

LITIGATION, DISPUTE RESOLUTION AND INVESTIGATIONS
HEALTHCARE AND LIFE SCIENCES DISPUTES

COVID-19: Practical Considerations for Life Sciences: Supply Chain Disruption and Medicines Shortages

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The risk of a serious and long-term impact on pharmaceutical supply chains as a result of COVID-19 is considered low at present. However, supply chain disruption may be nowhere as acutely felt, nor as vital to prevent, as in the life sciences sector.

Marketing authorisation holders, manufacturers and wholesale distributors should take timely and proactive steps to ensure that they are prepared to deal with disruption that may occur.

SUPPLY CHAIN DISRUPTION

The global nature of the pharmaceutical industry, with particular reliance on China, and to a lesser extent India, for the manufacture of active pharmaceutical ingredients, creates an inherent risk. The industry has shown significant resilience to date by reason of typically large inventory, and future risk has reduced now that Chinese factories are getting back to work, and with pharmaceutical manufacturing exempted from the recent lockdown measures in India. However, as the virus continues to spread, we may see shortages on materials coming from, or routed through, severely impacted areas, as well as capacity issues along various transport networks. This may impact domestic supply and import and export of product.

There are a number of other ways in which supply chains may be affected here in Ireland. The Health Service Executive's guidance regarding quarantine measures, and the advice to practice physical distancing, even within workplace settings, can all affect the operation of factories and infrastructure. The potential impact of Ireland's new emergency legislation (the Health (Preservation and Protection and Other Emergency Measures in the

Public Interest) Act 2020) should also be considered.

The legislation gives the Minister for Health the power to declare an area or region in Ireland to be an "affected area", and to introduce travel restrictions to, from or within that affected area. As an essential service, the supply of medicinal products is likely to be exempted from any "affected area order" that may be made by the Minister, but we have yet to see how any such orders would operate in practice (Read our briefing on this [here](#)). There may also be a rise in contractual disputes if the risk of disruption becomes a reality.

So what can marketing authorisation holders, manufacturers and distributors do now to minimise disruption to global and local supply chains and to reduce their legal risk? Consideration should be given to the following:

- 1. Carry out risk assessments and monitor supply chains closely** to ensure shortages do not occur. In particular, identify any products which are most at risk of being affected by supplier shutdowns or logistics interruptions and take steps to reinforce supply chains and operations. A review of inventories in the full supply chain should also be undertaken to gain an understanding of the potential impact over the coming months, and to help identify alternative distribution channels and methods.

- 2. Review contracts with suppliers and customers** which could be affected by the COVID-19 pandemic and analyse the risk allocation in those contracts. Be aware of the risks and consequences of a potential breach of contract involving suppliers or customers. In particular, any force majeure clauses should be carefully reviewed to understand when non-performance will not constitute a breach of contract. A force majeure clause will also usually define the remedy available to the party and the steps to be taken to trigger the clause. There are also obligations to mitigate the risk by having contingencies in place. (Read our briefing on force majeure clauses [here](#)).
- 3. Keep good records of any supply problems** in anticipation of potential contractual disputes. Ensure the reasons for any supply disruption are closely documented, whether it be due to quarantine, staff illness or a government required shutdown.
- 4. Consider whether any insurance or indemnification** agreements may cover losses caused by supply chain disruption and provide notice to any insurers in accordance with the relevant policies.
- 5. Maintain communications with customers** to provide regular updates and reassurance that supply will continue and stockpiling of medicinal products is unnecessary. If your supply chain is affected, aim to provide

information to customers quickly and make sure to identify the steps being taken to address supply.

ENSURING A CONSISTENT SUPPLY OF MEDICINES

The European Medicines Agency has stated that there have been no reports of shortages or supply disruptions of medicines marketed in the EU due to the outbreak. In Ireland, the Health Products

Regulatory Authority (HPRA) is working to minimise and proactively address any risks posed to ongoing supply, including working with manufacturers and wholesalers to ensure continuous access to medicines. As there are already additional stocks of medicines routinely built into the Irish medicine supply chain, the HPRA has advised that Ireland is unlikely to face general supply issues as a result of any COVID-19 related issues. The HPRA is reviewing this position on an ongoing basis.

[A framework document](#) published by the HPRA in 2018 provides clear and helpful guidance for stakeholders in relation to dealing with potential and actual shortages. In addition, the HPRA maintains a list on its website of shortages currently affecting the Irish market that have been notified to it. When the HPRA is notified as to normal resumption of supply, the list of shortages is updated to reflect the current status of the shortage situation.

MEDICINE SHORTAGE MITIGATION - WHAT CAN I DO?

To help mitigate any risk, marketing authorisation holders, manufacturers and wholesale distributors should notify the HPRA of any potential or actual medicine shortages. Early communication of shortages can significantly reduce the impact on our healthcare system.

It is also important to develop and implement preventative measures, including business continuity plans and medicine shortage prevention and response plans, to help avoid shortages occurring. These plans will need to be continually reassessed throughout the evolving crisis.

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