



The Danish Medicines Agency may order Danish life science companies to undertake far-reaching commitments to secure supplies during the COVID-19 pandemic



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COVID-19 has caused a great demand for medical devices including personal protective equipment and disinfectants which has resulted in reports of shortage in several areas of the healthcare sector. Beyond that, there is a need to ensure the supply of pharmaceuticals during the COVID-19 crisis.

Consequently, the Danish Minister of Health has adopted far-reaching rules to secure the supply of medical devices, personal protective equipment and disinfectants and pharmaceuticals. These rules may have significant implications for life science companies.

The rules for medical devices, personal protective equipment and disinfectants

The rules will allow the Danish Medicines Agency to, among other things, compel Danish producers, importers and distributors of medical devices and personal protective equipment and disinfectants to

- *Report* their supplies of certain products;
- *Build up stocks* of certain products; and
- *Deliver certain products* to regions and municipalities – in return for payment.

The new rules allow the Danish Medicines Agency to decide that certain products may only be sold in pharmacies. The Danish Medicines Agency can determine the retail price or a price cap for the products, which may then not be sold at another price.

Breach of any of the above orders may be punished by fine or imprisonment.

The orders are laid down in [only in Danish]

- [Bekendtgørelse om særlige foranstaltninger vedrørende forsyning af medicinsk udstyr og personlige værnemidler i forbindelse med håndtering af Coronavirussygdom 2019 \(COVID-19\)](#), og
- [Bekendtgørelse om særlige foranstaltninger vedrørende forsyning af desinfektionsmidler i forbindelse med håndtering af Coronavirussygdom 2019 \(COVID-19\)](#)

Rules for pharmaceuticals

In order to secure the supply of pharmaceuticals, the Danish Minister of Health can activate the drug preparedness program at a preventive level or at an action level. As part of handling the COVID-19 pandemic, the minister has decided to activate the entire drug preparedness program.

This allows the Danish Medicines Agency to compel pharmaceutical companies to

- *Report their stock* of pharmaceuticals, intermediate products and pharmacologically-active substances to the agency;
- *Increase their stock* of pharmaceuticals, including pharmaceuticals that has not yet been approved or marketed in Denmark, intermediate products and pharmacologically-active substances;
- *Reduce their stocks* of pharmaceuticals, including pharmaceuticals that has not yet been approved or marketed in Denmark, intermediate products and pharmacologically-active substances in accordance with specific instructions given by the Agency. The Danish Medicines Agency may further determine the terms for such distribution;
- *Keep prices unchanged* for all or certain pharmaceuticals or only increase prices by a specified percentage;
- *Immediately change prices* to a price level determined by the Danish Medicines Agency if the prices are estimated to have increased disproportionately. After that, the pharmaceuticals may only be sold at the price determined by the Agency.

Breach of any of the above orders may be punished by fine or imprisonment.

Also, the Danish Medicines Agency may order deviations from generic substitution groups.

Finally, the Danish Medicines Agency can grant special time-limited authorizations for production, import, export, storage, trading, distribution, delivery, splitting and packaging of approved and non-approved pharmaceuticals.

The orders are laid down in [only in Danish]

- [Bekendtgørelse om lægemiddelberedskabet i forbindelse med håndtering af Coronavirus sygdom 2019 \(COVID-19\)](#)

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