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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 – 15 May 2020 update

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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. This piece is an update to our earlier article published 27 March 2020.

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 updated regulations and discuss the effects of the measures adopted to date in the respective jurisdictions that may affect the life sciences industry.

Country by country updates

Italy

Since the beginning of the COVID-19 emergency in Italy, the Italian government has adopted many measures to ensure the supply of Personal Protection Equipment (PPE) and other essential medical devices to prevent the spread of the virus. Despite the reduction of new COVID-19 infections, the emergency has not ended yet and the Italian government is still strongly engaged to ensure the availability of PPE.

In this regard, the Italian government issued a Decree (Law Decree 17 March 2020 no. 18, the so-called "Cura Italia" – "Heal Italy" – ratified with amendments by Law 24 April 2020 no. 27) 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**.

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. By Order no. 4 dated 23 March 2020, the Special Commissioner – with powers granted by the same Decree – has specified what expenditures are eligible for funding and what requirements manufacturers have to meet in order to benefit from such funding;
- Simplification of the public purchase procedures of PPE and other medical devices essential to tackle the coronavirus outbreak;
- **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.

The prohibition of exporting PPE without the prior authorisation of the Department of Civil Protection – provided for in the Order no. 639 issued by the Department of Civil Protection on 25 February 2020 – is no longer effective from 24 April 2020, i.e. the date of publication on the Official Journal of the Order no. 667 issued by the Department of Civil Protection on 22 April 2020.

Furthermore, appropriate measures have been taken to speed up the import of PPE in Italy, from the point of view of both customs clearance and health controls which the USMAF (Office of Maritime, Air and Border Health) is competent for. Indeed, the Order of 28 March 2020 no. 6 of the Special Commissioner provides that the *Agenzia delle dogane e dei monopoli* (the Customs and Monopolies Agency) must improve any useful action to enable the rapid customs clearance of all PPE. In particular, the Agency must proceed with the direct release of the PPE, with exemption from customs duties and value-added tax (VAT), but exclusively towards the regions, autonomous provinces, local territorial authorities, public administrations, public hospitals and private hospitals accredited and included in the regional emergency network and subjects exercising essential public services. The Order of 9 May 2020 no. 13 of the Special Commissioner adds that Federfarma, Assofarm, Farmacie Unite, Unaftisp, FTPI, FNP, PI, Federfardis, MNLS, ULPI, Federfarma servizi ed ADF, Confcommercio, Federdistribuzione, and ANCD Conad may also benefit from the rapid and direct customs clearance of all PPE adopted by the Agency pursuant to the Order of 28 March 2020 no. 6. In addition to such measures, the Order of 2 April 2020 of the Ministry of Health provides that the import of goods needed to contrast the COVID-19 emergency and bought – not for commercial purposes – by subjects referred to in the above

mentioned Order 28 March 2020 no. 6 of the Special Commissioner, may be completed on the condition that the USMAF's health clearance is delivered to the customs offices within five working days after the release of the goods. Such health clearance – pursuant to Order of the Ministry of Health dated 26 April 2020 – is issued by USMAF on the basis of controls on the CE marking and compliance with Legislative Decree of 24 February 1997 no. 46 (*Implementation of Directive 93/42/EEC concerning medical devices*).

Finally, pursuant to the Decree of the Ministry of Health dated 2 April 2020, permits for the export, import and transit of narcotic drugs and psychotropic substances shall be issued only electronically to the email address indicated by the applicant signed with an electronically reproduced and non-autograph signature of the Director of the Central Narcotics Office of the Directorate-General for Medical Devices and the Pharmaceutical Service.

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 and continues to be extraordinarily prolific and the legal framework in this sector is in continuous evolution. In this context – considering the current decrease of COVID-19 infections, and hoping that there will be no future escalation of the virus spread – the Italian government should gradually lighten the adopted measures.

Germany

In order to combat the COVID-19 pandemic and to mitigate the effects and consequences for the German population, the German Federal Government has amended various existing laws and adapted new ones in the recent weeks in order to safeguard the supply of critical products. The main purpose of the legislative measures is to facilitate and speed up the fight against the health crisis, strengthening the competences for the Federal Government in doing so, and harmonizing national legislation. These measures are taken alongside others combating the economic and social fallout of the pandemic.

Since 28 March 2020, the **Act on Protection of the Population in Case of a National Epidemic** (*Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite)* has been in effect. Among other measures, the Act amended the **Infection Protection Act** (*Infektionsschutzgesetz – IfSG*) and empowered the German Federal Ministry of Health in the event of an epidemic situation of national coverage like COVID-19 – without prejudice to the powers of the German states – to adopt certain ordinances without the consent of the Federal Council. The aim of the measure is to ensure the supply of medical products, including pharmaceuticals, active ingredients, starting materials and auxiliary materials, medical devices, laboratory diagnostics, aids, personal protective equipment and products for disinfection.

On this legal basis, the German Federal Ministry of Health has, among others, already enacted the following ordinances:

- **Ordinance on the Procurement of Medical Devices and Personal Protective Equipment during the SARS-CoV-2 Epidemic** (*Verordnung zur Beschaffung von Medizinprodukten und persönlicher Schutzausrüstung bei der durch das Coronavirus SARS-CoV-2 verursachten Epidemie*) of 8 April 2020: According to this ordinance, the Federal Republic of Germany is the importer within the meaning of the Medical Device Act (*Medizinproduktegesetz – MPG*) or the EU Regulation on personal protective equipment if medical devices or personal protective equipment is ordered within the "Procurement Programme of the German Federal Government" (*Beschaffungsprogramm*) since 27 March 2020 and placed into the territory of Germany.

Under the procurement programme, the Federal Government is making use of third parties to procure certain devices abroad. To this end, it is necessary to exempt third parties from certain risks as importers under the respective regulations. The ordinance stipulates that the Federal Republic of Germany assumes responsibility for the role of importer of medical devices and personal protective equipment procured on its behalf. The natural or legal persons entrusted with the shipment are not themselves importers within the meaning of the above provisions. An important restriction regarding the placement of imported medical devices/personal protective equipment on the market, however, is that these they may only be given to a selected group of people as defined by the German Federal Ministry of Health.

- **SARS-CoV-2 Drug Supply Ordinance** (*SARS-CoV-2-Arzneimittelversorgungs-verordnung*), of 20 April 2020: The ordinance enables competent authorities to deviate from provisions of the Pharmacy Act (*Apothekengesetz*) and the Pharmacy Operating Regulations (*Apothekenbetriebsordnung*) if this is necessary to continue ensuring the proper supply of relevant products, including pharmaceuticals, narcotics, medical devices, and other goods customary in pharmacies. Among other things, the ordinance provides pharmacies with a temporary remuneration for the courier service and facilitated exchange options when dispensing medicines. The aim is to ensure the care of the chronically ill and of patients in quarantine and domestic isolation. In addition, the German Federal Ministry of Health will be given the opportunity to control the sale of medical supplies.

In addition to these ordinances, the Federal Ministry of Health has published further proposals for regulations with regard to COVID-19:

- **Draft Ordinance to Ensure the Supply of Medical Products to the Population** in the Event of the Epidemic Caused by the Coronavirus SARS-CoV-2 (*Medizinischer Bedarf Versorgungssicherstellungsverordnung – MedBVSV*) of 6 April 2020: The draft ordinance enables **central procurement of medical products** by Federal Authorities to supply the population during the epidemic. Medical products include, among others, pharmaceuticals, medical devices, laboratory diagnostics, personal protective equipment, and disinfectants. The draft ordinance provides for several exceptions from the German Medicinal Products Act (*Arzneimittelgesetz - AMG*), including fast track assessment of medicines procured by certain Federal Authorities for which no marketing authorization is granted in Germany. The draft ordinance stipulates quality criteria for such medicines, including a positive benefit-risk profile. Other provisions include exceptions on labelling, use of expired products, and exceptions regarding the ordinance on manufacturing of medicines and active pharmaceutical ingredients, to name but a few. Further important exceptions would concern the GCP-ordinance and EU Regulation on personal protective equipment.

- **Bill Concerning a Second Act on Protection of the Population in Case of a National Epidemic** (*Zweites Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite)* of 5 May 2020: On 7 May 2020 the first hearing of the German Parliament took place to discuss the draft bill. It is intended to develop and further supplement 14 regulations and measures already taken by the German Government. These are, among others, **amendments to the Infection Protection Act** to also **cover vaccines** and **substances and materials** required for the manufacture and transport of the products to ensure the supply.

Due to COVID-19, the German Federal Institute for Drugs and Medical Products (*Bundesinstitut für Arzneimittel und Medizinprodukte*) has temporarily changed its regulatory approval process to a more simple and accelerated procedure in order to be more efficient in the authorisation of medicines, in line with the European Commission, the European Medicines Agency, and the Heads of Medicines Agencies. During the COVID-19 crisis, there are also special approval mechanisms available under the Medical Devices Act, which applies for some personal protective equipment and medical devices.

The existing federal COVID-19 legislation has not provided any special product liability protections. Although the Federal Ministry of Health was empowered to provide for exceptions regarding provisions on liability, **no particular liability protections have been implemented to date.** With regard to product liability, risks to producer and supplier remain the same, while some regulatory risks were decreased.

The Draft Ordinance to Ensure the Supply of Medical Products to the Population in the Event of the Epidemic Caused by the Coronavirus SARS-CoV-2 would provide an exception regarding product liability. Instead of the liability regime of the AMG, liability for products in the scope of the ordinance would be governed by the Ordinance on Authorization of Exceptions from Provisions of the Medicines Act for Civil and Disaster Protection, for the Army, for the Federal Police and for the States' Riot Police of 17 June 2003 (*AMG-Zivilschutzausnahmeverordnung – AMGZSAV).*

We will continue monitoring the further developments and are available to discuss any questions you may have.

Spain

Since our last update on 26 March 2020, the health situation in Spain has remained severe. As of 12 May 2020 and according to the figures published in Update No. 103 of the Spanish Ministry of Health, the number of registered COVID-19 cases has increased to 228,030 (with 26,920 deceased). Consequently, the need to continue combating the situation has led to the issuance of numerous further legislative measures to the ones analyzed on our previous note. Some of these regulations have also had an impact on the supply of medical devices and medicines in the Spanish market. In this sense, the most relevant regulations and provisions can be summarized as follows:

(i) It should firstly be noted that the state of alarm that was declared on 14 March 2020 by means of Royal Decree 463/2020, has been extended provisionally until 24 May 2020 (and could be furtherly extended if necessary). As a result of this, the faculties delegated by Royal Decree 463/2020 to both the Ministry of Health and the government analyzed on our previous note shall remain in force at least until that date.

(ii) Secondly, on 6 April, Order SND/326/2020 that establishes **special measures for the granting of licenses for the operation of installations and of certain medical devices without CE marking** was published. This regulation allows for surgical gowns and masks to be donated to the Ministry of Health without obtaining any kind of benefit and without the need for these products to have previously obtained the usually mandatory CE marking. Moreover, article 5 of this Order establishes that any possible liability will be assumed by the General State Administration always provided that the product was donated with the aim to attend the affected by the pandemic.

(iii) In addition, Order SND/344/2020 was published on 13 April. This order sets out more exceptional measures to strengthen the National Health System. The main novelty introduced by it is that **it makes available to the Autonomous Communities** (the Spanish administrative regional entities) **all privately owned clinical diagnostic health centers**, services, and establishments located in their territory that are not already providing services in the National Health System, as well as their personnel, to conduct diagnostic tests to detect COVID-19. This availability of resources also includes the possibility to eventually adopt the necessary measures to regulate the prices of diagnostic tests for the detection of COVID-19, in order to avoid the service being abused. However, note that diagnostic test prices have not been regulated for the time being.

(iv) In our previous article, we explained how Order SND/276/2020 obliged manufacturers and marketing authorisation holders of certain medicines specified in the Annex to the Order **to provide information, to supply, and to manufacture certain medicines** whenever the Ministry of Health or the Spanish Agency of Medicines and Health Products required it. Well, **those obligations have been extended to other medicines** by means of Order SND/353/2020, of 17 April.

(v) Furthermore, on April 19, Order SND/354/2020 was published, establishing **exceptional measures to guarantee the population's access to products recommended as hygienic measures** to prevent the spread of COVID-19. This order establishes the procedure for setting the maximum retail price of medical products, as well as those products necessary for the protection of the population's health from COVID-19, determines the information that must be established on the labelling of hygienic masks, and defines the conditions for the unit sale of surgical masks that are not individually packaged to the public.

(vi) The **price of masks, antiseptic washes, and antiseptic gels was subsequently set** following the proceedings established by **Order SND 354/2020** by two Resolutions of the General Directorate of the Common Portfolio of Services of the National Health and Pharmacy System of 22 April and 2 May respectively. The current established price is €0.96 for surgical masks. As per the set price for antiseptic wash, up to 150 milliliters it is set at €0.032 per milliliter, from 151 milliliters to 300 milliliters at €0.023 per milliliter and from 301 milliliters to 1,000 milliliters at €0.015 per milliliter. Finally, with regards to the price set for gels, up to 150 milliliter it is set at €0.025 per milliliter, from 151 milliliters to 300 milliliters €0.021 per milliliter and from 301 milliliters to 1.000 milliliters, at €0.015 per milliliter.

(vii) Finally, Royal Decree Law 15/2020, of 21 April, on urgent complementary measures to support the economy and employment determines, among other things, that the rate of 0 percent of VAT will be applied to the supply of goods, imports and intra-community acquisitions of certain products detailed in its Annex (and which include all types of medical products such as PPE, masks, or respirators) whose recipients are public entities, clinics or hospital centers, or private entities of a social nature.

All the above referred regulations consist of extraordinary measures that are undoubtedly having a powerful impact on the pharmaceutical and medical devices' industries as these are (i) setting prices of specific products, (ii) imposing new obligations to collaborate with health authorities, provide information, and supply and manufacture certain products, and (iii) adding further requirements in respect of product labelling regarding certain products, among others. As time

progresses, these measures will continue to adapt and change according to the circumstances. In this context, we will keep monitoring the legal framework and provide updates.

France

Since the outset of the COVID-19 crisis, the French Government has taken numerous (and quickly evolving) measures to address the current health crisis and resulting economic consequences. As of 13 May 2020, France has reported 140,734 confirmed cases and 27,074 deaths, making these emergency measures still relevant.

1. Emergency Law of 23 March 2020 addressing the COVID-19 epidemic and Law of 11 May 2020 extending the state of health emergency

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

As the lockdown is gradually coming to an end as of 11 May 2020, the French Government adapted and specified this legislation with **Law no. 2020-546 of 11 May 2020 extending the state of health emergency** (hereafter the Extension Law). The French Constitutional Council reviewed, marginally amended and approved the Extension Law.

Firstly, the Emergency Law had authorized the Government to declare the "**state of health emergency**" (*état d'urgence sanitaire*) for a limited period of time. The state of health emergency was initially decided for a two-month period until the Extension Law extended this period up to 10 July 2020.

Under this regime, the Prime Minister and the Minister of Health are allowed to take exceptional measures to tackle a health crisis, and in particular:

i. **Restrict public freedoms** (including the freedom to conduct business) and impose potential complete lockdown, with higher penalties in case of non-compliance. The Extension Law expands such powers so as to regulate or prohibit the movement of persons and vehicles and to regulate access to transportation means and the conditions for their use;

ii. **Impose price caps on certain products to prevent or resolve stock or supply tensions**, such products as hydro-alcoholic gel and protective masks;

iii. **Order requisitions of necessary goods, persons, 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 or the population;

iv. **Order 14-day isolation and quarantine measures** for persons who, before arriving to France, have stayed during the previous month in an area where the COVID-19 is circulating. Where the measure prohibits said persons from leaving home, the French Constitutional Council requires that the extension of such isolation or quarantine measures could not take place without a judge's authorization. This provision is not applicable to travelers coming from the Schengen area and the UK, regardless of their nationality;

v. **Collect and process data of persons with COVID-19 and persons who have been in contact with them.** The system is intended to identify infected people and collect information on persons who have been in contact with them, if necessary without the consent of data subjects, in order to break the chain of infection. The processing is

unrelated to the tracking mobile application (which is not yet ready) and is subject to strict conditions (in particular with respect to the purpose of processing, the retention period, and data subjects' rights);

vi. **Take all measures to ensure that appropriate drugs are made available** to patients.

All the measures must be strictly proportionate to the health crisis, appropriate to the circumstances of time and place, 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 emergency (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)). Such cases must be heard as a matter or emergency.

Secondly, the Emergency Law authorized the French Government, for a three-month period starting on 12 March 2020, to **use Government Orders (*ordonnances*) to enact new legislative provisions** without first having to 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 on 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.

To this end, **the Government has so far taken more than 30 Government Orders**. Among these, Government Order no. 2020-306 of 25 March 2020 has, for instance, modified procedural time limits and legally set periods before jurisdictions during the state of health emergency and Government Order no. 2020-313 of 25 March 2020 has eased the conditions for operating and financing social and social healthcare institutions, such as nursing homes.

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

In the early stages of the crisis, in addition to the Emergency Law, the French Government has issued several urgent Decrees and Ministerial orders, which for example ordered the seizure of protective masks (see Decree no. 2020-293 of 23 March 2020, now abrogated).

Most of these measures have been abrogated or replaced by provisions from **Decree no. 2020-548 of 11 May 2020**, issued in the wake of the Extension Law. The following measures are worth noting:

- **Hydro-alcoholic gel**: there is still a price cap on hydro-alcoholic gel, including hydro-alcoholic gel made by pharmacies (Decree of 11 May 2020, Article 16);
- **Protective masks:** the 11 May Decree establishes a price cap for single-use surgical masks that meet the definition of medical devices (Decree of 11 May 2020, Article 17). The retail price is now capped to €0.95 per unit (including VAT), while the wholesale price is capped to €0.80 per unit (excluding VAT). In addition, pharmacists are allowed to sell non-sanitary masks, manufactured according to an industrial process and meeting the applicable technical specifications (Ministerial order of 25 April 2020, Article 1);
- **Requisition orders:** where the health situation requires it, the representative of the state in the concerned department (*Préfet*) is entitled to issue seizure or requisition orders on health establishments and on any goods, services or persons that may be necessary for such establishments to operate, such as healthcare professionals (Decree of 11 May 2020, Article 18). The representative of the state in the department can also seize any raw materials necessary for the manufacture of masks and protective clothing;

- **Derogating measures to facilitate the availability of medical treatments:**

- **Hydroxychloroquine:** Health establishments can prescribe, dispense and administer hydroxychloroquine and the association lopinavir/ritonavir to patients with COVID-19 provided that the decision is taken collegially and that it complies with the recommendations of the French High Council for Public Health (*Haut Conseil de la santé publique*) (Decree of 11 May 2020, Article 19);

- In addition, Plaquenil© and hydroxychloroquine preparations can only be dispensed by pharmacies as part of an initial prescription from specialists in rheumatology, internal medicine, dermatology, nephrology, neurology or paediatrics or as part of a prescription renewal from any doctor. The French Administrative Supreme Court (*Conseil d'Etat*) dismissed four petitions requesting that access to Plaquenil© be extended to patients suffering from COVID-19. The French Administrative Supreme Court in particular based its decision on the "*methodological inadequacies*" of the scientific studies available to date (French Administrative Supreme Court, April 22, 2020, decisions no. 440009, 440026, 439951 and 440058);

- **Rivotril©:** Rivotril© in injectable form may be dispensed by pharmacies for patients suffering or suspected to be suffering from COVID-19 whose clinical condition justifies it, and provided that they have a prescription specifying "*Off-label Prescription in the context of COVID-19*" (Decree of 11 May 2020, Article 20);

- **Paracetamol:** the 11 May Decree also provides that medicinal products with paracetamol in injectable form may be dispensed in accordance with their marketing authorisation by health establishments' pharmacies (*Pharmacies à usage intérieur*) to treat fever and pain of patients suffering or suspected to be suffering from COVID-19 and whose clinical condition justifies it (Decree of 11 May 2020, Article 20);

- **Drug shortage:** in case of a shortage of human use pharmaceutical specialties, medicinal products for veterinary use with the same therapeutic purpose, having been granted a marketing authorization for the same active substance, may be prescribed, prepared, dispensed, and administered in the same way in health establishments (Decree of 11 May 2020, Article 21).

The Decree of 11 May 2020 is further completed by the amended Ministerial order of 23 March 2020, which in particular provides for the following measures:

- **Extension of the validity of drug prescriptions:** the Ministerial order provides for exceptional drug dispensation by pharmacists to avoid treatment discontinuation. In particular, exceptionally for the treatment of chronic illnesses, when the period of validity of a renewable prescription has expired and in order to avoid any interruption of treatment harmful to patients' health, pharmacists, service providers, or medical equipment distributors can – until 31 May 2020 and within the limits of the prescription initially provided – **dispense a volume of products or services ensuring continuation of treatment until the end of the state of health emergency** (Ministerial order of 23 March 2020, Article 4). This derogation also applies to prescriptions for nursing care that have expired;

- **Restriction of over-the-counter sale of paracetamol by pharmacists:** pharmacists may sell over the counter 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, Article 6) The sale of such products on the Internet is suspended;

- **Restriction of sale of nicotine products:** the provision by pharmacists of products containing nicotine and used for the treatment of tobacco addiction is limited to the number of boxes necessary for a one-month treatment (Ministerial order of 23 March 2020, Article 6). The number of boxes dispensed is recorded in the patient's pharmaceutical record, irrespective of whether the patient had a medical prescription or not. The sale of such products on the internet is suspended;

- **Derogatory conditions for the reimbursement of telecare (*téléconsultation*) activities** (Ministerial order of 23 March 2020, Article 8)**.**

In addition to these measures, the French Health Authority ANSM (*Agence nationale de sécurité du médicament et des produits de santé*) allowed for derogations in the supply of products, in particular:

- **Serialisation:** ANSM provides for the possibility for pharmaceutical companies to suspend serialisation until 31 May 2020, on a voluntary and temporary basis, in order to speed up the manufacture, release and availability of batches of medicinal products (link);

- **Labelling and risks of medication errors:** for some specific drugs imported from abroad and essential for the care of patients, ANSM has waived the obligation to label them in French language. ANSM asks health establishments' pharmacists to share with healthcare teams the conditions and special precautions for using these drugs (link);

- **Innovative medical devices**: ANSM has provided guidelines aiming to facilitate the use of alternative medical devices, while preserving patient safety (link).

ANSM also issued specific recommendations **with respect of clinical trials.** ANSM 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 any considered adaptations with regard to the safety of patients and the integrity of the clinical trial data. Priority must of course be given to patient safety. The European Commission published on 28 April 2020 guidance to ensure that clinical trials can continue to take place in the European Union during the COVID-19 pandemic (link).

Conclusions

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 several developments and will provide regular updates. We are pleased to provide any help you may need.

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