CUATRECASAS

COVID-19: Impact on the health sector

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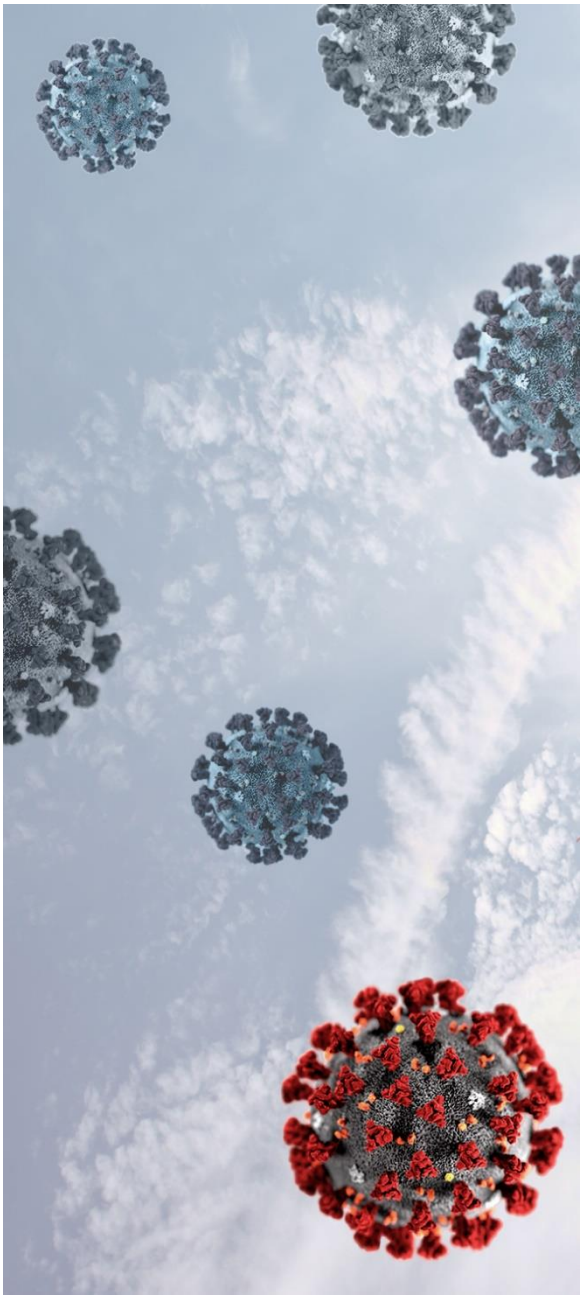

Impact on the health sector

- Supply of medicines
- Community pharmacies, drug manufacturers and wholesalers
- Clinical trials
- Product placement in the market without EC marking

COVID-19 and the impact on the health sector

The SARS-CoV-2 (COVID-19) virus outbreak has led to an exceptional measure being adopted in Portugal and many other countries: the Presidential decree declaring a state of emergency, with the inherent, exceptional and temporary limitations to exercising certain rights and freedoms.

To protect public health, the Government decrees regulating the state of emergency include several measures aimed at ensuring the supply of medicines and other health products and guaranteeing health care and the performance of clinical trials.

These measures may call for the temporary requisitioning of medicines, medical devices, industries, factories and private health services. Today, however, we will examine the measures that have already been effectively applied and that have a direct impact on health sector operators.

I. Supply of medicines

One of the main concerns raised by the COVID-19 outbreak is how to ensure the normal operation of the supply chain of medicinal products and medical devices in the internal and EU market, preventing any possible product shortages or supply difficulties of these products.

To prevent this scenario, after the initial COVID-19 outbreak in Portugal, the national health authorities decided to increase stocks of medicines, medical devices and personal protective equipment (PPE) in the National Health Service' (SNS - *Serviço Nacional de Saúde*) hospitals and health centers.

Through Informative Circular 062/CD, of March 5, 2020, the National Authority of Medicines and Health Products (*INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.* "Infarmed") established that all SNS hospitals should immediately and directly proceed to acquire certain medicines to increase their stock by 20% above the annual consumption for 2019.

These medicines were also included in the Prior Notification List described in article 100.2.b) of the Portuguese Medicinal Products Act (*Estatuto do Medicamento)*,[1] i.e., on the list of products whose export and distribution to other Member States must be previously notified by the seller to Infarmed. This measure is intended to guarantee an adequate steady supply to pharmacies, hospital pharmaceutical departments and other entities

[1]Decree Law 176/2006, of August 30.

involved in acquiring, selling and dispensing drugs in Portugal, safeguarding the supply to the domestic market and satisfactorily meet patients' needs.

Infarmed also determined that marketing authorization holders (MAH) for the medicinal products included in the Circular must submit weekly reports on the availability of the products at their facilities, as well as weekly purchases and sales and their recipients.

Informative Circular 073/CD, of March 23, 2020, updated the Prior Notification List and expanded the list of medicinal products subject to prior notification.

II. Community pharmacies, drug manufacturers and wholesalers

Community pharmacies are also at the frontline in the fight against COVID-19 outbreak.

Acknowledging the need to regulate the actions of these entities in such a critical phase, Infarmed made several recommendations to community pharmacies, especially in connection with dispensing medicinal products, through Regulation 003/2020, of March 16, updated on March 22, and Informative Circular 002/CD, of March 16.

First, pharmacies were advised to strictly comply with the guidelines and recommendations for dispensing medicinal products based on the symptoms presented in each case, without neglecting the users' needs, but discouraging hoarding and appealing to the principles of responsible use and good citizenship. This recommendation, which also applies to hospital pharmacies, affects the dispensation of both prescription and over-the-counter drugs.

Regarding prescription medication, in exceptional cases, the pharmacy's technical director or a pharmacist appointed by the latter may dispense a three-month supply of medication to chronically ill patients to ensure their ongoing treatment, without the need for them to show the corresponding prescription.

In addition, exceptional regulations were approved with regard to the minimum staff needed to guarantee the operation of pharmacies and other health sector workers. Therefore, in the case of pharmacies, the technical director may be replaced by an unregistered pharmacist. Also, drug manufacturers can employ staff from the respective quality control departments when no Qualified Person is available.[2] Like pharmacies, medicinal product wholesalers that do not have a technical director available can appoint an unregistered pharmacist, even if this may lead to the doubling up of functions.[3]

[2]Regulation 006/2020 of March 26, published by Infarmed, I.P.

[3]*Idem.*"

III. Clinical trials

Several recommendations have been approved, and certain exceptional measures have been adopted for scientific research by clinical trial centers ("CEC"), allowing amendments to the Clinical Trial Authorizations issued to the different centers.

Among the measures to be adopted with immediate effect, without prior notification to Infarmed, is the suspension of clinical trial patient recruitment, as it could pose a COVID-19 infection risk.

Infarmed even recommends an immediate halt to trial treatments and to find alternatives for their participants. This recommendation applies specifically to studies involving patients who are immunocompromised or display other risk factors.

At the same time, these recommendations are aimed at ensuring the availability of health professionals for priority tasks.

Exceptionally, experimental medication may be directly dispensed at the patients' homes. However, this treatment must comply with a series of requirements, including the continuous supervision of the process by the principal investigator and the research team, the patient's consent to the use of his personal data, the follow-up and logging of the transport and its conditions together with the assurance that the patient clearly understands how the trial drug is administered and monitored.

Patient transfers between CEC trial centers is also allowed, as is the exchange of health information, documents and transport of stocks of trial drugs.

Finally, Infarmed states that priority will be given to clinical trials for treatment or prevention of the COVID-19 virus.

IV. Placement of products in the market without EC marking

The use of the EC mark on a product shows that it complies with EU legislation and harmonized standards, i.e., it meets the safety, health and environmental protection requirements to circulate freely in the internal market.

Faced with the urgent need to ensure the safety and protection of health workers who are exposed to the virus, Infarmed has authorized the placement of products in the market without EC marking.

In the exceptional framework provided in Recommendation (EU) 2020/403 of the Commission, of March 13, applicable to imports of products needed for the protection of health professionals, Infarmed and the Economic and Food Safety Authority (*ASAE*) are responsible for assessing conformity of products without EC marking, to ensure they meet the minimum safety and functional requirements.

This way, manufacturers that do not usually make the products and equipment necessary for the safety of health professionals will be authorized to manufacture them. The Portuguese Directorate-General of Health (*DGS*) published a list of equipment, with a summary of the features required, the indication of the applicable community provisions and the necessary documentation to be submitted to Infarmed or the ASAE. Hence, domestic manufacturers can contribute to supporting the national health service with medical devices and PPEs.[4]

[4] Available at https://covid19.min-saude.pt/dispositivos-medicos-e-equipamentos-de-protecao-individual

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Cuatrecasas has set up a Coronavirus Task Force, a multidisciplinary team that constantly analyses the situation emerging from the COVID-19 pandemic. For additional information, please contact our taskforce by email TFcoronavirusPT@cuatrecasas.com or through your usual contact at Cuatrecasas. You can read our publications or attend our webinars on our website.