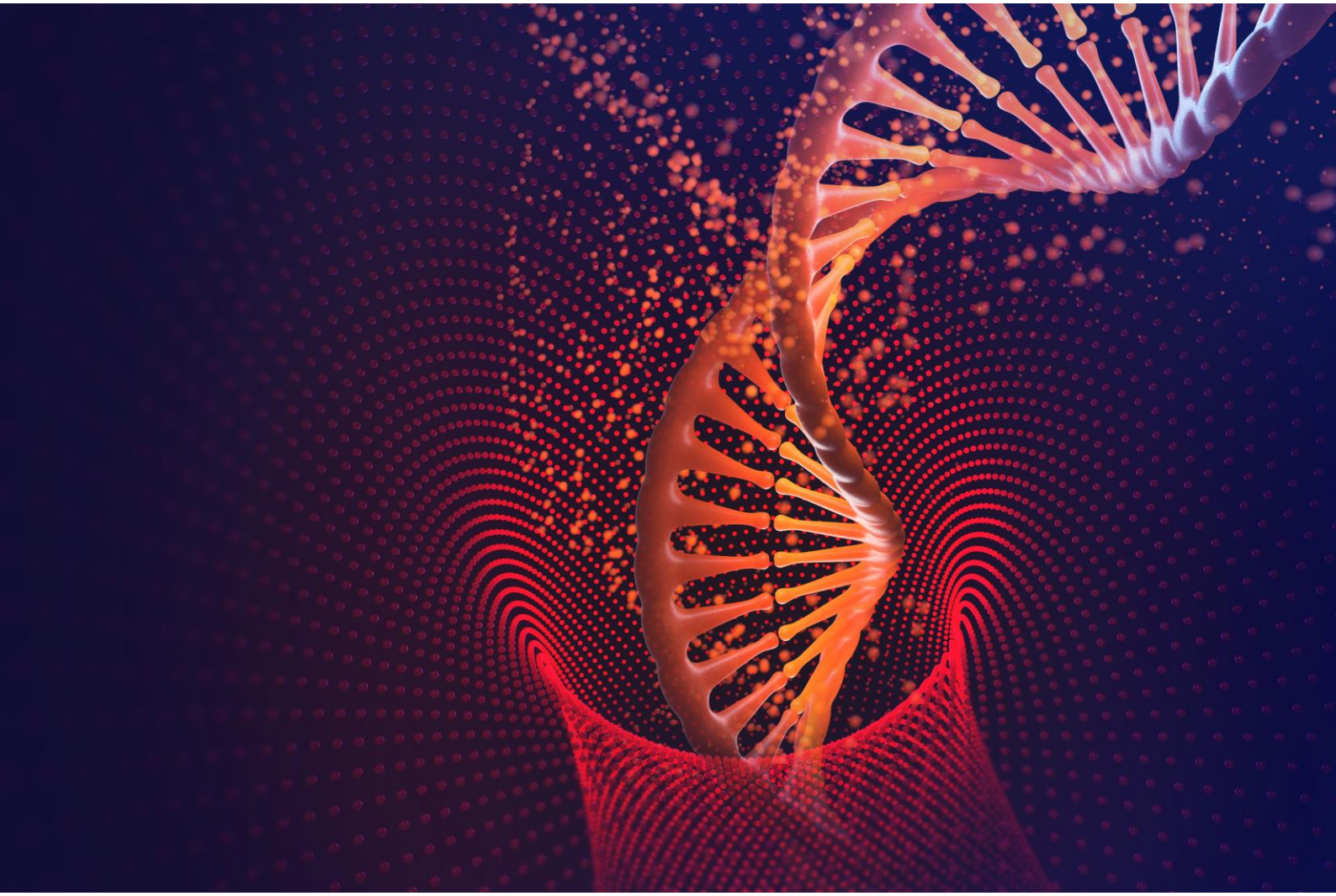
Baker McKenzie.

Healthcare and Life Sciences



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 new risks emerging for pharma and medtech companies.

For an overview of measures that EMEA governments have taken in the life sciences sector please access our **EMEA COVID-19 life sciences survey**.

General Issues

Employment Law

The COVID-19 outbreak raises challenging issues for employers. Aspects to focus on from an employer's point of view:

- Maintain a safe working place, whilst at the same time maintain volume and standard of operations
- Minimize exposure to liabilities:
  - Protect the health and safety of employees
  - Protect the health and safety of vendors, clients and persons liaising with the firm
  - Protect employees unduly or unexpectedly retained abroad due to travel bans
- Review applicable government health alerts, track travel and health restrictions
- Maintain communication with employees
- Facilitate remote working where possible

Useful resources:

- **Covid-19 Global Employer Guide** answering for 41 jurisdictions the most pressing questions employers are currently facing, including legal requirements, practical and operational considerations, and emerging government regulation related to the outbreak
- Click **here** for an overview of other recently issued multi-jurisdictional guides and resources assisting multinational employers understand and address the most pressing issues they are facing in light of the COVID-19 outbreak
- **Webinar: Key Employer Obligations and Data Privacy Implications**. HR operational issues such as working from home, providing a flexible work environment and hours, and timely communication. Data privacy implications
- **Updated COVID-19 Data Privacy & Security Survey**. A ,multijurisdictional guide designed to assist employers assess whether or not certain data processing they may consider in light of COVID-19 is compliant with data privacy regulation

Contractual Liabilities

COVID-19 has a direct impact on supply contracts. This impact is particularly relevant in the healthcare and life sciences sector, where the supply chain is vast and complex. It is therefore important to review supply contracts in order to assess the following:

- Possibility to invoke *force majeure* provisions in order to cancel or delay shipments
- 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.

Useful resources:

- Video: **Is COVID19 a Force Majeure Event?**
- **Global alert on force majeure and international 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 right 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. As a result, companies are facing significant and urgent business and legal challenges. What can be done to relieve the pressure?

- 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 ways of performing the contractual obligations
- Consider whether there are ways of mitigating the effects
- Are new contracts needed? If yes, 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

Useful resources:

- **COVID-19 and the Trade, Anti-Corruption, and Human Rights Compliance Risks it Poses to Your Supply Chain**
- **EU facilitates Member State support to businesses suffering as a result of the COVID-19 outbreak: Temporary Framework for State aid adopted**
- **How to protect yourself from distress in the supply chain?**

Corporate Compliance

Travel restrictions and remote working may also have an impact on the important activities of in-house regional and global compliance teams who are not able to provide direct oversight, training and risk assessments to their local business operations. Below are some actions to consider to maintain compliance during these challenging times:

- maintain communication with employees and third parties
- continue to maintain oversight over all employees and monitor adherence to compliance policies
- invest in technology, such as video conferencing and e-discovery/review software, to quickly and proactively respond to any compliance issues identified
- follow the latest legislative developments and new rules related to the COVID-19 outbreak
- Donations - if the company decides to make donations to support the fight against the COVID-19 outbreak, pay special attention to the qualifications of the receiving parties, donation procedures and document donation processes
- Supply chain and third parties - If having to make alternative arrangements to the supply chain, try to use previously-vetted and trusted suppliers that can meet production and sourcing needs. If this is not possible, companies should always ensure that procurement processes are followed and diligence is conducted on any new third parties before they are engaged

Ultimately, a well-run corporate compliance program must not be sidelined by COVID-19.

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, risks, etc. borne by each entity, to, in turn, assess in particular who should be bearing the costs or losses associated with the factual situation faced (same if the situation actually generates exceptional profits). This must be appropriately documented
- Major crises often give rise to donations / gifts from corporations to support their employees, the health system, etc. thus playing their 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

Useful Resources:

- **COVID-19 Checklist of Taxation-related considerations**
- **The Impact of the Coronavirus Pandemic on Fund and Alternative Capital Managers: Tax Considerations in the Rapidly Changing Landscape**
- Guide: **COVID-19 Tax measures and relief information**

Disclosures

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

- Include COVID-19 in the 'risk factor' section of their periodic reports, prospectuses and SEC filings
- Describe how COVID-19 could affect their businesses. (SEC recommends to be as specific as possible)
- Subsequent updates to the reports may be needed depending on the evolution and impact of the outbreak

Useful Resources:

- **COVID-19 Government Intervention Schemes**

Data Privacy

As a result of the outbreak many companies are having to make urgent decisions to keep their workforce safe and ensure business continuity. This involves additional data processing because of the crucial role that data plays in containing the spread of the virus. Employers will need to assess the following:

- Assess whether data privacy regulations allow you to lawfully collect and process from employees or visitors, certain personal, and sometimes sensitive data, such as body temperature and travel information
- Check if your local data privacy regulator has issued any guidance either permitting or restricting the collection of personal data for the purposes of identifying COVID-19 cases
- Assess, under both data privacy and employment legislation, whether as an employer you may establish information channels requiring employees to notify certain COVID-19 information about themselves or colleagues to HR or line managers
- Ensure any teleworking strategy you design and implement minimizes the related cybersecurity and data privacy risks that arise, for instance, because you open up usually restricted systems for remote access, you allow employees to use personal devices for accessing organization systems and resources, or malicious actors leverage COVID-19 to attack organizations

In recent dates, data protection authorities across the world are providing guidance on data processing activities and the fight against COVID-19. On 16 March, the European Data Protection Board issued a statement that data protection rules do not hinder measures taken in the fight against the COVID-19 pandemic. However, even in these exceptional times, data controllers must ensure the protection of the personal data of the data subjects.

Useful resources:

- **Updated COVID-19 Data Privacy & Security Survey**. A multijurisdictional guide designed to assist employers assess whether or not certain data processing they may consider in light of COVID-19 is compliant with data privacy regulation

Healthcare Specific Issues

Shortages of Medicines , Medical Devices and Biocides

The disruptions caused by the COVID-19 outbreak may lead to a shortage of medicines, medical devices and biocides. Regulators and industry associations are working to prevent and mitigate any potential shortages through close coordination and communication with stakeholders. However, if the situation persists there may be inevitable disruptions due to the shutting down of factories and shipping infrastructures, reduced workforce as a result of quarantines and travel bans, additional import and export controls and increase in demand.

These challenges are aggravated by the fact that China is the world's largest producer of active pharmaceutical ingredients (**APIs**) on which manufacturers of final medicinal products highly depend. China also manufactures a significant amount of upstream components used to manufacture final medical products. Drug, medical device and biocides shortages as a result of COVID-19 could therefore ultimately lead to:

- Companies having to urgently select alternative suppliers of products, components, or raw materials to fill gaps – even if just temporarily – caused by supply chain interruptions. This may undermine product safety compliance and potentially introduce product defects that could trigger consumer recall and product liability related risks
- Export restrictions
- National authorities requesting to release products outside regulatory requirements, when test results are not yet confirmed. Consequences of such premature release could include product liability and insurance issues
- Government appeals for emergency supply of products to state-owned customers (e.g. health services, hospitals) vs other customers
- Reallocation of stocks across hospitals and pharmacies
- Price regulation imposed by national authorities on some products
- Delayed/declining quality control (site inspections by US/EU regulators interrupted due to travel bans)
- Potential need to identify alternative suppliers (added delays)
- Surge of anticompetitive practices (see below)
- Launch of joint procurement procedures (see below)
- Despite the outbreak, companies will still need to ensure sufficient stock of critical medicinal products and medical devices for which there are no alternatives in the market and which relate to life threatening conditions. Obligations to keep the market supplied may still apply and can be regarded as a reputational issue
- The European Commission has adopted guidance on the optimal and rational use of medicines to avoid shortages foresees the following measures:
  - Solidarity: Pharmaceutical companies may need to cooperate and coordinate with other companies in the supply chain
  - Relaxation of regulatory measures in the context of certain variations to marketing authorizations
  - Reallocation of medicines across hospitals and pharmacies

Useful resources:

- **New EU and national export controls on face masks and medical protective equipment**

- **COVID-19 European Commission guidance on antitrust and medicines supply**
- EU measures: **Commission Implementing Regulation (EU) 2020/402**, as amended by **Commission Implementing Regulation (EU) 2020/426**; and Commission **Guidance Note** on export controls
- EU measures: **Commission guidance on the optimal and rational supply of medicines to avoid shortages**
- EU measures: **Questions and answers on regulatory expectations for medicinal products**

Competition Law / IP Law

Shortages as a result of the disruption caused by the outbreak are likely to have an impact on competition law related aspects, such as:

- Parallel trade restrictions
- (Excessive) pricing of medicines, medical devices and raw materials
- Possibility for Governments to draw upon compulsory licensing schemes
- IP rules around new COVID-19 treatments
- Donations and generic supplies impacting on pricing and IP protection
- Companies that own IP which is relevant to the manufacture of essential equipment such as ventilators may want to, or be required to, license their technology to others, either competitors in the same industry, or to other players who are drafted in to turn their hand to manufacturing in demand items
- European Standardization Organizations have made standards on manufacturing of essential equipment, such as ventilators, accessible free of charge for all interested companies
- The Commission has issued antitrust guidance to companies that need to cooperate with each other in order to overcome the effects of the outbreak and contribute to the protection of patient's health. See EU measures listed below

Useful resources:

- **Making Medical Devices to Tackle Coronavirus**
- **New EU and National Export Controls on Face Masks and Medical Protective Equipment**
- **Manufacturing Personal Protective Equipment to Tackle Coronavirus**
- **COVID-19 European Commission guidance on antitrust and medicines supply**
- EU measures: **European standards for medical supplies made freely available to facilitate increase of production**; **Commission Questions and Answers document to help increase production of safe medical supplies**; **Commission Recommendation 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat**
- EU measures: **Temporary Framework for assessing antitrust issues related to business cooperation between** competitors

Clinical Trials

The outbreak has led to the launching of numerous new trials for COVID-19 treatments. It has also had an impact on ongoing trials for other conditions. As a result of the outbreak:

- Difficulties may arise in relation to patient recruitment and the managing of multi-center trials
- Clinical trial patients may need to stay at home due to home confinement issues. Medicines may need to be supplied at home and the managing and follow-up of the trial may need to be carried out remotely
- COVID-19 may lead to delays in enrolment and to the suspension or extension of the duration of a trial
- These adjustments may have implications on data protection requirements and alternative arrangements should be adequately documented
- These adjustments may also ultimately delay drug launches
- At EU level EMA has urged the research community to prioritize large randomized controlled clinical studies

Useful resources:

- EU measures: **Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic**

Digital Health

COVID-19 may lead to travel restrictions and hospitals saturation and therefore to:

- Increased reliance on decentralized and dematerialized clinical trials
- Increased reliance on remote healthcare support through telemedicine, wearable devices and provision of health data
- Relaxed regulation of remote medical services and monitoring tools by national authorities

Market Access of Medicines

Regulators are ready to support speedy development and approval of diagnostics and treatments to fight COVID-19. The outbreak could also have the following effects on market access of medicines and medical devices:

- Delays in normal regulatory work for products unrelated to COVID-19, due to:
  - Reduced workforce combined with an increase in workload
  - Regulatory inspections put on hold as a result of travel restrictions
  - Authorities relying on alternative tools to maintain oversight over international manufacturers
- Potential future vaccine cooperation agreements at global or regional/EU level
- Authorities prepared to facilitate and streamline regulatory procedures
- Increased risk of falsified medicines and devices to treat or prevent COVID-19 through unregistered websites

Useful resources:

- EU measures: Application date of the **Medical Devices Regulation (MDR)**, which was due to become applicable on 26 May 2020 will be postponed for one year. See **here**.
- EU measures: **EMA Scientific advice is free of charge and can be fast-tracked for potential novel coronavirus treatments or vaccines:**

- EU measures: **Questions and answers on regulatory expectations for medicinal products**

Public procurement and Joint Procurement

Some governments have simplified public procurement rules to facilitate the purchase of supplies, services and works needed to address the crisis. These measures include:

- Simplified procedures
- Reduced deadlines
- Increased use of negotiated procedures with less stringent publication requirements
- Greater flexibility for public buyers when engaging with suppliers

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

- At EU level, the European Commission has already launched accelerated joint-procurement procedures for personal protective equipment, medical ventilators and testing kits
- These agreements are between Member States (and the United Kingdom and Norway). The European Commission has a coordinating role, while the Member States purchase the goods
- Some EU Governments have also called for a joint procurement procedure of the COVID-19 vaccine once it is authorized

Useful resources:

- EU measures: **Commission guidance on using the public procurement framework in the emergency situation related to the COVID-19 crisis**
- Further details on EU joint procurement agreements can be found **here**

Please access the **EMEA COVID-19 life sciences survey** for an overview of measures that EMEA governments have taken in the life sciences sector to fight the outbreak.

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