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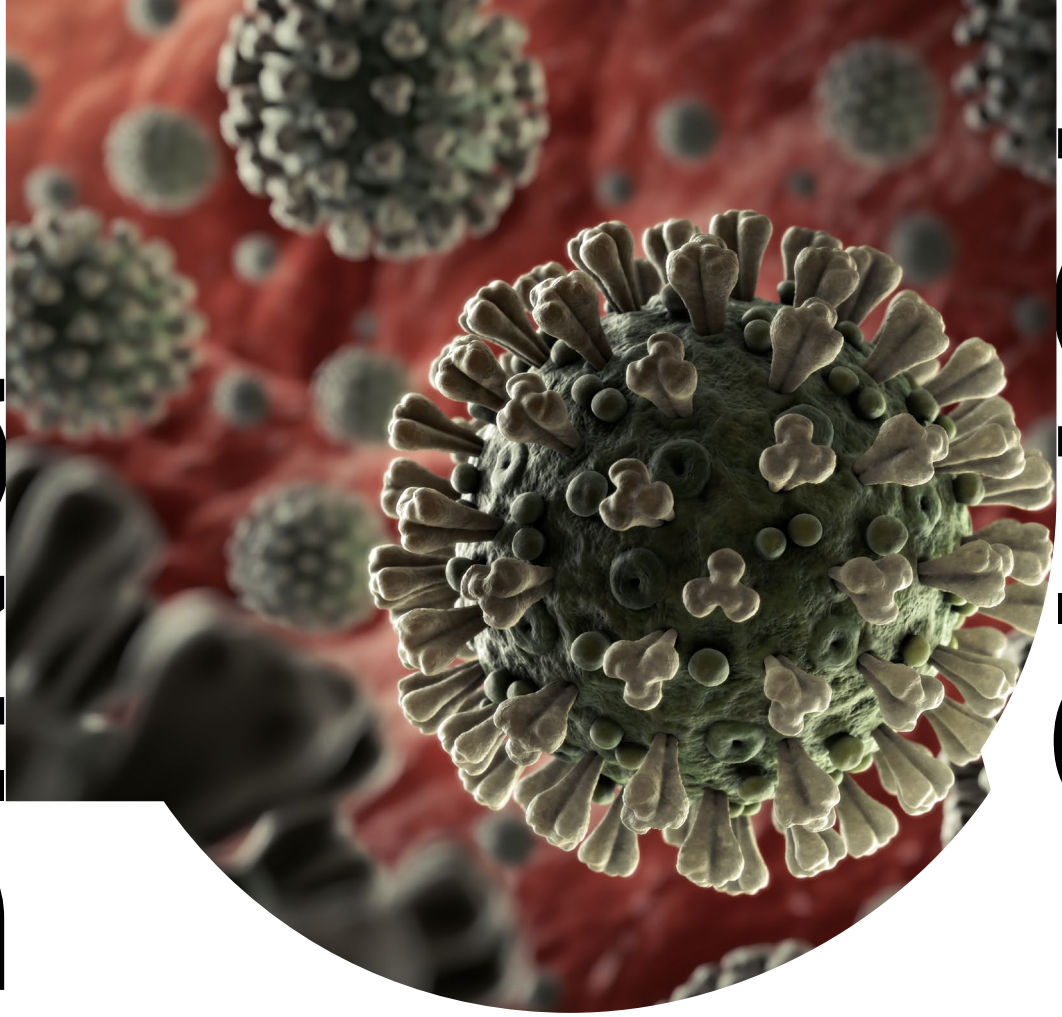

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HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

# Coronavirus: Measures for manufacturers and wholesale distributors of medicines

INFARMED and the DGS have published a set of guidelines for manufacturers and wholesale distributors of medicinal products for human use. The aim of these guidelines is to ensure supply to the domestic market and, at the same time, to prevent the spread of Covid-19 and protect the employees of these operators.

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In addition to the contingency plans introduced by the entities in the medicine supply chain, the DGS and INFARMED have published some specific measures applicable to manufacturers and wholesale distributors to safeguard the health of employees and ensure market supply.

In this context, besides adopting the measures in the contingency plan and strengthening and intensifying cleaning and sanitising, all undertakings covered by the guidelines must carefully and judiciously manage stocks, with respect to all consumables and goods to be supplied to third parties that are considered critical to their activity, to ensure the continuity of the service.

Supplying the domestic market and access to medicines by Portuguese citizens are considered priorities. Therefore, the necessary steps should also be taken to increase stocks of the medicinal products listed in the annex to Circular 62/CD/100.20.200 in good time, and provide them continuously to hospital units.

To mitigate the risk of constraints on access to medicines by part of the population, the deadline for disposing of non-generic medicines in the context of the 2020 Annual Price Review has been extended until 27 April 2020 (inclusive), for wholesale distributors. This situation will be reviewed before the end of this period, depending on how the outbreak develops.

Taking into account the real risk of manufacturers and wholesale distributors suffering a reduction in their technical staff due to the outbreak, the minimum numbers of personnel necessary for these entities to function have been defined.

When it comes to manufacturers of medicinal products for human use, procedures have been established that must be observed if:

i) The Qualified Person referred to in Annex 5 of the Manufacturing Authorisation cannot perform their duties; and

ii) It is not possible for the manufacturer to continue to operate because it is impossible to maintain the activities of production, quality control and batch release of medicinal products for human use.

As regards wholesale distributors, the procedures cover cases in which:

i) The technical director cannot perform their duties;

ii) There is a need to increase personnel to respond to the development of the outbreak; and

iii) It is not possible to maintain the activities of the wholesale distributor because it is impossible for the technical management and/or non-pharmacist qualified staff to perform their duties.

Exceptional measures have also been introduced that manufacturers and wholesale distributors of medicinal products for human use should activate when certain situations occur, to ensure they continue to operate.

**"INFARMED and the Directorate-General of Health have published a set of guidelines for manufacturers and wholesale distributors of medicines. The aim of these guidelines is to ensure the protection of their employees, prevent the spread of Covid-19 and ensure that manufacturers and wholesale distributors remain fully operational."**

PLMJ

**"Supplying the domestic market should be the focus of entities in the chain in compliance with both their legal obligations and their social responsibility."**

For manufacturers of medicinal products for human use, the measures are to:

- Adopt specific measures if there is confirmation of the infection of any operator who has been in a production area, including sampling and weighing raw materials (decontamination and cleaning of all areas and equipment, and a risk and impact analysis of this situation);
- Prompt notification to INFARMED whenever production may be compromised by constraints on the supply of raw materials, including packaging materials, personal protective equipment, and uniforms;
- Contact INFARMED for it to assess the exceptional measures to be adopted if the affixing of unique identifiers on the packaging of medicinal products that are part of the Strategic Stockpile of Medicines compromises regular and timely supply to the domestic market;
- Indicate and discuss with INFARMED any regulatory changes on which the adoption of exceptional measures may depend and which may not be included in the system to submit annual reports.

For wholesale distributors, the measures are:

- Contact INFARMED for it to assess the exceptional measures to be adopted if the operation to check and decommission unique identifiers on the packaging of medicinal products that are part of the Strategic Stockpile of Medicines compromises timely and regular supply to the domestic market;
- The possibility to adopt measures to bring flexibility to the usual periods agreed between holders of marketing authorisations (AIMs) and wholesale distributors of medicinal products for human use as regards reverse logistics (except if the collection of medicines is due to issues of quality or safety).

Finally, several measures have also been established that must be adopted by manufacturers and distributors to reduce contact between their employees and third parties to a minimum. These measures include; (i) banning all visits to the premises, (ii) cancelling or rescheduling internal and external audits, regarding both suppliers and customers, (iii) a preference for delivery of orders without the warehouse delivery person coming into the customer's premises; and (iv) the adoption of measures to clean and disinfect the packaging of medicines and health products. ■