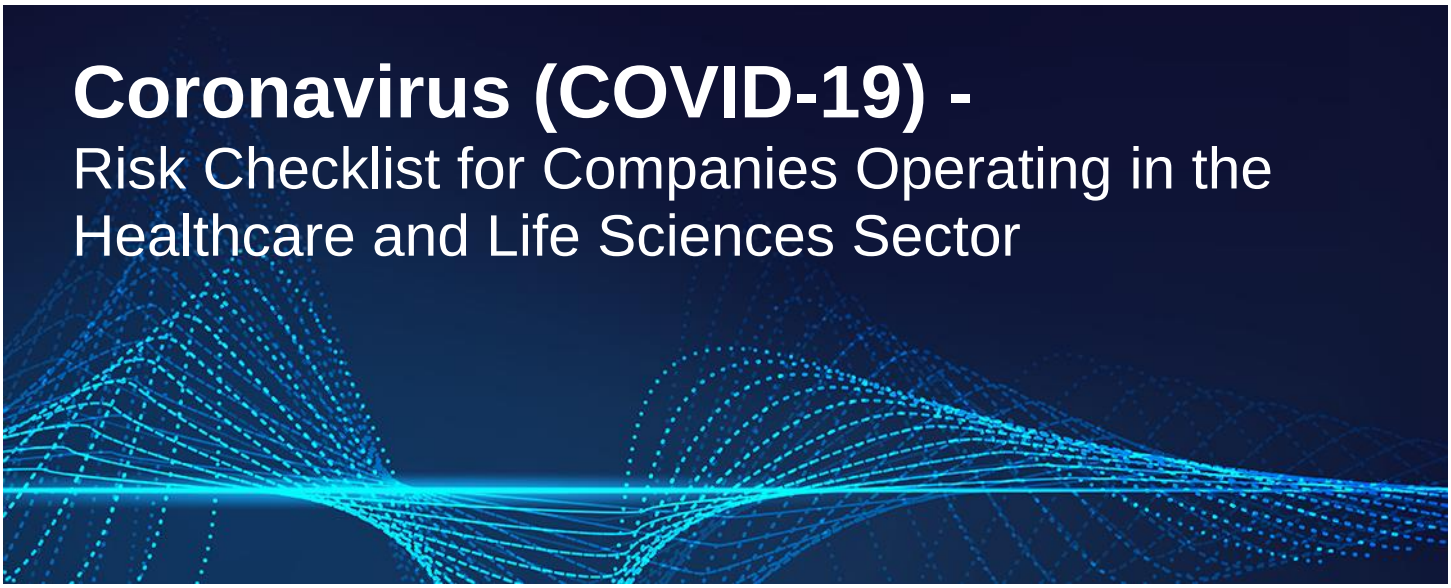
Baker McKenzie.

Asia Pacific

Coronavirus (COVID-19) -
Risk Checklist for Companies Operating in the Healthcare and Life Sciences Sector



As the 2019 Novel Coronavirus (COVID-19) continues to spread across the world, the challenges for companies operating in the healthcare and life sciences sector are increasing. Below is a list of some of the risks emerging and evolving for companies in this sector.

In this document, we included links to Asia Pacific and global resources we have developed in each issue outlined in the checklist. Issues are rapidly changing and our client-facing materials are frequently updated - we recommend that you always visit our **Beyond COVID-19 Resource Center**.

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General Issues

Employment Law

The COVID-19 outbreak raises challenging issues for employers. Our recommendations:

- ✓ Keep yourself and your staff updated on government health alerts, travel alerts and restrictions
- ✓ Monitor the location of your staff and ban travel to high risk locations
- ✓ Facilitate remote working where possible, including by providing access to appropriate facilities
- ✓ Identify the places where your staff work (e.g., your workplace, home offices and offsite locations) and ensure that they are safe:
  - Conduct risk assessments and eliminate or reduce any identified health risks (including risks faced by staff who are on the road and also psychological risks associated from isolated work)
  - Implement COVID-19 specific health and safety policies
  - Train your staff to work safely in light of COVID-19 (e.g., by maintain hygiene standards)
  - Ensure your staff have access to safety equipment (e.g., washing facilities, facemasks, gloves, etc.)
  - Enforce your health & safety policies (e.g., by ensuring that staff who display symptoms remain isolated and do not attend your workplaces)
  - Maintain contact with staff working from home
- ✓ Ensure that your health and safety measures extend to persons with who your staff come into contact (e.g., vendors, health professionals and patients)
- ✓ Modify but continue your performance management procedures to ensure employee efficiency
- ✓ Monitor work levels and reshuffle responsibilities where required
- ✓ Promote flexible work practices and duties

Useful resources:

- Webinar: Key Employer Obligations and Data Privacy Implications
- Asia Pacific Employment Update COVID-19
- COVID-19 Global Employer Guide

Contractual Liabilities

COVID-19 directly impacts supply, which is relevant in the healthcare and life sciences sector, where the supply chain is often vast and complex. We recommend reviewing supply contracts to:

- ✓ Assess whether to invoke *force majeure* provisions in order to cancel or delay shipments
- ✓ Assess the validity of *force majeure* claims made by counterparties
- ✓ Explore other avenues, such as contract frustration

Invoking *force majeure* ultimately depends on the wording of the contract. Some key questions to consider when reviewing the contract include:

- ✓ Is "*force majeure*" defined? Does it expressly include pandemics, epidemics or other similar crises? Does it include events, which are beyond the parties' reasonable control?
- ✓ What kind of failure of performance does the clause cover? Does the clause cover hindrances and delays to performance?
- ✓ Does the clause require any steps to be taken to invoke it? Are there other clauses in the contract providing alternative ways of performance?

It is also necessary to assess the consequences of invoking a *force majeure* clause. These depend on what the contract provides. Common types of relief include the right to:

- ✓ Suspend contractual obligations
- ✓ Be excused from liability for non-performance or delay
- ✓ Terminate the contract
- ✓ Renegotiate the terms of the contract
- ✓ Even if the contract does not include *force majeure* provisions, there may be other avenues of relief. It is also important to consider other side aspects, such as reputational risks and potential damage to long-term supply relationships.

Apart from supply chain contracts, companies in the sector may also consider invoking *force majeure* business alliances such as licenses, joint-developments, co-marketing and co-promotion arrangements. We also recommend reviewing contractual obligations in this respect.

Useful resources:

- Webinar: Understanding Force Majeure and Assessing Your Legal Position
- Webinar: Tackling Force majeure and Material Adverse Change in Hong Kong and China
- Global Guide to Force majeure and International Commercial Contracts

Insurance

The impact of COVID-19 on business continuity, supply chains and travel needs may lead to significant losses. It is important to assess and understand whether these losses are covered by insurance policies. Companies should therefore:

- ✓ Determine whether the insurance policies provide the applicable types and levels of coverage for crisis situations and are responsive to any changes in the business
- ✓ Understand the losses they are seeking to guard against (e.g., pandemics). Determine whether these losses are covered
- ✓ Assess the impact of force majeure on insurance arrangements

Supply Chain

The outbreak has a direct impact on supply chains, such as due to port manpower shortage, travel restrictions/lockdown impacting manpower for projects, factory closures impacting supply and increased demand for healthcare goods. As a result, companies are facing significant and urgent business and legal challenges. In light of this, we recommend that you:

- ✓ Conduct a full risk assessment on the impact of the outbreak on their business activities
- ✓ Evaluate options when core supply chains are disrupted (e.g., alternative suppliers, prioritization of certain categories of customers)
- ✓ Consider whether there are alternative yet compliant ways of performing the contractual obligations
- ✓ Consider whether there are ways of mitigating the effects
- ✓ Consider whether new contracts are needed, and if so, draft provisions clearly and comprehensively so as to cover eventualities such as the present outbreak
- ✓ Consider the possibility of invoking force majeure clauses
- ✓ Monitor the announcement of any new governmental or regulatory policies
- ✓ Consider having a without-prejudice discussion with counterparties since a joint effort may sometimes lead to resolution of issues
- ✓ Assess transfer pricing activity undertaken in response supply chain disruptions
- ✓ Consider losses suffered as a result of supply chain disruption, who should bear such losses within the group – whether it be your production entity, a local sales subsidiary or the headquarters
- ✓ Consider how additional cash paid for example to your production entity to cover operating expenses will affect your transfer pricing and financing model

Useful resources:

- How to Protect Yourself from Distress in Your Supply Chain
- Webinar: COVID-19 and supply chains: navigating the immediate, changing, mid and longer-term issues
- Understanding How COVID-19 Alters BRI

Disclosures

Public companies and companies with listed securities are required to warn investors of possible business or legal risks that could affect their operations. Failure to do so could lead to litigation. These companies should therefore consider:

- ✓ Including COVID-19 in the *risk factor* section of their periodic reports, prospectuses and SEC filings
- ✓ Describing how COVID-19 could affect their businesses. (SEC recommends to be as specific as possible)
- ✓ Providing subsequent updates to the reports if necessary depending on the evolution and impact of the outbreak

Useful resources:

- COVID-19: Government Intervention Schemes Guide

Tax

- ✓ Companies belonging to the same group may be required to engage at arm's length terms(as if they were third parties to one another)
- ✓ Decisions affecting the supply chain require looking at intercompany agreements, functions and risks borne by each entity to assess who should bear the costs or losses associated with the factual situation faced (same if the situation actually generates exceptional profits). This must be appropriately documented and companies will need to be prepared to deal with tax authorities' queries and potential tax controversies
- ✓ Advance pricing agreements should be reviewed and renegotiated if impacted by changes in factual circumstances
- ✓ COVID-19-related international travel restrictions and border controls may give rise to concerns about tax residency statuses for both companies and individuals, as well as tax issues pertaining to remote workforce and permanent establishment issues.
- ✓ Refinancing, restructuring of loans and intercompany waivers may give rise to tax issues (e.g., thin capitalization and earning stripping rules, withholding tax and deductibility issues)
- ✓ Major crises often give rise to donations/gifts from corporations to support their employees, the health system and others, thus playing a part in the resolution of the issues. This type of support is generally quite regulated (as it can give rise to tax credits) and should be carefully reviewed. Also, incentives may be available for donations (e.g., further deductions) in certain circumstances if appropriately documented.
- ✓ Incentives/exemptions may be available for the manufacture or importation of COVID-19-related healthcare equipment, medical supplies and other materials
- ✓ In the event that there are disruptions to supply chains and production slowdowns, the impact on existing incentives should be considered (e.g., if there will be difficulties complying with the terms of the incentives) and potentially, companies will need to engage in discussions with the relevant authorities to resolve this

Useful resources:

- COVID-19 Tax Measures Resource
- The Special Report, COVID-19: Impact on (the Other) TP, produced in partnership with Bloomberg Tax and Accounting

Competition Law/Intellectual Property Law

Shortages as a result of the disruption caused by the outbreak and supply chain adjustment are likely to have an impact on:

- ✓ Parallel trade restrictions
- ✓ (Excessive) pricing of medicines, medical devices and raw materials
- ✓ Pricing and IP protection due to donations and manufacturing for donation purposes

- ✓ Possibility for governments to draw upon compulsory licensing schemes in the event of public health crisis to allow manufacturing, import and stockpiling activities despite existence of patents protecting originators pharmaceutical products.
- ✓ IP rules around new COVID-19 treatments. Innovators and collaborates should monitor and review IP ownership and protection strategy carefully, in view competition law, government intervention and PR implications.
- ✓ Exposure to IP infringement due to expanded capacity (e.g., outside of licensed scope) or manufacturing of medical products.

Useful resources:

- COVID-19 and Antitrust Law: Avoiding Legal Risks in a Time of Uncertainty
- COVID-19 and Antitrust Law Global Update
- COVID-19 Impact on Merger Control: Global Map
- China Patent: Patent Donation not a Legitimate Defense Against Patent Infringement

Compliance Risk Management and Mitigation

The outbreak has resulted in financial stress, supply chain and other operational disruptions and compromised monitoring and oversight capabilities - all of which increase compliance risks. In our recent client alert, we discuss several key risks and the practical steps companies can take to pre-empt and mitigate them. For instance, non-compliant behavior may increase when parties seek to:

- ✓ Speed up processes that may be stalled due to short-staffing of government offices (e.g., customs clearance)
- ✓ Shift manufacturing to alternative suppliers that are less affected by COVID-19 but that have higher risk profiles

These risks are particularly salient for healthcare companies that may be seeing an increase in demand at this time (and the need to meet that demand swiftly). It is therefore crucial that companies ensure their compliance programs continue to operate appropriately. This includes:

- ✓ Emphasizing the company's commitment to compliance to all employees and third parties
- ✓ Monitoring operations to keep conduct in check and to enable the company to swiftly identify and address potential violations

Our team is available to provide on-the-ground assistance in vetting third parties and conducting investigations and risk assessments in a range of jurisdictions.

Useful resources:

- COVID-19: Don't let your Corporate Compliance Program become another casualty of this crisis

Healthcare Specific Issues

Shortages of Medicines, Medical Devices, Personal Protective Equipment and Disinfectants

The disruptions caused by the COVID-19 outbreak has led to a widespread shortage of medical products, including personal protective equipment (PPE, including face masks and medical gowns), disinfectants and ventilators, as well as rush of activities for finding and producing efficient tests, vaccines and treatment options. Supply chain challenges due to shutdown of factories in China (the world's largest producer of active pharmaceutical ingredients (APIs), exporter of PPE and home to many large medical device OEM manufacturers) in February, travel restrictions, ban on export of certain strategic medical supplies and quarantine requirements continue to impact on the effectiveness of control over the outbreak. Regulators and industry associations are working to alleviate and mitigate the impact. This will likely continue into the second quarter of 2020 due to lockdown still in place in many countries.

Due to the continuing demands of healthcare products and services, we recommend to:

- ✓ Monitor export and import restrictions of PPE. For example, China implemented a new policy effective April 1, 2020 to require local registration of five types of PPE and medical device products before export. Prior to that, products for export needed to only comply with product registration requirements in the destination country.
- ✓ Monitor availability of expedited approvals and exemptions by national health authorities (now available in most countries) for new producers to manufacture medical products and existing producers to add capacity.
- ✓ Assess supply obligations, including prioritized supply of PPE, ventilators and disinfectants to public hospitals. Ability to supply is important from contractual, IP and reputational perspectives.
- ✓ Monitor government intervention measures, which can lead to (a) likely issuance of compulsory license (or other urgent emergency orders) requiring review of patent status and exercise of patent rights (see further below under Competition and IP) and involve (b) mandatory manufacturing of medical products requiring regulatory and operational review and compliance.
- ✓ Assess IP protection and exposure to IP infringement as part of supply chain management and product expansion exercise (see above under IP).
- ✓ Monitor available subsidies and incentive schemes for COVID-19 related research and development and provision of COVID-19 related medical products.
- ✓ Monitor price control imposed by national authorities on certain products (e.g., face masks) to prevent price gouging.
- ✓ Assess ongoing impact on site inspections by regulators and clinical trial management due to travel restriction and difficulties in trial administration due to limited resources for anything non-COVID 19 related (see below under Clinical Trials and Market Access of Medicines).
- ✓ Assess need and feasibility of alternative suppliers on short term (noting added delays) and longer-term basis.
- ✓ Assess risks of anticompetitive practices, bribery and corruption and other non-compliance practices in urgent/interim business measures and conducts (see above under Compliance Risk Management and Competition), such as responding to joint procurement procedures (see below under Joint Procurement).
- ✓ Monitor evolving regulatory framework for telemedicine and digital health products and services, including evaluation as longer term opportunities beyond COVID-19 (see below under Digital Health).

Clinical Trials

COVID-19 is causing delay in clinical trials generally due to:

- ✓ Lockdown and quarantine measures prevent patient enrolment to clinical trials
- ✓ Difficulty in distributing trial drug to test subjects as they are advised not to visit hospitals to avoid risk of infection
- ✓ Reduction in international air traffic makes it much more difficult to ship trial drugs to the hospital sites
- ✓ CRO staff are not allowed to attend hospital sites to conduct monitoring to avoid unnecessary infection and even if allowed, the quarantine requirements after visiting hospital site make monitoring extremely difficult
- ✓ Lack of healthcare staff to run the trial as most healthcare workers are tied up with dealing with COVID-19 patients

That said, clinical trial approval involving multiple countries have been expedited for COVID-19 treatment drugs.

Digital Health

COVID-19 may lead to:

- ✓ Increased use of telemedicine for consultation as patients are avoiding going to hospitals or clinics for fear of infection
- ✓ Prescription online by doctors through telemedicine and offline dispense of drugs in pharmacy
- ✓ More relaxed regulation of telemedicine service, online promotion of medical products and e-pharmacy

Useful resources:

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

Market Access of Medicines

While regulators in most countries are willing to expedite the review and approval of diagnostics and treatment drugs to fight COVID-19, the outbreak is causing delays on market access of other products due to:

- ✓ Lockdown and quarantine at home prolong the review time
- ✓ Physical meeting with applicants not possible during this period
- ✓ Regulatory inspections put on hold as a result of travel restrictions;
- ✓ Renewal of approval and license would be affected due to the same reasons

Joint Procurement

The magnitude of the outbreak has led certain authorities to consider the need to combine joint procurement actions:

- ✓ For example, the European Commission has launched an accelerated joint-procurement procedure for personal protective equipment with 20 Member States and a second procurement on respiratory machines is expected soon. Some EU Governments have also called for a joint procurement procedure of the COVID-19 vaccine once it is authorized
- ✓ The International Chamber of Commerce (ICC) and the World Health Organization (WHO) have urged global implementation of similar measures

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General Issues

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