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HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

# Coronavirus: Implications for the management of medicines and medical devices

To ensure people have access to medicines and medical devices during the Coronavirus (COVID-19) pandemic, extraordinary measures have been introduced that apply to those involved in the circulation of medicines.

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Following the World Health Organization's declaration of a public health emergency of international concern (PHEIC) and given the lack of availability of drugs to treat COVID-19 effectively, the decision was taken to establish a Strategic Stockpile of Medicines (*Reserva Estratégica de Medicamentos* – REM) for the whole of Portugal. This stockpile will include:

- Drugs necessary to support life in an intensive care environment, in particular, for COVID-19 patients with progression to pneumonia, ARDS and septic shock.
- Drugs necessary to treat comorbidities when infection with COVID-19 has the potential to cause clinical decompensation.

In this context, various measures have been taken by the authorities to ensure availability of medicines and other products, in particular:

- The immediate acquisition – by all NHS hospitals and health units, and the Ministry of Health, whose use is regular and necessary for the type of unit in question – of certain medicines, medical devices and personal protection equipment, to increase their stocks by 20% compared with their annual consumption in 2019 in the same units;
- The inclusion of Strategic Stockpile Medicines on the list of medicines subject to prior notification to INFARMED (the Portuguese National Authority of Medicines and Health Products), for the purposes of export or distribution to other Member States of the European Union;

**"Given the absence of drugs available to treat COVID-19 effectively, a decision was taken to establish a Strategic Stockpile of Medicines (Reserva Estratégica de Medicamentos – REM)."**

- The specific monitoring of the availability of certain medicines by imposing an obligation on marketing authorisation holders and wholesale distributors of medicines to provide information weekly to INFARMED on (i) the available stock of these medicines on their premises, and (ii) the weekly purchases and sales, with identification of the recipients;
- The extension of the deadlines for disposing of non-generic medicines in the context of the 2020 Annual Price Review (until 27/04/2020 inclusive, for wholesale distributors and until 08/06/2020 inclusive, for pharmacies), with re-evaluation before the end of the first period established.

Provision has also been made to implement preventive measures to discourage the bulk acquisition of packages of medicinal products not corresponding to real needs, and to introduce measures to ensure judicious management of stocks. This applies across the board to all those involved in the medicines sector.

In this context, the following has been decided:

o Non-prescription medicines:

Pharmacies and points of sale of medicinal products not subject to prescription should ensure the quantity of medicines sold to users is appropriate to the symptoms of the specific case, the dosage, and the time the medicine is expected to be taken for.

o Prescription medicines:

In dispensing prescribed medicines, pharmacies must follow the guidelines and not dispense excessive quantities of the same active substance at the same time. They should also give advice to the user on the therapeutic indications of the drug, the importance of not interrupting the treatment, and the importance of meeting the needs of all users in the current situation.

**"In addition to the exceptional measures implemented in face of the COVID-19 pandemic, there are legal obligations that already existed, but whose fulfilment is of particular importance in this situation."**

Manufacturers, marketing authorisation holders and wholesale distributors of medicines must ensure the proper management of their stocks and the careful management of distribution.

Besides the exceptional measures implemented in face of the COVID-19 pandemic, there are legal obligations that already existed, but whose fulfilment is of particular importance in the current circumstances.

Examples of these existing obligations are:

- o The obligation on marketing authorisation holders to notify INFARMED at least two months in advance of the date any medicine is expected to run out and be unavailable in the Portuguese market, except in cases of properly justified urgency;
- o The obligation on marketing authorisation holders to always have available – even if the drug is not out of stock – an up-to-date set of information to prevent situations of scarcity of medicines for which part of the manufacturing process depends a single production facility and there are no, or only limited, alternative therapies, and where an interruption in their supply could result in a risk to public health;
- o The obligation on marketing authorisation holders, wholesale distributors, pharmacies and points of sale of non-prescription medicines to notify INFARMED of any shortage of a particular medicine;
- o The obligation on wholesale distributors to notify INFARMED of the unavailability of a specific of a medicinal product when the request for it has not been satisfied by a marketing authorisation holder. ■