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Legal Implications Of COVID-19 For Pharmaceutical And Medical Device Companies In France

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The impact of Coronavirus (COVID-19) on pharmaceutical and medical device companies has been unique as, not only have these businesses had to set up emergency management systems practically overnight in order to maintain their “normal” business operations, the population also expects the sector to make significant contributions to the fight against COVID-19.

The current crisis mode raises a variety of legal and commercial questions. This article addresses a number of key issues that specifically affect the pharmaceutical and medical device industry in France.

IN DEPTH

Clinical Trials

The European Medicines Agency (EMA), together with the European Commission and the Heads of Medicines Agencies (HMA), on 20 March 2020 published an initial Guidance on the Management of Clinical Trials during the COVID-19 pandemic. EMA points out that sponsors should carefully and critically question whether or not they need to start a new clinical study or include new study participants in an ongoing study. With regard to ongoing studies, sponsors should in particular consider whether and to what extent they may temporarily suspend the study in certain facilities and/or extend the intended overall duration of the study. In individual cases—in the interest of the health of the study participants—it may also make sense to modify the conduct of a study, e.g., transfer study participants to another institution or replace visits with video or telephone conferences.

The French drugs agency, the Agence Nationale de Sécurité du Médicament (ANSM) has published a Q&A with recommendations for on-going clinical trials being conducted in France. The ANSM further invites sponsors to email their specific questions to questions.clinicaltrials@ansm.sante.fr or ccs-pole-recherche@sante.gouv.fr, with “COVID-19” in the subject line.

Accelerated Market Access for Drugs to Treat COVID-19

Legislation relating to the pharmaceutical sector provides for a number of procedures to ensure rapid

market access for drugs in particularly sensitive cases.

At EU level, these procedures include, in particular, the Priority Medicine (PRIME) system, which enables accelerated assessment and granting of conditional approval for priority medicines. The EMA currently offers free scientific advice for the benefit of companies developing vaccines or therapeutics against COVID-19. These companies are invited to contact EMA at 2019-ncov@ema.europa.eu.

The EMA's Guidance on the Management of Clinical Trials specifically addresses the launch of new clinical trials for treatments of COVID-19, and requests the use of large, multinational trial protocols in line with the call by the Committee for Medicinal Products for Human Use for robust trial methodology in clinical trials for potential COVID-19 treatments or vaccines.

The European Commission has called for startups, and small and medium-sized enterprises with technologies and innovations that could help with treating, testing, monitoring, or otherwise supporting the global response to the Coronavirus outbreak to apply to a €164 million round of funding from the European Innovation Council.

In France, the ANSM has implemented accelerated procedures for the initial assessment of authorisation requests for clinical trials related to COVID-19. In order to ensure proper follow-up of these requests, the ANSM recommends that trial managers submit an authorisation request as soon as possible to enable the ANSM to prioritise the clinical trial, guide the evaluation and determine whether or not additional information is needed. Trial managers should also contact the French Ministry of Health (the DGOS) before the finalisation of the initial authorisation procedure to make sure that clinical trial centres are prepared.

Export of PPE and Selected Medical Devices Subject to Authorisation

Personal protective equipment (PPE) and certain medical devices in particular demand as a result of COVID-19 are currently manufactured in only a few Member States. Some countries have already prohibited the export of protective equipment to ensure they meet their own needs.

In order to continue to meet the high demand for PPE and selected medical devices in the European Union in the future, the Commission, in Regulation (EU) 2020/402 of 14 March 2020, temporarily made the export of certain products, including protective goggles and visors, face shields, oral and nasal protective equipment, and protective clothing and gloves, subject to authorisation. An export license will only be issued in special, individual cases. At the time of publication, the Regulation is due to expire on 26 April 2020.

Market Entry Facilitation for PPE and Selected Medical Devices

The market entry of PPE usually requires a—sometimes lengthy—conformity assessment procedure and Conformité Européene (CE) marking.

In order to adapt the supply of these products to the increasing demand as quickly as possible, the European Commission seeks to simplify, to a considerable extent, the market entry for PPE and medical devices with its Recommendation (EU) 2020/403 of 13 March 2020.

In the Recommendation, the Commission requests the competent market surveillance authorities and notified bodies to take all available measures to provide immediate access to PPE and medical

devices for healthcare professionals for the duration of the current health threat. Accordingly, PPE and medical devices may be placed on the market temporarily and, in certain circumstances, even without CE marking.

Medical device companies should carefully consider, and coordinate with the competent supervisory authorities and notified bodies to determine, whether or not their products are eligible for market access facilitation in line with the Commission's Recommendation.

Hoarding of and Profiteering From Restricted Medicines and Products

Through a series of orders issued throughout March, the French Government has attempted to prevent shortages of medicines and products.

An order adopted on 17 March 2020 provides that the sale of non-prescription paracetamol is limited to two boxes for patients who have symptoms such as fever or pain, and one box in other cases. Online sales of paracetamol, ibuprofen and acetylsalicylic acid (aspirin) have been suspended until 31 May 2020.

The French Government has called on several producers to manufacture and distribute hydro-alcoholic gels in order to prevent the risk of a national shortage. The formulations, labeling, storage and batch release obligations are specified in the annexes of the order of 6 March 2020 and the order of 20 March 2020.

In view of the shortage of protective masks available, most notably to health professionals, the French Government has, through Decree No. 2020-247 of 13 March 2020 decided to requisition existing masks and those in production. According to the Decree, the stocks of respiratory protection masks of types FFP2, FFP3, N95, N99, N100, P95, P99, P100, R95, R99 and R100 held by any legal entity under public or private law (including companies in the food sector) and stocks of anti-projection masks held by the companies that manufacture or distribute them, are requisitioned until 31 May 2020. In addition, these types of masks produced between the publication of the Decree (14 March 2020) and 31 May 2020 will also be requisitioned for the same purposes.

Responding to a call from the Directorate General of Armaments (Direction Générale de l'Armement) to tackle the shortage of protective masks linked to the Covid-19 epidemic, the French textile industry has retooled their factories to produce protective masks. The society for sterilisation sciences (Société Française des Sciences de la Stérilisation) and the society for hospital hygiene (Société Française d'Hygiène Hospitalière) have issued a joint opinion on the materials that could be used for these purposes and in particular on the sterile materials and their specific indications to provide these companies with guidelines for production. These provisions only apply to protective masks already manufactured or produced within French territory.

The Decree No. 2020-293 of 23 March 2020 outlines new provisions related to imported masks. According to the Decree, stocks of imported masks above a threshold of five million units per quarter per company may be entirely or partially requisitioned by order of the Minister for Health.

The website www.stopcovid19.fr allows manufacturers and distributors of essential products and equipment to distribute those items to health professionals and public institutions committed to the fight against COVID-19.

The government further tackled the increase in selling prices (profiteering) of hydro-alcoholic gels

caused by the COVID-19 outbreak through Decree No. 2020-197 of 5 March 2020. This Decree caps both wholesale and retail prices of hydro-alcoholic gels until 31 May 2020. An order dated 14 March 2020, however, applies a multiplying factor for hydro-alcoholic gels manufactured by pharmacies.

Telemedicine

Decree No. 2020-2027 adopted on 9 March 2020 (the Telemedicine Decree) has loosened the requirements applicable to reimbursement for teleconsultations requested by any affected or potentially affected COVID-19 patients until 30 April 2020.

Under the usual legal framework, to be reimbursable, the teleconsultation must be performed under specific conditions: it must be conducted within the mandatory care pathway (*parcours de soin*), and the physician must be a general practitioner who adheres to the national physician agreement and already knows the patient, i.e., a physical consultation must have been performed in the 12 months preceding the teleconsultation.

Under the 9 March Telemedicine Decree, teleconsultations requested by COVID-19 patients will be reimbursed even if performed outside the *parcours de soin* and with a physician who does not "know" the patient. The preamble of the Telemedicine Decree notes that teleconsultation can be performed by any technological means currently available for the transmission of videos, such as a dedicated location equipped with telemedicine devices, but also a secure site or application used on a computer, tablet or smartphone, equipped with a webcam and connected to the internet.

Broadening the Use of Digital Tools

An order dated 19 March 2020, completing the Telemedicine Decree, further allows healthcare professionals performing teleconsultations with COVID-19 patients to use digital tools that comply with the general policy on health information systems security and regulations on the hosting of health data. This order also specifies that the monitoring of Covid-19 patients by nurses can be performed with telemedicine tools (*télésuivi*). These provisions apply until 31 May 2020 and the French Ministry of Health recently issued practical guidelines on telemonitoring Covid-19 Patients.

In addition, software companies providing telemedicine tools for COVID-19 are encouraged to notify the French Ministry of Health and the French eHealth Agency of their teleconsultation, monitoring, and document sharing solutions and their features, in order to assist health professionals in choosing the most appropriate telemedicine software, depending on their needs.

Impending Supply Bottlenecks

The increasing spread of COVID-19 poses a medium and long-term risk to the supply of medicinal products.

For several weeks now, attention has also been turning anxiously to China, which supplies raw ingredients to other countries, particularly India, and where production has been adversely affected due to COVID-19. In India, many contract manufacturers have restricted or completely stopped production given concerns regarding the retention of drugs for local needs. In addition, the Indian Government has recently limited the export of 26 pharmaceutical ingredients, including paracetamol, certain antibiotics, progesterone, and vitamins B12, B1 and B6.

Pharmaceutical companies should keep an eye on the production networks and supply chains

relevant to them and, where possible, ensure that they do not depend exclusively on individual suppliers. If there is a risk of a supply bottleneck in a specific case, e.g., owing to a contract manufacturer having to reduce or discontinue its activities, pharmaceutical companies should review their rights under the respective contracts in order to at least limit adverse commercial effects.

Moratorium and Emergency Plan for the Medical Devices Regulation?

In the light of COVID-19, leading associations in the medical device industry are calling for a moratorium on the conversion to the Medical Devices Regulation (MDR), which could barely be achieved in time even before the crisis.

The temporary closure of competent authorities and notified bodies is making it even more difficult for medical device companies to obtain new CE certificates under the MDR requirements. Whether and to what extent COVID-19 will have an impact on the date of application of the MDR is, however, currently still open.

Support to Companies

In response to the COVID-19 outbreak, the French Government has implemented immediate measures to support businesses and published a list of all these measures and the procedures companies have to follow to benefit from them. These measures include

- Extended payment deadlines for, e.g., Unions de Recouvrement des Cotisations de Sécurité Sociale et d'Allocations Familiales (URSSAF) and direct taxes
- Rebates of direct taxes
- Deferred payment of rent, as well as water, gas and electricity bills for small businesses in difficulty
- Financial aid of €1,500 euros for small businesses, self-employed people and micro-enterprises in the most affected sectors
- A guarantee fund of €300 billion to secure bank loans, in order to ensure that companies have the necessary cash to continue their activity
- Support from the French State and the Banque de France (credit mediation) to negotiate the rescheduling of bank loans
- Maintaining employment through the simplified and upgraded part-time work system
- Support from the Business Mediator to resolve conflicts with customers or suppliers
- Recognition by the French State and local authorities of COVID-19 as force majeure for their public contracts. Late payment penalties relating to all French State and local authority contracts will therefore not be applied.

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