
# HELPING HEALTHCARE COMPANIES NAVIGATE CORONAVIRUS – COVID-19

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With the outbreak of the novel coronavirus (SARS-CoV-2) companies in the Healthcare and Life Sciences sector are now facing a multitude of supply chain and regulatory challenges. With the very rapid spread of the disease progressing, a multi-jurisdictional wave of new sector rules and (national) regulations is under way.

## Introduction

This note discusses selected regulatory requirements and upcoming changes across various European jurisdictions which international Healthcare and Life Sciences companies that are active in the European market should be aware of. We have divided the following topics into three groups: Customers, Regulatory, and Liability Risks. Contractual issues, such as force majeure situations, are outside the scope of this note (see the Clifford Chance coronavirus microsite **HERE**).

As a general remark, there is no global solution for any of the legal topics discussed in this briefing, which does not constitute legal advice. The main lesson learnt in recent weeks is that any situation heavily depends on local law requirements in the relevant jurisdictions. This holds true even for regions where laws and regulations are mainly harmonised, e.g. in the European Union. Often, it comes down to different regulations and COVID-19 responses across jurisdictions, and even municipalities. Therefore, whilst this briefing touches upon many different European countries, it can only provide a snapshot of the developments as they stand in March 2020.

We see three overarching principles which every company should use for guidance:

1. **It's a big battle:** The interests of governments and jurisdictions are both aligned and also conflicting. All jurisdictions wish to fight COVID-19, but sometimes this means a battle between countries. Right now, this is a battle for the appropriate regulatory response, but it could also end up in a battle over pharmaceutical supplies.
2. **Variety of rules:** There is neither a global, nor European legislation. The applicable rules differ in each jurisdiction. Often, it may be domestic or municipal rules that international companies need to be aware of.
3. **The only constant is constant change:** Actions, measures and recommendations of governments, municipalities and local authorities are extremely dynamic and often subject to sudden changes. Therefore, it is crucial to closely monitor the current developments. In addition, long-term changes may result from this crisis, which companies in the Healthcare and Life Sciences sector may already try to influence and anticipate.

## 1. Customers

The relationship between healthcare industries and their customers (e.g. wholesalers, distributors, hospitals and health insurance funds) might encounter the following three challenges as a consequence of the COVID-19 outbreak:

### Allocations of products

If production capacity or stock availability is not sufficient to meet all customer orders, the question arises of how a company may allocate the (insufficient) supply capacity to its customers. For instance, the company will need to consider if it should make its production capacity available on a *pro rata* basis across all customers, or if it should prioritise certain customers based on varying contractual obligations and liabilities owed to different customers. Pricing and loyalty may also be crucial factors. In some cases, if a party is contractually obliged to deliver a certain level of stock, it may not be possible to adopt a *pro rata* approach to supply without risking a breach of contract, unless a force majeure exemption happens to apply. Provided that there are no requirements defined under local laws requesting the concerned stakeholders to follow specific criteria, a company with reduced stock (and that has no contractual commitments on supply) is generally free to decide the amount each customer will be supplied with. However, antitrust regulations need to be duly considered, in particular, if rules relating to market dominance apply to the product in question.

In certain jurisdictions, the competent authorities have exceptional power in the event of a health crisis:

In *France*, for example, during a major health threat (for instance, an epidemic), the Ministry of Health may take any measure proportionate to the risks incurred in order to prevent and limit the potential consequences on public health. Given the generality of this wording, these measures may include requirements to follow specific criteria to allocate any limited supply of medicinal products. For instance, vaccination against the swine flu virus (2009 A(H1N1)) had to be offered with priority allocated to the most exposed or at-risk persons. Specific regulations have recently also been enacted to authorise pharmacists to prepare hydro-alcoholic gel solutions (an action which was similarly permitted to *German* pharmacies with respect to disinfectants).

In *Spain*, the Spanish authorities may order a controlled distribution by the marketing authorisation holder, which means that a maximum number of units will be supplied to each applying entity in order to ensure distribution according to real needs. Just recently, on 14 March 2020, the Spanish Government has declared the state of emergency (*estado de alarma*), which allows the Ministry of Health, for example, to adopt any instruction necessary to avoid shortage of supplies or to temporarily seize any type of goods necessary to protect public health. Further regulations implementing the declaration of the state of emergency are expected to be adopted shortly.

In the *UK*, the UK Department of Health and Social Care (UKDHSC) has requested that key suppliers continue fulfilling orders and supplying products to the NHS. Further, suppliers still holding any "EU exit stockpiles" have been asked to retain their stockpiles while the UKDHSC considers more targeted approaches to potential supply disruptions. Accordingly, ensuring continuity of supply of medical goods to the NHS during the coronavirus outbreak is critical to the UKDHSC, and suppliers to the NHS should be taking immediate steps to mitigate the risks of any shortages in stock where possible.

## Public procurement specifics

In *Russia*, in the context of public procurement, failure to supply under a signed contract can result in a company being banned from state tenders for two years. Supply interruptions resulting from COVID-19 may serve as a basis to justify delays or non-supply, which was just confirmed by the Russian government. However, the Russian authorities are closely monitoring supplies and international companies may come under pressure and increasing scrutiny if Russian state tenders are not fulfilled while the product in question remains available in other countries.

In *Poland*, a contracting authority may cite a previous intentional non-performance or improper performance as grounds for exclusion of a company from a tender under public procurement law. In addition, and as exceptional rule subject to certain conditions, contracts for goods or services necessary for counteracting COVID-19 may be temporarily (for 180 days from 8 March 2020) concluded without the application of the public procurement law.

In *Spain*, in the event of a justified urgency, hospitals of the public sector are entitled to follow an urgency tender procedure where the timing of the different steps of the ordinary tender procedure is reduced. Similarly, in *Romania*, according to an ordinance adopted just recently, public authorities may enter into framework agreements with one or several suppliers, bypassing their public tender and publicity obligations. Until the maximum stocks required for emergency medical products are reached, the public authorities may enter into contracts after direct negotiation with suppliers.

## Providing products for free

### General prohibition of gifts

Products specifically targeted to COVID-19 (e.g. diagnostic test kits, medicinal products, including vaccines) are only gradually becoming available and, as of their launch, there is particularly strong demand for these products on the market. In this context, the question arises whether – and under which circumstances – companies may provide products for free to doctors, hospitals, health insurers, patients, etc. (exceeding the relevant standards applicable to product sampling).

Generally, in the majority of jurisdictions, providing healthcare products for free is prohibited, mainly due to anti-corruption principles and codes intended to ensure the independence of doctors' clinical or prescribing decisions. In addition, certain local advertising and/or regulatory provisions prohibit granting gifts and benefits (including free products) to physicians and/or patients. In the *UK*, for example, companies are generally prohibited from providing free samples of medicinal products to consumers. There are a number of specific rules that companies must comply with in respect of advertising medicinal products, which are strictly enforced by the UK's advertising regulatory authority. Therefore, any activity in this respect requires a very thorough legal assessment.

In *Germany*, the free provision of products to healthcare professionals can conflict with criminal law. As prosecutors closely monitor free product distribution and are generally not hesitant to intervene, free product distribution must be approached particularly cautiously in order to avoid the risk of criminal investigations, for which a reasonable initial suspicion is sufficient and which can cause serious damage to the company image even if the suspicion is later shown to be unfounded. Therefore, any action or measure must leave no doubts that an undue and unfair influence of healthcare professionals is not intended.

In certain countries, e.g. the *Czech Republic*, exceptions may be available. According to the Czech State Institute for Drug Control, related matters are assessed on a case-by-case basis.

**Donations**

Making product donations of fully authorised and marketable medicinal products may be permissible. In *Russia*, charitable donations to state hospitals are often permitted. Similarly, in *Poland*, donations of medicinal products as humanitarian aid are allowed, subject to several conditions. In *France*, providing medicinal products for free may be permitted for humanitarian purposes (in practice, many pharmaceutical industries resort to a single non-profit organisation to coordinate their donations and distribute donated products). In *Romania*, a donation is permissible subject to conditions. The donation must be based on a medical need, and the beneficiary may only be a medical unit with an affiliated pharmacy, a social assistance unit or a non-governmental organisation with authorised medical staff. A specific endorsement is also required from the Ministry of Health or competent agency. In *Spain*, donations to certain healthcare institutions may be permissible under certain conditions, including that they are conducted for the purpose of social or humanitarian care.

In *Belgium*, donations to healthcare organisations, such as hospitals, are generally prohibited. In practice, however, donations are allowed for educational, humanitarian or philanthropic purposes. Since the scope of this exception is not free of ambiguities, a case-by-case assessment is necessary.

## 2. Regulatory

In some jurisdictions, the applicable regulatory regime provides for specific laws governing the situation of supply shortages, related import, export and redirection of products, as well as pricing:

### Specific requirements in the event of supply shortages

**Obligations of the industry**

A considerable number of jurisdictions provide for specific regulatory requirements and obligations to be met in the event of supply shortages. They range from notification requirements to specifications on minimum quantities for storage, and stockpiling of medicinal products of major therapeutic interest, or concrete action plans to anticipate, prevent and manage shortages.

In the *UK*, the Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI) have recently produced guidelines for companies to follow in the event of a supply shortage of medicinal products. This includes notifying the DH about any foreseeable supply shortages that might have an impact on patient health care as soon as possible so that the DH and the pharmaceutical industry can mitigate shortages and implement back-up arrangements where possible.

In *France*, requirements applying to supply shortages have recently been strengthened. Among other obligations, pharmaceutical companies must constitute a safety stock covering four months of pharmaceutical needs (entry into force on 30 June 2020).

### Sanctions

In most of these jurisdictions, non-compliance may lead to sanctions, including fines. For example, in the *Czech Republic*, if a supply shortage leads to a suspension or termination of the supply, and if this is not notified to the relevant authorities, the registration holder as well as the distributor may face a fine in millions of CZK. In *France*, a fine of up to 30% of the annual turnover achieved with the medicinal product, with a cap at EUR 1 million, may be incurred in case of a breach of the obligations related to stock shortages. In *Italy*, small fines of up to EUR 18,000 can be imposed. Similarly, in *Romania*, small fines of up to EUR 20,000 apply to suppliers who fail to observe their obligation to maintain adequate and continuous supply of medical products. If the breach occurs more than once within a period of three months, this may lead to a withdrawal of the marketing authorisation of the relevant supplier.

### Exporting, importing, redirecting products and pricing

Considering the strongly increasing demand for face masks and similar products, a number of countries have enacted orders – or are considering taking action– to regulate the export, import or pricing of these products. In addition, a company may decide to redirect certain products between jurisdictions in order to meet market demands. Since the regulations on the labelling of medicinal products provide for local specifics, in particular, labelling in the national language, companies must be aware of the relevant requirements and possible exceptions.

#### Imports and exports

Just recently, the European Commission has adopted an implementing regulation (EU(2020/402)) making the exportation of certain products, such as medical protective gear, subject to the production of an export authorisation. With the regulation now adopted, the Commission aims to ensure a uniform European procedure.

Besides, national authorities are, in certain circumstances, authorised to take appropriate measures to address supply shortages, and many of them have already made use of their respective competencies:

In *Germany*, export limitations have been put in place, prohibiting the export of protective gear, such as respiratory masks, gloves and protective overalls. *Russia's* government imposed a similar ban, with masks, respirators and products for medical disinfection ordered to remain in the country until at least June 1, 2020. In *France*, the French Prime Minister just recently. decided to requisition all FFP2 and anti-projection masks to ensure their priority allocation to patients and health professionals. In the *Czech Republic*, the Ministry of Health has ordered a ban on the export of face masks and their sale to all but medical and social facilities and administration bodies.

Authorities of other countries may enact similar orders and prohibitions:

In *Poland*, the Minister of Health maintains a list of medical products threatened with shortage. Following the outbreak of COVID-19 this list has been recently updated by adding more than a thousand new products, including masks and surgical caps. Export of these products requires consent from the chief pharmaceutical authority, subject to a fine of up to EUR 22,000. Based on a new law, the Chief Sanitary Inspector may issue decisions imposing obligations relating to the distribution of certain products, including medicinal products, medical devices and personal protective equipment.

In *Spain*, the Spanish Drug Agency is, under certain circumstances, allowed to limit the outflow of medicinal products from the territory of Spain, in order to guarantee supply, to authorise the import of those medicinal products not authorised in Spain but legally authorised in other jurisdictions, or to grant exceptional manufacturing authorisations to allow the authorisation holder itself to recondition or relabel the product. Moreover, the Spanish Drug Agency may grant exceptional marketing authorisations to allow the commercialisation of products which do not have the registered specifications. These exceptional authorisations are usually granted for products which are equally authorised in Spain and abroad, but which are either not labelled in Spanish or which provide for an expiry date of less than six months.

In *Italy*, the Italian Medicines Agency ('AIFA') may take appropriate measures, which are decided by a specific task-force on a case-by-case basis, to address and overcome the unavailability of certain medicines. AIFA may grant, in cases of shortage of essential and/or irreplaceable medicinal products, temporary authorisations to import these medicinal products from other countries where they are still available.

In *France*, except in cases of *force majeure*, the French Health Authority may, in certain situations, order a pharmaceutical company to import equivalent medicinal products to France. The respective company is then also required to compensate the French social security for additional costs.

### Redirecting products: Labelling and related requirements

Where medicinal products are redirected from one country to another, applicable labelling requirements need to be observed. Generally, a medicinal product may enter a market only if local labelling requirements are met, in particular if it is labelled in the national language. However, various jurisdictions, e.g. the *Czech Republic* or *France*, have made use of exceptional rules set forth in EU Directive 2001/83/EC. According to these rules, the competent authorities of the member states may grant an exemption to certain requirements relating to the language of labelling or the package leaflet. A corresponding national provision will apply in *Germany* as soon as a current draft bill is enacted.

### Pricing of products

Several European jurisdictions have pricing regimes for certain products, such as essential, innovative or high-cost drugs. However, current demands often relate to pharmaceuticals and medical devices, such as masks and medical disinfectants, which are not or at least less regulated by statutory pricing schemes. In addition, antitrust rules prohibiting excessive and discriminatory pricing are usually not applicable to products without market dominance. In response to substantial price fluctuations and price hikes in recent weeks, some jurisdictions have enacted respective orders:

In *Russia*, legislation is expected to be passed soon, that will authorise the government to fix the retail price of any pharmaceutical or medical device for up to 90 days during an epidemic or similar emergency situation. In *France*, specific measures have recently been enacted to regulate the price of hydro-alcoholic gel. In the *Czech Republic*, a price cap to regulate (maximum) prices of face masks has been enacted. In *Poland*, the Minister of Health is currently authorised to set maximum prices for specific products used for COVID-19 counteractions.

## 3. Liability Risks

A pandemic situation might lead to potential, extended liability risks when treating a patient with COVID-19. In order to respond to the COVID-19 pandemic and to protect the public health to the greatest extent possible, some players in the Healthcare and Life Sciences sector are taking steps to develop drugs and vaccines specifically targeted at COVID-19 as quickly as possible.. In addition, patients may be treated with medicinal products which are not necessarily licensed for COVID-19 or its symptoms (e.g. off-label use). This raises questions about who will be liable if patients suffer harm as a result of these products.

### Products targeting COVID-19

As a general note, the manufacturer of the product is responsible for any defect of its products. A defect, in this sense, refers to a deviation of the actual specifications from the products' specifications as stated in the respective marketing authorisation or CE certificate.

In *France*, if, during a major health threat, a medicinal product is administered without a marketing authorisation or an authorisation for temporary use, its manufacturer will not be liable for damage caused by it if such use was required or recommended by a Ministerial Order.

In *Russia*, the antitrust regulator has initiated its first case against a Russian pharmaceuticals company advertising a medicinal product as "also for treating COVID-19", and for making efficacy claims without clinical evidence and off-label.

### Administering products to COVID-19 patients outside their label / intended use

Under usual circumstances, outside of a pandemic situation, when patients are treated with pharmaceuticals off-label, or where medical devices are used in ways other than their intended use, the liability lies with the attending physician who makes the decision of administering the product outside its authorised label or intended use. However, the marketing authorisation holder of the drug or the manufacturer of the medical device, respectively, may also be liable if it can be established that they knew about the off-label use, or even promoted or otherwise supported it. In the event of a pandemic, different rules may apply.

In *France*, if, during a major health threat, a medicinal product is administered off-label, its manufacturer will not be liable for damages caused by it if such use was required or recommended by a Ministerial Order.

Similarly, in *Romania*, the liability of the marketing authorisation holder of the medicinal product, the manufacturer, or the specialised medical personal is not triggered if such a medicinal product is used upon the recommendation or request of a national competent authority.

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