices listed in the Resolution and its subsequent amendments, and diagnostic reagents for in vitro use for COVID-19 and must carry out the expansion of the expertise area and/or the provisional authorization of the company.

In the case of imported devices, regardless their origin, the following documentation will be exceptionally accepted: (i) Certificate of free sale (CFS) of a country of high sanitary surveillance, which may be submitted with simple translation at all, without apostille and legalizaton, or (ii) the valid registration certificate issued by the competent Health Authority and/or with the European Conformity (EC) mark.

In these cases, the following text must appear in the indication of use of the device:
"Device registered in the context of the COVID-19 health emergency."

For the point (ii) above, the mechanism for requesting the "Expansion of the Expertise Area and Provisional Authorization" may be used for 90 calendar days from the publication of the circular (15 April 2020).

Notwithstanding the foregoing, in the context of the health emergency and for the purpose of supplying society with safe products, those who have the operational capacity to manufacture critical medical devices in this context may do so (as third parties) to companies authorized by ANMAT through the National Institute of Medical Devices. Said authorized companies will be the holders of the device registration and responsible for their manufacture and commercialization.

The Federal Government reduced formalities for Governmental purchase of medicines, medical devices and medical supplies.

Companies involved in the manufacture, distribution and commercialization of the Key Supplies must increase production to their maximum capacity and report to the Sanitary Regulatory Authority and the Ministry of Production, production plans as well as the amount of goods produced and sold and identify the buyers. Health institutions will have priority to acquire Key Supplies.

Supply Law No. 20,680 will apply to any deviations. This law gives the Government broad powers to intervene in economic processes (e.g., manufacturing of products) to protect essential needs of the population. The Supply Law sets forth fines (among other sanctions).

Argentina

Last updated: 07 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

On May 18, 2020, ANMAT issued a press release informing that filings made on hard copy, which are related to medical devices, can now be reconverted and filed electronically through ANMAT's online system - HELENA.

Through Circular No. 2 published by ANMAT, as of June 18, 2020, two new rates for in vitro medical devices were incorporated for agile modification through the ANMAT online system, HELENA. It is applicable only for requests that do not modify the in vitro medical device itself, nor its basic methodology, nor its performance characteristics.

In addition, the Federal Government, through the Secretariat of Inner Commerce, has intervened more strongly on the prices and production of specific medicines and medical devices. For instance, such Secretariat has prohibited increases on sanitizers' and liquid oxygen's prices, and has mandated their production at maximum capacity. These regulations been enacted not only generally (i.e., for all market players) but also specifically regarding a single market player that is considered to bear substantial market power. Moreover, some of these regulations have even been issued on orphan drugs that are not specifically related to the pandemic.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Mandatory quarantine established mid March for the entire population, except for those working in exempted activities, creates disruption in regulatory filings as well as imports and exports of products creates a challenge. It especially impacts on non COVID-19 related products.

However, ANMAT has allowed for digital processing of filings for specific drugs and for requests for temporary registration under special conditions.

Argentina

Last updated: 07 July 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

There is no other impact on market access, except for the delay in the analysis of unrelated products. However, Argentine Federal Government imposed certain actions to reduce the manage costs of the health care system. In addition, several resolutions have been issued in connection with a specific orphan drug, including pricing controls and the exclusion of the mandatory reimbursement plan. This is an important precedent that should be monitored by manufacturing ad importers of high cost drugs.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The main issue is in connection with the on-site clinical trials and the isolation measures, which makes the recruitment and the development of the trials more challenging. ANMAT has issued guidelines tending to ensure that trials in progress are not interrupted.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

See (a) above.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Record keeping of changes in protocols following ANMAT guidelines is critical. Extra care on patient safety in any protocol deviations is recommended.

With regards of the current health emergency situation, the ANMAT, established the following measures and recommendations in order to preserve the activities of clinical pharmacology studies (CFS) while protecting safety and well-being of the study participants.

The CFS sponsors must prepare a risk mitigation plan to take extreme measures to avoid the spread and dissemination of COVID-19 as well as the saturation of the country's health system. This plan must be duly documented in the file of each study and will be notified to researchers, research centers, ethic committees and the ANMAT. Its application does not require prior approval as a substantial modification by ANMAT.

The Health Ministry published on May 12, 2020 Resolution No. 908/2020, which approves the ethical and operational guidelines to carry out an accelerated research evaluation on individuals related to the coronavirus. The purpose of the ethical and operational guidelines is to guide research ethics committees and health authorities in different jurisdictions in the development of procedures for an accelerated evaluation of research projects related to COVID-19.

ANMAT published on June 11, 2020, a guide of recommendations on pharmacovigilance in the context of COVID-19. The Department of Pharmacovigilance and Risk Management of ANMAT generated the document with the aim of facilitating the compliance of pharmacovigilance obligations to which the Holders of Registration and Marketing Authorizations (TARC) of medicinal specialties in Argentina are subject, and also to guide health professionals and drug users in general.

Argentina

Last updated: 07 July 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

The Argentine Patents and Utility Models Law No. 24.481 (Section 45), as well as the TRIPs Agreement and Paris Convention -treaties for which Argentina is a party to-, establish the possibility of granting Compulsory Licenses in case of Sanitary Emergency or National Security.

Up to this date, we are not aware of any compulsory license having been requested to/granted by relevant authorities.

The Argentine Patents and Utility Models Act establishes the conditions under which compulsory licenses can be granted by the State:

- the license to use the patent shall be granted by the Argentine PTO;
- it shall be non-exclusive;
- such license cannot be assigned to third parties;
- on general basis, the authorization only enables the licensee to supply the internal market;
- fair compensation shall be granted to the owner of the patent, the amount of which shall be established by the circumstances of the case;
- the use of the licensed patent outside the scope of authorization as well as compensation shall be reviewed by a court; and
- the party requesting the compulsory license shall have the economic capacity to efficiently exploit the patent and shall possess an authorized venue by competent authority.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

No. However under Section 70 of Law 27,541 (the Social Support and Reactivation of Manufacture Act of December 21, 2019) and as a general provision, the Government has authorized the Health Ministry to grant compulsory and mandatory licenses in the health sector,should the need arise.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

Several regulations have been issued allowing physicians to prescribe via email or WhatsApp. HMOs will reimburse pharmacies accepting these virtual prescriptions.

HMOs have started to accept telephone or video doctor visits and physicians have been authorized to charge payments who contact them remotely. This is to avoid circulation of people in the country and unnecessary visits to ER.

On April 13, 2020, the ANMAT has officially published the telehealth and public distance communication (telemedicine services) platform "TeleCOVID" that reaches the patient's home for the first time. The service is intended for people with suspected or mild symptoms of COVID-19 and for those who must monitor chronic diseases.

In the practice, each province receives health telephone consults through two main channels: (i) through the monitoring of a suspected case of COVID-19 or a vulnerable pathology of a patient who is treated in a hospital that is part of the telehealth network, and (ii) begins from the telephone call to the COVID-19 specific consultation numbers of each province, that alerts of a suspect COVID-19 case or the case of a person with health vulnerabilities in which it is necessary to prevent circulation.

Brazil

Last updated: 20 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Brazilian Federal Health Agency (ANVISA) has issued several regulations providing exceptions to regulatory requirements for pharmaceutical products, medical supplies and medical devices related to COVID-19. Requirements for corporate permits for sanitizers and certain medical devices, as well as for the extraordinary acceptance of importation of products that are not registered in Brazil, have been relaxed under certain conditions.

For example, companies are allowed to manufacture alcohol 70% in the Brazilian market without previous registration before ANVISA and without Operating Authorization - AFE. ANVISA also allows the manufacturing and import of determined medical devices (such as masks, protection, face shields, disposable hospital gowns, caps and thongs, valves, circuits and respiratory connections for use in healthcare services) by companies without AFE and other authorizations issued by the health authorities. The acquisition of these products without registration/regularization is also permitted.

Also, there is a commitment to faster analysis of products that are connected, but not directly related to COVID-19.

Finally, the federal government enacted a law allowing the waiver of public tender procedures for the acquisition of medicines, medical devices and medical supplies, and reducing the formalities needed for such procurements

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

In addition to the exemption of registration in certain cases as well as the expedited analysis (for example, at least 17 medical devices for diagnostic of COVID-19 have been approved as of 20 April 2020), the authorities are more open to discuss with companies the strategy for regularizing products. On the other hand, the incremental workload made ANVISA and Ministry of Health officers more focused on matters related to COVID-19, so other matters not related to the outbreak are somehow neglected.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

We have seen issues due to changes in the supply chain and to the annual readjustment in drug prices, since the Government suspended the annual readjustment for a period of 60 days.

Also, the expropriation of product by the government and contractual force majeure are topics commonly questioned by companies.

We are not aware about problems related to delays occurring in normal regulatory work for matters unrelated to COVID-19; however we are sure that this will be a problem in the near future, considering that we are still at the beginning of the pandemic.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The main issue is in connection with on-site clinical trials and the isolation measures, which makes recruitment for and the development of the trials more challenging. ANVISA has invited the relevant stakeholders to discuss the challenges and to implement pathways to resolve the matter.

Brazil

Last updated: 20 April 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

There has been no concrete measure, but ANVISA issued Technical Note No. 3/2020, as guidance for sponsors, researchers and institutions involved in ongoing clinical trials, in order to mitigate the issues during the COVID-19 crisis. The Agency has invited the relevant stakeholders to discuss the challenges and to implement pathways to deal with them

(c) Are there any general tips and recommended solutions under the local regulatory framework?

Our general tip is to communicate with ANVISA about eventual problems or concerns regarding clinical trials. ANVISA is concerned about the continuity of ongoing procedures and is flexible to align different approaches, if needed (i.e., delivery of the investigational drug at research subject's home).

In case a company enjoys or uses any of the exceptions or relaxations measures, it is crucial that the company keep records of the relevant supporting documents regarding the security and efficiency of the products, as well as other quality-related aspects of the plant, such as quality control policies and data, which must be aligned with good practices requirements.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

Emergency purchases of medicines, medical devices and biocides have been reported, but to date, this has not had an impact on the IP protection of the products in question. The Brazilian Industrial Property Law does provide for compulsory licenses of patents under certain circumstances, including in the event of national emergencies or public interest which have been declared as such by the Executive Branch - and the COVID-19 pandemic has been acknowledged as an event of public health emergency through Ordinance # 188/20 issued by the Ministry of Health (which is part of the Executive Branch). Under such circumstances, a temporary and non-exclusive compulsory license may be granted ex officio if the patent owner or its licensee does not meet market needs. However, no compulsory licenses have been granted as of this date. As regards importation, products must be imported by the registration holder, so there has not been a relaxation on parallel importation

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

The Brazilian Patent and Trademark Office (INPI) announced that it will prioritize the examination of patent applications related to processes, equipment and materials used in the diagnosis, prevention and treatment of COVID-19. Applicants must apply for priority by 31 June 2021 to be eligible for this special procedure

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

The Ministry of Health has temporarily allowed telemedicine through Ordinance No. 467, issued on 23 March 2020. This ordinance provides for the possibility of telemedicine in both public and private health systems during the coronavirus pandemic in Brazil. The appointment must be made directly between HCP and patient only, through an IT system that ensures integrity, security and confidentiality of patient information. E-prescriptions are also temporarily permitted, but it is necessary to use systems with certifications and passwords issued by the Brazilian organization of e-signature.

Subsequently, Federal Law No. 13,989/2020, published on April 16, confirms the authorization for the use of telemedicine in any activities of health services during the coronavirus pandemic in Brazil.

Chile

Last updated: 01 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

No measures have been adopted yet in connection with the granting of marketing authorizations or relaxation of restrictions. However, on 25 March 2020, Decree No. 10 was published in the Official Gazette. This decree granted the following powers to the Undersecretary of Public Health:

- To set the maximum price for certain pharmaceutical products, medical devices, health items and supplies; as well as for health benefits and health services and for all goods and services necessary to meet health needs.
- To limit the maximum number of goods and services that can be sold and delivered to each person by the sales establishments and service providers.

These powers are in addition to those that had already been granted through Decrees No. 4 and 6. Decree 4 declared a Sanitary Alert for the Public Health Emergency of International Importance, and Decree No. 6 modified Decree No. 4. These two decrees grant broad powers, including the coordination of the distribution of pharmaceutical products and medical supplies, the authorization to hire more personnel, and the authorization to directly acquire equipment.

The following powers were granted to the Undersecretary of Assistance Networks, in addition to those included in Decree No. 4

- To coordinate the country's healthcare network of public and private providers. As a result, the Undersecretary is authorized to request public and private establishments to provide healthcare benefits that they cannot be postponed without causing serious prejudice.
- To authorize that periodic treatments for chronic diseases that are prescribed for biweekly or monthly periods can be prescribed to cover treatment for up to three months, provided that the conditions of dispensing and preserving the drug allow it.

In addition, on 18 March 2020 a bill of law was approved by the Chamber of Deputies (and should now be revised by the Senate) which would modify the Sanitary Code, including a new article (94 bis), which would prohibit price increases in the event of a sanitary alert, epidemic or pandemic.

In the case of an epidemic or pandemic, and when the corresponding sanitary authority has declared a sanitary alert, the article prohibits the price increase of pharmaceutical products, foodstuff and medical devices for the prevention and treatment of diseases related with said alert, epidemic or pandemic, as well as of products useful to prevent, directly or indirectly, the sanitary alert or pandemic, and those used for personal, domiciliary or environmental hygiene.

If approved, the article will be applicable to laboratories, drugstores, pharmaceutical warehouses, and other establishments selling or commercializing these products. The sanitary authority will determine the complete list of products that will be subject to this measure. This prohibition will be valid only during the sanitary alert, epidemic or pandemic.

The proposed law establishes that if there is a sanitary alert, epidemic or pandemic in place when this law comes into effect, drugstores, pharmaceutical warehouses and commercial establishments should change the prices back to the price at the time the circumstances were declared.

Chile

Last updated: 01 April 2020

Market Access

(b)	**What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?**	There is no information available on this matter to date.
(c)	**Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?**	Not applicable.

Clinical Trials

(a)	**What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?**	There is no information available on this matter to date.
(b)	**Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**	There have been none.
(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	Not applicable.

Chile

Last updated: 01 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

There have been none to date.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

The Chamber of Deputies issued a non-binding draft resolution that refers to the granting of compulsory licenses contemplated in the Chilean Industrial Property Act (No. 19.039) to facilitate access and availability of medicines and technologies for the prevention, treatment and cure of COVID-19.

The draft states that even though we do not know what the vaccines, medications, diagnosis, equipment and other technologies useful for the prevention, treatment and cure of COVID-19 are, we have to be prepared as a country so that the necessary measures can be taken rapidly.

Pursuant to this background, the Chambers of Deputies considers that the coronavirus epidemic constitutes sufficient justification for the granting of non-voluntary licenses contemplated in article 51 No. 2 of the Industrial Property Act, for public health reasons and/or national emergency, as provided in international laws, particularly the Doha Declaration on the TRIPS Agreement. In view of this, it requires the Minister of Health to declare the existence of public health reasons for the granting of non-voluntary licenses as provided in the referred article, regarding all patent applications and issued patents related to vaccines, drugs, diagnostics, devices, supplies and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of persons with coronavirus SARS-CoV-2, for public health grounds.

In addition, it requires the Minister of Health to instruct the corresponding ministerial departments, as well as health services and the Supply Center, to report the vaccines, drugs, diagnostics tests, supplies, equipment and other technologies that are projected to be required as essential for the purposes of determination by the National Institute of Industrial Property of the existence of patents or other industrial rights that restrict their importation or national production.

Finally, it requires the Minister of Health to require the World Health Organization Global Observatory on Health R&D to collect information on the research and development costs directly associated with vaccines, drugs, diagnostics, devices, supplies and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of COVID-19, including investments made by public sector institutions, private sector institutions and charities.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

On 27 March 2020, Resolution No. 204 issued by the Ministry of Health was published in the Official Gazette. It establishes that during the sanitary alert, certain types of medical attention, as detailed in the resolution, can be provided remotely but maintaining the same terms required for in-person attention (full list of specialties mentioned in attached resolution No. 204).

Colombia

Last updated: 03 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

Within the context of the national government's health emergency declaration, the National Institute for Medicines and Foods Surveillance (INVIMA) has set into motion a group of safety measures to face the rapid growth of the COVID-19 pandemic in Colombia.

INVIMA has declared all COVID-19 protection items and products, such as medicines and medical devices necessary for health professionals to care patients with COVID-19, as non-available vitals.

This means that companies can import certain products, such as face masks, medicines, medical devices and antibacterial gel, without the sanitary license granted by INVIMA to sell them in Colombia.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

INVIMA has reduced the timing to grant the importation approval for non-available vital products from six (6) days to one (1) business day. It has also arranged for a straightforward communications channel to share information related to the COVID-19 pandemic.

INVIMA has classified as "priority" the approval of new sanitary licenses or renewals for medicine products listed in pharmacological standards as essential for the treatment of pathologies originating from COVID-19.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

We anticipate delays in the study of applications for products unrelated to COVID-19 since the regulatory entity currently prioritizes attending to cases of products necessary in addressing this pandemic.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

Due to the current quarantine measures established by the national government, INVIMA has given some indications for the continuance of clinical studies of medical devices that are currently approved or in the process of being approved, but on the condition that the safety and well-being of the participants are guaranteed.

Studies next to begin with medical devices: These studies will NOT be received by the regulatory entity until the end of the health emergency, EXCEPT for those of medical devices that are related to the diagnosis, prevention, supervision, treatment or relief of the symptoms of COVID-19.

However, for those clinical studies that were in progress, sponsors and researchers should assess the risk of the measures to be implemented during the health emergency, which should be based on a risk-benefit analysis, and ensure the protection of data from participants.

Meanwhile, INVIMA has also established specific requirements for the presentation of initial grade protocols contributing to achieving information on possible treatment alternatives for COVID-19.

To study the protocols, INVIMA's clinical research task group will review each protocol within five (5) days following submission.

Colombia

Last updated: 03 April 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The specialized room for medical devices through Act No. 3 of March 2020, recommends the following measures for clinical studies of medical devices that are in progress:

- Suspend the recruitment of new participants for the studies in order to avoid unnecessary risks.
- Evaluate the cancellation of the visits scheduled in the study.
- Instead of physical visits, consider telephone/video calls or home visits to the patient.
- If specialized examinations are required, the sponsor must ensure the patient safe, individualized transportation and protection measures to prevent infection in a hospital environment.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

All imported products must be stored under the conditions established by the manufacturer that guarantee their quality and safety. In addition, any adverse event or incident associated with the use of the products must be reported through the systems designated by the regulatory entity.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

From a sanitary perspective, none, because INVIMA grants import authorizations as long as certain requirements, including the manufacturer's information and its authorization to import the product, are met.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

There have been none from a health perspective.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

In order to facilitate the access, opportunity, and the provision of health services, the Ministry of Health and Social Protection issued Resolution 2654 of 2019, which sets provisions regarding telemedicine services and establishes the parameters for the practice of telemedicine in Colombia, as well as regarding the use of technological equipment, the quality and security of care, and data information. There have been no additional provisions regarding telemedicine as a result of the pandemic.

Mexico

Last updated: 05 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The federal government for a very long time ignored international experience as well as recommendations of international organizations to prepare for the imminent outbreak, including acquiring additional ventilators and enhancing testing capacity. It was only recently that they ordered the urgent purchase of a few medical devices, including ventilators, which were bought in China.

The federal government also took a strong position against widespread testing, which affected: (i) testing at private hospitals; (ii) testing at private labs; and (iii) making available rapid tests. It has been said that the government wanted to have tight control over the number of cases to avoid panic and being forced to act earlier than expected. They argued that testing should only be done on people with respiratory symptoms and who have travelled abroad to certain countries of concern. In the case of testing at private hospitals and labs, the federal government stopped the certification process that is recommended by the National Institute of Epidemiological Research and Diagnostics (InDRE) -- and aggressively enforced that against these private hospitals and labs -- until there was a public outcry and they were forced to certify a small number of private companies.

In the case of rapid tests, the federal government argued that because there was a risk of false positives with these types of tests and they did not have confirmatory power, they did not promote its adoption. It was leaked that the Abbott testing platform had been offered to the Ministry of Health, almost as a donation, and that they declined. It was not until very recently that COFEPRIS opened a hotline for a fast-track approval procedure for rapid tests, although none have been approved.

The federal government issued a decree on 27 March 2020, announcing a catalogue of possible measures to be taken to expedite the acquisition and import of medicines and medical equipment to tackle COVID-19, including: (i) using private hospitals as supplementary resources to tackle the pandemic; (ii) acquiring medical products locally or abroad without public tender; (iii) importing without regulatory approvals; and (iv) adopting any measure to avoid price speculation for key products. The decree was implemented by COFEPRIS by issuing a communiqué: https://www.gob.mx/cofepris/articulos/acciones-estrategicas-de-la-cofepris-por-la-emergencia-de-COVID-19?idiom=es. It announced that it will: (i) expedite donations of equipment; (ii) create a pre-certification process for importing ventilators; (iii) open the hotline for private lab testing; and (iv) shorten to 24 hours the approval of protocols for COVID-19 experimental therapeutic treatments.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

The Ministry of Health issued a decree implementing the federal decree of 24 March 2020, where it indicated that it was closing operations, including COFEPRIS. However, COFEPRIS clarified that it was open for certain applications, which were later defined (see above).

The federal government has deliberately refrained from issuing an Incentives Plan, declaring that the private sector should not dream about being subsidized like in the neoliberal past. State governments have been issuing decrees that do contain incentives.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Since COFEPRIS is shutting down, normal approvals for applications unrelated to COVID-19 will be affected.

Mexico

Last updated: 05 April 2020

Clinical Trials

(a)	**What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?**	It is unclear if they will receive applications related to ongoing clinical trials that are not related to COVID-19.
(b)	**Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**	No special measures have been adopted.
(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	Add a cover letter to any formal application related to an ongoing clinical trial. Call attention to the right of protection of health of patients enrolled, as well as to the administrative liability of public officers involved, in the case of rejection to receive or delay to approve applications related to ongoing clinical trials.

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	The first federal decree contained a declaration of COVID-19 as a "serious disease of priority attention," which was similar to a prior declaration issued in 2009 when AH1N1 emerged in Mexico. Such term is contained in the Law of Industrial Property and constitutes the first step for initiating a process to issue a compulsory license for patented medical products in case of shortages. However, there has been no sign that the federal government intends to tackle any shortage through these means. It has rather opted for international acquisitions. In an unrelated federal decree issued on 28 January 2020, in order to tackle constant shortages of medicines affecting the public health sector, including oncology drugs for children, the federal government allowed the import of products without prior marketing authorization as long as they have been approved by any regulatory agency as enumerated in a long list of more than 35 countries, which triggered great concerns because the list included China and India.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	There are none.

Telemedicine

(a)	**How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**	The federal government has not made use of any technological innovation to tackle the pandemic. Perhaps the only development worth noting would be that the biggest public health institution, which provides health services for employees in the formal economy, created an electronic platform that enables employees to obtain a certificate of illness, which is a key requirement for documenting sick days and avoid discounts.

Peru

Last updated: 17 July 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Peruvian government has been enacting a series of measures to fight the COVID-19 crisis, which include the application of a zero-tariff for the import of goods related to the sanitary emergency (medicines and medical supplies). In addition, the health authority on pharmaceutical products, medical devices and sanitary products (DIGEMID) announced that it will prioritize: (i) exceptional authorizations for the import and use of medicines, medical devices and health products for personal prevention and treatment; and (ii) marketing authorizations and major changes on the registry of pharmaceutical products and medical devices related to the prevention, diagnosis and treatment of COVID-19.

Moreover, to date, masks (mask used as a non-sterile mouthpiece, disposable mask, disposable non-sterile protection mask type N95) and gloves (adapted glove or mitt, antimicrobial glove, support glove) do not need an authorization for their manufacture, use and import. Other products that are not subject to marketing approval are: face shield, reusable or disposable eye protection goggles, non-sterile disposable mandrel, non-sterile disposable surgical gowns and non-sterile patient gowns.

However, by means of an official communication through its website, DIGEMID has informed that, as of January 01, 2021, surgical respirators for medical use N95, KN95, FFP2, FFP3 or their equivalents will be subject to marketing approval, likewise, pharmaceutical establishments will be able to initiate proceedings by October 01, 2020.

Concerning certificates, DIGEMID made available at its website the links to the certifying entities in order to verify via online the validity of certificates. It further adopted several measures making flexible the requirement of certificates. In particular, for purposes of registering, re-registering, importing and changes of pharmaceutical products and medical devices, it will be accepted until December 31, 2020, those Good Manufacturing Practices Certificate and Free Sales Certificate, which are issued by the competent authority of the high surveillance country or the country of origin, or equivalent recognized as such by DIGEMID and expire between March 11 and December 30, 2020. Likewise, during the State of Sanitary Emergency, sanitary authorizations to operate as a pharmaceutical establishment will be granted without prior inspection, which will be carried out upon conclusion of such state.

Additionally, by means of an official communication, DIGEMID informed that it is virtually handling the communications of information of pharmaceutical establishments.

Peru

Last updated: 17 July 2020

Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

With regard to opportunities, the National Council for Science, Technology and Innovation (CONCYTEC) has launched a short-term grant called "Special Projects: Response to COVID-19." which aims to find fast solutions for COVID-19 issues. Proposals must be related to: (i) Development and/or Validation of Detection Systems; (ii) Telehealth and Mobile Health; (iii) Technological Developments and Innovation; (iv) Treatment; and (v) Epidemiological and Social Studies. Financing amounts are between PEN 150,000 and PEN 350,000. Depending on the subject, maximum execution time is 3-6 months. Moreover, the Ministry of Health has standardized the production of masks due to the shortage of this product. This technical standardization specifies the types of fabrics, models and dimensions that masks must have in order to reduce transmission and attain maximum protection. Although masks require no marketing approval, technical standardization will allow production considering shortages.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

Given that DIGEMID is prioritizing proceedings related to the prevention, diagnosis, and treatment of COVID-19, companies applying for the registration of other products not related to the sanitary emergency will face a delay in their proceedings, which could impact the access of those products to the market. This delay could be even more critical considering the authority's workload.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

In line with the suspension of all proceedings declared by the Peruvian government due to the COVID-19 pandemic, the National Health Institute (the health authority on clinical trials) had announced that all proceedings were suspended. Later on, it created a special email to receive, advise and prioritize clinical trials related to COVID-19.

Peru

Last updated: 17 July 2020

Clinical Trials

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

The National Health Institute announced that it will prioritize the evaluation of clinical trials related to the prevention, diagnosis and treatment of COVID-19. To that effect, it made available an email address (ensayosclinicosCOVID@ins.gob.pe) that all sponsors or legal representatives having a clinical trial related to COVID-19 may reach.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

No.

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

The Peruvian government has ordered more than 1.6 million tests to detect new COVID-19 cases in the country. Of that total, 1.4 million will be rapid tests and another 200,000 will be molecular tests. There are no emergency supply measures for medicines or medical devices so far.

There have not been compulsory licensing issues. The government is making great efforts to guarantee access to food, medicines and essential goods related to the sanitary emergency, so the market does not suffer shortage. In line with these decisions, it is also relaxing import proceedings, so that the products related to the sanitary emergency can enter into the market faster.

In the last month, the Customs Authority has seized containers declared as certain products but concealing COVID-19 related products with no marketing approval or counterfeit products

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

There have been none so far.

Peru

Last updated: 17 July 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

In Peru, as in most Latin American countries, telemedicine was regulated for use in rural or remote areas.

During the sanitary emergency due to the COVID-19 outbreak, the Ministry of Health has approved a directive for the implementation and development of synchronous and asynchronous telemedicine services that establish the criteria for the insertion of these services in the Health Services Providers in the country. Although this has already been approved, it could take time to comply with the requirements of human and technobgical resources.

Morever, in an attempt to adequately allocate resources to handle COVID-19 cases, the Ministry of Health made available a toll free line (113) where coronavirus cases may be reported. However, the lines are manned by non-healthcare professionals: (i) giving information about COVID-19 symptoms; and (ii) identifying suspected cases to send healthcare professionals over to collect samples.

As of today, patients with COVID-19 symptoms are compelled to stay home and wait for healthcare professionals to come over and collect the samples. If treatment is necessary, they are referred to public hospitals.

Furthermore, in accordance with the restrictions and quarantine measures, private and public clinics and hospitals continue operating to attend only to emergency cases and in a limited capacity. Scheduled appointments and procedures have been postponed.

Venezuela

Last updated: 30 September 2020

Market Access

(a) **How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?**

The Venezuelan government has issued an exemption on the payment of VAT, import duties and fees for the definitive import by public entities of facemasks, surgical masks and other related goods destined to address the spread of the COVID-19 pandemic. The same exemption applies to the sale of facemasks, surgical masks and other related goods inside the country. In addition, the exemption could be extended to other supplies deemed by the Ministry of Health as necessary to avoid the spread of the pandemic. The corresponding decree was issued on 17 March 2020.

(b) **What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?**

The Venezuelan government issued an exemption on the payment of VAT, import duties and fees for the definitive import by public entities of facemasks, surgical masks and other related goods destined to address the spread of the COVID-19 pandemic. Although the authorities implemented a 7x7 quarantine scheme, delays in all procedures are expected. Notwithstanding, it is probable that regulatory approvals related to COVID-19 may be expedited.

(c) **Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?**

Delays in all ongoing proceedings are expected, especially for those not related to COVID-19.

Clinical Trials

(a) **What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?**

There have been no specific coverage in the news or by the authorities. Due to the quarantine measures explained above, delays should be expected.

Venezuela

Last updated: 30 September 2020

Clinical Trials

(b)	**Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?**	There have been none to date.
(c)	**Are there any general tips and recommended solutions under the local regulatory framework?**	If the clinical trials continue, extra special measures should be taken in terms of hygiene, bio hygiene, etc. These special measures should be duly documented by the company conducting the clinical trial.

IP Risks

(a)	**Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?**	As noted, the Venezuelan government issued an exemption on the payment of VAT, import duties and fees for definitive imports by public entities of facemasks, surgical masks and other related goods destined to prevent the spread of the COVID-19 pandemic, as well as sale of these supplies within the country. However, no specific measures concerning IP rights have been issued in this regard.
(b)	**Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?**	There have been none to date.

Telemedicine

(a)	**How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?**	There have been no specific measures taken by nor are expected from the authorities to date. In practice, there has been a rise in the provision and use of telemedicine services due to the pandemic.

Baker McKenzie.

North America

COVID-19: A Global Review of Healthcare and Life Sciences Industry Issues

North America

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Canada

Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

The Canadian response to COVID-19 regarding the public's access to medicines and devices (including diagnostic devices and personal protective equipment) has involved the implementation of both expedited procedures by which sponsors can seek authorization to import, distribute and sell products in Canada, as well as a relaxation of certain requirements relating to labelling and clinical data, among other things. The below highlights the primary measures in this regard effective as of September 16, 2020.

- **Drugs and Vaccines**

Canada's Regulatory Authority, Health Canada, issued specific guidance for health professionals (the COVID-19 Guidance), which outlines a number of the measures being implemented given the exceptional circumstances created by the COVID-19 pandemic. These measures include a commitment to fast-tracking the scientific review of drugs and vaccines to treat or prevent COVID-19 through a priority review, as well as expediting clinical trial applications for new vaccines, new or repurposed antivirals, or supportive therapies. The COVID-19 Guidance also specifies that when a new COVID-19 treatment or vaccine is authorized for sale in the US, Switzerland, or EU, it will be placed on the list of drugs for urgent public health need, which will expedite its importation into Canada.

Additionally, the existing approval pathway for Extraordinary Use New Drug Submissions (EUND pathway) is available for sponsors to seek approval for COVID-19-related vaccines and treatment. This mechanism provides for an expedited (or emergency) means for authorization of drugs based on non-clinical and limited clinical information for use in extraordinary circumstances. The EUND pathway provides access to extraordinary use new drugs based on a pre-market review for quality, safety and efficacy despite limited clinical data packages. EUND products will be monitored more extensively for clinical safety and effectiveness during the post-market phase.

- **Mechanism to Respond to Drug Shortages**

In order to accommodate anticipated drug shortages, the Minister of Health issued an Interim Order on March 30, 2020 (March 30 IO) allowing the exceptional importation and sale of certain drugs that may not fully meet regulatory requirements in Canada. The objective ofthis measure is to address significant drug shortages that have the greatest impact (based on low availability of alternative supplies, ingredients or therapies) on Canada's health care system. Drugs eligible for importation under the March 30 IO must be manufactured in accordance with Good Manufacturing Practices (GMP), and importers/distributers/wholesalers must have a Drug Establishment Licence (DEL) that covers importation under the applicable drug category and dosage form.

- **Vaccines**

The Government of Canada has been pursuing the purchase and development of COVID-19 vaccines. Several measures were introduced in August 2020, including the creation of the COVID-19 Vaccine Task Force ("Task Force"), which will help the government facilitate and prioritize vaccine solutions, including identifying promising international vaccine candidates, and supporting research, development, and supply chain coordination. The Task Force is made up of members from Canadian medical, pharmaceutical and research facilities. Since the creation of the Task Force, the Government of Canada has entered into four agreements with pharmaceutical companies to secure millions of doses of COVID-19 vaccine candidates upon approval by Health Canada (as of the date of this update).

Additionally, the Government of Canada is making investments in Canadian research and clinical trial efforts, with ongoing recommendations from the Task Force. For example, on August 5, 2020, the Government of Canada announced an investment of up to $56 million to support clinical trials for a vaccine candidate from Variation Biotechnologies Inc.

Canada

Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- **Medical Devices**

Health practitioners can obtain COVID-19 diagnostic test kits or supportive devices not yet approved for sale in Canada through the existing Medical Devices Special Access Program (SAP). The SAP allows the importation and sale of medical devices that have not been approved for sale in Canada in emergency use cases or when conventional therapies have failed, are unavailable, or are unsuitable to treat patients.

On March 18, 2020, Health Canada issued an Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19 (March 18 IO). The objective of the March 18 IO is to expedite the importation and sale of medical devices, including diagnostic (testing) kits that are integral to diagnose, treat, mitigate or prevent COVID-19 on the basis of an urgent public need. This expedited authorization pathway is available on a temporary basis for:

1. New COVID-19 devices that are not yet licensed in Canada or any other jurisdiction;
2. The addition of COVID-19 related uses for existing devices licensed in Canada, or under the Interim Order; and
3. COVID-19 devices that leverage an authorization of a device from a trusted foreign regulatory authority (Health Canada maintains the ability to request additional information on a case-by-case basis).

The above-mentioned March 30 IO also mandates manufacturers and importers of medical devices to report shortages of medical devices where the inability to meet current or future demand is actual or anticipated for the device, its components, parts or consumable materials, and no other substitute device, etc. is available. Similar to drug products, eligible devices, etc. may be imported on an exceptional basis.

Lists of all approved devices, including those authorized under the March 18 IO and the March 30 IO, are published and updated online, including (i) authorized testing devices, (ii) authorized medical devices other than testing, (iii) medical devices approved for expanded use, and (iv) medical devices for exceptional import and sale ("designated medical devices").

In an effort to ensure that only authorized devices are distributed, Health Canada has released guidance on identifying valid COVID-19 medical devices. Medical devices may be licensed or authorized in Canada by the following:

- The manufacturer or importer holds a Medical Device Establishment Licence (MDEL);
- Class II, III and IV devices must be issued a Medical Device Licence and be included on the Medical Devices Active Licensing Listing that is maintained by Health Canada; or
- The inclusion of the device on one of the above-mentioned lists of authorized devices published by Health Canada.

Canada

Last updated: 30 September 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- **Ventilators, PPE and Disinfectants**

Health Canada responded to the unprecedented and urgent demand for products that can help to limit the spread of COVID-19 by the issuance of an alert on March 18, 2020 and updated on March 25 (the Alert). The Alert advises that, as an interim measure, Health Canada will expedite the authorization of, and access to, supplies of hand sanitizers, swabs (for testing), ventilators, and personal protective equipment (PPE) such as masks, gowns, and shields even where such products do not fully comply with all regulatory requirements (e.g., English-only labelling, different packaging from what was authorized, etc.). Specifically as to ventilators, and other respiratory devices, stakeholders are encouraged to reference the U.S. FDA's guidance document. In addition, access will be provided to products that are not authorized for sale in Canada, but are otherwise approved for sale in a trusted jurisdiction outside of Canada (meaning that it operates under a similar regulatory and quality assurance framework). In order to expedite product approvals, Health Canada is expediting approvals of medical device / drug establishment and site licences (MDEL, DEL and SL, respectively) related to these types of products with a view to issuing licences within 24-hours from receipt of a completed application.

Health Canada is committed to innovative strategies to respond to potential shortages of PPE, including the safe reprocessing of devices intended for single use. For example, on April 17, 2020, Health Canada formally invited applications from medical device companies to develop technologies specific to the reprocessing of N95 respirators. As with all COVID-19-related applications, the applications for these reprocessing products will be expedited and prioritized in Health Canada's review.

- **Importation Measures**

Upon authorization of COVID-19-related devices (per Section 1(ii) above), Health Canada will issue to the licence holder an "authorization to import" document. A copy of this document must accompany each shipment of the device imported into Canada and in so doing, will facilitate its expedited transportation across the Canadian border.

Additionally, the Canada Border Services Agency (CBSA) implemented a number of emergency measures by facilitating more flexible importation of goods for emergency use in response to COVID-19. Among other things, this measure grants relief from the payment of import duty and tax for these goods that are imported by or on behalf of Health Canada, and any other federal, provincial or municipal entity involved in the response to COVID-19, such as healthcare facilities, medical response teams, and other first response organizations (e.g., police, fire and local civil defence groups).

Canada

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Market Access

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- **Funding and Collaborations**

The Canadian Government has responded to the need to fund research relating to the coronavirus by a series of funding announcements. As of March 11, 2020, the total amount available to researchers is more than CAD $300 million to fund the research and development efforts on coronavirus-related medical countermeasures, including antivirals, diagnostic tool development, vaccine development and support for clinical trials. Numerous research funding requests have already been accepted.

On June 25, 2020, the Federal Minister of Health announced a further investment of $109 million over one year in COVID-19 research. This investment will support 139 research projects across the country that will focus on accelerating the development, testing, and implementation of mitigation, prevention and diagnostic measures. Many of these projects will involve collaboration with other research teams around the globe to contribute to efforts to curb the virus overseas.

- **Innovation & Procurement**

The Canadian Government has formally called upon all suppliers to provide their products and services to help front-line responders. Public Services and Procurement Canada is prepared to purchase products that are approved by Health Canada and the Ministry of Innovation, Science and Industry. More than 2,000 Canadian businesses responded within less than a week of the request. Pursuant to this announcement, the Canadian Government expects to enter contracts within a matter of days for the manufacture and supply of PPE, ventilators, test kits and other COVID-19-related equipment. In a rare move, the Canadian Government has more recently taken on the source management and transportation logistics for the importation of much-needed PPE, ventilators and testing supplies from such countries as China, instead of reliance upon private entities to source and bring these supplies in to the country.

- **International Collaboration**

Recognizing that COVID-19 is truly a global challenge, Canada is committed to collaborating with international counterparts. Canada is playing an active international role, joining foreign regulators in leveraging resources on issues related to clinical trials, market authorizations, risk assessments, and potential shortages. By engaging in these partnerships, such as the International Coalition of Medicines Regulatory Authorities, and the Australia-Canada-Singapore-Switzerland Consortium, the Canadian government and healthcare industry can more readily anticipate and prepare for regulatory and safety challenges related to approved and experimental therapies and devices. Canada is also an active member in the World Health Organization's blueprint vaccine subgroup, and the Pan American Health Organization, and is thereby contributing to global efforts in the discovery and testing of COVID-19 therapies and vaccines.

Canada

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Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- **Health Canada Response Timelines**

Health Canada has notified the industry and its stakeholders that process times for non-COVID-19-related product authorizations and establishment licensing may be impacted. In order to avoid continuing delays to already regulated parties, Health Canada launched a pilot project on April 2, 2020, implementing the electronic issuance of DELs (or e-DELs) via email with electronic signatures, along with instructions for DEL applicants on their submissions for COVID-19 related authorizations. However, Health Canada advises that it will otherwise be "focused on critical services directed at facilitating a response" to COVID-19. This necessary shift in priority may temporarily defer some non-critical services, including the processing of DEL applications, and inspections.

- **Site Inspections**

Health Canada has advised that, until further notice, on-site inspections that are required to support establishment licensing, including in respect of controlled substances, are for the most part not being conducted at this time. However, on-site inspections may be conducted on a case-by-case basis, when a health risk has been identified, or when an establishment will be manufacturing a drug that is medically necessary or considered important in mitigating COVID-19 risks. Therefore, inspections that are deemed critical during the pandemic will continue. Accordingly, any application for a product or establishment licence that requires the support of an on-site inspection relating to QMS, GMP or, in the case of controlled substances, security procedures, may be delayed until such time as Health Canada's normal operations resume. In the meantime, Health Canada has been exploring the implementation of remote inspections. While Health Canada had previously extended annual licence review timelines to July 1, 2020, it now requests that all enquiries about DEL review applications be directed to them via e-mail.

- **Foreign Investment Review**

On April 18, 2020, the Ministry of Innovation, Science and Economic Development (ISED) announced that it intends to evaluate foreign investments into critical sectors in Canada with heightened scrutiny during the global pandemic (ISED Policy). The objective of the ISED Policy is to avoid opportunistic foreign investment into Canadian businesses that are related to public health or involved in the supply of critical goods and services to Canadians or to the Government and that have been adversely affected by the pandemic. Under the *Investment Canada Act* (ICA), ISED has the authority to review foreign direct investments into Canadian businesses by non-Canadian entities that, regardless of value, that could threaten national security or economic interests by potentially influencing Canada's industrial and economic activities. While the ICA already has a robust review process, the ISED Policy introduces heightened scrutiny to foreign investments of any value, which will continue until the economy recovers from the effects of the COVID-19 pandemic. Canadian critical sector businesses seeking foreign investments may expect delays during the pendency of the ISED Policy.

Canada

Last updated: 30 September 2020

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The most significant impacts of COVID-19 on the management of clinical trials has been: (i) the recruitment, assessment, and monitoring of participants given self-isolation and social distancing protocols, and (ii) the availability of healthcare providers involved in such clinical trials that have otherwise been deployed to hospitals and urgent care centers to treat patients impacted by the coronavirus.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

In response to the above challenges, Health Canada released guidance on April 3, 2020 to clinical trial sponsors on the management of clinical trials during the COVID-19 pandemic (CT Guidance). In acknowledging an expected increase in deviations from approved clinical trial protocols, Health Canada is emphasizing the importance that all clinical trial sites have a system in place to identify, document, assess, and report all protocol deviations to the sponsor and the REB. Only deviations that may place participants at risk shall be reported to Health Canada. As provided by the COVID-19 Guidance, Health Canada will be taking measures to fast-track COVID-19-related clinical trials for new vaccines, new or repurposed antivirals, and other supportive therapies.

On May 27, 2020, the Minister of Health issued an Interim Order (May 27 IO) to authorize a more flexible process for COVID-19-related clinical trials specifically: (i) allowing a wider range of health professionals, such as nurse practitioners, to run clinical trials; (ii) allowing a wider range of investigators, such as physicians (previously limited to manufacturers), to be involved in running clinical trials for medical devices; (iii) ease the requirements associated with labelling and record-keeping for clinical trials investigating the expanded or new use(s) of approved drugs to treat COVID-19; (iv) allowing multi-stream clinical trials to continue when one stream has ceased; and (v) continue to expand clinical trial protocols with remote participants, when feasible. Following the release of the May 27 IO, Health Canada, the Canadian Institutes of Health Research (CIHR), and the Canadian Association of Research Ethics Board (CAREB) also released a Joint Statement introducing a new commitment to monthly engagement sessions between policy makers, regulators, funders, and oversight bodies on clinical trial oversight and implementation in Canada.

As of the date of this update, Health Canada has approved 57 clinical trials for potential COVID-19-related therapies and vaccines.

(c) Are there any general tips and recommended solutions under the local regulatory framework?

In addition to the CT Guidance, Health Canada is reminding clinical trial sponsors that the FDR do not prohibit the shipment of clinical trial investigational products (including drug products and medical devices) from Canadian sites directly to participants. However, this approach is only appropriate for specific trial designs and investigational products, e.g., where the CT participant was enrolled in the trial prior to the commencement of the physical distancing protocol, instructed on the safe administration of the investigational product, and where the product is not required to be administered in a clinical setting. Verification that the participant received the correct investigational product is required.

Canada

Last updated: 30 September 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

On March 25, 2020, the Canadian Government introduced wide-sweeping emergency measures in response to the COVID-19 pandemic. These measures in Canada include amendments to the *Patent Act* that increase the scope and applicability of compulsory licences for patented inventions. While the *Patent Act* has always made available a semblance of a compulsory licensing regime, it was limited in its application, in that the Commissioner of Patents **may** authorize the use of a patented invention by the Canadian Government or a province. Under the amended legislation, the Commissioner no longer has discretion to grant the authorization—it **must** grant the authorization provided that the Minister of Health has confirmed the existence of a public health emergency of national concern, among other requirements. Similar to other emergency measures described above, the Commissioner is prohibited from granting authorizations to patent inventions after September 30, 2020 and any authorization granted otherwise ceases to have effect after the earlier of one year after the day on which it is granted, or the day upon which the public health emergency ends.

The amendments specifically provide that authorized use of patented inventions pursuant to this temporary regime is not an infringement of the patent and the patentee will not be able to pursue infringement proceedings. However, where a patented invention is used in a manner that is inconsistent with the authorization, a patentee is permitted to bring an application to the Federal Court for an order requiring that the authorized user cease making, constructing, using or selling the patented invention. While the patentee is entitled to receive "adequate remuneration" forthe use of their patented inventions taking account of the economic value of the authorization and the extent to which the patented invention is made, constructed, used or sold, the Commissioner has broad authority to determine the applicable amount.

The expectation is that patented inventions relating to ventilators and other PPE that would assist in the COVID-19 response may be initially targeted.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

Please see above.

Canada

Last updated: 30 September 2020

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

In Canada, telemedicine for the delivery of general care is not standardized across the country, nor federally regulated. Instead, the provinces and relevant regulatory bodies set the standards and codes of conduct for the delivery of telemedicine. To this end, such national healthcare professional bodies as the Canadian Medical Association (CMA) and the Royal College of Physicians and Surgeons of Canada (RCPSC) have outlined physician obligations with respect to video consultations and online prescribing. Prior to the COVID-19 pandemic, together with the College of Family Physicians of Canada, the CMA and RCPSC had created a national task force to identify the regulatory and administrative changes needed to support safe and comprehensive virtual care in Canada, with a view to developing a standard approach to the delivery of telemedicine across the country.

In the wake of COVID-19, and in the absence of a national framework, many provinces have now expanded their telemedicine services and are advising physicians and psychiatrists to provide virtual care whenever possible. Some provinces, such as Alberta, have gone so far as permanently adding virtual care codes to the provincial schedule of medical benefits, allowing residents to continue to access telemedicine services under the provincial insurance scheme even after the pandemic subsides. A comprehensive list of the telemedicine and virtual care guidelines in response to COVID-19, organized by province, can be accessed online.

United States

Last updated: 01 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

- FDA has taken a focused, flexible and proactive approach to address the impact that COVID-19 pandemic is having on the availability and need for drug product and medical devices, including personal protective equipment (PPE). FDA has dedicated countless regulatory personnel to support the publication of industry guidance related to COVID-19 mitigation and containment efforts and has issued immediately effective guidance instead of allowing for the normal public comment period. FDA Guidance has been issued in several key areas, including ventilators; PPE (gowns, gloves and other apparel); diagnostics test; clinical trials; filtering facepiece respirators (FFRs); drug shortages; and sterilizers, disinfectants and air purifiers.
- In March, FDA updated a policy to address diagnostic testing for COVID-19 and provide guidance to laboratories and commercial manufacturers. The goal of the policy is to help expand the number and variety of diagnostic tests and testing capabilities in health care settings and laboratories.
- The FDA is encouraging industry and those that have capabilities to produce needed medical products or to participate in the supply chain to offer assistance where appropriate. The focus has been on increasing supply of much needed medical products by reviewing emergency use authorization requests, supporting clinical trial efforts and maintaining open engagement opportunities with industry.
- On 31 March, the FDA announced the creation of a new program, known as the Coronavirus Treatment Acceleration Program (CTAP), to aid in expediting the development of potentially safe and effective life-saving treatments, a delicate balancing of the need to bring therapies to sick patients as quickly as possible while supporting needed research to evaluate the safety and efficacy of medical countermeasures. CTAP continues the FDA's dedication to provide assistance to companies, researchers, academia, scientists, and others who are all working non-stop to find and determine how to move forward medical countermeasures against COVID-19.
- Enforcement priorities have been adjusted to meet the current healthcare needs. Specifically, the FDA has issued guidance explaining that the Agency will exercise enforcement discretion and does not intend to object to the distribution and use of alternative face masks that are not FDA-cleared, so long as the distribution and use is consistent with the policy set forth in the FDA's March guidance entitled Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. FFRs intended to be used in a healthcare setting must meet the requirements in the guidance.
- The FDA has heightened its awareness of potential issues and disruptions to the supply chain that may be caused by COVID-19. FDA has increased its communication with drug and medical device manufactures to stress the importance of notifying FDA of potential shortages or interruptions in the supply chain. FDA promulgates regulations and monitors drug shortages that may occur due to manufacturing and quality problems, delays, and discontinuations. Manufacturers are required to report the reasons for and expected duration of drug shortages to the FDA so the agency can work with them to prevent or reduce the impact of shortages. Notification to the FDA of medical device shortages is voluntary.

  The spread of COVID-19 has resulted in import and export difficulties and delays of inspections of facilities, leading to shortages of the active pharmaceutical ingredients (APIs) used in certain drugs. China accounts for 14 percent of APIs contained in common drugs and starting chemicals used to produce those drugs elsewhere -- the third highest proportion after India and the European Union. FDA has reported that since January, it has been in contact with more than 180 manufacturers in an attempt to anticipate supply chain disruptions, especially where components of the drugs are manufactured in China. FDA has asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in any area of the supply chain due to the COVID-19 outbreak. As part of these efforts, FDA identified about 20 other drugs for which the finished drug or API in the drug is solely sourced from China. However, those drugs were identified as "non-critical" and as of late February, the manufacturers had not reported any shortage.

United States

Last updated: 01 April 2020

Market Access

(a) How has the regulator in charge been addressing the urgent need for medicines, medical devices and medical supplies? Has the focus been on a faster review and the granting of marketing authorizations, the exception to or relaxation of import/use/licensing restrictions, or any other available mechanisms?

On 27 February 2020, the FDA issued a COVID-19 Supply Chain Update reporting that a manufacturer alerted the FDA to a shortage of an undisclosed drug related to a site affected by coronavirus, resulting from an issue with manufacturing of an API used in the drug. FDA stated that other alternatives can be used by patients and FDA is working with manufacturers to mitigate any shortages The FDA's drug shortage database lists nearly ten new shortages and discontinuations since March 24, 2020, but the majority appear to be manufacturer discontinuations. Over two dozen other drug shortages are listed as "updated" but many if not all appear to have originated prior to the COVID-19 outbreak and therefore may be unrelated. Nevertheless, the continued spread and ramifications of COVID-19 in the coming months could have greater production impacts and lead to more frequent or significant drug shortages.

The FDA's drug shortage database lists nearly ten new shortages and discontinuations since 24 March 2020, but the majority appear to be manufacturer discontinuations. Over two dozen other drug shortages are listed as "updated" but many if not all appear to have originated prior to the COVID-19 outbreak and therefore may be unrelated. Nevertheless, the continued spread and ramifications of COVID-19 in the coming months could have greater production impacts and lead to more frequent or significant drug shortages.

(b) What opportunities and challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- **New Mechanisms (Yes)** - The key mechanism that the FDA is employing to facilitate the urgent need for medical products is the Emergency Use Authorization (EUA). EUAs allow the use of unapproved drugs and other medical products, or unapproved uses of those products, in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. EUAs expire at the end of the emergency that precipitated the declaration. On 4 February 2020, the Secretary of The Department of Health and Human Services authorized the consideration of EUAs for emergency use of diagnostics for detection and diagnosis of COVID-19.
- **Faster Review (Yes)** - FDA is reviewing and granting EUAs in as little as 24 hours of receiving applications. And, on 9 March 2020, HHS also announced that it was providing USD 669 thousand in funding to accelerate the development of a molecular diagnostic test that could process up to 1,000 tests in 24 hours, with test results available to clinicians in less than three hours. The FDA has worked with more than 220 test developers that are interested in submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. With more than 20 EUAs issued to date, FDA has shown a concerted effort to embrace speed and efficiency without sacrificing scientific rigor. While the FDA is expending great effort and commitment in working through this pandemic, frustration and concern exist on the shortage of PPEs, FFRs and ventilators. Manufacturers and suppliers must adhere to the EUA process, which allows the FDA to work diligently to balance the current risk environment and safety and effectiveness concerns for usage of such medical products.
- **Import climate (No)** - We have not seen a relaxed import climate, as there is concern regarding the importation of counterfeit COVID-19 test kits and potentially other COVID-19 related medical product. The FDA is communicating with importers and the general trade community to facilitate the entry of authentic medical products, including FFRs. The FDA has also increased surveillance for not only counterfeit test kits but also companies who are selling products that purport to prevent, treat or cure COVID-19.

United States

Last updated: 01 April 2020

Market Access

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges has the COVID-19 outbreak brought for market access in terms of regulatory approval?

- We anticipate forthcoming delays in product approval as an outgrowth of limitations on the FDA's ability to conduct inspections of domestic and foreign facilities, and the reprioritization of the review of certain marketing applications based on the global healthcare needs related to efforts to explore treatment and diagnosis of COVID-19.
- Some applications may avoid impact because the therapeutic area is not one that would share resources with those staffed to COVID-19 efforts. Notably, the longer the pandemic continues to proliferate the greater the impact on market access and regulatory approvals. The lack of resources and market demand for products outside of COVID-19 and other serious life threatening diseases will compel industry players to reconsider their product pipeline strategy.

Clinical Trials

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

- Many clinical trials have been disrupted as a result of the COVID-19 pandemic. The disruption and delay to trials is not quantifiable at this time; however, many trials in the recruitment phase have stopped recruiting patients. We anticipate clinical trial sponsors may have to confront challenges including patient's access to investigational product, access to clinical trial sites and availability of investigators to provide clinical trial oversight and conduct. Regulators recognize the anticipated impact the COVID-19 pandemic will likely have on clinical trials and has issued an industry guidance document referenced below.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

- FDA has issued a guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice ("GCP), and minimizing risks to trial integrity during the COVID-19 pandemic.

(c) Any general tips and recommended solutions under the local regulatory framework?

- Sponsors must consider the impact of the COVID-19 pandemic on the study participants and the sponsor's ability to comply with good clinical practice (GCP) requirements, including record-keeping; adherence to the protocol; and data integrity. To date, regulators have not limited a sponsor's ability to continue clinical trial studies. Nonetheless, sponsors should be cautious to commence new studies and should engage the FDA regarding any current studies that may be impacted by the COVID-19 pandemic.

United States

Last updated: 01 April 2020

IP Risks

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

- The U.S. Government often retains "march-in rights" under 35 U.S. Code § 203 to require that federally funded inventions are made available for public use. If a required medicine, device or biocide is not adequately supplied to the public, the Government can require the patent owner to grant third party licenses under reasonable terms. If the patent owner declines to offer such licenses, then the Government retains the right to grant the licenses itself. The ongoing emergency and short supply of critical equipment and materials could present the extraordinary conditions justifying the Government's employment of march-in rights to increase production and supply to affected areas.
- In addition, the U.S. Government could potentially use or have manufactured products covered by patents privately owned without Government funding. Under 28 U.S. Code § 1498, the remedy available to a private party for such Government use or manufacture is the recovery of reasonable and entire compensation by the patent owner. Notably, injunctive relief is not available for such Government use or manufacture.
- More generally, the accelerated decision making, close cooperation among producers and suppliers and work-at-home environment increases the risk that important IP rights could be lost. Companies may be inclined to relax IP management rules or allow for workarounds from the usual security measures. Such exigent conditions increase the risk of premature publication or disclosure as employees adopt short cuts in sending, downloading and discussing confidential information. Compounding these risks are unknowns such as whether your employees' home networks have security adequate to prevent intrusion, misappropriation and/or destruction.

(b) Are there any issued or discussions on the likely issuance in response to the COVID-19 outbreak in your jurisdiction?

None to date.

Telemedicine

(a) How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there any interim measures or anticipated legislative changes?

- With much of the United States under Stay at Home orders and/or with the need to practice social distancing, the use of telemedicine services has expanded greatly. This trend will likely continue as part of further attempts to slow the spread of the virus and protect patients and healthcare workers where possible. As such, to promote the use of telemedicine or telehealth, the Office of Civil Rights of the Department of Health and Human Services, the agency charged with enforcing the US Health Insurance Portability and Accountability Act (HIPAA) has announced certain changes in terms of approach to enforcement.
- At a high level, the guidance allows covered health care providers (covered entities) subject to the HIPAA Privacy and Security Rules to communicate with patients and provide telehealth services through remote communications technologies, even if some of these technologies (and the manner in which they are used) may not be fully compliant with HIPAA requirements, which generally mandates that covered entities must execute business associate agreements (BAAs) with service providers/business associates that have access to Protected Health Information or PHI. It is important to note that organizations will still need to comply with other obligations under HIPAA, including those regarding patient confidentiality and breach notification, and also will need to bring their telemedicine practices into full compliance with HIPAA for longer term use.

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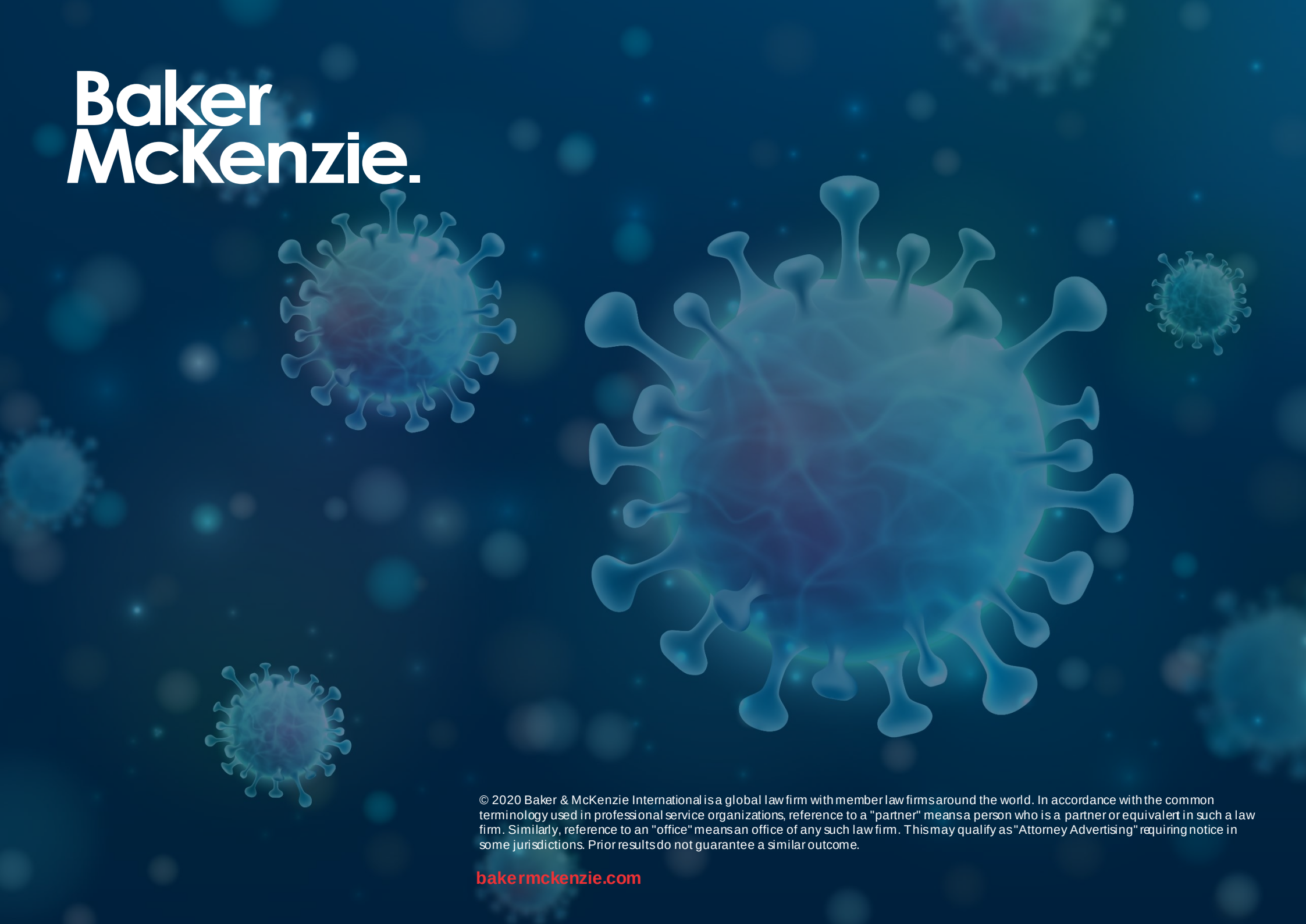

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