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Combating COVID-19: Government powers for safeguarding supply of critical products and potential conversion of production – Italy, Germany, Spain, and France

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The spread of COVID-19 is causing Europe to experience one of the greatest health crises in decades, the consequences of which are still unpredictable. Faced with this unprecedented situation, the governments of different European countries have been forced to issue a series of legislative measures to alleviate the social, economic, administrative, and health effects of the COVID-19 crisis. These circumstances have, among effects on other industry sectors, a significant impact on the pharmaceutical and medical devices' industries. **One matter of importance for the public and for manufacturers is the supply of critical products and potential conversion of production.**

In this informative note prepared by the teams of Hogan Lovells Milan, Munich, Madrid, and Paris, we provide a brief overview of the new regulations and discuss the effects of the measures adopted so far in the respective jurisdictions that may affect the life sciences industry.

Country by country updates

Italy

As COVID-19 infections escalate in Italy, the fear of a shortage of Personal Protection Equipment (hereinafter **PPE**) and other essential supplies to prevent the spread of the virus increases; in particular, the Italian government issued a Decree (D.L. 17 March 2020 no. 18, the so-called "Cura Italia" – "Heal Italy") with measures, more or less intrusive, impacting manufacturers of medical devices.

Article 6 of the Decree provides that, until the end of the state of emergency (that is, for the time being, until the 31 July 2020), **the Head of Civil Protection Department can order the requisition of "*sanitary and medical-surgical supplies, as well as movable property of any kind*" needed to tackle the crisis**. The administration will pay a requisition indemnity calculated on the supplies' market value on 31 December 2019**.** Referring to the Italian Code of Military Organization, **this article prevents any jurisdictional authority from suspending the enforceability of any such measures**.

A Senate Commission, now scrutinising the Decree, warns against the vagueness of this article: the absence of a list of supplies might allow the authorities to make arbitrary requisitions. It is worth highlighting that, according to the Decree, no production site can be seized for manufacturing purposes. Furthermore, a well-established Constitutional Court's case law supports the right to indemnification: the amount has to be "serious, reasonable, adequate and not merely symbolic" making this a point on which unjust orders from the authorities could be challenged. Some authors have also harshly condemned the reference to the Italian Code of Military Organization, since it is uncertain which consequences such reference might have.

Furthermore, the Decree sets out several urgent measures to tackle the crisis:

- **Ordinary clinical tests will not be required to market PPE**: manufacturers will only have to send a self-declaration of conformity and other useful information to the competent authority and receive its approval;
- **PPE manufacturers will be entitled to non-refundable grants** from the Italian Agency for inward investments promotion (Invitalia); in addition, funds have also been allocated for the purchase of the similar devices;
- Previous decrees prohibiting the export and simplifying the public purchase procedures of PPE are confirmed and shall remain in force;
- **The Head of the Civil Protection Department can temporarily seize any structure** (private hospitals, hotels and others) **to accommodate subjects under sanitary surveillance** when such measure cannot be enforced within their usual domicile – also in this case an indemnification to the premises' owner is due;
- Protocols to obtain medical and nursing license are temporarily streamlined.

Businesses shall keep abreast with the requisition powers and use increased flexibility in negotiations, to quickly move things along. Due to the ever-changing situation, the Government has been extraordinarily prolific and the legal framework in this sector is in continuous evolution. It is not far-fetched to think that other decrees will intervene in the next days, probably strengthening these measures, and consequently, we will continue to closely monitor the situation.

Germany

In the wake of combatting the COVID-19 pandemic, the German Federal Government proposed to enable further measures on the federal level. The proposal includes important measures concerning the supply of medical devices, diagnostics, protective gear, pharmaceuticals and narcotics, active pharmaceutical ingredients, and auxiliary materials. It is relevant for manufacturers, suppliers of raw material, and component parts, as well as auxiliary products and services for these goods.

The German parliament passed the bill – which is called *Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite* – on 25 March 2020. Once the Federal Council accepts the bill – which is expected on 26 March 2020, the new law will come into force within short time. Among other provisions, the bill will amend the Infection Protection Act (*Infektionsschutzgesetz - IfSG*). The Infection Protection Act is the central German law for combating infectious diseases. The purpose of the law is to prevent contagious infectious diseases among humans, to detect infections at an early stage, and to prevent their further spread. The Infection Protection Act was enacted by the German Federal Government on 1 July 2000. Against the background of Germany's federal structure, however, the German states enforce laws such as

the Infection Protection Act. As a result, the German Federal Government can – as it has repeatedly done – make recommendations for action on how to handle infectious diseases such as COVID-19, but these recommendations must first be implemented by the states in order to become legally binding. For this reason, the German Federal Government intends to amend the law.

The bill provides for a number of **new competencies for the Federal Government in case of a national epidemic.** Provided Parliament will accept the proposal, the law grants new powers to the Federal Ministry of Health. By way of ordinance – i.e., not requiring consent of the Federal Council – the Federal Ministry of Health may, among other, order:

- **Measures for procurement, storage, distribution, and supply of medical devices, diagnostics, protective gear, pharmaceuticals and narcotics, active pharmaceutical ingredients, and auxiliary material.** This may include reporting and notification obligations. If necessary, **seizure and use of such products can be ordered**. Where this amounts to dispossession, adequate provisions for compensation must be arranged for.
- **Prohibition of sale of products or other assignment of goods.** This may include prohibition to fulfill contractual obligations. Where this amounts to dispossession, adequate provisions for compensation must be arranged for.
- **Provisions for supply, price setting and reimbursement.**
- **Measures for continuance, conversion, opening, or closure of manufacturing plants or individual facilities** of companies manufacturing goods within the scope of the ordinance. Where this amounts to dispossession, adequate provisions for compensation must be arranged for.
- **Exceptions to existing medical device regulations and the German Medicines Act (*Arzneimittelgesetz – AMG*).** The Federal Ministry of Health will have the competence to order exceptions to German and European medical device regulations and to the German Medicines Act (*Arzneimittelgesetz – AMG*) and other regulations concerning manufacturing, labelling, market authorisation, clinical trials, application, and supply of such goods. That includes the possibility to establish exceptions to the conformity assessment procedure and, where applicable, market authorisation procedures. This comes in addition to an already existing ordinance enabling exceptions from the German Medicines Act in case of disaster (*AMG-Zivilschutzausnahmeverordnung – AMGZSAV*).
- **Exceptions regarding liability for products.** The Federal Ministry of Health will have the competence to amend rules on liability for pharmaceuticals, medical devices, and other goods in the scope of the bill. This comes in addition to an already existing ordinance enabling exceptions from the German Medicines Act in case of disaster.

Those new competencies will presuppose an "epidemic situation of national significance". This national epidemic must be determined by the German parliament. Earlier drafts of the bill required a decision by the Federal Government.

Such an "epidemic situation of national significance" is defined as a "serious danger to public health in the entire Federal Republic." This is possible if either the World Health Organization (WHO) has identified a "health emergency of international significance" and the introduction of a

threatening communicable disease into the Federal Republic of Germany is imminent or if the infectious disease threatens to spread in at least two Federal States.

If corresponding measures are taken and are unduly infringing rights, affected companies may seek relief before German administrative courts. Where applicable, compensation may be sought. We will monitor the further development of the new law and are available to discuss any questions you may have.

Spain

In Spain, as of 24 March 2020 and according to Update No. 54 of the Spanish Ministry of Health, 39,673 cases of COVID-19 have been registered (with 2,696 people deceased and 3,794 patients cured). The severity of the situation has led the Spanish Government to adopt a series of urgent legislative measures to try to deal with the COVID-19 pandemic, aimed at protecting the health and safety of citizens, containing the progression of the disease, strengthening the public health system, and reducing the social and economic impact of the pandemic. Many of these measures could have a major impact on pharmaceutical and medical device companies.

With the declaration of the state of alert on 14 March 2020 by means of Royal Decree 463/2020, numerous competencies and powers were effectively delegated to the Ministry of Health for the duration of the state of alert. Further regulations have been issued which have further increased these powers. For their part, the Autonomous Communities (the administrative territorial entities into which Spanish territory is divided) and their Administrations, retain the powers related to the management of the local administration of health services.

In view of their relation to the pharmaceutical and medical devices industries, we would like to highlight the following powers delegated to the Spanish Ministry of Health until the end of the state of alert:

1. **Powers established to strengthen the National Health System throughout the country** (as set forth in Article 12 of Royal Decree 463/2020 and further developed by Order SND/232/2020).

    i. All civil health authorities of the public administrations shall remain under the direct orders of the Minister of Health, who may impose extraordinary services on them.

    ii. The Minister of Health shall ensure the possibility to determine the best distribution to the territory of all technical and personal means, in accordance with the needs of the health crisis.

    iii. The Minister of Health may also exercise all powers necessary for these purposes in respect of privately owned health centers, services, and establishments.

2. **Powers aimed to ensure the provision of goods and services necessary for the protection of public health** (as set forth in Article 13 of Royal Decree 463/2020).

    i. The Minister of Health may issue orders to ensure the supply of the market and the operation of the services of the production centers affected by the shortage of products.

    ii. The Minister of Health may also intervene and temporarily occupy premises of any kind, including privately owned health centers, as well as those operating in the pharmaceutical sector.

iii. Additionally, the Minister of Heath may practice temporary procurements of all types of goods and impose mandatory personal benefits if necessary.

In addition to the aforementioned powers vested in the Minister of Health, different exceptional provisions have been established that may affect the pharmaceutical and medical devices industries:

1. **Reinforcement measures in the field of health** (as set forth in Articles 1 to 7 of Royal Decree- Law 7/2020).

   i. An extraordinary credit has been granted by the Ministry of Health to cover extraordinary expenses of the National Health System.

2. **Measures to support COVID-19 research** (as set forth in Articles 36 to 38 of Royal Decree-Law 8/2020).

   i. Public entities that comprise the Spanish System of Science, Technology, and Innovation, when exceptional measures have to be developed in the field of management of the health emergency caused by the COVID-19, may establish extraordinary working hours for its workers who will have to be financially compensated for said hours.

3. **Information duties** (as set forth in Order SND/233/2020 and Order SND/234/2020).

   i. The regulated entities shall submit information on the following products: surgical masks, protection masks, COVID-19 diagnostic PCR kits, rapid diagnosis kits, swabs, protective glasses, nitrile gloves, disposable gowns, hydroalcoholic solution, invasive mechanical ventilation devices, sanitary alcohols, and chlorhexidine.

   ii. The Autonomous Communities must communicate the Ministry of Health their epidemiological information, healthcare capacity, and human and material resource needs.

4. **Measures concerning Personal Protective Equipment** (as set forth in the Resolution of 20 March 2020, of the General Secretary of Industry and of Small and Medium sized Companies).

   i. In view of the shortage of PPE with the regulatory CE marking on the national market and the need for them to protect against COVID-19, during the period of the alarm state, PPE without CE marking that meet certain specifications are accepted.

5. **Obligations for the provision of information, supply, and manufacture of certain drugs** (as set forth in Order SND/276/2020).

   i. Manufacturers and marketing authorization holders of certain drugs specified in the Annex to Order SND/276/2020 must provide information on them whenever required by the Ministry of Health or the Spanish Agency of Medicines and Health Products.

   ii. They shall also lay down the necessary measures to ensure the supply of these drugs to health centers and services in accordance with their needs, and their supply may be demanded on a once-a-day basis.

It is clear that the powers delegated to the Spanish Ministry of Health and all the exceptional measures decreed in Spain can have a significant impact on the pharmaceutical and medical devices' industries and it should be kept in mind that these measures may change and increase in the following weeks as further development and updates are announced. We will be monitoring the legal framework.

In spite of these intrusive measures, Spanish Health Authorities have encouraged manufacturers, importers, and distributors of pharmaceutical products and medical devices to continue their businesses and maintain their normal supply to their respective clients. The challenge is clear. A high degree of transparency, collaboration, and flexibility with the Authorities and stakeholders is key.

France

Since the outset of the COVID-19 crisis, the French Government has taken numerous measures aiming to address the current sanitary crisis and resulting economic consequences.

1. **Emergency Law of 23 March 2020 addressing the COVID-19 epidemic**

The French Government adopted on 23 March 2020 a specific legislative arsenal to fight the COVID-19 crisis, i.e., the **Emergency Law no 2020-290 to address the COVID-19 epidemic** (hereafter the Emergency Law).

Firstly, the Emergency Law authorizes the Government to declare the "**state of health urgency**" (*état d'urgence sanitaire*) for a limited period of time. With the publication of the Law on 24 March 2020, this state of health urgency came into force throughout the French national territory for a period of two months. Under this regime, the Prime Minister and the Minister of Health are allowed to take exceptional measures to tackle a sanitary crisis, and in particular:

i. **restrict public freedoms** (including the freedom to conduct business) and impose potential complete lockdown, with higher sanctions in case of non-compliance;

ii. **impose price caps on certain products in case of stock or supply tensions**;

iii. **order seizure of necessary goods and services**: pursuant to this provision, private companies could for instance be enjoined to produce medical devices or drugs to ensure appropriate supply to health establishments.

All the measures must be strictly proportionate to the sanitary crisis, appropriate to the time and place circumstances, and cease as soon as they are no longer necessary. The Emergency Law provides for a way to challenge governmental measures taken under the state of health urgency (summary proceedings before administrative courts known as *référé-liberté* (petition for protection of fundamental freedoms) or *référé-suspension* (petition for suspicion of a measure under certain conditions), despite the fact that French Courts are currently closed but for urgent cases. Such cases would be heard as a matter or emergency.

Secondly, as time is of the essence, the Emergency Law authorizes the French Government, for a three month period starting on 12 March 2020, to **use Government Orders ("*ordonnances*") to enact new legislative provisions** without having to first submit bills to the French Parliament. The French Government thus has the ability to legislate directly in order to take measures to mitigate the impact of the crisis on companies and workers. The scope of intervention conferred to the French Government is **very broad and concerns all sorts of**

economic and social measures that are deemed necessary to address the economic consequences of the crisis. The Government adopted 25 "*ordonnances,*" which have been published on 26 March 2020.

2. **Other decrees and ministerial orders addressing the Covid-19 epidemic**

In the early stages of the crisis or in addition to the Emergency Law, the French Government has issued several urgent Decrees and ministerial orders. In particular:

- **a seizure order** (now under consolidated Decree No. 2020-293 of 23 March 2020) to compel owners of protection masks on the French territory to hand them to the French State, in exchange of an indemnity compensating the direct loss and not the loss of profit.

  Stocks of protection masks are therefore requisitioned through 31 May 2020 in order to ensure priority access to caregivers and patients, notably:

  - stocks of respiratory protection masks (types FFP2, FFP3, N95, etc.) held by any legal entity (company, association, public body…) under public or private law;

  - stocks of anti-projection masks complying with standard EN 14683 held by the companies that manufacture or distribute them.

  As regards stocks of imported masks, they may be requisitioned in whole or in part by an order of the Minister of Health above a certain threshold.

- to ensure the production and dissemination of hydroalcoholic products, the Government provided for a **price cap** to limit price surged on hydroalcoholic gel, an **authorization for the placing on the market of certain hydroalcoholic biocidal products for human hygiene** until 31 May 2020, and an authorization for pharmacies to make their own hydroalcoholic gels until 31 May 2020 as well (under consolidated Decree No. 2020-293 of 23 March 2020);

- **restriction of sale of paracetamol by pharmacists to patients without prescription.** Pharmacists may dispense without prescription only 1 box of paracetamol (500 mg or 1g) per symptom-free patient, or 2 boxes (500 mg or 1g) in case of symptoms (pain and/or fever) (ministerial order of 23 March 2020 from the Health Minister);

- In addition, said ministerial order of 23 March 2020 from the Health Minister provides for exceptional drug dispensation by pharmacists to avoid discontinuation of treatments. In particular, exceptionally for chronic treatment of patients, when the period of validity of a renewable prescription has expired and in order to avoid any interruption of treatment detrimental to the patients' health, pharmacists, service providers, or medical equipment distributors can – until 15 April 2020 and within the limits of the prescription initially provided – proceed to **dispensation a volume of products or services guaranteeing the continuation of treatment until the end of the state of health urgency**;

- **derogatory conditions for the reimbursement of telecare (*téléconsultation*) activities;**

- powers given to the general directors of the regional health agencies (*ARS – Agences régionales de santé*) to authorize health establishments to carry out a care activity other than the one for which they had been authorised (ministerial order of 21 March 2020 from the Health Minister).

Regarding **clinical trials**, the French Health Authority ANSM (*Agence nationale de sécurité du médicament et des produits de santé*) **recommended that priority should be given to clinical trials related to the management of patients infected with COVID-19.** More generally, **sponsors should re-evaluate whether it is appropriate to initiate or continue a clinical trial**; and, where appropriate, consider potential necessary adaptations to ongoing clinical trials. In such cases, the sponsor should assess in coordination with the investigators the risks of the contemplated adaptations with respect to the safety of the patient and the integrity of the clinical trial data. Priority must of course be given to the safety of patients. Such assessment should be held available to the authorities.

Conclusion

With the aim to tackle the COVID-19 outbreak, the governments of several European countries are granting great powers and are adopting, to a greater or lesser extent, intrusive measures that may have a high impact in the medical devices and pharmaceutical products industries. Among others, these measures include possible seizures, reporting and notification obligations, temporarily occupation of premises, duty to supply certain medical devices and drugs, or restrictions in the supply of specific products.

Some of these measures may imply compensations to the affected companies so where applicable, compensations which must be sought. Companies should also be aware that in certain cases they can bring court proceedings in order to challenge unjustified specific adopted measures.

The legal framework is constantly evolving these days. We will be monitoring the several developments and will provide regular updates. We are pleased to provide any help you may need.

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