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Gómez-Acebo & Pombo

COVID -19 | PHARMACEUTICAL

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INFARMED reiterates to the Wholesale Distributors of Medicines for Human Use and to Parallel Distributors the recommendations of the European Medicines Agency.

According to Infarmed's Information Circular No. 074/CD/100.20.200, of March 25, 2020, Wholesale Distributors of Medicines for Human Use and Parallel Distributors must:

- Adopt additional precautionary measures when evaluating proposals from new suppliers and notify Infarmed of any suspicious proposals.

- In advance, qualify and approve any new supplier prior to purchasing drugs from them and only purchase supplies from holders of Wholesale Distribution Authorization (WDA) or Manufacturing and Import Authorization (MIA) located in the European Union. Said authorizations must be verified in the EudraGMDP and must not have associated non-compliance reports.

- Ensure that customers are approved.

- Ensure that the packaging of medicines contains safety devices according to Directive No. 2011/62/EU and check all these devices when receiving the products;

- Pay extra attention to non-prescription drugs (such as paracetamol) that do not have safety devices.

Also according to the Information Circular, Wholesale Distributors of Medicines for Human Use who intend to import medicines into the European Union must hold a Manufacturing and Import Authorization.

With regard to drugs that are suspected of counterfeiting, Infarmed and the Marketing Authorization Holder must be informed immediately and the procedures in force regarding counterfeit or suspected counterfeit drugs must be followed.

Finally, recalls Infarmed that the information contained in the Information Circular does not dispense with consulting the Medicines Statute, the Regulation on good practices for the distribution of medicines for human use, on the Infarmed and the Guidelines on good practices for the distribution of medicines for human use in the European Union.

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European Commission publishes questions and answers to help increase production of safe medical equipment

The Commission has issued guidelines that will assist manufacturers to step up the production of essential medical equipment and supplies in three areas:

The first guidance document assists manufacturers in assessing the applicable technical and legal requirements before importing new products into the EU or before creating new facilities or reconverting existing ones in order to produce personal protective equipment (PPE).

The second document aims to provide guidance to economic operators, including small and medium-sized enterprises, on the legal framework applicable for the purpose of placing hydro alcoholic gel on the EU market and the information that can be given to users.

The third document provides guidance on procedures for assessing the conformity of 3D printing and 3D printed products, which are intended to be used in a medical setting in the context of the coronavirus outbreak.

In the coming days, guidance on medical devices will also be made available.

The purpose of the above guidelines is to assist manufacturers and market surveillance authorities to ensure that the products in question meet the necessary safety standards and are effective.

Exceptional and temporary regime for the design, manufacture, import, national marketing and use of medical devices for human use (DM) and personal protective equipment (PPE)

Following Commission Recommendation (EU) 2020/403, of 13 March, on conformity assessment and market surveillance procedures in face of the COVID-19 threat, an exceptional and transitional legal regime was set regarding the manufacture, import, placement and making available on the national market of medical devices (MD) and personal protective equipment (PPE), for the purpose of preventing the spread of the new coronavirus (SARS-CoV-2).

This regime aims to guarantee the supply of the MD and PPE referred to above, in view of the exponential increase in demand, while ensuring an adequate level of protection of the health and safety of users as well as an adequate level of performance.

The aforementioned regime came into force on April 14, 2020, taking effect from March 13, 2020.

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Limitation of the percentage of profit on the sale, wholesale and retail, of medical devices and personal protective equipment

The profit percentage on the sale of medical devices and personal protective equipment - listed in the annex to Decree-Law 14-E / 2020, of April 13 - as well as ethyl alcohol and of alcohol-based skin disinfectant gel, was set at 15%.

Said limit entered into force on April 19 and will remain in effect until the end of the state of emergency.