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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 and enhanced risks emerging for companies in this sector.

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.

SHORTAGES OF MEDICINES, MEDICAL DEVICES, MEDICAL SAFETY EQUIPMENT AND BIOCIDES

The disruptions caused by the COVID-19 outbreak will likely continue lead to a shortage of medicines, medical devices, medical safety equipment and biocides. Regulators and industry associations are working to prevent and mitigate any potential shortages through close coordination and communication with stakeholders. However, disruptions are inevitable 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, medical safety equipment and biocide shortages as a result of COVID-19 could therefore ultimately lead to:

- ✓ Export restrictions
- ✓ National authorities' request 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
- ✓ Price regulation imposed by national authorities on some products
- ✓ Delayed/declining quality control (site inspections by regulators interrupted due to travel bans)
- ✓ Potential need to identify alternative suppliers (added delays)
- ✓ Surge of anticompetitive practices, bribery and corruption and other non-compliance 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

EMPLOYMENT LAW

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

- ✓ 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 kept abroad due to travel bans
- ✓ Review applicable government health alerts, track travel and health restrictions
- ✓ Maintain communication with employees
- ✓ Facilitate remote working where possible

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 (link), we discuss several key risks and the practical steps companies can take to pre-empt and mitigate them. For instance, non-compliant behaviour may increase when parties seek to:

- ✓ Speed up processes that may be stalled due to short-staffing of government offices (e.g., customs clearance); and/or
- ✓ 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.

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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:

- ✓ Determine whether theIR 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, consider to:

- ✓ 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

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
- ✓ 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

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

COMPETITION AND INTELLECTUAL PROPERTY LAW

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

- ✓ 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

CLINICAL TRIALS

COVID-19 may lead to delayed drug launches due to:

- ✓ Delays in enrolment to clinical trials
- ✓ Difficulties in patient recruitment and managing of multi-center trials
- ✓ Clinical trial patients needing to stay at home due to home confinement issues
- ✓ Necessity of supplying medicines at home and carrying out the managing and follow-up of the trial remotely

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 level

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