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COVID-19
EMEA Life Sciences Survey

What measures have EMEA governments taken in the life sciences sector to fight COVID-19?

16 November 2020

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INTRODUCTION

What measures have EMEA governments taken in the life sciences sector to fight COVID-19?

As COVID-19 rapidly spreads to every corner of the globe and is officially declared a pandemic, governments across the world are adopting emergency measures to fight against this extraordinary situation. Ultimately, all these measures are aimed at protecting the health and wellbeing of citizens. However, on the healthcare and life sciences front in particular, such measures range from intervention powers to guarantee adequate supplies of treatment and medical equipment, to the relaxation of deadlines and regulatory requirements to simplify administrative procedures wherever possible, so that competent authorities, manufacturers and other actors can focus on urgent priorities related to the COVID-19 crisis.

The Baker McKenzie Healthcare and Life Sciences Industry Group is pleased to provide you with an overview of the measures that governments across the EMEA region, which includes some of the worst hit countries, have adopted in the area of healthcare and life sciences in response to the COVID-19 outbreak.

In this guide, Baker McKenzie lawyers across EMEA share their high-level views on the following areas:

Requisition powers
- Has the Government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals / medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products / medical devices?

Price and reimbursement
- Has the price and reimbursement procedures for medicinal products and medical devices been affected?

Public procurement
- Has the Government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for Covid-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

Legal deadlines
- Have legal/ administrative deadlines been suspended / relaxed?
- Have these measures had an impact on MA approvals, public procurement, etc.?

Relaxation of regulatory rules
- Has the Government relaxed regulatory rules?
- Have special measures been adopted?
- What are the main changes?

This guide offers only a high-level view and does not constitute legal advice. The COVID-19 outbreak is an escalating situation, authorities are issuing advice on a daily basis and it is crucial to assess these measures on a case-by-case basis.

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Quick Glance Overview

	Belgium	Czech Rep	France	Germany	Hungary	Italy	Kazakhstan	Netherlands	Poland	Russia	South Africa	Spain	Sweden	Switzerland	Turkey	UK	Ukraine	Uzbekistan
Specific COVID-19 legislation enacted?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Has the government established any powers to requisition assets and premises?	✗	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✗	✓	✗	✗	✗	✗
Are you seeing hotels being converted into hospitals/medical centers for quarantine and self-isolation?	✗	✗	✓	✓	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗	✓
Is it controlling the distribution of medicinal products/medical devices?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Has the price and reimbursement procedures for medicinal products and medical devices been affected?	✗	✗	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓
Has the government adopted exceptional public procurement measures?	✗	✗	✓	✓	✓	✗	✓	✗	✗	✗	✓	✓	✗	✗	✗	✓	✓	✓
Have procedural requirements been relaxed for COVID-19 related medicines and devices?	✓	✗	✗	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗	✗	✗	✓	✓	✓
Have legal/administrative deadlines been suspended/relaxed?	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Have these measures had an impact on MA approvals, public procurement, etc.?	✗	✓	✓	✓	✓	✓	✗	✗	✗	✓	✗	✓	✗	✗	✓	✓	✓	✓
Has the government relaxed regulatory rules?	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Have special measures for clinical trials been adopted?	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

European Union

At the EU level, the Commission is making an effort to coordinate a common European response to the outbreak. This is not proving an easy task due to the dramatic times in which Member States are living; actions are being taken unilaterally at a national level.

The following measures are worth highlighting:

Guidance on the optimal and rational supply of medicines to avoid shortages

On 8 April 2020, the Commission published guidance aimed at ensuring the continued supply of medicines necessary for the treatment of COVID-19 and an equitable distribution of such medicines for patients in Europe. This guidance is addressed to EU Member States and EEA countries.

In the spirit of European solidarity, Member States are called to lift export bans which are impeding the trade of medicines within the internal market and to refrain from requisition of medicines, intermediates or active pharmaceutical ingredients even when these measures are legally justifiable.

Member States are also called to ensure that companies increase production where needed and work at full capacity.

The guideline foresees significant **relaxation of regulatory measures**. In particular, Member States shall streamline and accelerate variation procedures concerning change of API suppliers, designation of new manufacturing sites or extension of expiry dates. The guideline does not address products approved through the EU centralized procedure. The argument could, however, be made that similar flexibility should be demonstrated for those products.

According to the guideline, Member States should be able to reallocate stock between hospitals, hospital protocols should be shared EU-wide and the following measures should be adopted in case of confirmed shortages:

- Extension of expiry dates where possible
- Use of magistral formulas and veterinary medicines
- Use medicines off label and in clinical trials

The need for coordination extends to pharmacy level, where Member States are called to prevent excessive purchasing and to introduce restrictions on sales.

EU export controls

The Commission has introduced temporary authorization requirements on exports of certain medical/protective equipment to destinations outside the EU. See Commission Implementing Regulation (EU) No 2020/568, which replaces Commission Implementing Regulation (EU) 2020/402, as amended by Commission Implementing Regulation (EU) 2020/426).

The overall aim of these measures is to ensure adequate supply of medical and protective equipment across the Union. Regulation (EU) No 2020/568 amends the list of products that require export authorization outside of the customs territory of the EU to masks, spectacles and protective garments and extends the geographical exception, including to the Western Balkans.

Further information on EU export controls can be found in our blog-post here.

Public procurement

On 31 March 2020, the Commission published guidance aimed at simplifying public procurements while still upholding high safety and quality standards. The guidance offers an overview of the options and flexibilities available for the purchase of supplies, services and works needed to address the crisis.

Further to the guidance, in cases of urgency public buyers can reduce the deadlines to accelerate open or restricted procedures. If the shortened deadlines are not sufficient, public buyers may opt for a negotiated procedure without prior publication. The guideline also encourages public buyers to find alternative ways of engaging with the market to supply much-needed medical products.

The magnitude of the outbreak has also led the Commission to enter into **Joint Procurement Agreements (JPA)** with Member States (and the United Kingdom and Norway) to enable the joint purchase of medical equipment and supplies. To date, the Commission has launched four different calls for tender with participation of up to 25 Member States. Further details on these JPAs can be found here.

European Union

Legal deadlines

On 25 March 2020 the Commission announced its intention to postpone for one year the application date of the Medical Devices Regulation (**MDR**), which was due to become applicable on 26 May 2020. The aim is to take pressure off national authorities, notified bodies, manufacturers and other actors so they can focus fully on urgent priorities related to the COVID-19 crisis. The legislative procedure to amend the MDR was launched on 3 April and can be found here.

Relaxation of Regulatory Rules

The Commission has made calls for relaxation of measures in relation to the authorization of medicines (see the guidance on the optimal supply of medicines to avoid shortages described above).

In addition, on 10 April 2020, the Commission, Heads of Medicines Agencies (**HMA**) and the European Medicines Agency (**EMA**) adopted a question-and-answer (Q&A) document to provide guidance to stakeholders on adaptations to the regulatory framework to address challenges arising from COVID-19.

This guidance document covers national and centralized authorization procedures. The document focuses on marketing authorizations, manufacturing and importation, quality variations and product information. It reminds of the existing tools foreseen in the legislation that allow for certain flexibility (e.g., compassionate use, sunset clause exemptions) and contemplates the possibility for companies to request postponement of renewal deadlines, speedier variations for COVID-19 medicines and lighter product information requirements. In the context of manufacturing and importation, the guidance foresees specific processes for COVID-19 related medicines (Exceptional Change Management Process, ECMP).

In relation to medical products, the following should be noted:

On 20 March 2020, the European Commission and Standardization Organization agreed that all the relevant European harmonized standards will exceptionally be made freely available for all interested companies. This was followed by the adoption of revised harmonized standards on 24 March 2020 in relation to critical devices such as medical facemasks, surgical drapes, gowns and suits, washer-disinfectors or sterilization.

On 30 March, the Commission issued a Question and Answers document to help increase the production of medical devices by providing guidance on the following three fronts:

- Legal and technical standards for PPE manufacturing and reconverting existing facilities
- Helping economic operators, including SMEs, on the legal framework for the placing on the EU market of hydro-alcoholic gel
- Clarifying conformity assessment procedures for 3D printing and 3D printed products for medical use in the context of the outbreak

These measures complement Commission Recommendation 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. The Recommendation recognizes the importance to ensure that appropriate protective equipment and medical devices are swiftly made available to those who need it most, and that the efforts of manufacturers and distributors lead to increased supply without delay. The Recommendation therefore proposes:

- Opening the EU market to protective equipment manufactured in accordance with WHO recommendations rather than in strict adherence to EU harmonized standards, provided that they give a level of protection corresponding to EU requirements
- For medical devices, that Member States use their discretion to authorize derogations from EU conformity assessment procedures, as is currently permitted by EU law in exceptional circumstances
- That for a limited period of time, market surveillance authorities allow the circulation of protective equipment or medical devices for which conformity assessment procedures, including the affixing of CE marks, have not been fully finalised, provided that the products are otherwise safe in accordance with EU law
- That Member States take appropriate measures to ensure that protective equipment or medical devices not bearing the CE mark are only made available to healthcare workers

Clinical trials

On 9 March 2020, EMA urged the EU research community to prioritize large randomized controlled clinical studies as these are most likely to generate the conclusive evidence needed to enable rapid development and approval of potential COVID-19 treatments.

On 20 March 2020, the European Commission, EMA and the national Heads of Medicines Agencies published guidance on how to manage the conduct of clinical trials in the context of COVID-19. The guidance serves as an EU-level harmonized set of recommendations but warns that sponsors and investigators must also take into account specific national legislation and guidance, which may complement or take priority over the recommendations in the EU guidance.

The guidance provides information on changes and protocol deviations in ongoing trials that may be needed and includes a harmonized set of recommendations to ensure the safety of trial participants and the quality of the data generated by the trials. There is also specific advice on the initiation of new clinical trials for treatments of COVID-19, and in particular on the need for large, multinational trial protocols. The guidance was amended on 27 March 2020 to cover safety reporting, the distribution of in-vitro diagnostics, medical devices and auditing. Changes were also introduced to sections on the communication with authorities, informed consent and the distribution of investigational medicines.

On 1 April 2020, EMA issued a guidance notice against non-COVID-19 related off-label use of chloroquine and hydroxychloroquine medicines. EMA advised patients and healthcare professionals to only use chloroquine and hydroxychloroquine medicines for their authorized indications or as part of clinical trials or national emergency use programs for the treatment of COVID-19.

On 3 April 2020, EMA provided recommendations on compassionate use of remdesivir for COVID-19

Belgium

Matters	Summary
Specific COVID-19 legislation	**Legislation**: ▪ Royal Decree of 24 March 2020 on special measures to address shortages of medicines in the framework of the SARS-CoV-2 pandemic ▪ term: as from 25 March 2020 until 31 March 2021 ▪ Decision of the Chief Executive Officer of the FAMHP, dated 1 April 2020, on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic ▪ Term: as from 1 April 2020 until 1 May 2020 (which can be renewed for one month) ▪ Renewals: ▪ Decision of the Chief Executive Officer of the FAMHP, dated 27 April 2020, on the extension of various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic: as from 2 May 2020 until 1 June 2020 ▪ Decision of the Chief Executive Officer of the FAMHP, dated 29 May 2020, on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic: as from 2 June 2020 until 1 July 2020 ▪ Decision of the Chief Executive Officer of the FAMHP, dated 26 June 2020, on the extension of various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic: as from 2 July 2020 until 28 July 2020 ▪ Decision of the Chief Executive Officer of the FAMHP, dated on 27 July 2020, on the extension of various urgent measures regarding specific medicines in the context of the SARS-CoV-2 pandemic: as from 29 July 2020 until 28 August 2020 ▪ Decision of the Chief Executive Officer of the FAMHP, dated on 27 August 2020, on the extension of various urgent measures regarding specific medicines in the context of the SARS-CoV-2 pandemic: as from 29 August 2020 until 28 September 2020 ▪ Decision of the Chief Executive Officer of the FAMHP, dated on 25 September 2020, on the extension of various urgent measures regarding specific medicines in the context of the SARS-CoV-2 pandemic: as from 29 September 2020 until 28 October 2020 ▪ Amendments: ▪ Decision of the Chief Executive Officer of the FAMHP, dated 8 April 2020, amending the various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic ▪ Decision of the Chief Executive Officer of the FAMHP, dated 29 May 2020, on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic ▪ Decision of the Chief Executive Officer of the FAMHP, dated 23 June 2020, amending the various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic

Belgium

Matters	Summary
Specific COVID-19 legislation	**Legislation**: ▪ 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 ▪ Term: as from 1 March 2020 and the measures apply until further notice ▪ Implementing orders: ▪ Royal Decree of 20 July 2020 implementing Articles 47, § 1 and 51, § 5 of Royal Decree n° 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 (concerning the compensation for triage centres) **Guidance documents:** ▪ Clinical Trials ▪ Addendum to the Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic ▪ v1 - 25 March 2020: https://www.fagg.be/sites/default/files/content/guidance_on_the_management_of_clinical_trials_during_the_covid-19_coronavirus_pandemic.pdf ▪ v2 - 29 April 2020: https://www.fagg.be/sites/default/files/content/national_guidance_corona_20200429c_clean.pdf ▪ Guidance on the Management of Clinical Investigations during the COVID-19 (Coronavirus) pandemic ▪ v1 - 30 April 2020: https://www.fagg.be/sites/default/files/content/guidance_during_covid19_pandemic_for_ci.pdf ▪ Circular on the shorter time periods to process applications for clinical trials COVID-19 ▪ 8 July 2020: https://www.fagg.be/sites/default/files/content/omzendbrief.pdf ▪ Face masks ▪ Conditions for the supply and release of surgical masks ▪ v1 - 28 March 2020: https://www.fagg.be/sites/default/files/content/info_aanbieden_chirurgische_maskers_2.pdf ▪ v2 - 12 May 2020: https://www.afmps.be/sites/default/files/content/20200509_afmps_conformite_masques_chirurgicaux.pdf ▪ v3 - 25 May 2020: https://www.famhp.be/sites/default/files/content/20200525_en_info_aanbieden_chirurgische_maskers_clean_0.pdf ▪ Information on the Alternative Test Protocol (ATP) for surgical face masks ▪ v1 - 14 April 2020: https://www.fagg.be/sites/default/files/content/informatie_over_het_alternativetest_protocol_atp_def.pdf ▪ v2 - 28 April 2020: https://www.fagg.be/sites/default/files/content/atp_chirurgische_maskers_20200428_def.pdf ▪ v3 - 4 June 2020: https://www.fagg.be/sites/default/files/content/alternatief_test_protocol_atp_mondmaskers_v3.pdf ▪ v4 - 30 June 2020: https://www.fagg.be/sites/default/files/content/alternatief_test_protocol_atp_mondmaskers_v4_def.pdf

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Matters	Summary
Specific COVID-19 legislation	▪ Guidance for the reprocessing of surgical masks and filtering facepiece respirators (FFP2, FFP3) during the Coronavirus disease (COVID-19) Public Health Emergency ▪ v1 - 6 April 2020: https://www.fagg.be/sites/default/files/content/national_guidance_mask_reprocessing_finalversion1_0_0.pdf ▪ v2 - 5 May 2020: https://www.fagg.be/sites/default/files/content/famhp_national_guidance_mask_reprocessing_v1.1_05052020.pdf ▪ Conditions that deliveries of FFP2 and FFP3 face masks must fulfill in order to be released ▪ Version 202003403: https://economie.fgov.be/sites/default/files/Files/Entreprises/Conditions-deliveries-FFP2-FFP3.pdf ▪ Use of the ATP to test FFP2/FFP3-masks ▪ https://economie.fgov.be/nl/themas/ondernemingen/coronavirus/mondmaskers-en-filters/conformiteit-voor-mondmaskers/coronavirus-niet-conforme ▪ Medical devices ▪ FAMHP Circular - The manufacture, outsourcing and reprocessing of medical devices and their accessories within care facilities to tackle shortages in the fight against the SARS-CoV-2 pandemic ▪ v1 - 9 April 2020: https://www.fagg.be/sites/default/files/content/afmps_circulaire-omzendbrief_fabricage_fabrication_meddev.pdf ▪ Guidelines for in-house fabrication of respiratory devices accessories using 3D printing ▪ v1 - 6 April 2020: https://www.fagg.be/sites/default/files/content/guidance_afmps_3d_printing.docx ▪ Good practices when changing consumables used with COVID-19 patient ventilators ▪ v1 - 29 April 2020: https://www.afmps.be/sites/default/files/content/afmps_guidance_consommables_ventilateur_covid-19.pdf ▪ Guidance on how COVID-19 tests should be made available in Belgium ▪ v1 - 30 April 2020: https://www.famhp.be/en/news/coronavirus_how_should_tests_be_made_available_in_belgium ▪ Recommendations for replacing closed suction systems ▪ v1 - 5 May 2020: https://www.afmps.be/sites/default/files/content/afmps_guidance_close_aspiration_system_v1_200520220.pdf

Belgium

Matters	Summary
Specific COVID-19 legislation	▪ Public procurement ▪ Wallonia: Circular on the consequences of measures related to Covid-19 on Walloon public contracts – Recommendations for Walloon contracting authorities (26 March 2020, https://marchespublics.wallonie.be/files/Circulaire%20du%2023.03.2020%20publi%c3%a9e%20au%20MB%20le%2026.03.20.pdf) ▪ Flandres: Circular KB 2020/01 on the impact of the corona measures on public procurement (10 April 2020: https://overheid.vlaanderen.be/sites/default/files/media/Overheidsopdrachten%20en%20raamcontracten/VR%202020%201004%20MED.0132-2%20OZB%20corona%20en%20overheidsopdrachten%20-%20bijlage.pdf?timestamp=1586880864) **Procedures:** Application procedure for manufacturers seeking a recommendation of antibody or antigen tests during the COVID-19 outbreak in Belgium (2 October 2020: https://www.fagg-afmps.be/sites/default/files/content/new_application_procedure.pdf)

Belgium

Matters	Summary
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	I. Since 25 March 2020, 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;

Belgium

Matters	Summary
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	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. 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.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	It is important to note that health care providers are not allowed to pass on costs related to personal protective equipment -such as gloves, face masks etc.- to their patients. The government will provide for financial assistance to help health care providers to cover these COVID-19-related costs.

Belgium

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The existing public procurement rules must be respected, also with regard to medicine and devices. However, the existing rules provide the possibility to use the negotiation procedure without prior publication in the event of unforeseeable urgency (Law of 17 June 2016 on Public Procurement, art. 42, §1, 1°, b). In this way, the public authority can award the contract in a flexible and fast manner. In the context of the current crisis, it is conceivable that this procedure could apply, for example, in case of urgent purchase of material or in case of need for quarantine measures in case of risk of contamination. The federal government has stated in a communication that it will adopt a flexible attitude with regard to (federal) public procurement. If the delay or non-performance is due to COVID-19, the federal authority will not impose any fines or penalties. Wallonia and Flandres have affirmed in their circular letters that no penalties will apply to infringements for which it can be demonstrated that the shortcomings are due to the Covid-19 measures. If fines for delays have been withheld or penalties have been imposed, the contractor can still obtain a full or partial refund of these fines and penalties if the delay is due to unforeseeable circumstances or if there is a disproportion between the fine or penalty and the extent of the delay or defective performance (Royal Decree of 14 January 2013 laying down the general rules for the implementation of public contracts, art. 50-51).
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	All deadlines foreseen in the law of 14 July 1994 on compulsory insurance for medical care and benefits are suspended, except for time limits relating to benefits and maternity insurance and control services (see Royal Decree nr. 20). This law foresees, among others, the applicable time limits to amend the list of reimbursable benefits. These time limits have been suspended since 13 March 2020 and the end date of the suspension still needs to be determined. Other deadlines are not suspended or relaxed as a general rule. The authorities will rather take the individual elements and context of each case into account before they allow any suspension or relaxation of deadlines.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	**Medical devices in general** ▪ 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.

Belgium

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- 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.

Face masks

I. 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 ATP only 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 via the 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.

II. 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.

Belgium

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- 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.

Serology tests

In April 2020, the FAMHP and scientific institute Sciensano established a specific validation procedure for SARS-CoV-2 serological tests to guarantee their reliability. This procedure proved effective during the initial phase of the pandemic. Now, the situation at the manufacturers and distributors of these tests and at the clinical laboratories carrying out these tests has been normalised whereby a gradual return to the classic procedures used for in-vitro diagnostics is being made. To ensure the gradual return to the classic procedures, the FAMHP has provided a new intermediate procedure which is based on the verification of performance data (https://www.fagg-afmps.be/sites/default/files/content/new_application_procedure.pdf).

Clinical trials

- Have special measures been adopted?
- What are the main changes?

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 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 is also allowed to send the shipment from the distributor to the patient provided that all the conditions prescribed in the European and the national guidance are respected. The distributor (not the courier service) is not allowed to work with the details of the clinical trial's participant. He can only work with the 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.

Belgium

Clinical trials

- Have special measures been adopted?
- What are the main changes?

Only trial medication which 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 to be 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 working days**. This commitment is laid down in a circular of the FAHMP (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.

II. 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.

Belgium

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	▪ 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 prevention of COVID-19 infection or a COVID-19 related illness.

Czech Republic

Matters	Summary
Specific COVID-19 legislation	In the Czech Republic, the State of Emergency ended as of 17 May 2020, but was reintroduced as of 5 October 2020. Various preventive and protective measures of the Government and of the Ministry of Health are currently in force, including measures: ▪ introducing the partial lock-down (i.e. significant limitation of free movement and public gatherings, including night curfew, substantial limitations in the area of sport and cultural events, as well as the closure of shops, with the exception of groceries, drugstores, pharmacies, petrol stations, post offices, banks and several other minor exceptions) ▪ restricting the crossing of state borders (e.g. by requiring coronavirus testing in case of travelling from certain higher-risk countries) ▪ introducing specific rules in healthcare sector ▪ closing schools ▪ obligating persons to wear face masks in public areas (e.g. in public transport, inside publicly accessible buildings) ▪ providing economic support to entrepreneurs damaged by the first State of Emergency and related measures and postponing tax payments From May to July 2020, a gradual relaxation of the coronavirus-related restrictions was ongoing. However, due to the worsening of the pandemic situation since the second half of July 2020, some measures have been readopted (currently including the partial lock-down). Since the declaration of the second State of Emergency, many further restrictions have been implemented, e.g. closure of schools and restrictions in the area of cultural events.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	During the State of Emergency, the Government has specific powers to limit certain rights of natural and legal persons, including requisition powers. Recently, the Czech Army has finished the construction of a field hospital on the premises of exhibition grounds in Prague - Letnany; this is however subject to a lease agreement between the state and the operator of the exhibition grounds. Another field hospital is under construction in Brno, subject to a symbolic lease agreement. No requisition powers have been exercised with respect to the above field hospitals. In addition, various types of medical facilities have been ordered to adjust their activities to ensure enough capacity for the treatment of COVID-19 patients. 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, while HCPs from certain specialist areas (such as dermatovenerology, infections, rheumatology, etc.) may only prescribe the medicinal product in strictly enumerated cases and in stipulated quantities.

Czech Republic

Matters	Summary
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	For the regulation of prices of FFP3 respirators, please see above. In addition, the Ministry of Health has stipulated the maximum overall price for PCR tests to CZK 1,756 (approx. EUR 65) for payers and administrative offices.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	No specific rules regarding public procurement have been adopted so far.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	In general, no relaxation of legal / administrative deadlines is currently in place. However, the State Institute for Drug Control declared that applications for new clinical trials regarding COVID-19 would be assessed in reduced time limits.

Czech Republic

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	In connection with the State of Emergency, the Czech State Institute for Drug Control (SIDC) decided to refrain from imposing sanctions on the use of medical devices without a valid Safety-Technical Control (STC) (i.e. it allowed such use), under the following conditions: ▪ no more than 6 months have lapsed from the end of validity of the previous STC or from the end of respective time period set out by the manufacturer, if shorter; ▪ STC is not necessary for further safe use of the medical device (e.g. calibration, exchange of a critical component, software update, etc.); ▪ the manufacturer (including through a servicing organization) did not prohibit the use of the medical device without a valid STC; ▪ records are kept of the use of such medical devices. 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.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	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 assess whether the trial subjects (patients) are positive to COVID-19 or could have been exposed thereto, to properly assess 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.

Czech Republic

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	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.

France

Matters	Summary
Specific COVID-19 legislation (as modified)	▪ Decree No 2020-73 dated 31 January 2020 (as modified) ▪ Order of 13 March 2020 authorizing, by way of derogation, the temporary placement on the market and use of certain hydro alcoholic products used as disinfectant biocides for human hygiene (as modified) ▪ Law No. 2020-290 of 23 March 2020 as an emergency response to COVID-19 (as modified) ▪ Ordinance No. 2020-319 of 25 March 2020 on various measures to adapt the rules for public procurements (as modified) ▪ Ordinance No 2020-306 of 25 March 2020 relating to the extension of time limits during the period of health emergency and the adaptation of procedures during this same period (as modified) ▪ Ordinance No 2020-460 of 22 April 2020 on various measures adopted to deal with the COVID-19 (as modified) ▪ Inter-ministerial Instruction of 9 June 2020 relating to the implementation of the European Commission Recommendation (EU) 2020/403 of 13 March 2020 ▪ Exceptional measures applicable to clinical trials during COVID-19 (ANSM website) ▪ Order 10 July 2020 prescribing the general measures necessary to deal with the COVID-19 epidemic in territories that have emerged from the state of health emergency and in those where it has been extended. ▪ Decree No. 2020-860 of 10 July 2020 prescribing the general measures necessary to deal with the COVID-19 epidemic in territories that have emerged from the state of health emergency and in those where it has been extended. ▪ Decree No. 2020-858 of 10 July 2020 relating to the selling of hydro-alcoholic products and single-use surgical masks.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	**Has the government established any powers to requisition assets and premises?** **Yes.** Following the publication of the law dated 23 March 2020, the French government is authorized to take measures that, in principle, fall within the scope of the law. Article 2 of Law No. 2020-290 of 23 March 2020, declaring a state of health emergency to manage the current COVID-19 health crisis, includes a new Article L. 3131-15 in the French Public Health Code allowing the government, for the sole purpose of guaranteeing public health, to take some emergency measures, including: ▪ order measures to quarantine persons likely to be affected ▪ order measures for the placement and maintenance in isolation at their home, or at any other suitable accommodation, of persons affected ▪ order the requisition of all goods and services necessary for the fight against the health crisis, as well as any person necessary for the operation of these services or the use of these goods ▪ take temporary measures to control the prices of certain products made necessary to prevent or correct the tensions observed on the market for certain products ▪ take all measures to make available appropriate medicines to patients for the eradication of the health crisis

France

Requisition powers

- Has the government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products/medical devices?

Article 48 of Decree No 2020-860 of 10 July 2020 authorizes the State to order the requisition of:

- any healthcare or medico-social establishment and any goods, services or persons necessary for the operation of such establishments, including healthcare professionals
- any goods, services or persons necessary for the functioning of the regional health agencies, the French National Agency for Medicines and Health Products (ANSM) and the National Public Health Agency
- medical biology laboratories and/or the equipment and staff necessary for carrying out additional SARS-CoV-2 test
- some establishments to meet accommodation or storage needs resulting from the health crisis (with the exception of restaurants and drinking establishments for example)

Article 13 of the Order of 10 July 2020 allows the directors of the regional health agencies to authorize, under certain conditions, healthcare establishments to carry out a care activity other than that for which they have been authorized.

Two orders, dated 13 March 2020 and 10 July 2020, temporarily authorize pharmacists, pharmaceutical companies, cosmetic products companies, biocide product companies and classified installations for the protection of the environment to produce and market biocidal products (hydroalcoholic solutions).

Is the government converting hotels into hospitals / medical centers for quarantine and self-isolation?

Yes. The French Prime Minister mentioned a few weeks ago the possibility to use hotels for isolating COVID-19 patients. At this stage, we are not aware of any official measures in this respect.

Is the government controlling the distribution of medicinal products / medical devices?

Yes. The government has taken several measures to control the distribution of medicinal products, medical devices and biocides in the context of COVID-19:

- Maximum prices for the sale of hydroalcoholic gels and of some surgical masks that qualify as medical devices are imposed on companies and pharmacies.
- The 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 COVID-19 whose clinical condition justifies it upon presentation of a medical prescription bearing the wording "Prescription Outside MA in the context of COVID-19."
- The dispensation of paracetamol in injectable form is authorized by hospital pharmacies (PUI) upon presentation of a medical prescription bearing the wording "Prescription for COVID-19."

France

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ In territories where a state of health emergency is in effect, the delivery of paracetamol by pharmacies, without medical prescription, is temporarily limited (one box of paracetamol (500 mg or 1g) per asymptomatic patient, and two boxes (500 mg or 1g) for patients with symptoms (pain and/or fever)). Internet sales of paracetamol, ibuprofen and aspirin medicines are suspended. ▪ The substitution (under specific conditions) of a medical device by the service provider, the distributor or the dispensing pharmacist is now authorized in the event of a proven shortage of a medical device necessary for the continuity of a patient's care.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	**Has the price and reimbursement procedures for medicinal products and medical devices been affected?** **Yes.** Due to COVID-19, the French health authorities prioritize health products to be assessed for price and reimbursement. 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 registered indication) for medicines in oncology, paediatrics or serious diseases where there is an unmet medical need. Likewise, the relevant Committee will review, as a matter of priority, 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 reimbursement for a new indication is filled. This includes COVID-19 products.

France

Public procurement

- Has the government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for COVID-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

Has the Government adopted exceptional public procurement measures?

Yes. Following Ordinance No. 2020-319 dated 25 March 2020 (as modified), the government has adopted several exceptional public procurement measures:

- Except where the services covered by the public procurement cannot be delayed, the time limits for the receipt of applications and offers in procedures under way will be extended by a period fixed by the contracting authority sufficient to allow economic operators to submit their applications or offers.
- Where the competitive tendering procedures laid down in the documents relating to the consultation cannot be complied with by the contracting authority, the latter may amend them during the procedure in accordance with the principle of equal treatment of candidates.
- Public procurement contracts expiring between 12 March 2020 and 24 July 2020 may be extended beyond the period provided for in the contract where the organization of a competitive tendering procedure cannot be implemented.
- Public purchasers may modify the conditions of payment of the advance to the public tender holders.
- Several measures are provided for in the event there are difficulties in the performance of the contract (extension of time limits for the performance of the contract by the holder, no penalty where the holder demonstrates that it does not have sufficient means to perform the contract, etc.).

The French Ministry of Economy has also published some recommendations according to which public purchasers, with regard to the exceptional character of the crisis, will not hesitate to acknowledge that the difficulties encountered by their co-contractors are attributable to an act of God (force majeure) or other theories.

Have procedural requirements been relaxed for Covid-19 related medicines and devices?

No. Except for the measures mentioned above, at this stage, we have not identified any specific procedural requirements that have been relaxed for COVID-19 related medicines and public procurement contracts.

Are sanctions foreseen for unfulfilled orders?

No. The above-mentioned legal provision expressly mentions that where the holder is unable to execute all or part of the contract, in particular, where it demonstrates that it does not have sufficient means, the holder may not be sanctioned, have contractual penalties or be held contractually liable on that ground.

France

Legal deadlines	**Have legal / administrative deadlines been suspended / relaxed?**
▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	**Yes.** Following an Ordinance No. 2020-306 dated 25 March 2020 (as modified), legal/administrative deadlines have been relaxed. ▪ Any authorizations (e.g. health data hosting authorization as per the French Digital Health Agency website) expiring between 12 March 2020 and 24 June 2020 will be automatically extended until at 24 September 2020. ▪ During the period between 12 March 2020 and 24 June 2020 (unless the state of emergency is extended), the time limits for any act, appeal, legal action, formality, registration, declaration, notification or publication prescribed by a law or regulation that were due to expire will be suspended. ▪ Moreover, the time limits imposed by the French administration that should have started to run between 12 March and 24 June 2020 are postponed as of 24 June 2020, provided that the time limit, imposed in accordance with the law to comply with measures of any kind, has not expired, and does not result from a court decision. However and as a derogation, the administration (including ANSM, DGCCRF, etc.) could, where justified, decide for the immediate application of such measures within a time limit that it determines taking into account the constraints linked to the state of health emergency. At this stage, existing exemptions from the above mentioned regime for administrative time limits, which relate to the French Public Health Code, concern only measures taken by the nuclear safety authority. **Have these measures had an impact on MA approvals, public procurement, etc.?** **Yes.** These measures have had an impact on marketing authorization approvals, as well as any other administrative measures related to medicines and medical devices. The impact of these measures on public procurements is described in the section above.

France

Relaxation of regulatory rules	**Has the government relaxed regulatory rules?**
▪ Has the government relaxed regulatory rules?	**Yes**. ▪ Importation of non-CE marked masks, glasses and protective visors to France Pursuant to an inter-ministerial Instruction dated 9 June 2020, the French Government authorizes the importation to France of non-CE marked masks, glasses and protective visors (whether personal protective equipment or medical device), under certain conditions (which differ depending on whether the product qualifies as PPE or a medical device and whether or not it is intended for healthcare professionals) - provided that these products comply with certain foreign standards recognized as equivalent to the standards that usually apply. ▪ Use of non-CE marked In Vitro medical devices (IVDs) Where difficulties in the supply of IVDs prevent medical biology laboratories from carrying out enough examinations to face the health crisis, non-CE-marked IVDs may be used, under restrictive conditions. ▪ Importation of medicines to France In order to deal with medicine related supply tensions, medicines with an importation authorization and which list is set by ANSM may be imported to France by the National Public Health Agency without carrying out the finished products' controls required by the French public health code ▪ Reimbursement conditions for remote consultations The conditions for the reimbursement of remote medical consultations for COVID-19 infected patients or showing symtoms 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, by way of derogation, authorized to conduct remote consultations.

France

Clinical trials

- Have special measures been adopted?
- What are the main changes?

Have special measures been adopted?

Yes, special measures relative to clinical trials have been adopted by the French authorities.

- For **new and ongoing clinical trials**: In March 2020, ANSM requested clinical trials sponsors to re-evaluate the relevance of setting up new clinical trials, given the priority given to 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.

- The French Data Privacy Authority (**CNIL**) is also indicating 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.

What are the main changes?

The main change is the possibility of using fast-track procedures (with the ANSM, ethics committees and the CNIL) to set up COVID-19 clinical trials.

Germany

Matters	Summary
Specific COVID-19 legislation (as modified)	▪ Act on the Protection of the Population against Epidemic Emergencies on a National Scale of 27 March 2020 ▪ COVID-19-Hospital-Relief-Act of 27 March 2020 ▪ Announcement according to Sec. 79 § 1 of the Drug Act of 26 February 2020 ▪ Announcement according to Sec. 79 § 1 of the Drug Act of 16 March 2020 (label waiver for a pneumococcal vaccine) ▪ Bavarian Infection Protection Act of 25 March 2020 (non-exhaustive list)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Yes, statutory instruments are available and could be used as measures of last resort by regulators on the level of the federal states, as recently invoked by the state of Bavaria which on 16 March 2020 declared a state-wide state of emergency. State Disaster Relief Acts (e.g. in Bavaria Art. 9 BayKSG) empower local enforcement authorities to seize citizens' property. Further measures can be taken authorized through the Federal Infectious Diseases Protection Act (IfSG). Already now, medical clinics in Bavaria have to report their inventory of ventilators to authorities (order issued by the Bavarian secretary of health on 17 March 2020). ▪ In Bavaria, one vacant hotel near Munich will be converted to treat 120-180 Covid19 patients, according to reporting of 3 April 2020. Except for Bavaria, at present, there is only an earlier unspecific and legally non-binding "plan" on the subject of hotel conversion. On 17 March 2020, the federal and state governments decided on an emergency plan for hospitals in Germany to combat the spread of the coronavirus. The resolution states that "additional capacities can be built up for the numerous easier treatment procedures by upgrading, expanding and converting rehabilitation facilities, hotels or larger halls". ▪ Not yet, but based on the aforementioned Act on the Protection of the Population against Epidemic Emergencies on a National Scale, the Federal Ministry of Health has proposed on 6 April 2020 and 7 April 2020, respectively, two regulations. The draft regulation of 6 April 2020 ("SARS-CoV2 Drug Supply Regulation") provides that: ▪ medical supplies, including medicinal products, their active substances and excipients, medical devices, diagnostics, personal safety equipment and disinfectants, may become subject to direct oversight by the Ministry of Health ▪ pharmaceutical companies may be required to report to the Ministry of Health the existing stock, production, distribution and prices of such concerned medical supplies ▪ the Ministry of Health may restrict the trade, dispensing and pricing of such medical supplies. Where necessary to ensure the continued supply of the public, the Ministry of Health may prohibit the sale of such products and compel manufacturers to supply such medical supplies to the government (federal, state, or local) or other entities instead. The price for such compelled supplies will be set by the government, and shall be linked to the regular sales price The draft emergency regulation proposed by the Ministry of Health on 7 April 2020 ("Medical Need Health Care Assurance Ordinance - MedBVSV") provides: ▪ that the Federal Ministry may procure, store, manufacture and market products of medical need directly or through commissioned bodies; and ▪ for numerous exemptions from pharmaceutical legislation requirements, notably regarding labelling, package leaflets, expiration dates and so on

Germany

Matters	Summary
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Under the aforementioned draft regulation of 6 April 2020 (draft SARS-CoV-2 Drug Supply Regulation), among other measures: ▪ pharmaceutical companies may be required by the Ministry of Health to supply products at a price set by the government (see above) ▪ pharmacies are granted more latitude when filling prescriptions by allowing, if necessary, the dispensing of medicines of a different manufacturer, different size, or different strength than prescribed; and ▪ certain compounding requirements are relaxed to the extent necessary for pharmacies to ensure the supply of the public with medicinal products (including controlled substances), medical devices and other pharmacy-typical products.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The effects of COVID-19 do not per se allow for a deviation from public procurement law. However, a more lenient approach may apply during an interim period. ▪ procurements which cover an urgent need to contain the corona pandemic (e.g. procurement of respiratory masks, servers or buildings/conversion work to create new hospital beds, etc.), urgency justifies the implementation of accelerated procedures. ▪ Procurements to meet an extremely urgent demand to contain the corona pandemic, for which it can be proven that even the accelerated procedures take too long, **directs awards** pursuant the negotiated procedure without a call for tenders are justified. For instance, the German government has initiated under these rules on 2 April 2020 a procurement for the supply of personal safety equipment. With a view to incentivize the ramp-up of domestic production, only personal safety equipment manufactured in Germany qualifies.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ According to a proposal for an MDR amendment from the EU Commission of April 3, 2020 (2020/0060(COD)), the key date of 26 May 26 2020 is to be pushed back by one year to 26 May 2021 throughout the MDR. This would in the first place change the date of the MDR application to 26 May 2021, but also the timelines for the CTS and (anyway in doubt) Eudamed. The deadline for making available and putting into service of certain legacy devices taking advantage of the transition period until 25 May 2025 (Art. 120(4)) will also be deferred by one year.

Germany

Matters	Summary
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	▪ On 20 March 2020, the German FDA (**BfArM**), in coordination with the Health Ministry, announced by general ruling that certain deviations from the content of the marketing authorization would be permitted for alcoholic medicinal products authorized exclusively for hand disinfection. This measure is limited until 30 June 2020 and serves to ensure the supply of these drugs, whose virucidal effect and safety are still guaranteed. Similarly, three general decisions by the competent authority on biocidal products taken on 4 March 2020, 20 March 2020, and 2 April 2020, have allowed the manufacturing and placing on the market of hand disinfectants containing certain biocidal active substances without a product registration and under relaxed manufacturing and labelling requirements. ▪ Exemptions **from the marketing authorization requirement for medicinal products, or from any other compulsory licenses**: Individual case by case exemptions on the level specific MAs or other specific permits may be granted by competent state authorities through special administrative orders. So far local authorities have only occasionally taken advantage of the conferred exemption authority (State of Saxony, order of Apr. 1: MA and label waiver for a pneumococcal vaccine). Regarding medical devices, German Health Ministry, by letter of 13 March 2020, instructed the heads state-level surgeon generals that specific protective equipment (FFP masks, medical masks, protective gowns) shall be deemed to have clearance for being placed on the market even without CE mark if those products had obtained marketing approval (may be lawfully marketed) in the U.S., Canada, Australia or Japan (China is not mentioned). Otherwise (in the absence of CE marking or recognition of the aforementioned third-country approvals), "suitable bodies", which may be Notified Bodies, are to inspect conformity with EU safety/protection standards. Notified Bodies Dekra and IFA have published a condensed checklist for inspecting basic technical EU compliance of COVID-19 pandemic face masks.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	▪ Sponsors may probe options for re-organizing studies in a way that investigational products are administered to study patients in the patients' homes (possibly assisted by study nurses) rather than at the study centers. According arrangements with regulators and IRBs might be legally supported by the EU guidance on Clinical Trial Management of 27 March 2020 jointly issued by EMA, CTFG, CTEG, GCP Inspectors Working Group, supplemented by an according BfArM guidance. A number of measures may be considered: # Remote Monitoring / Visits / Auditing, # Shipment of study medication ex trial center or ex sponsor site, or through licensed pharmacies, directly to subjects for at-home application, # facilitated Informed Consent (orally obtained), # transfer of patients, # leniency of Protocol Deviations.

Hungary

Matters	Summary
Specific COVID-19 legislation	▪ Governmental Decision No. 1101/2020 (III. 14.) on Further Necessary Measures Regarding Protection Against COVID-19 Pandemic ▪ Governmental Decision No. 1109/2020 (III. 18.) on the Professional Support for the Emergency Operation of Certain State-Owned and Private Companies of Strategic Importance ▪ Act LVIII of 2020 on the temporary rules related to the termination of the state of emergency and the epidemiological preparedness ▪ Government Decree No 282/2020. (VI. 17.) on the termination of the state of emergency announced on 11 March 2020 has repealed several Decrees that have been passed by the Government during the state of emergency ▪ Government Decree No 283/2020. (VI.17.) has introduced the epidemiological preparedness from 18 June 2020 ▪ Government Decree No 285/2020. (VI. 17.) on the protective measures during the epidemiological preparedness lists the applicable protective measures: ▪ Government Decree No 286/2020. (VI. 17.) on the Operational Body operating during the epidemiological preparedness ▪ Government Decree No 287/2020. (VI. 17.) on the measurements necessary for protecting the medical health supplies ▪ Government Decree No 409/2020. (VII. 30.) on certain rules applicable in case of epidemiological surveillance related to COVID-19 ▪ Government Decree No 410/2020. (VII. 30.) on the coopreation of the Hungarian Defense Forces related to the tasks on the epidemiological preparedness

Requisition powers
 	
▪ Has the government established any powers to requisition assets and premises?
▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
▪ Is it controlling the distribution of medicinal products/medical devices?
	▪ Governmental Decision No. 1101/2020 was issued to set up an action committee (**Committee**) to protect and secure the operation of companies of strategic importance. The Committee identified the relevant companies and prepared to take control over those companies if needed.
	▪ Government Decree No 286/2020. (VI.17.) on the Operational Body operating during the epidemiological preparedness establishes an Operational Body which
	  ▪ makes and discusses proposals to the Government in connection with the epidemiological preparedness
	  ▪ enforces the aspects arising from the epidemiological preparedness during the development and implementation of governmental decisions.
	▪ We are not yet aware of any measures of the government of Hungary that may aim to convert hotels into hospitals/medical centers for quarantine and self-isolation. However, some hospitals in the capital city of Budapest and certain Hungarian country towns have been nominated as centers for quarantine. In addition, all hospitals in Hungary have implemented special measures due to the pandemic and they have been preparing for the acceptance of patients with COVID-19. Furthermore, the construction of a mobile epidemic hospital has started in a Hungarian country town called Kiskunhalas.
	▪ Pursuant to Governmental Decision 1109/2020, the Committee will place military personnel at companies of strategic importance to facilitate effective communication and cooperation between the companies, the government and the Committee.
	  ▪ Military personnel have already visited certain pharmaceutical companies with manufacturing facilities in Hungary and a pharmaceutical wholesaler; however, further actions have not yet been taken.
	  ▪ The Committee might have an impact on the operation of pharmaceutical companies and wholesalers and, consequently, on the production and distribution of medicinal products and/or medical devices in the near future..

Hungary

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ The National Institute of Pharmacy and Nutrition (**OGYÉI**) also published a decision on the same export ban based on the Medicine Economy Act ▪ On 3 April 2020, the OGYÉI confirmed the shortage of medicinal products containing propofol and prohibited the export of such medicines from Hungary from 12:00 AM on 3 April 2020 until six months to prevent supply disruption. ▪ Medical Devices and Personal Protective Equipment (**PPE**): ▪ The competent authority for PPEs (i.e. the Work Safety Department under the competence of the Technology and Innovation Ministry of Hungary) published information on its official website regarding the implementation of Regulation (EU) 2020/402 of 14 March 2020, based on which the exportation of certain PPE products outside of the EU shall be subject to an export authorization. These products include protective spectacles and visors, face masks, mouth-nose-protection equipment, protective garments, gloves as listed in annex 1 of the Regulation. In Hungary, the competent authority that issues the export authorization is the Department of Commerce, Military Engineering, Export Control and Precious Metal Certification of the Budapest Government Office. Authorizations are valid until 6 weeks from the promulgation of the Regulation. ▪ 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. 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 recently received significant quantity of face masks and other PPE from China.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	▪ We are not aware of any further information on price and reimbursement issues regarding the state of emergency due to COVID-19.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ We are not aware of any further information on public procurement issues regarding the state of emergency due to COVID-19.

Hungary

Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ Public healthcare certificates: Should the validity of public healthcare certificates expire after 1 March 2020 during the state of emergency due to COVID-19, the validity of public healthcare certificates will be extended by 90 days after the expiration date (the competent authority is NEAK). ▪ The clinical trial requests related to the treatment or prevention of COVID-19 will be evaluated in an expedited procedure by OGYÉI (the competent authority).

Relaxation of regulatory rules
 	
▪ Has the government relaxed regulatory rules?
	▪ Prescription of medicines:
	  ▪ Specialists' medical recommendations for medicines and medical aids to be prescribed with increased and special reimbursement will remain valid for the duration of the state of emergency and for 90 days after the end of the state of emergency.
	  ▪ Healthcare providers should provide patients with more prescriptions. Consequently, patients may receive the quantity available in the pharmacy and be able to purchase the missing amount later.
	  ▪ Visiting ban: Medical sales representatives and persons monitoring clinical trials will not visit institutions providing inpatient and outpatient care or general practitioners.
	▪ Public healthcare certificates: Please see our input indicated under the section "Legal deadlines."
	▪ OGYÉI will publish a list of the substances of "medicines with prescription for an unauthorized indication" (off-label use). OGYÉI has already published this list with the following substances: hydroxychloroquine-sulfate, chloroquine, remdesivir, lopinavír, ritonavir, ruxolitinib, azithromycin and oseltamivir. If a medicine or a substance is not included in this list, their prescription or use for an unauthorized indication for the purpose of the treatment of COVID-19 will be authorized by OGYÉI based on a request submitted. OGYÉI will process this request with priority.
	▪ For the above substances neither preliminary notification, nor prior authorization of the OGYÉI is required to off-label use for the treatment of diseases caused by COVID-19, as written above. However, a retrospective notification on off-label use shall be submitted to OGYÉI within 90 days after the end of the state of emergency.
	▪ The dissemination of Direct healthcare professional communications (**DHPCs**) according to OGYÉI's decision: DHPCs and important risk minimization guidelines should only be disseminated electronically where possible. They should also be provided to the professional associations requested to assist in the digital dissemination. However, as long as dissemination by post is possible, OGYÉI will disregard the submission of the confirmation receipts to OGYÉI. Therefore, drug safety materials may be delivered by regular mail. Personal distribution of DHPCs is not considered appropriate during this period.

Hungary

Clinical trials

- Have special measures been adopted?
- What are the main changes?

OGYÉI is the relevant authority regarding clinical trials. OGYÉI publishes information on the continuity of clinical trials during the coronavirus pandemic in compliance with the harmonized EU-wide recommendation on the conduct of clinical trials during the COVID-19 pandemic.

- General and specific considerations are included in OGYÉI's recommendation related to certain issues such as the authorization practice, study visits, monitoring and the supply of investigation medicinal products.
- The following are some examples of major measures raised by OGYÉI's recommendation:
  - The most important issue is to ensure the continuity of clinical trials.
  - In-depth risk assessment of ongoing trials will be performed and measures will be taken to prioritize the patient's safety and data validation. In case of conflict, the patient's safety must be the priority.
  - Risk assessment must be repeated and properly documented, if needed.
  - The use of electronic patient information and consent forms is not allowed.
  - If wet ink signature may only be obtained with difficulty, alternative documentation tools (such as printed email) may be applied.
  - Based on the risk assessment, the sponsor and the principal investigator will consider postponing or stopping the site visits, or will perform them via telephone.
  - Visits performed in a patient's home are not supported by OGYÉI.
  - A patient's enrolment will be considered stopped during the state of emergency.
- OGYÉI does not support the study drug being provided by the sponsor directly to the patient's home, as the sponsor does not know the patient's personal data (name, address, etc.).
- If the transfer of study drugs requiring special storage conditions must be changed, the way of the amended transfer will be documented (e.g., in a refrigerator bag). However, OGYÉI will not be notified of this amendment.
- OGYÉI will evaluate the clinical trial requests related to the treatment or prevention of COVID-19 in an expedited procedure.

Italy

Matters	Summary
Specific COVID-19 legislation	▪ Decree-Law No. 23 dated April 8, 2020 providing urgent measures on access to credit and tax obligations for enterprises, special powers in strategic sectors as well as provisions on the matter of health and work, extension of administrative and procedural deadlines ▪ Decree of the President of the Council of Ministers dated April 1, 2020 implementing Decree-Law No. 19 dated March 25, 2020 on urgent measures to deal with the epidemiological emergency by COVID-19 ▪ Decree-Law No. 19 dated March 25, 2020 on urgent measures to deal with the epidemiological emergency by COVID-19 ▪ Order of the Head of the Civil Protection Department No. 655 dated March 25, 2020 on further urgent measures for the emergency relating to the health risk connected with the occurrence of diseases from transmissible viral agents ▪ Decree of the President of the Council of Ministers dated March 22, 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency by COVID-19 ▪ Order of the Minister of Health and the Minister of the Internal Affairs dated March 22, 2020 prohibiting all persons from moving from one municipality to another, except for proven urgent professional needs or health reasons ▪ Decree-Law No. 18 dated March 17, 2020 on measures to strengthen the National Health Service and provide economic support to families, workers and businesses in connection with the COVID-19 epidemiological emergency ▪ Workplace Safety Protocol signed on March 14, 2020 by trade unions and industry associations ▪ Decree of the President of the Council of Ministers dated March 11, 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency by COVID-19 ▪ Decree of the President of the Council of Ministers dated March 9, 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency by COVID-19 ▪ Decree-Law No. 9 dated March 2, 2020 on urgent supporting measures for families, workers and businesses in connection with the epidemiological emergency by COVID-19 ▪ Decree-Law No. 6 dated February 23, 2020 on urgent measures for the containment and management of the epidemiological emergency by COVID-19 ▪ Decree of the President of the Council of Ministers dated 26 April 2020 introducing further urgent measures to contain and deal with the epidemiological emergency by COVID-19 applicable in the whole national territory ▪ Decree-Law No. 28 dated 30 April 2020 providing for urgent measures for the introduction of the COVID-19 alert system ▪ Decree-Law No. 29 dated 10 May 2020 introducing urgent measures in relation to home detention or deferment of execution of the sentence, as well as the replacement of pre-trial detention in prison with house arrest, for reasons related to the health emergency by COVID-19, of persons detained or interned for certain crimes such as mafia-type and terrorism-type crime ▪ Decree-Law No. 30 dated 10 May 2020 on urgent measures concerning epidemiological studies and statistics on SARS-COV-2 ▪ Decree of the President of the Council of Ministers dated 12 May 2020 on the Integration of the Committee of Economic and Social Experts ▪ Decree-Law No. 33 dated 16 May 2020, No. 33 introducing further urgent measures to deal with the epidemiological emergency from COVID-19

Italy

Specific COVID-19 legislation	▪ Decree of the President of the Council of Ministers dated 17 May 2020 implementing urgent measures to deal with the epidemiological emergency from COVID-19 ▪ Decree of the President of the Council of Ministers dated 18 May 2020 providing for Amendments to Decree of the President of the Council of Ministers dated 17 May 2020 implementing urgent measures to deal with the epidemiological emergency from COVID-19 ▪ Decree-Law No. 34 dated 19 May 2020 on Urgent health measures, support for work and the economy, and social policies related to the epidemiological emergency from COVID-19 ▪ Decree of the President of the Council of Ministers dated 11 June 2020 implementing urgent measures to deal with the epidemiological emergency from COVID-19 ▪ Decree of the President of the Council of Ministers dated March 8, 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency by COVID-19 ▪ Decree-Law No. 52 dated 16 June 2020 introducing further measures on wage supplementation treatment, as well as extension of deadlines for emergency income and the emergence of employment relationships ▪ Decree of the President of the Council of Ministers dated 14 July 2020 extending to 31 July 2020 the provision introduced by the Decree of the President of the Council of Ministers dated 11 June 2020, which implemented urgent measures to deal with the epidemiological emergency by COVID-19 ▪ Decree-Law No. 76 dated 16 July 2020 introducing urgent measures for the simplification and the digital innovation ▪ Decision of the Government dated 30 July 2020 extending the duration of the COVID-19 emergency period from 31 July to 15 October 2020 ▪ Decree-Law No. 83 dated 30 July 2020 extending from 31 July to 15 October 2020 the provisions granting emergency powers and enabling the adoption of specific measures to contain the epidemic ▪ Decree of the President of the Council of Ministers dated 7 August 2020 extending the minimum precautionary measures against the spread of COVID-19 until 7 September 2020 (e.g. social distancing, obligation to wear masks) ▪ Decree-Law No. 104 dated 14 August 2020 introducing urgent measures to support and relaunch the economy ▪ Decree-Law No. 125 dated 7 October 2020 extending the emergency period from 15 October 2020 to 31 January 2021 and introducing urgent measures relating to the extension of the emergency period and for the operational continuity of the COVID-19 alert system, as well as the implementation of Directive (EU) 2020/739 of 3 June 2020 ▪ Decree of the President of the Council of Ministers dated 13 October 2020 relating to COVID-19 emergency response and containment measures ▪ Decree of the President of the Council of Ministers dated 18 October 2020 aimed at supplementing the provisions of the previous Decree dated 13 October 2020 with further restrictive measures in order to contain the COVID-19 spread

Italy

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	Pursuant to Decree Law No. 18 dated 17 March 2020, as converted by Law No. 27 of 24 April 2020, the Head of the Department of Civil Protection can order the requisition, either for use or title, of health and medical-surgical facilities and equipment, as well as movable properties of any kind belonging to public or private persons necessary to deal with the health emergency, also to ensure their supply to healthcare structures located in the Italian territory and to increase the number of specialized beds in wards for hospitalization of patients affected by said disease. Decree-Law No. 76 dated 16 July 2020 (Section 8, paragraph 8) confirms the above-mentioned provision. Furthermore, pursuant to Decree Law No. 18/2020, Prefects may order the requisitioning of hotels or other buildings with similar characteristics to house individuals under health surveillance. Said Decree Law also provides for ad hoc funding through non-repayable and operating grants, as well as subsidized loans, to ensure the manufacturing and supply of medical devices and personal protective equipment in light of the inadequate availability of same during the COVID-19 emergency period. To this end, the Decree Law authorizes the expenditure of 50 million euros for 2020 and entrusts an Extraordinary Commissioner, appointed by decree of the President of the Council of Ministers, with the task of approving the disbursement of the relevant funding.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	With order dated April 26, 2020, the Extraordinary Commissioner for the COVID-19 Emergency established that the final consumer price of surgical masks (standard EN 14683) must not exceed, for each unit, EUR 0.50 net of VAT. The order clarifies that the above-mentioned price has been set with the purpose of ensuring the maximum dissemination of personal protective equipment. Furthermore, the Extraordinary Commissioner considered that the increase in demand for these products necessary to cope with the emergency could lead to an unjustified rise in consumer prices capable of jeopardizing the widest access to this type of devices and, consequently, the full effectiveness of the measures adopted to combat the spread of COVID-19. The Extraordinary Commissioner has also signed an agreement with the Order of Pharmacists, Federfarma (the Italian association of private pharmacies affiliated with the National Healthcare System) and Assofarm (the Italian association of public pharmacies). On May 1, 2020, the Extraordinary Commissioner for the COVID-19 emergency and the associations of pharmacies, para-pharmacies and distributors of medicinal products signed a Memorandum of Understanding according to which pharmacies that have purchased surgical masks at a higher price will be reimbursed. The Memorandum provides that the reimbursement applies to face masks falling within the scope of the above-mentioned Order (i.e. those conforming to the standard UNI EN 14683 - Type I, II and IIR), as well as to similar single-use masks. Conversely, all other types of reusable masks, among which Type FFP2 and FFP3 personal protective equipment, are excluded.

Italy

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Furthermore, the Memorandum of Understanding sets out maximum reimbursement limits and clarifies that only face masks that have been delivered to recipients by May 3, 2020 shall be admitted to reimbursement; to this end, the Memorandum also identifies the necessary technical documentation to support the relevant requests for reimbursement. Lastly, the Memorandum provides for the Commissioner's commitment to supplement supplies of face masks to pharmacies and para-pharmacies on a weekly basis and to adopt new agreements necessary to deal with any new shortages also clarifying that distributors shall purchase face masks at a price of EUR 0.38 and shall sell them to pharmacies at EUR 0.40, without prejudice to the final consumer price established by the above-mentioned Order.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	CONSIP, the Italian central purchasing entity, has been appointed the "responsible body" for public procurement activities related to the health emergency. Pursuant to Article 63, paragraph 2, letter c), of Legislative Decree No. 50/2016 on Code of Public Contracts, CONSIP has been allowed to carry out negotiated procedures without prior publication of the tender notice, aimed at entering into framework agreements for supplies required by healthcare structures. In particular, in order to deal with the strong demand for and the shortage of medical devices intended for the current health emergency, CONSIP, in accordance with the Civil Protection's directives, has already awarded several urgent negotiated procedures, amongst which, those for the supply of medical devices for intensive and sub-intensive care, swabs and diagnostic kits, personal protective equipment and electro-medical equipment. Moreover, with Order No. 655 dated March 25, 2020 the Head of the Civil Protection Department introduced the possibility for Local Authorities to award public contracts for the supply of services/equipment in derogation from the deadlines and methods for the publication of the tender notice provided for by Articles 60, 61, 72, 73 and 74 of Legislative Decree No. 50/2016 on Code of Public Contracts.

Italy

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	On May 2, 2020, the Italian Anti-Corruption Authority published a handbook addressed to contracting authorities with the purpose of accelerating and simplifying the management of public procurement procedures during the COVID-19 pandemic. In this regard, the handbook provides an overview of existing legislative provisions on public procurement in order to support contracting authorities in dealing with the current emergency and in all cases where it is necessary, to the extent permitted by the law, to accelerate or simplify public tender procedures. In particular, among the various operational solutions suggested for the current health emergency, the handbook focuses on the use of legal instruments already available under the relevant regulatory framework also indicating, where necessary, the specific conditions for their application; said solutions include facilitated awarding methods, such as the direct administration, the direct award and the negotiated procedure without publication of the call for tenders; the reduction of deadlines for the submission of tenders; the early execution of the contract and the early performance of the contract as a matter of urgency. We are not aware of any specific sanctions for unfulfilled orders other than those which normally apply under Legislative Decree No. 50/2016 on Code of Public Contracts. In order to boost public investments in the public procurement field, as well as to address the negative economic effects of the COVID-19 emergency, Decree-Law No. 76 dated 16 July 2020 introduced a number of exemptions from the ordinary tender procedures, depending on the relevant economic threshold of the public contract, and faster deadlines, applicable until 31 July 2021. With specific regard to sanctions, pursuant to Decree-Law No. 76/2020, the failure to comply with the deadlines provided therein for the award of the contract, the delays in concluding the contract and/or in executing the same shall constitute grounds for the exclusion from the tender procedure or for termination of the contract.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	The relevant suspension provisions, which were temporarily adopted, have been repealed.

Italy

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

With Decree Law No. 18 of March 17, 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, 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 fulfil all safety requirements established by the in-force regulations. No later than 3 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 to make use of said derogation is limited to the duration of the state of emergency resulting from the COVID-19 outbreak (currently, 6 months from January 31, 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.

Clinical trials

- Have special measures been adopted?
- What are the main changes?

With notice published on 7 April 2020, the 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:

- As regards 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

Italy

Clinical trials

- Have special measures been adopted?
- What are the main changes?

- In light of difficulties of patients in reaching trials 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
- As regards 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, 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 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.

Moreover, Decree Law No. 18 of March 17, 2020, as converted by Law No. 27 of 24 April 2020, allows the AIFA to access all data of clinical trials and compassionate use programs on medicines for patients with COVID-19 in order to improve the coordination and analysis capability of available scientific evidences. The Decree Law also provides that the relevant study protocols shall be subject to the preliminary assessment by the AIFA's Technical Scientific Committee and to the opinion of the Ethics Committee of the National Institute for Infectious Diseases Lazzaro Spallanzani of Rome, in its capacity as single national Ethics Committee.

Kazakhstan

Matters	Summary
Specific COVID-19 legislation	▪ The Code on Population Health and Healthcare System No. 193-IV (**Healthcare Code**). The Healthcare Code provides general regulations for quarantine and special protection measures. ▪ The Law on State Emergency No. 387-II (**State Emergency Law**). The State Emergency Law sets forth grounds for requisitions of assets and premises. ▪ The State Property Law No, 413-IV (**State Property Law**). The State Property Law sets forth a procedure for the requisition of assets and properties. ▪ Minister of National Economy Order No. 239 dated 20 March 2015 On the Quarantine Procedure (**Order 239**). ▪ Presidential Decree No. 285 dated 15 March 2020 On State Emergency in the Republic of Kazakhstan (**Decree 285**). Decree 285 introduced the state emergency in Kazakhstan from 16 March until 15 April 2020 because of COVID-19, protection measures, including quarantine, and ordered the provision of the required state funds for protection measures from state financial and asset funds. ▪ Presidential Decree No. 286 dated 16 March 2020 On Economic Stability Measures (**Decree 286**). Decree 286 granted the government the right to adopt measures to support the local economy, including a simplified procurement procedure. ▪ Governmental Resolution No. 127 dated 20 March 2020 On Implementation Special Procurement Rules (**Resolution 127**). Resolution 127 implemented simplified procurement rules on acquisition goods and services while the state of emergency is in place. The procurement can be performed through the request of bids or from a single source. ▪ Prime-Minister Decree No. 10-p dated 27 January 2020 on Establishment of Special Interministerial Commission On Protection Against COVID-19 (**Commission**). ▪ Prime-Minister Decree No. 14-p dated 29 January 2020 On Adoption of the Plan on Protection Measures Against COVID-19.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ The State Emergency Law sets forth grounds for requisitions of assets and premises. ▪ We are not aware of any measures of the Kazakhstani government that may aim to convert hotels into hospitals/medical centers for quarantine and self-isolation. All centers for quarantine are located in state hospitals and state residences. No construction of mobile epidemic hospitals has started in Kazakhstan. ▪ Pursuant to Decree 285, military personnel took under their protection anything of strategic importance to facilitate effective communication. ▪ The Commission might impact on the operation of local pharmaceutical companies and wholesalers and, consequently, on the production and distribution of medicinal products and/or medical devices in the near future. ▪ The police monitor unauthorized sales of face masks and antiseptics and confiscate them from unofficial traders.

Kazakhstan

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	We are not aware of further information on price and reimbursement issues regarding the state of emergency due to COVID-19.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ Resolution 127 laid down simplified procurement rules on acquisition goods and services, specifically on procurements in connection with the state of emergency against COVID-19. ▪ All acquisitions may be procured through requests of bids or from a single source. Resolution 127 does not provide special rules on acquisitions of medicines and medical devices. ▪ The procurement rules for acquisition medicines and medical devices No. 1729 dated 30 October 2009 provides a special procedure on acquisition of medicines and medical devices during epidemic and/or state emergency. This procedure presumes that single state distributor acquires the medicines and medical devices though a request of bids. According to information published on the website of single state distributor for medicines and medical devices SK-Pharmacia LLP, since 19 March 2020, the latter acquires medicines with or without marketing authorization in the Republic of Kazakhstan through this procedure. If the medicines and medical devices have no local marketing authorization, the supplier has to submit a permit from the Ministry of Healthcare on the importation of such products. An epidemic is one of the grounds to obtain such permit. ▪ The Administrative Code and the Criminal Code may apply to offenders of Resolution 127.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ A major portion of state officials has been sent to remote work because of the state of emergency. The quarantine introduced in Nur-Sultan, Almaty, Karaganda, Aktau and five other small towns closed all state offices, excluding central governmental offices. However, it is unclear whether the state of emergency and quarantine will affect the administrative deadlines of the national healthcare authorities. ▪ Since 19 March 2020, the National Center for Expertise of Medicines and Medical Devices works remotely and accepts all documents through the governmental digital communication service egov.kz and through emails. There are no publications in open sources suggesting that the National Center for Expertise of Medicines and Medical Devices will suspend its work or its administrative procedures. ▪ SK-Pharmacia LLP is continuing with the procurement of medicines and medical devices as discussed above. There are no publications in open sources suggesting that SK-Pharmacia LLP will suspend its operations during strict quarantine on 31 March-5 April 2020, which was introduced in Nur-Sultan, Almaty, Aktau, Karaganda and five other small towns in the Karaganda region.

Kazakhstan

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	There has been no relaxation of regulatory rules except those discussed above by the government, the Commission or the Ministry of Healthcare.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	No changes to the clinical trial procedure have been introduced. We understand that Kazakhstan expects the creation of a COVID-19 vaccine; then, it may establish a simplified clinical trial for this vaccine. As an alternative, if the COVID-19 vaccine has the Eurasian Economic Union (EAEU) marketing authorization, this authorization will apply to Kazakhstan under the EAEU Treaty.

The Netherlands

Matters	Summary
Specific COVID-19 legislation	▪ Ministerial regulation of the Minister for Medical Care of 28 January 2020, with reference 1643096-201442-PG, under Article 20 of the Public Health Act (Regulation 2019-nCOV); ▪ Decree of the Ministry of Health, Welfare and Sport of 19 March 2020, with reference 1664163-203347-GMT, establishing the designation of the competent authority regarding Regulation 2020/402 with regard to the export of personal protective equipment ▪ 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 (**Temporary Regulation Gene Therapy**) ▪ Emergency orders of the president of the security region, such as the emergency order of the president of the security region Flevoland establishing provisions to avoid further circulation of the coronavirus/COVID-19 dated 26 March 2020 ▪ Temporary regulations on alternative handling of permit applications gene therapy relating to the fight against COVID-19.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Since 28 January 2020, COVID-19 has been added to Group A of the Dutch Public Health Act. The Public Health Act regulates the fight against and prevention of infectious diseases in the Netherlands. The Public Health Act authorizes the president of the security region to take measures against COVID-19, such as having a person hospitalized for isolation, putting persons under quarantine or closing down buildings or sites. ▪ In the Netherlands, it appears that hotels have not been converted into hospitals or medical centers for quarantine and self-isolation. However, to relieve hospitals, the venue Ahoy in Rotterdam has been turned into a temporary care location for patients with and without COVID-19. ▪ On 26 March 2020, the minister for medical care announced that there would be no export ban with regard to the export of medicines within the EU. The export of medicines outside the EU is also allowed in principle. However, due to the entry into force of Regulation 2020/402, exports of personal protective equipment outside the EU are subject to an authorization. Due to the current shortage of personal protective equipment, the Health and Youth Care Inspectorate (**IGJ**), in principle, will not issue the export license.

The Netherlands

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	▪ Reference is made in the section "Legal deadlines" to the Medicine Prices Act. The minister for medical care postponed the change of the maximum prices of medicines for six months. Furthermore, the minister for medical care announced that the maximum prices of medicines would be released in the event that there is, or may be, a shortage of medicines and the price of such medicines may be an obstacle. ▪ The Ministry of Health, Welfare and Sport made arrangements with the Working Group Medicine Shortages, which includes pharmacies, drugstores and wholesalers, regarding the delivery and sale of medicines with and without prescriptions. This means that patients can have their usual amount of medicines, but not for longer periods of time. ▪ The minister for medical care 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 for medical care spoke to several market parties regarding medicine provision. For instance, the minister for medical care asked healthcare providers to consider changing the market conditions when concluding agreements with manufacturers or pharmacies. ▪ The Central Office for Drugstore Companies has advised drug stores to limit over-the-counter sales of paracetamol to a maximum of two packs and to only place paracetamol behind the drugstore's counter. ▪ The Dutch government instituted a national approach regarding the distribution of personal protective equipment. The GGD GHOR Nederland, in cooperation with the Regional Consultation Immediate Care, is responsible for such distribution.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ It appears that the Dutch government has not (yet) adopted national exceptional public procurement measures relating to COVID-19 and has not (yet) relaxed any procedural requirements regarding public procurement for COVID-19 medicines and devices.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ Due to the amendment of the Medicine Prices Act, the maximum prices for medicines in the Netherlands would have been lowered from 1 April 2020. However, the minister for medical care postponed the change of the maximum prices for six months. The new date is now 1 October 2020. ▪ The Dutch Healthcare Authority extended the deadline for the application for the quality budget 2020 of healthcare providers from 1 April 2020 to 30 April 2020. ▪ It appears that these measures have not had an impact on MA approvals or public procurement.

The Netherlands

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- The IGJ announced that it would temporarily give manufactures and suppliers of medical devices the opportunity to supply medical devices without a CE mark or without completing the required assessment procedure 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.
- The Inspectorate SZW has temporarily created scope for introducing non-CE marked personal protective equipment (**PPE**), such as FFP1, FFP2 and FFP3 mouth and nose masks, into the Dutch market, provided that such materials meet the health and safety requirements and such PPEs aim to protect the healthcare professionals against COVID-19. 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 PPEs. The LCH is the central procurement and distribution point for PPEs and medical devices. The manufacturers of non-CE marked PPEs must notify such PPEs to the LCH by sending an email to middelencorona@nfu.nl.
- The IGJ can temporarily grant permission to license holders to deliver medicines with different (non-Dutch) packaging. 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.
- The IGJ is adopting a more flexible attitude regarding the enforcement of the Individual Healthcare Professions Act. This means that healthcare institutions are allowed to assign support personnel, such as non-registered doctors, in the event of a personnel shortage due to COVID-19.
- In order to prevent problems relating to the delivery of medicines causing medicine shortage, the IGJ allows pharmacists to exchange their medicine supplies amongst themselves. The following conditions must be met: (i) the requesting pharmacist must submit the request for medicines in writing; (ii) the requesting pharmacist must be able to demonstrate the provision and the receipt of such medicines afterwards; (iii) the supplying pharmacist must keep proper records; (iv) the pharmacist must organize the transport of the medicines in such way that the good quality of the medicines remains.
- The IGJ announced that, under certain conditions, medicines may be stored outside the pharmacy in temporary COVID-19 care centres. The following conditions must be met (i) the responsible pharmacist and the location must be notified to the IGJ; (ii) the storage space must be safe and good, safeguard the quality of the medicines and not be accessible for unauthorized parties; (iii) the records must be kept properly; and (iv) the medication of patients must be monitored on the basis of a complete and actual medication file.

The Netherlands

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	The following measures have been adopted: ▪ Due to the entry into force of the Temporary Regulation Gene Therapy, the decision-making period for permit applications relating to clinical trials for gene therapy with regard to COVID-19 is temporarily accelerated. There is now a 28-day decision-making period, instead of 120 days. ▪ The Central Committee on Research Involving Human Subjects (**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 Multicentre Research Ethics Committees (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, and until further notice, all submissions to the CCMO must be submitted digitally. The obligation for accredited MRECs and the 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. The relevant authorities are the CCMO, as the review committee, the Ministry of Health, Welfare and Sport, as the competent authority, and 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. Temporary halts 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 of the review committee is not required. The procedures for notifications to the Dutch competent authority both during and after the study, as well as for submitting a substantial amendment to the review committee, have not be changed due to COVID-19.

Poland

Matters	Summary
Specific COVID-19 legislation	▪ Act of 2 March 2020 on specific arrangements for the prevention, counteraction and combating of COVID-19, other infectious diseases and the resulting emergencies (link) ▪ (Not yet in force — still subject to works in Parliament) Draft Law of 26 March 2020 Act 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 (link to the bill) ▪ Regulation of 20 March 2020 of the minister of health on declaring the state of the epidemic in the Republic of Poland (link) ▪ (Not yet in force — still subject to works in Parliament) Draft Law of 26 March 2020 amending certain healthcare-related laws in connection with prevention and combating of COVID-19 (link) ▪ Amendment of the Regulation of 20 March (link)

Requisition powers
 	
▪ Has the government established any powers to requisition assets and premises?
▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
▪ Is it controlling the distribution of medicinal products/medical devices?
	▪ During the state of epidemic, there is an order for the provision of immovable property, premises and land indicated in anti-epidemic plans.
	▪ No, but a number of hospitals are being converted to hospitals treating infectious diseases to treat patients who are infected with COVID-19.
	▪ Yes, the sale and distribution of medical devices has been limited and, problematically, it is subject to three different regimes:
	  ▪ There is a list of medicinal products/medical devices that are subject to an "export ban" and may not be exported or sold abroad without notifying the chief pharmaceutical inspector, who can oppose such export of such products or devices.
	  ▪ 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 wholesaler (this is the current regulation). However, once the Draft Law of 26 March 2020 amending certain healthcare-related laws in connection with the prevention and combating of COVID-19 is adopted, the above-mentioned regulation will be stricter — the pharmaceutical wholesalers will need to be located in Poland (this provision is still subject to works in Parliament).
	  ▪ An entrepreneur is obliged to notify the voivode no later than 24 hours before the intended export or sale outside Poland of products such as protective goggles, TYVEK-type overalls, FFP2/FFP3 masks, surgical masks, shoe protectors, latex and nitrile gloves, 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 export or sale of ventilators or cardiomonitors outside of Poland is prohibited.

Poland

Pricing and reimbursement
 	
▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?
	▪ The minister of health will define the maximum prices of medicinal products with 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.
	▪ Significant changes in this respect are provided in the Draft Bill of 26 March (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 will 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 because no new or amended reimbursement decisions may be issued before 1 September.

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ The provisions of the Public Procurement Law will not apply to contracts for goods or services that are necessary to counteract coronavirus. A condition for this exclusion of provisions is the existence of a high probability of the rapid and uncontrolled spread of the disease or a requirement to protect public health. The exemption from the application of public procurement provisions in the above case has been limited in time — it will be in force for 180 days from 8 March 2020. In addition, changes can be made to a public procurement contract if COVID-19 affects its performance. The parties are allowed to introduce changes to the contract related to deadlines, the scope of the contract and the contractor's remuneration provided that the increase in prices included in each subsequent change does not exceed 50% of the value of the original contract. If the public procurement contract includes beneficial regulations for the contractor, the change may be introduced in accordance with such regulations. However, the circumstances related to COVID-19 cannot constitute a sole basis for the withdrawal from the contract.

Legal deadlines
 	
▪ Have legal/administrative deadlines been suspended/relaxed?
▪ Have these measures had an impact on MA approvals, public procurement, etc.?
	(These provisions are still subject to works in Parliament.)
	▪ Administrative deadlines will be suspended or withheld in the following cases, among others:
	  ▪ deadlines that need to be met to be eligible for legal protection before a court or authority
	  ▪ deadlines for the performance of actions creating rights and obligations for oneself or the other party
	  ▪ statute of limitations
	  ▪ statutory time limits, the omission of which results in a definite loss of right
	In addition, deadlines in legal proceedings in civil and administrative cases, among others, are suspended or withheld.

Poland

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	According to a draft resolution of the Council of Ministers, the minister of health will be authorized to make purchases of personal protective equipment to use them for the needs of personnel providing healthcare services, including sanitary transport in connection with preventing the spread of SARS-CoV-2 virus and the COVID-19 disease caused by it. Personal Protective Equipment (PPE) may be made available for use before the completion of the conformity assessment and without affixing the CE marking no later than 30 days after the end of the epidemic.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	It is recommended to take into account the current epidemiological situation and the fact that the medical staff of hospitals are involved in activities related to SARS-CoV-2 infections in the supervision of clinical trials (monitoring and 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 e-mail. The information on immediate safety measures shall include a detailed assessment of the risks resulting from the changes." An analogical approach has been recommended for 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.

Russia

Matters	Summary
Specific COVID-19 legislation	▪ Federal Law № 67-FZ "On Amending Article 60 of the Federal Law №61-FZ "On the Circulation of Medicines" and Article 38 of the Federal Law 323-FZ "On the Fundamentals of Citizens' Health Protection in the Russian Federation" as of 26 March 2020 ("**Federal Law № 67-FZ**"); ▪ Federal Law № 98-FZ "On Amending Certain Legislative Acts of the Russian Federation on the Issues Related to Prevention of and Response to Emergencies" as of 1 April 2020 ("**Federal Law № 98-FZ**"); ▪ Federal Law № 105-FZ "On Amending Article 15-1 of the Federal Law "On Information, Information Technologies and the Protection of Information" and the Federal Law "On the Circulation of Medicines" as of 03 April 2020; ▪ Federal Law № 166-FZ "On Amending Certain Legislative Acts of the Russian Federation with the Purpose of Taking Urgent Measures to Ensure Sustainable Development of Economy and Prevent the Consequences of the Spread of COVID-19" as of 08 June 2020 ("**Federal Law № 166-FZ**"); ▪ Decree of the President of the Russian Federation № 187 "On the retail sale of medicines" as of 17 March 2020; ▪ Decree of the President of the Russian Federation № 206 "On the announcement of non-working days in the Russian Federation" as of 25 March 2020; ▪ Decree of the President of the Russian Federation № 239 "On measures to ensure sanitary and epidemiological welfare of the population in the Russian Federation in connection with the spread of COVID-19" as of 02 April 2020; ▪ Decree of the President of the Russian Federation № 294 "On extension of measures to ensure sanitary and epidemiological welfare of the population in the Russian Federation in connection with the spread of COVID-19" as of 28 April 2020; ▪ Decree of the President of the Russian Federation № 316 "On determining the procedure for extending the measures to ensure sanitary and epidemiological welfare of the population in the constituent entities (regions) of the Russian Federation in connection with the spread of COVID-19" as of 11 May 2020; ▪ Decree of the Government of the Russian Federation № 637 "On invalidation of certain acts of the Government of the Russian Federation" as of 30 April 2020 ("**Decree of the Government № 637**"); ▪ Decree of the Government of the Russian Federation № 299 "On Amending the Rules on the State Registration of Medical Devices" as of 18 March 2020; ▪ Decree of the Government of the Russian Federation №. 419 "On the implementation of the decision of the Council of the Eurasian Economic Commission as of 16 March 2020 № 21 and amending the list of medical devices, the sale and import of which on the territory of the Russian Federation and other territories under its jurisdiction shall be exempted from value added tax" as of 02 April 2020; ▪ Decree of the Government of the Russian Federation № 545 "On Amending Clause 1 of Decree of the Government of the Russian Federation №. 419 as of 02 April 2020" as of 18 April 2020; ▪ Decree of the Government of the Russian Federation № 430 "On the peculiarities of circulation of medical devices, including state registration of a series (batch) of medical device" as of 03 April 2020;

Russia

Matters	Summary
Specific COVID-19 legislation	▪ Decree of the Government of the Russian Federation № 500 "On suspension of Decree of the Government of the Russian Federation № 431 as of 3 April 2020" as of 13 April 2020 ("**Decree of the Government № 500**"); ▪ Decree of the Government of the Russian Federation № 440 "On the extension of validity of permits and other peculiarities of licensing activities in the year 2020" as of 03 April 2020 ("**Decree of the Government № 440**"); ▪ Decree of the Government of the Russian Federation №. 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 and for the purposes of medical assistance to persons affected by emergencies, prevention of emergency situations, prevention and treatment of dangerous diseases, diseases and injuries resulting from exposure to favorable chemical, biological, radiological factors" as of 03 April 2020 ("**Decree of the Government № 441**"); ▪ Decree of the Government of the Russian Federation № 697 "On approval of the Rules for issuing permits for the distance selling of medicines, the implementation of distance selling and delivery of medicines to citizens …" as of 16 May 2020 ("**Decree of the Government № 697**"); ▪ Decree of the Government of the Russian Federation № 789 "On amending the Rules for the organization and conduct of inspections of pharmaceutical manufacturers for compliance with Good Manufacturing Practice Rules, as well as issue of reports on pharmaceutical manufacturers' compliance with these requirements" as of 29 May 2020 ("**Decree of the Government № 789**"); ▪ Decree of the Government of the Russian Federation № 804 "On amending the peculiarities of circulation of medical devices, including state registration of a series (lot) of a medical device" as of 02 June 2020; ▪ Expanded recommendations of the Ministry of Industry and Trade of Russia and the Ministry of Economic Development of Russia on temporary measures related to inspection control, sampling and other scheduled work subject to the spread of COVID-19; ▪ Decree of the Chief State Sanitary Physician of the Russian Federation № 6 "On additional measures to reduce the risks of the spread of COVID-19" as of 13 March 2020; ▪ The plan of priority measures (actions) to ensure the sustainable development of the economy due to the spread of a new coronavirus infection (approved by the Government of the Russian Federation on 17 March 2020); ▪ Information of the Government of the Russian Federation "On measures to protect public health from a new coronavirus infection" as of 19 March 2020; ▪ Information of the Chamber of Commerce and Industry of the Russian Federation as of 24 March 2020 explaining the procedure for issuing reports on force majeure circumstances; ▪ Letter of the Ministry of Health of Russia № 20-1/*И*/2-3651 regarding the conduct of clinical trials of medicines in connection with the spread of COVID-19 as of 27 March 2020. ▪ Letter of the Ministry of Health of Russia № 30-4 / 1178 "On recommendations on the procedure for monitoring the quality of medical care for patients COVID-19" as of 08 July 2020.

Russia

Requisition powers

- Has the government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products/medical devices?

- As of 23 July 2020, there is no state of emergency in the Russian Federation and there are currently no governmental powers related to requisition of assets and premises.
- Days starting from 30 March 2020 to 30 April 2020, from 6 to 8 May 2020 were declared as non-working days in Russia. Starting from 12 May 2020 non-working days regime was abolished. At the same time, the regional authorities were entitled to introduce such a regime in respect of individual organizations, as well to extend the restrictive measures in case of necessity.
- In accordance with the Decree of the Government № 500 dated 13 April 2020, the Government of the Russian Federation decided to suspend restrictions on the sale of certain medical devices, namely filter respirators, medical masks, gauze, medical gloves.
- In addition, under the Decree of the Government № 637 dated 30 April 2020, the Government of the Russian Federation lifted the ban on the export of certain medical devices, namely, masks, bandages, cotton wool, gauze, different types of gloves, overalls and suits of chemical protection, medical surgical gowns, respirators, disinfectants, etc.
- According to Federal Law № 98-FZ, 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.
- Under Federal Law № 98-FZ, 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 into the list determined by the Government for a period not exceeding 90 calendar days from the date of adopting the relevant decision.
- In accordance with Federal Law № 166-FZ the Russian Government is authorized to determine:
  - the peculiarities of organization of medical care in case of a threat of spread of diseases that pose danger to people (for example, COVID-19);
  - the procedure for collecting and recording information on the spread of such diseases, as well as its composition.

Russia

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Federal Law № 67-FZ, which entered into force on 26 March 2020, allows the Russian Government 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, which are not included into the List of Vital and Essential Medicines, that will fall under the State regulation. 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 the spread of a dangerous disease; ▪ detection of the growth of 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.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	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.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Currently, the situation with the legal/administrative deadlines is uncertain. The Chamber of Commerce of the Russian Federation indicated that the regional Chambers of Commerce may issue reports on force majeure circumstances, if there are appropriate personnel. This document attests the existence of force majeure circumstances that does not allow to fulfill obligations under contracts entered into between Russian legal entities. In respect of the international contracts, force majeure circumstances may be confirmed by the force majeure certificate. It is issued by the Chamber of Commerce of the Russian Federation and its regional units. This service is free of charge starting from 26 March 2020. In accordance with the Decree of the Government № 440, 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.

Russia

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- 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 (Roszdravnadzor).
- 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 that 25 %). The latter provision is valid until 31 December 2020.
- Moreover, on 18 May 2020 the Decree of the Government № 637, which regulates the launch of distance selling of medicines, entered into force. In order to engage in distance sales of OTC medicines pharmacies need have to own/have:
  - license to carry out pharmaceutical activities for at least one year;
  - at least 10 places (pharmacies) for carrying out pharmaceutical activities on the territory of a Russian region;
  - premises for storing orders;
  - a website with the ability to choose a payment method (mobile application is allowed);
  - their own (or contractual) courier service equipped with thermo-transportation technologies;
  - a system of electronic and (or) mobile payments that allows customer to pay for the goods directly at delivery location.

- Roszdravnadzor is authorized to issue permits for distance sales of medicines and maintain a register of pharmacy websites that are allowed to engage in distance sales. The decision to issue / refuse to issue a permit shall be made by Roszdravnadzor within five working days.

- Following the initiative of the Ministry of Economic Development of Russia, the Council of the Eurasian Economic Commission exempted 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.

- In order to get exemption from customs duties with respect to the abovementioned goods, it is necessary to obtain confirmation of their designated purpose. Such confirmation may be issued by the authorized executive bodies of the constituent entities (regions) of the Russian Federation, by the Ministry of Health (for finished products) and by the Ministry of Industry and Trade (for raw materials, materials and components).

Russia

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- 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 on 14 May 2020 the extended recommendations related to inspection control, sampling and other scheduled work subject to the spread of COVID-19:
  - in relation to valid certificates of conformity for serial products, if the next scheduled inspection control falls within the period from 15 March to 31 December 2020, the certification body may decide to postpone the inspection control for up to six months,
  - in relation to certificates of conformity for serial products, whose validity period expires in the period from 15 March to 31 December 2020, as well as in relation to certification of new products that have slight differences in design (formulation) and manufacturing technology that do not affect their safety, the certification body may decide to issue a new serial certificate.

- The Decree of the Government № 789 introduced amendments into the rules for inspecting pharmaceutical manufacturers and issuing GMP certificates. In case of emergency, when it is impossible to inspect the manufacturing site, the validity of the GMP certificate must be calculated in a different manner, namely, it shall be calculated from the day when the inspection of the manufacturing site was completed in accordance with the documents (including with the use of remote communication tools, including audio or video). This special rule shall be applied, if at least one of the following situations exists:
  - threat of occurrence, occurrence and liquidation of emergencies;
  - threat of spread of dangerous diseases (such as COVID-19), as well as diseases and injuries resulting from adverse chemical, biological, radiation factors.

  Regardless of the situation the GMP certificate shall be issued for 3 years, as before. The validity of GMP certificates, that have expired or expire in the period from 15 March to 31 December 2020, shall be extended for 12 months from the date following the date of expiration of such GMP certificates.

- The Government of the Russian Federation has established a separate, simplified, procedure for 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 5 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 his medical device and submit to Roszdravnadzor the documents 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.

Russia

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- The Government of the Russian Federation has approved the 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 363 items, including: ventilators, extracorporeal membrane oxygenators, surgical suits, insulating suits and disposable masks, thermometers, pulse oximeters, protective screens for face and eyes, humidifiers, filters. 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 two days and, in the absence of remarks, shall issue a temporary registration certificate to be valid until 1 January 2021. Moreover, it is allowed to put into circulation, import, transport, carry out storage, use and destruct 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 № 441 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;
  - 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;
  - the Russian Ministry of Health issues to the applicant a registration certificate which shall be valid until 1 January 2021.

Russia

Clinical trials

- Have special measures been adopted?
- What are the main changes?

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.

Moreover, on 27 March 2020, the Association of Clinical Research Organizations (AOKI) asked the Russian Prime Minister to clarify the procedure for the air transportation of pharmaceuticals in connection with the spread of COVID-19. The main issue nowadays is how to organize the process of importing medicines and exporting biological samples. The Association of Clinical Research Organizations requested to clarify whether the measure introduced by the Russian Government to stop regular and charter flights from 27 March 2020 applies to air cargo.

South Africa

Matters	Summary
Specific COVID-19 legislation	Legislation: ▪ Disaster Management Act 57 of 2002 (accessible here) Regulations: The following regulations have been published in accordance with the declaration of a national state of disaster and the imposition of a Nationwide Lockdown (defined below) across South Africa: ▪ COVID-19 Block Exemption for the Healthcare Sector (accessible here) ▪ Classification of a National Disaster (accessible here) ▪ Disaster Management Act Regulations, published on 18 March 2020 (accessible here) ▪ Amended Disaster Management Act Regulations, published on 25 March 2020 (accessible here) Guidelines: The following guidelines, as it relates to healthcare businesses, have been published in accordance with the declaration of a national state of disaster and the imposition of a Nationwide Lockdown (defined below) across South Africa: ▪ Guidelines for case finding, diagnosis, management and public health response in South Africa (accessible here) Notices and announcements: The following notices and announcements, as they pertain to healthcare businesses, have been made in accordance with the declaration of a national state of disaster and the imposition of a Nationwide Lockdown (defined below) across South Africa: ▪ Competition Act: regulations related to COVID-19 (accessible here) ▪ National Institute for Communicable Diseases (NICD) announcements (accessible here) ▪ South African Health Products Regulatory Authority announcement in relation to medicine and medical device supply challenges (accessible here)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	Measures adopted by the government: ▪ Designated hospitals in each province have been identified to deal with the COVID-19 outbreak. Additionally, a public health management program has been implemented to significantly increase screening, testing, contact tracing and medical management. ▪ Community health teams will focus on expanding screening and testing where people live, focusing first on high density and high-risk areas. ▪ A system for "centralized patient management" for severe cases and "decentralized primary care" for mild cases has been implemented. ▪ The Department of Science and Technology has negotiated the repurposing of various facilities and laboratories to respond to the COVID-19 outbreak. ▪ As stated in the Disaster Management Act Regulations, accommodation used for persons rendering essential services, quarantine, isolation and the lockdown are prohibited from closing and are to remain open.

South Africa

Requisition powers

- Has the government established any powers to requisition assets and premises? Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products/medical devices?

- The government and hospitals operating in the private sector have agreed to accommodate people who may need to be hospitalized to treat COVID-19 even when they cannot afford it.
- Hospitals in both the public and private sector throughout South Africa have closely cooperated with the NICD and the Department of Health (DoH) on an ongoing basis, and have aligned the DoH's clinical protocols for managing COVID-19 patients with their own clinical guidelines. Additionally, hospitals throughout the country have implemented comprehensive measures to detect, identify and appropriately respond to any suspected or confirmed cases of COVID-19[2].
- Throughout the Nationwide Lockdown (defined below), no hospital visits are permitted, except for instances constituting a grave emergency.
- The government is not currently controlling the distribution of medicinal products or medical devices. However, this may change as it was reported on 29 March 2020 that South Africa is facing a shortage of ventilators (more on this report can be accessed here).

Declaration of a Nationwide Lockdown:

- The president of South Africa declared a nationwide lockdown, which will be effective from 23:59 pm on Thursday, 26 March 2020 until 23:59 pm on Thursday, 16 April 2020 (**Nationwide Lockdown**).
- During the Nationwide Lockdown, the movement of all persons outside of their residences will be strictly restricted to performing essential services, obtaining essential goods or seeking medical attention. No other movement of persons may occur during the Nationwide Lockdown. All businesses that are not regarded as essential services will be required to cease operations for the duration of the Nationwide Lockdown.
- It should be noted, however, that healthcare businesses, including health workers in the public and private sectors, paramedics, laboratory services, essential care of the elderly and sick persons (including home-care and old-age homes), pharmacies and those involved in the supplying, manufacturing and transportation of medical and hygiene products, will be regarded as essential services and will be exempt from the restrictions imposed under the Nationwide Lockdown.

Restrictions imposed at ports of entry into South Africa:

- South Africa's main ports will continue to operate. However, berths at Durban and Cape Town, Port Elizabeth and the deep-water Port of Ngqura in the Eastern Cape have been reduced, while Richards Bay and East London are being closed during the Nationwide Lockdown.
- Ports may receive essential cargo whereby medical supplies and food products will be prioritized. All shipments will be subject to sanitization processes to combat the spread of COVID-19.

[2] This has been done by, among other things: (i) ensuring that every person entering their facilities sanitizes their hands; (ii) ensuring that all persons entering their facilities are verbally screened for COVID-19 risks at the main points of entry as a first line of defense, and conducting further screening where indicated; (iii) erecting gaze bos or tents at entrances to emergency departments and main hospital entrances where authorized staff members will conduct the relevant screenings; (iv) closing certain entrances to facilities to ensure adherence to hand cleaning and screening; (v) deploying ultraviolet light disinfection robots in those hospitals that do not yet have their own as soon as possible; (vi) restricting visiting times in hospitals and the number of visitors allowed to visit a patient at one time; (vii) screening all staff on a daily basis, including personnel of external service providers in all areas of the business; and (viii) recording all persons entering into hospitals.

South Africa

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Pricing of medical products (including medicines and medical devices): ▪ The Competition Act: Regulations related to COVID-19 control the pricing of essential goods and services during the Nationwide Lockdown, which includes medical products. ▪ The Competition Act: Regulations related to COVID-19 creates strict prohibitions on the excessive pricing of emergency products, services, medical and hygiene supplies to the detriment of consumers or customers. ▪ Contraventions of the Competition Act: Regulations related to COVID-19 carry a fine of up 10% of a firm's turnover and/or a period of imprisonment not exceeding 12 months.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	Exceptional public procurement procedures: ▪ 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/or commodities required to reduce and control the spread of the COVID-19 virus, which would naturally include medical-related products. ▪ It 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. ▪ As of 29 March 2020, no procedural requirements have been relaxed in any sphere, including medication and devices. ▪ Currently, no sanctions are foreseen for unfilled orders.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ A directive issued by the chief justice of South Africa (accessible here) has declared that courts should only remain open for extremely restricted matters. ▪ This includes the filing of papers and hearing urgent applications (mainly related to the Nationwide Lockdown), bail applications and appeals or matters relating to violations of liberty, domestic violence, maintenance and matters involving children. This will be applicable for the duration of the Nationwide Lockdown. ▪ Additionally, on 26 March 2020, the minister of justice and correction services issued a directive that provides that, among other things, time limits imposed by any rules of court will be suspended and will recommence after the termination or lapsing of the period of the national state of disaster.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	▪ Parts of the competition regulations allow 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.

South Africa

Clinical trials

- Have special measures been adopted?
- What are the main changes?

- 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 (the report is accessible here).
- Eight 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 there are no regulatory delays.

Measures adopted by the South African Health Products Regulatory Authority:

- 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 anti-virals will be implemented.
- The South African Pharmacy Council and Regulatory Affairs Association has not yet issued a statement on whether they will shut down operations. They are proactively working with institutions for research purposes, and to develop a vaccine as a matter of urgency, and they have given approval for Austell Pharmaceuticals to donate 500,000 chloroquine phosphate tablets for use by the DoH. They are also issuing updates on the status of medicinal supplies and calling upon the public not to bulk buy purchases of essential supplies and medical items (accessible here).

Medical research:

- The University of Cape Town, the Council for Scientific and Industrial Research and Biovac have started researching and developing a potential vaccine for COVID-19.
- The Department of Science and Innovation has availed ZAR 12 million and it will redirect an additional ZAR 30 million to further the development of a vaccine for COVID-19.

Spain

Matters	Summary
Specific COVID-19 legislation	With the end of the State of Alarm on 21 June 2020, several Orders and Resolutions issued by the Spanish authorities over the last months and linked to the State of Alarm are no longer in place. Nevertheless, many other measures remain in force: ▪ Royal Decree Law 7/2020 of 12 March adopting urgent measures to tackle the economic impact of COVID-19 ▪ Royal Decree Law 8/2020 of 17 March on extraordinary urgent measures to deal with the economic and social impact of COVID-19 ▪ Royal Decree-Law 15/2020, of 21 April on extraordinary urgent measures to deal with the economic and social impact of COVID-19 ▪ Royal Decree Law 16/2020, of 28 April adopting procedural measures to combat COVID-19 ▪ Royal Decree-Law 17/2020, of 5 May adopting proceeding measures to combat COVID-19 ▪ Royal Decree-Law 21/2020 of 9 June on urgent prevention, containment and coordination measures to address the health crisis caused by COVID-19 ▪ Order SND/354/2020 of 19 April establishing measures to guarantee access to the products recommended preventing COVID-19 infection ▪ Resolution of the National Health System General Directorate of 22 April establishing the prices to the public of certain products ▪ Resolution of the National Health System General Directorate of 2 May establishing the prices to the public of certain products ▪ Resolution of the Industry General Directorate of 23 April regarding PPE related to the healthcare crisis caused by the COVID-19 ▪ Resolution of the Spanish Agency for Medicines and Medical Devices of 19 June establishing the list of medicines considered essential in the management of the health crisis caused by COVID-19 ▪ Guideline with instructions to obtain the temporary operating licenses ▪ Recommendations for action in the pharmaceutical production and distribution industry in cases of COVID-19 infection published by the Spanish Agency of Medicines and Medical Devices (**AEMPS**) ▪ Exceptional measures applicable to clinical trials during the COVID-19 emergency

Spain

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Royal Decree 463/2020 of 14 March declaring a state of alarm to manage the current COVID-19 health crisis provided authorization for the Ministry of Health to intervene and occupy several types of facilities and to seize all types of property. However, the effects of Royal Decree 463/2020 expired on 21 June 2020. ▪ At present, and 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 upon availability of new information 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) 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. ▪ The Spanish Agency of Medicines and Medical Devices has also established the controlled distribution of the stock of hydroxychloroquine/chloroquine. The marketing authorization holders cannot introduce more hydroxychloroquine/chloroquine units in the market unless agreed by the health authorities.

Spain

Pricing and reimbursement

- Has the price and reimbursement procedures for medicinal products and medical devices been affected?

- Article 7 of Royal Decree Law 7/2020 of 12 March amends Article 94.3 of the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices. It is expected that the government will be allowed to regulate the mechanism for pricing non-prescription medicines and medical devices, along with other products necessary to protect the general public health, that are dispensed on Spanish territory in accordance with an objective and transparent general scheme. It also provides for the eventuality that in the event of exceptional public health circumstances, such as the present one, the Interministerial Medicinal Product Pricing Committee may set the maximum amount of sales to the public of these medicines and products for the time that the exceptional circumstances last. Therefore, currently, the committee may adopt such decision for any of these medicinal products or medical devices during the state of alarm.
- The Ministry of Health has approved the procedure to set the maximum sale price to the public of certain medical devices and other health protection products (such as masks or hydroalcoholic solution, etc.). It has also established the information that must appear on the labelling of hygienic masks and some requirements regarding the fulfilment of certain technical specifications. Also, it has clarified that those masks that are not individually packed can only be sold to the public in pharmacies.
  For the moment, the authorities have established the prices to the public (VAT or IGIC included) for the following products:
  - Surgical masks: EUR 0.96 per unit;
    The prices will be applicable from 24 April 2020, but the authorities can review and modify such prices.
  - Antiseptic wash of healthy skin authorized by the AEMPS (biocides):
    - Up to 150 ml: EUR 0.032 per ml;
    - Between 151 ml and up to 300 ml: EUR 0.023 per ml;
    - Between 301 ml and up to 1000 ml: EUR 0.015 per ml.

    The prices will be applicable from 6 May 2020, but the authorities can review and modify such prices.
  - Gels and hydroalcoholic solutions temporary authorized by the Spanish Medicines and Medical Devices Agency (AEMPS). The prices applicable from 24 April 2020 until 5 May 2020 are the following:
    - Between 150 ml and up to 300 ml: EUR 0.018 per ml;
    - Between 300 ml and up to 1000 ml: EUR 0.015 per ml.

    The prices applicable from 6 May 2020 are the following:
    - Up to 150 ml: EUR 0.025 per ml;
    - Between 151 ml and up to 300 ml: EUR 0.021 per ml;
    - Between 301 ml and up to 1000 ml: EUR 0.015 per ml (price not modified).

    The authorities can review and modify such prices.

  The authorities have also established that the prices of the hygienic masks and antiseptic wash of healthy skin authorized by the AEMPS will be established in the next meeting of the Commission adopting such decisions (they are obtaining further information on costs to establish the prices).

  The Spanish Government has also established a 0% rate of the VAT of the supply of goods, importations, and acquisitions within the EU of the products listed on the Annex of the Royal Law-Decree 15/2020 (which mainly are medical equipment, PPE -some gloves, masks, and coveralls are included-, some medicines and medical devices) provided that the purchasers are public entities, hospitals or medical centres, or social private entities. The above will apply from 23 April and until 31 July 2020.

Spain

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ With regard to services and supply public sector contracts that must be provided on an ongoing basis (such as the supply of medicinal products or medical devices), they can now be suspended if their performance becomes impossible as a result of COVID19 or the measures taken by the authorities to combat it. The above is subject to the contracting authority, at the request of the contractor and within five calendar days, determining that it is impossible to execute the contract (meaning "absolute unfeasibility to execute the contract"). ▪ Regarding supply and service contracts other than successive execution contracts where the contractor is delayed as a result of COVID-19 or the measures taken by the authorities to combat it, and the contractor offers to meet its obligations if the deadline is extended, the contracting authority: (i) will grant an extension for a period that will be at least equal to the time lost, unless the contractor requests a shorter one; and (ii) pay the additional salary costs actually incurred up to a limit of 10% of the initial contract price (following a request and due evidence by the contractor). In such cases, no penalty will be imposed on the contractor and the contract will not be terminated. ▪ With regard to public works concession and service concession contracts, the de facto situation created by COVID-19 and the measures taken by the authorities will be considered force majeure, entitling the concessionaire to restore the economic balance of the contract by extending its initial duration by a maximum of 15% or by amending the economic clauses included in the contract. This rebalancing will in any case compensate the concessionaires for the salary costs paid during the period of the situation (following a request and due evidence by the contractor). This will only apply if the contracting authority, at the request of the contractor, recognizes that it is impossible to perform the contract. ▪ The above will not apply to contracts for health, pharmaceutical or other services or supplies whose object is linked to the health crisis caused by COVID-19, which will be subject to the emergency procedure. Any contract entered into by the General State Administration or its public bodies and public law entities to cover the need to protect the public and other measures adopted by the Council of Ministers to address COVID-19 constitutes an emergency contract and is therefore subject to the emergency procedure provided for in the Public Sector Contracts Law. ▪ Procedural requirements have not been formally relaxed for COVID-19-related medicines and devices. However, a modification of the Public Procurement Law has been approved in connection to the open simplified procedure to allow the non-public opening of the offer. ▪ No specific sanctions have been approved in case of unfilled orders
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ As a rule, procedural and administrative deadlines (including periods of prescription or limitation) were suspended and interrupted for the duration of the State of Alarm. However, since the end of the State of Alarm on 21 June 2020 said deadlines have been resumed. ▪ Public procurement procedures were also suspended (even though the contracting body had the possibility to continue the procedures when justified) and have now been resumed.

Spain

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

The Ministry of Health has relaxed the authorisation requirements for manufacturing surgical masks and medical gowns. These measures include: (i) the possibility of granting temporary operating licences to manufacturing facilities, 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 products that are critical to protect public health and that have not obtained the CE mark, after evaluation of the available documentation and assessment of the health guarantees required in each case. The Ministry of Health has expressly stated that the Government will assume any liability from the relaxation of the established measures, if no commercial benefit has been obtained from such operations.

The Spanish regulator (AEMPS) has issued a guideline to help companies obtain the temporary operating licenses. These requests shall be processed as a matter of priority and urgency.

With regard to biocides, Royal Decree 21/2020 authorizes the use of bioethanol that complies with minimum specifications (as specified 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.

The authorities have agreed that PPE without CE mark can be sold to public entities and each contracting body will check whether the products are correct. Additionally, authorities have also established a temporary authorization for PPE that without having the CE mark comply with certain standards that guarantee a minim level of safety (the notification body will be the responsible to evaluate it). Said authorizations will be in force until the obtaining of the CE mark or until 30 September 2020. Information must be borne that the product does not have the CE mark and has been temporary authorized. The Annex to the Resolution of the Industry General Directorate, of 23 April, specifies harmonized standards that will be considered sufficient regarding protection masks (FFP2 and FFP3), gloves, protection clothes and ocular and facial protection equipment. Finally, the Resolution also allows the granting of such temporary authorization to those PPE that have a CE mark based on another technical specification according to sections 3 and 4 of the EU Recommendation 2020/403.

The above measures will only apply during the COVID-19 sanitary crisis.

Spain

Clinical trials

- Have special measures been adopted?
- What are the main changes?

- Clinical trial COVID-19 measures include:
  - replacing patients' appointments in person with telephone appointments and/or rescheduling the appointments
  - interrupting the treatment
  - accessing the medicinal products under treatment (supplying the patient with more medicinal products than usual, supplying individuals authorized by the patients and home delivery)
  - updating the monitoring plans of the clinical trial for the next four months and prioritizing centralized and remote monitoring
  - transferring patients from one center to another
  - prioritizing the evaluation of clinical trials addressed to treat or prevent coronavirus
- The measures on clinical trials taken during this period have to be included in the clinical trial file. The implementation of these measures does not require the prior approval of AEMPS or the Ethical Committee, except for the measure in the second bullet point above. During the four months after the date the COVID-19 emergency in Spain ends, the sponsor will send AEMPS and the Ethical Committee a report of the exceptional measures taken.
- The AEMPS has updated the initial recommendations on clinical trials and 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.
- Based on recent studies suggesting that hydroxychloroquine/chloroquine do not provide any clinical benefit against COVID-19, the AEMPS has adopted different measures aimed at ensuring ongoing trials based on such active ingredients offer new evidence on its effectiveness. Among others, recruitment efforts should target patients with different characteristics from those recruited in the trials that offered such conclusions.
- Finally, in the context of resumption of face-to-face scientific and technical activities (including face-to-face monitoring of clinical trials), Pharmaindustry (the Spanish Pharma industry association) has published a set of mandatory measures aimed at protecting the health of the professionals in the industry. Among other measures, professionals working on-site must have the adequate protective equipment, carry out diagnostic tests when indicated, and extreme the prevention and safety measures. The must also carry out training programmes regarding risk prevention and good health and hygiene practices before returning to on-site activity.

Sweden

Matters	Summary
Specific COVID-19 legislation	The government has proposed measures to mitigate the economic impact and the infection spread: ▪ Governmental Decree (2020:126) on appointing the National Board of Health and Welfare as the national purchasing center for medical supplies, protective equipment and certain medical devices, and achieving a good working environment for personnel in healthcare, social services and the Support and Service for Persons with Certain Functional Impairments Act ▪ Governmental Decree (2020:163) on temporary ban on visits to special housing for the elderly to prevent the spread of COVID-19 ▪ Government Bill (2019/20:152) on temporary permit exemptions for the construction of field hospitals ▪ Government Bill (2019/20:144) on the Swedish Parliament to classify COVID-19 as a disease dangerous to society and societal functions under the Swedish Communicable Diseases Act (2004:168) (non-exhaustive list)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ The government has not adopted any measures to requisite assets or premises. ▪ The government has not adopted any measures to convert hotels into hospitals. However, field hospitals are being built in collaboration with the Swedish Armed Forces to treat COVID-19 patients. ▪ The government has adopted measures to limit the purchase of prescription drugs to cover only three months' consumption. ▪ In response to the urgent need for medicines, medical devices and medical supplies, the 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 equipment across the country. ▪ Normally, it is not permissible to transfer medicines between pharmacies. However, the Swedish Medicines Agency (**MPA**) has imposed reliefs in this regard by allowing pharmacies that need to be closed for an extended period during the ongoing pandemic to transfer medicine to another pharmacy with the same licensee.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Price and reimbursement procedures for medicinal products and medical devices have not been affected.

Sweden

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ No exceptional public procurement measures have been adopted other than the above-mentioned reorganization of the national supply scheme, where the National Board of Health and Welfare was appointed as the national purchasing center for medical supplies to facilitate the supply of equipment across the country. ▪ No procedural requirements have been relaxed for COVID-19 related medicines and devices. ▪ Sanctions for unfilled orders are regulated in each specific agreement between the parties.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	The government has proposed the following measures: ▪ temporary suspension of the deduction from sick pay during the qualifying period ▪ the requirement of a doctor's medical report for an employer is temporarily suspended for the first two weeks of illness ▪ the requirement of a doctor's medical report for the application of sick pay is temporarily suspended from 27 March and during the first 21 days of illness The government has decided that the extradition of public documents at all Swedish authorities must proceed normally with urgency. However, the requisite to deliver urgently has been relaxed to delivering **as soon as possible** for some authorities.

Sweden

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

The MPA has granted emergency licenses 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 breathing problems. The relief means that treating physicians do not need to apply for a license from the MPA for each patient to treat them with remdesivir. Furthermore, the European Medicines Agency has recommended granting of use of remdevisir for COVID-19 patients.

The government has given the Swedish Work Environment Authority the authority to approve PPE not bearing CE marking, following the European Commission's recommendation (EU) 2020/403. The approved PPE may be used by healthcare workers, the military, first responders and other personnel enforcing law and order or involved in the efforts to contain the virus and avoid its further spread.

On June 29, 2020, the Swedish Work Environment Authority clarified that the following businesses may also use approved PPE:

- Measures to medically prevent, investigate and treat sicknesses and injuries;
- Rescue services;
- Care of deceased;
- Care for elderly;
- Home-help;
- Business conducted in accordance with the law (1993:387) on support and service to certain disabled persons, including personal assistance;
- Assisted living facilities and homes for care or living (HVB);
- Homes run by the Swedish National Board of Institutional Care (Sw. *Statens institutionsstyrelse*);
- Criminal care;
- Dental care;
- Animal healthcare; and
- Civil protection.

For example, the Swedish Work Environment Authority has granted temporary authorization for the use of non-CE marked military grade gas masks (*Skyddsmask 90*).

In addition, the government has amended the requirement that PPE must be accompanied with instructions written in Swedish. Now, PPE intended for professional use to combat the spread of COVID-19 may be accompanied with instructions written in other languages than Swedish, if the language is easily understood by the end user.

Sweden

Relaxation of regulatory rules
 	
▪ Has the government relaxed regulatory rules?
	The Swedish Medical Products Agency has released a regulation which allows instructions for medical devices to be written in other languages than Swedish. The instructions may be written in English, Norwegian or Danish, if the following conditions are fulfilled:
	▪ the product is intended for use in healthcare, and
	▪ the product meets the requirements for CE marking of medical devices, and
	▪ it is ensured that the product can be used safely by healthcare staff even though the product's labeling and user instructions are not written in Swedish, and
	  ▪ the product shall be used to diagnose patients suspected of having or having had COVID-19, or
	  ▪ the product shall be used in the care and treatment of patients with COVID-19, or
	  ▪ there is, or there is a risk for, a shortage situation in the Swedish market regarding the current product due to COVID-19.

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	Clinical trial COVID-19 measures include: ▪ Reliefs for delivering trial products to participants directly, allowing clinical trials to proceed as planned. ▪ The Ethical Review Agency has created a procedure to handle requests for granting priority to authorizations of clinical trials regarding COVID-19.

Switzerland

Matters	Summary
Specific COVID-19 legislation	Ordinance 3 on Measures to Combat the Coronavirus (COVID-19 Ordinance 3) of 19 June 2020 (as amended) - the previous Ordinance of 13 March 2020 has been repealed and replaced. Swiss Federal 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. The Ordinance on Measures to Combat the Coronavirus (COVID-19) of 19 June 2020 is now also based on such law in addition to Article 185 Para. 3 of the Swiss Constitution.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	***Healthcare Provision*** The government has the power to convert hotels into hospitals/medical centers for quarantine and self-isolation but has not yet done so. However, the federal government empowered the cantons to require private hospitals and clinics to make their facilities available for the admission of patients. ***Provision of Essential Medical Goods*** There is an exhaustive list of medicinal products, medical devices and protective equipment that qualify as essential medicinal goods. The Federal Department for Public Health (FDPH) determines the quantities of essential medical goods required in consultation with: (a) the Interdepartmental Working Group on Medical Goods: for active substances and drugs, medical devices, personal protective equipment and other equipment; (b) the Spiez Laboratory: for in-vitro-diagnostics (COVID-19 tests) and associated reagents. On procurement, to support the provision of essential medical goods to the cantons and their healthcare facilities, charitable organisations (for example Swiss Red Cross) and third parties (for example laboratories, pharmacies), essential medical goods may be procured if requirements cannot be covered through the normal procurement channels. The Armed Forced Pharmacy is responsible for procuring essential medical goods on behalf of the FDPH. The Armed Forces Pharmacy then manages the procured essential goods as instructed by the Interdepartmental Working Group on Medical Goods. In addition, a company with a wholesale or import license may be instructed to import medicinal products. As regards allocation, cantons submit requests for allocation for essential medical goods and allocation is made continuously based on the supply situation and the current number of cases in each canton. For COVID-19-Tests, laboratories, manufacturers and distributors regularly have to notify the Laboratory Spiez their current stock of such tests. The Laboratory Spiez is responsible for the allocation of these tests. If the provision of essential medical goods cannot be guaranteed, the FDHA at the request of the Interdepartmental Working Group on Medical Goods may require individual cantons or public healthcare facilities that have adequate stocks of medicinal products to deliver part of their stocks to other cantons or healthcare facilities. Furthermore, the FDHA at the request of the Interdepartmental Working Group on Medical Goods may order the requisitioning of essential medical goods held by companies. Finally, the federal government also has the power to request manufacturers to manufacture essential medical goods, to prioritize the manufacturing of such goods or to increase the number of the manufactured goods.

Switzerland

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	The federal government will pay the costs of outpatient molecular-biological analysis (max. CHF 156), serological antibodies analysis (max. CHF 99) and immunological analysis for antigens (max. CHF 99) for Sars-Cov-2 for persons who fulfill clinical criteria for suspicion, sampling and reporting as established and are tested by designated services providers or test centers (Article 24 COVID-19 Ordinance 3 together with Annex 6 to COVID-19 Ordinance 3). Persons tested shall not be required to pay a share of the costs and procedure for paying the analysis costs (between service providers, insurers and the government) is set out in the law (Article 26a COVID-19 Ordinance 3).
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The Armed Forced Pharmacy is responsible for procuring essential medical goods on behalf of the FDPH. The responsible authorities may also delegate the procurement of essential medical goods to third parties. Furthermore, if the provision of essential medical goods cannot be guaranteed, the FDHA at the request of the Interdepartmental Working Group on Medical Goods may require individual cantons or public healthcare facilities that have adequate stocks of medicinal products to deliver part of their stocks to other cantons or healthcare facilities. In addition, the FDHA at the request of the Interdepartmental Working Group on Medical Goods may order the requisitioning of essential medical goods held by companies. The federal government also has the power to request manufacturers to manufacture essential medical goods, to prioritize the manufacturing of such goods or to increase the number of the manufactured goods. Finally, a company with a wholesale or import license may be instructed to import medicinal products. Other than the measures mentioned above, no specific public procurement rules have been adopted so far.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	No legal deadlines have been suspended or relaxed with respect to the healthcare sector. However, to the extent that the applicable procedural law provides for a stay of the statutory limitation periods or periods set by the court over Easter, such stay was extended to run from 21 March 2020 to 19 April 2020. This has no impact on MA approvals or public procurement except on any subsequent lawsuit in that respect.

Switzerland

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	Yes. ***Medicinal Products*** Medicinal products that are manufactured with certain specific active substances explicitly mentioned by law for the treatment of COVID-19 patients may, provided an application for authorization of a medicinal product containing one of these active substances has been filed, be placed on the market without authorization pending the decision of Swissmedic (the Swiss Agency for Therapeutic Products) on authorization. When examining applications for authorization, Swissmedic may permit a relaxation of the relevant requirements for such medicinal products under the law on therapeutic products on the basis of 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 authorization for a medicinal product authorized in Switzerland containing a specific active substance listed by law that is used to prevent and treat COVID-19 in Switzerland may be made immediately after filing a corresponding amendment application. Swissmedic may permit a relaxation of the relevant requirements for such amendments. Swissmedic may on the basis of a risk-benefit analysis permit changes to the manufacturing process approved within the framework of the authorization of medicinal products used to prevent and treat COVID-19 in Switzerland. Swissmedic has published a guidance document on the authorization procedure for COVID-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 a pandemic 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

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	***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 evaluation criteria for the placing on the market of important non-conforming medical devices for combating the COVID-19 pandemic 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 take (re)introduce appropriate measures to ensure adequate supply of protective equipment. Personal protective equipment that was permitted before the amended of 11 September 2020 may continue to be placed on the market until 30 June 2021. Finally, due to public demand, Swissmedic has also issues 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.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	No. However, joint guidance from Swissmedic and swissethics on the management of clinical trials with medicinal drug products in Switzerland during the COVID-19 pandemic has been issued. The authorities will prioritize 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. During the COVID-19 pandemic period, the delivery of study medication directly to the study patient from the trial site might be permissible, provided that 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 their information. The guidelines also deal with other issues related to clinical trials such as the patient's informed consent. 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 trial activities following the COVID-19 pandemic. In fact, during the first wave in Spring 2020 and with the first set of measures 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.

Turkey

Matters	Summary
Specific COVID-19 legislation	▪ Presidential Circular No. 2020/3 regarding the postponement of meetings and organizations ▪ Amending Communique on Prohibited Goods and Goods Subject to Prior Approval (**Communique**) ▪ The Ministry of Health's Circular on COVID-19 Measures for Health Service Providers ▪ The Ministry of Health's Instruction Letter to Pharmacies regarding COVID-19 Measures ▪ Announcements, instructions and guidelines of the Turkish Pharmaceuticals and Medical Devices Agency (**TİTCK**) ▪ Amending Decrees on Import Regime (regarding respirators)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	No. The ministries, however, have been tightening their measures and increasing their inspectional activities. In this regard, although the Turkish government has not yet authorized the public authorities to requisition assets and premises, it may be possible for the government to adopt measures that are generally more restrictive in the immediate future due to the increase in COVID-19 cases. No specific regulation converting hotels into hospitals/medical centers has yet been introduced. Certain hotels, however, on their own initiative, have been providing accommodation services to healthcare personnel with no charge during the COVID-19 outbreak. The distribution of medical devices/pharmaceuticals is not directly restricted. On 26 March 2020, however, the TİTCK required hospitals to make unit dosage notifications through the Pharmaceuticals Track & Trace System for certain pharmaceuticals used for the treatment of COVID-19. In other words, the TİTCK will track these pharmaceuticals and it may possibly introduce restrictions for the distribution of such pharmaceuticals as a measure to combat COVID-19 effectively. 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%).
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	No specific price and reimbursement procedure for pharmaceuticals and medical devices has yet been adopted. As noted above, however, the ministries have already been taking certain measures such as customs restrictions and the tracking of pharmaceuticals. In this regard, it may be possible for the Turkish government to adopt certain price and reimbursement measures in the future due to the increase in COVID-19 cases.

Turkey

Public procurement

- Has the government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for COVID-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

No sector-specific public procurement measures have yet been adopted. The government has not adopted any exceptional public procurement measures. However, the COVID-19 outbreak may trigger emergency provisions embedded in the legal framework. In other words, the urgency stemming from the pandemic enables public tender authorities to use expedited emergency procurement procedures as opposed to lengthy and scrutinized open tender procedures. For your reference, please find brief explanations regarding these procedure changes below.

Under normal circumstances, much of the public procurement is done through open tenders and direct procurement.

- Open tenders, as regulated under the Public Tender Law, are complicated and thoroughly regulated processes that impose time-consuming safeguards such as tender announcements, seeking bonds from participants, awarding tenders and executing the contract between the procurement authority and the winning tenderer. Open tender processes are frequently appealed and put to judicial review throughout the process, which may lead to tenders being canceled. The process may take months.
- On the other hand, direct procurement, as regulated under Article 22 of the Public Tender Law, is a simplified procurement process. Direct procurement is only available in prescribed circumstances, including but not limited to: (i) the purchase of emergency, patient-specific or perishable medical consumables or supplies; and (ii) the rent or purchase of real estate per a public entity's needs. The procurement is expedited since the procurement authority is not obligated to prepare tender documents, make an announcement or set up a tender committee. In some cases, it is even possible not to have a technical specifications document or to execute a written contract at the end of the procurement. This process can be completed within days as opposed to months.

Under the emergency circumstances of COVID-19, a public procurement method called "bargaining tender," regulated under Article 21 of the Public Procurement Law, is available to address the outbreak. Public authorities frequently use this method to address urgent procurements. The emergency of COVID-19, however, activates Article 21(b) of the Public Procurement Law, which is reserved for infectious disease outbreaks when time is of the essence for the completion of the procurement. Accordingly, public authorities can use this tool when the procurement is: (i) related to the emergency of the infectious disease; and (ii) the procurement should be completed as soon as possible. Bargaining tenders do not have to be announced in principle, as only invited companies submit bids to the tenders, and the participants may not have to post a performance bond under certain conditions.

As noted above, there is no sector-specific guidance or relaxed procedures for public procurements in relation to pharmaceuticals or medical devices. Having said that, given the increase in COVID-19 cases in Turkey, the Turkish authorities may shed light on this matter in the immediate future.

Turkey

Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	All time limits regarding the origination, exercise and termination of any rights, including but not limited to the statute of limitations, peremptory terms for filing legal actions, commencing enforcement proceedings, warnings, notices, submissions, complaints, objections and mandatory administrative application timelines, and other timelines under certain laws (e.g., the Code of Administrative Procedure), are suspended from May 1, 2020 to June 15, 2020. Having said that, the TİTCK did not provide any guidance on whether these measures apply to the administrative timelines under the healthcare legislation. For the TİTCK's announcements on regulatory rules, please see the section "Relaxation of regulatory rules" below.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	In principle, all medical devices placed on the Turkish market must be registered with the Product Tracking System. For the 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 the physical submission of these documents and it will grant a 60-day 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. The TİTCK will also accept the submission of documents that do not have to be submitted physically (such as the ISO 13485 certificate or authorized distributorship certificate) if the apostillization procedures for these documents could be completed in a timely manner. The TİTCK also announced that the effective period of approvals for off-label use or the use of the pharmaceutical procured from abroad (name patient sales) is extended to 30 June 2020 if the approvals expire between 1 March 2020 and 30 June 2020. It is worth noting that the TİTCK has been very active recently, publishing official announcements on regulatory requirements on a daily basis. Therefore, we expect the TİTCK to provide further guidance on how the regulatory requirements should be interpreted during the COVID-19 outbreak.

Turkey

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	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: ▪ 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 rescheduled. The TİTCK also allows remote monitoring if physical monitoring at the research center is unfeasible, which is 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 volunteer visits to research centers to be postponed if 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. It stated that applications would be made electronically.

United Kingdom

Matters	Summary
Specific COVID-19 legislation	Coronavirus Act 2020 The Statutory Sick Pay (General) (Coronavirus Amendment) Regulations 2020
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	The UK government has not yet adopted any formal powers to: ▪ requisition assets and premises. ▪ convert hotels into hospitals / medical centers for quarantine and self-isolation. ▪ control the distribution of medicinal products / medical devices. However, there have been some developments in these areas. **Production of ventilators and CPAP devices:** The UK Government is looking for businesses which 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 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. **NHS staff use of hotel accommodation:** For those staff of the UK's National Health Service (NHS) affected by Public Health England's 14 day household isolation policy, the NHS is offering staff the alternative option of staying in NHS-reimbursed hotel accommodation while they continue to work. NHS England and NHS Improvement have established a single process for NHS staff to secure accommodation at hotels within their immediate area, if they have been affected by COVID-19 in some way. The supplier of this service to the NHS is Corporate Travel Management (CTM). CTM has national agreements with a wide number of hotel operators across the country. **Distribution of medicinal products / medical devices:** The NHS has introduced measures to manage the supply shortage. These include the NHS Urgent Medicine Supply Advanced Service (NUMAS), which allows patients whose GP practice is closed to continue receiving their medicines, and Medicines Delivery Service, which supports self-isolating and vulnerable individuals.

United Kingdom

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	The UK government has written to suppliers informing them that the National Supply Disruption Response is monitoring the supply situation and will provide solutions where possible. NHS Supply Chain are focussed on the fast and safe supply of both personal protective equipment (PPE) and other critical consumables. It has put in place new delivery processes to give suppliers visibility over orders, and ensure it maximises deliveries to NHS hospitals. **NHS Essential Medicine Supply** 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.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	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. (NICE's advisory committees are made up of a lot of frontline NHS staff who cannot fulfil their NICE role due to their more pressing work with patients.) NICE is therefore working on revised timelines for all our other guidance that is not related to COVID-19 or therapeutically critical, progressing guidance and any work they can do without committee engagement. NICE has said it will communicate with its advisory committee chairs, members and stakeholders as soon as possible. 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.

United Kingdom

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The UK Government has not introduced new legislation on public procurement in response to COVID-19. However, a procurement policy note from the UK government (see here) sets out how contracting authorities may approach procurement activities as they respond to COVID-19 challenges. The guidance summaries key existing provisions under the Public Contract Regulations 2015 which facilitate expedited procurement procedures for public authorities, including: ▪ direct award due to extreme urgency; ▪ direct award due to absence of competition or protection of exclusive rights; ▪ call off from an existing framework agreement or dynamic purchasing system; ▪ call for competition using a standard procedure with accelerated timescales; and ▪ extending or modifying a contract during its term.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	**Extension of deadline for NHS's Data Security and Protection (DSP) Toolkit:** NHSX has pushed the final deadline for DSP Toolkit submissions from 31 March 2020 to 30 September 2020. Organisations can choose to complete DSPT before that date. If they do so, and if they fully meet the standard, those organisations will be awarded 'Standards Met' status, as in previous years. For background, all organisations that have access to NHS patient data and systems must use the toolkit to provide assurance that they are practising good data security and that personal information is handled correctly. **CQC Inspections suspended:** The Care Quality Commission (CQC) has announced that it will be stopping routine inspections, to focus on its primary objective to support providers to keep people safe (see here). **Postponing MHRA Good Practice (GxP) inspections:** The UK's Medicines and Healthcare products Regulatory Agency (MHRA) will only be conducting essential inspections of laboratories, clinical trials, manufacturing, distribution and pharmacovigilance until further notice. However, the MHRA are expecting organisations to maintain GxP compliance (see here). The MHRA will prioritise essential on-site inspections linked to the UK Government's COVID-19 response or any other potential serious public health risk, where these sites cannot be assessed remotely. **Medicines Approvals and Variations:** 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

United Kingdom

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	**Exemptions from UK MDR:** 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 of ventilators 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. **MHRA Guidance for Manufacturers Specials licence holders on 'packing down' medicines:** Facilities with a Manufacturers Specials (MS) licence, may under normal circumstances pack down for their own use or in response to an order from a registered pharmacy, but not for retail sale. However, the MHRA are relaxing rules on packing down for distribution to community (retail) pharmacies, provided certain conditions are complied with (see here).
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	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.

United Kingdom

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	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.

Ukraine

Matters	Summary
Specific COVID-19 legislation	▪ Law of Ukraine No. 530-IX "On Amending Certain Legislative Acts of Ukraine Aimed at Preventing Emergence and Spread of Coronavirus Disease (COVID-19)" dated 17 March 2020 ▪ Law of Ukraine No. 533-IX "On Amending the Tax Code of Ukraine and other Laws of Ukraine to Support Taxpayers for the Period of Taking Measures Aimed at Preventing Emergence and Spread of Coronavirus Disease (COVID-19)" dated 17 March 2020 ▪ Law of Ukraine No. 540-IX "On Amending Certain Legislative Acts of Ukraine Aimed at Ensuring Additional Social and Economic Guarantees due to Spread of Coronavirus Disease (COVID-19)" dated 30 March 2020 ▪ Law No. 3539-IX "On Amending Certain Laws of Ukraine Aimed at Ensuring Treatment of Coronavirus Disease (COVID-19)" dated 30 March 2020 ▪ Resolution of the Government No. 211 "On Preventing Spread of Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-CoV-2" dated 11 March 2020 ▪ Resolution of the Government No. 224 "On Approval of the List of Pharmaceuticals, Medical Devices and/or Medical Equipment Required for Taking Measures to Emergence and Spread, Localization and Liquidation of Outbreaks, Epidemics and Pandemics of Coronavirus Disease (COVID-19) Exempt from Import Duty and Importation of which into the Customs Territory of Ukraine are Exempt from Value Added Tax" dated 20 March 2020 ▪ Resolution of the Government No. 223 "On Preventing Export (Sending) of Certain Anti-Epidemic Goods outside the Customs Territory of Ukraine by Citizens" dated 16 March 2020 ▪ Resolution of the Government No. 225 "On Amending Certain Resolutions of the Government" dated 20 March 2020
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ No, as of 2 October 2020 the government has not established any powers to requisition assets and premises. ▪ As of 2 October 2020, no measures aiming to convert hotels into hospitals/medical centers for quarantine and self-isolation have been approved. At the same time, the government is considering converting non-medical facilities (e.g., sports facilities) in several regions of Ukraine into hospitals. ▪ Based on Resolution No. 223 dated 16 March 2020, the government prohibited the export of certain personal protective equipment, including masks, gloves, etc.

Ukraine

Pricing and reimbursement

- Has the price and reimbursement procedures for medicinal products and medical devices been affected?

Yes, the price and reimbursement procedures for medicinal products and medical devices have been affected as follows:

- Under Law No. 3539-IX, in addition to existing powers to regulate prices, the government was additionally empowered to: (i) set maximum wholesale and retail prices for anti-epidemic goods and socially significant products; and (ii) prohibit the mass buying and selling of the same products at prices exceeding those set by the government during the quarantine. The government establishes the list of anti-epidemic and socially significant products. This list was approved by the Resolution of the Government No. 341 dated 22 April 2020. It includes, among other things, (i) seven INNs of pharmaceuticals, including Paracetamol and Azithromycin, (ii) 11 antiseptics and disinfectants and (iii) 20 items of personal protective equipment, including medical masks, gloves etc. Change of retail prices for such products is subject to declaration.
- In addition, liability for violating the pricing regulations was increased. The fine for violating the pricing regulations was increased from UAH 85-170 (approx. EUR 3-6) to UAH 1,700 (approx. EUR 57) for individuals, and UAH 2,550 (approx. EUR 86) for companies' officials. Fines for repeated violations within one year as of imposing a previous fine were increased from UAH 170-255 (approx. EUR 6-7) to UAH 2,550 (approx. EUR 86) for individuals, and UAH 3,400 (approx. EUR 115) for companies' officials. If violations of the pricing regulations occurred during the quarantine with respect to anti-epidemic goods and/or socially significant goods, and the price of such goods exceeds the maximum price set forth by the government by 1.2, the amount of the fine is UAH 3,400-4,250 (approx. EUR 115-144) for individuals, and UAH 4,250-5,100 (approx. EUR 144-172) for companies' officials.

Public procurement

- Has the government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for COVID-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

Yes, the government has adopted exceptional public procurement measures and relaxed procedural requirements for COVID-19 related medicines and devices:

- Law No. 530-IX dated 17 March 2020 and the Resolution of the Government No. 225 dated 20 March 2020 envisaged an expedited and simplified procedure for the procurement of goods, works and services required to combat COVID-19. Under the same procedure, public procurement entities may procure goods, works and services to combat COVID-19 outside the online ProZorro platform, which is used under the standard procurement procedure. Under the simplified procedure, the procurement entity is authorized to establish its own criteria for selecting successful bidders. The procurement entity must only upload the procurement report, procurement agreement and performance report to the ProZorro platform.
- No additional sanctions for unfilled orders have been introduced. In general, liability for unfilled orders should be set forth in the procurement agreement. There is also a high risk of criminal conviction for the failure to supply to public procurement entities, especially in view of the ongoing pandemic.

Ukraine

Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Yes, legal/administrative deadlines have been suspended/relaxed: ▪ Based on Law No. 3539-IX dated 30 March 2020, most of the court procedural terms established by the law were extended for the duration of the officially declared quarantine (e.g., terms for challenging court decisions, amending claims and the consideration of cases). Where the procedural term is established by the court, it will not be shorter than the term of the officially declared quarantine (for commercial and administrative courts only). The limitation period terms (both general and specific) were also prolonged for the time of the officially declared quarantine. ▪ The above measures did not have any impact on MA approvals, public procurement, etc. At the same time, originals of MA certificates will not be issued until the end of the quarantine (the MA will be confirmed by entering relevant data into the state register of pharmaceuticals). ▪ Based on Law No. 3539-IX dated 30 March 2020, the government must ensure there are expedited legal timelines for approving MA (variation) and clinical trials (significant amendment) applications of pharmaceuticals for treating COVID-19. The government must ensure that MA (variation) applications are approved within seven calendar days and clinical trial (significant amendment) applications are approved within 10 calendar days.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	Yes, the government has relaxed regulatory rules as follows: ▪ Based on the Resolution of the Government No. 226 dated 20 March 2020, personal protective equipment, medical devices, in vitro diagnostics and active implantable devices for combating COVID-19 may be placed on the market without conducting conformity assessments 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, e.g., the purpose of importation, the product and its manufacturer. 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. ▪ Based on Law No. 3539-IX dated 30 March 2020, the Parliament of Ukraine permitted the off-label use of certain pharmaceuticals. Off-label use is permitted in case a pharmaceutical has proven to be efficient in treating COVID-19 and/or if a pharmaceutical is recommended by the authorities of the US, EU member countries, the UK, Switzerland, Japan, Australia, Canada, China or Israel for the treatment of COVID-19. The Parliament of Ukraine also permitted using unapproved pharmaceuticals if the same are recommended by authorities of states set forth above for the treatment of COVID-19. At the same time, Law No. 3539-IX does not provide guidance on the form in which the same authorities should recommend pharmaceuticals for treating COVID-19 or guidance on how the proven efficiency of a product to treat COVID-19 should be confirmed. Apparently, these criteria must be clarified by the MOH. The use of unapproved pharmaceuticals and the off-label use of approved pharmaceuticals are only permitted subject to obtaining a patient's consent. Such pharmaceuticals must be used in compliance with the clinical protocol approved by the MOH on 2 April 2020.

Ukraine

Clinical trials

- Have special measures been adopted?
- What are the main changes?

Yes, the regulator for clinical trials (the **State Expert Center** of the Ministry of Health of Ukraine (State Expert Center)) 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 with phone calls, video calls, use of electronic communication devices, etc.
- remote monitoring, provided that it does not create extra burden on trial sites and the subjects consent to their personal information being shared outside the trial site
- withdrawal of subjects from trials
- 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
- 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.

Uzbekistan

Matters	Summary
Specific COVID-19 legislation	▪ Directive of the President of the Republic of Uzbekistan "On formation of the special republican commission on the preparation of a program of measures to prevent the entrance and spread of a novel coronavirus in the Republic of Uzbekistan" No. R-5537 dated 29 January 2020 (**Directive**) ▪ Decree of the President of the Republic of Uzbekistan "On primary measures to mitigate negative influence of the coronavirus pandemic on the economy and global crisis phenomena" No. UP-5969 dated 19 March 2020 (**Decree**) ▪ Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On additional measures for prevention of spread of coronavirus infection" No. 176 dated 23 March 2020 (**Resolution 176**) ▪ Resolution of the President of the Republic of Uzbekistan "On additional measures to prevent a wide spread of coronavirus infection in the Republic of Uzbekistan" No. PP-4649 dated 26 March 2020 (**Resolution 4649**) ▪ Resolution of the President of the Republic of Uzbekistan "On additional measures to support medical workers and employees of the sanitary and epidemiological service that are involved in combating the spread of coronavirus infection" No. PP-4652 dated 26 March 2020 ▪ Resolution of the President of the Republic of Uzbekistan "On additional measures for ensuring supply of the population's needs in medicines, medical devices, medical equipment and first necessity goods" No. PP-4662 dated 27 March 2020 (**Resolution 4662**)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal ▪ products/medical devices?	The Uzbek government has not established any powers to requisition assets and premises. According to Resolution 176, regional municipalities must establish three bases in every region (four in Karakalpakstan) adapted for a 14-day quarantine regime. State sanatoriums and other recreation facilities, as well as state rest hotels, may be used to establish such bases. Resolution 4649 allows private hospitals to provide medical services to coronavirus-infected patients until 1 September 2020. Hence, private hospitals are allowed to be converted into medical centers for quarantine without formal public procurement requirements/procedures and without obtaining necessary licenses. A private hospital is allowed to provide such services after the execution of the service contract between the hospital and the Ministry of Healthcare of Uzbekistan. It implies that the Uzbek government, represented by the Ministry of Healthcare, will cover the costs of private hospitals for the treatment of patients with coronavirus infections. Resolution 176 mandates the Special Commission[1] to monitor the continual supply of essential medicines, masks and medical devices (for disinfection and other) to the population at fixed prices. The Decree established an anti-crisis fund comprising approximately USD 1 billion. Anti-crisis fund proceeds will be partially used to finance the procurement of medicines and medical devices necessary to combat the spread of coronavirus infection.

[1] Special Republican Commission for the preparation of a program of measures to prevent the entrance and spread of a novel coronavirus in the Republic of Uzbekistan, established by the Directive.

Uzbekistan

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	The Directive mandates several state authorities to conduct the daily monitoring of prices for medicines, medical devices and medical equipment, as well as materials and substances used for their production, to prevent artificial price increases due to the coronavirus epidemic. In addition, as stated above, the Special Commission will monitor the supply of essential medicines and medical devices at fixed prices.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	According to Resolution 176, public procurement procedures do not apply to the public procurement of medicines, medical devices, medical equipment, and materials and substances used for their production (as per the list approved by the government) during the epidemic period. Hence, state purchases may proceed to execute direct contracts with suppliers that provide the best offers without formal tender/bidding procedures. Currently, the approved list of such medicines, medical devices and medical equipment is not publicly available.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	According to Resolution 4662, customs duties are not imposed on imports of medicines, medical devices, medical equipment, and materials and substances used for their production (a list of which is approved by the state authorities and is not publicly available). Moreover, Resolution 4662 authorized the Special Commission to: ▪ grant certain finished medicines and medical devices with exemption from value-added tax for a period of up to three months ▪ reduce the rates of customs duties and excise tax up to 0% for imports of certain types of essential goods for a period of up to three months (the list of essential goods may be approved by the Special Commission itself) Uzbekistan is planning to adopt a law that would allow imports of medicines used to prevent dangerous infectious diseases without marketing authorizations during epidemiological situations in the country. We expect the adoption of the law in the very near future.

Uzbekistan

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	Please see our comments above.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	N/A

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