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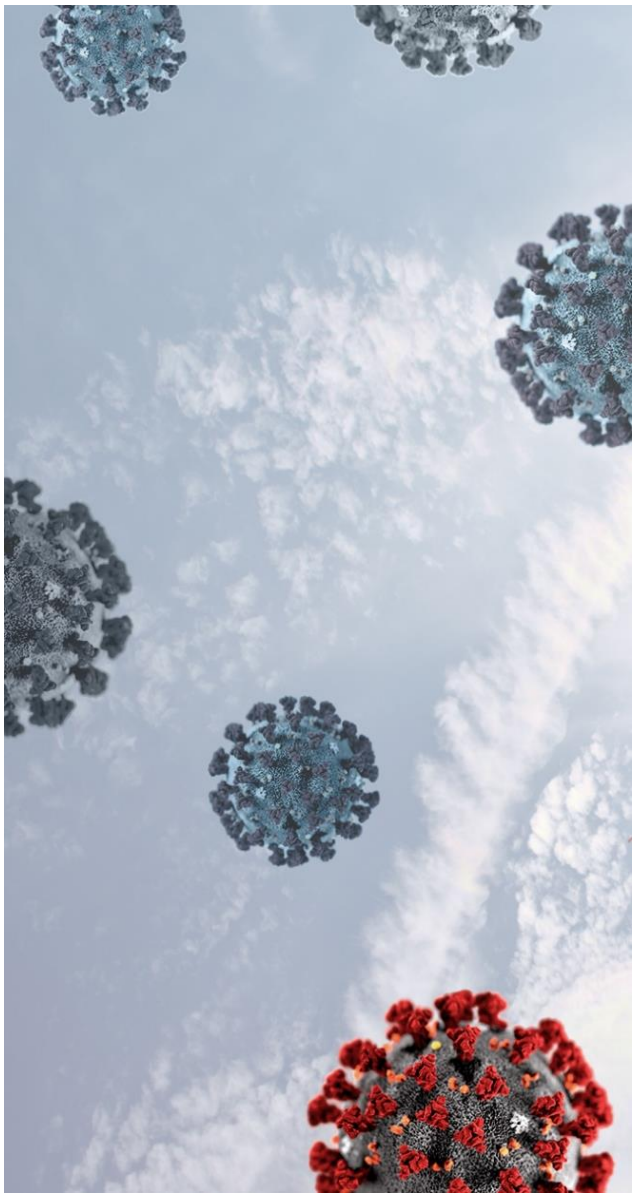
Covid- order snd/276/2020, of March 23, specifying obligations to provide information on, and to supply and manufacture certain medicinal products during the public health crisis caused by covid-19

Legal Flash

March 25th, 2020



On Tuesday, March 24, the Spanish Ministry of Health published *Order SND/276/2020* to ensure the supply of certain medicinal products in response to the public health crisis caused by COVID-19.

This Order imposes a series of obligations on manufacturers and marketing authorization holders of certain medicinal products (listed in *Annex I of the Order* and referred to below as the "**Medicinal Products**") to provide information on, and to supply and manufacture these Medicinal Products during the state of emergency and any potential extensions.

Specifically, manufacturers and marketing authorization holders of the Medicinal Products must meet the following obligations:

- They must inform the Spanish Agency of Medicinal Products and Medical Devices (AEMPS) of the availability and manufacturing forecast for the Medicinal Products within 24 hours. As this deadline was set at a number of hours and the Order entered into force on the same day it was published in the Official Gazette of the Spanish State, strictly speaking and according to the calculation rules provided under article 30.1 of Act 39/15 (the publication, as stated in the XML file, was issued at 0:00 hours, or midnight at the beginning of the day), this means that the deadline expired on **Tuesday, March 24 at 24:00 hours, or midnight at the end of the day**.

- They must update, on a daily basis, the following information regarding the Medicinal Products: available stock, quantities supplied in the last 24 hours, and forecast of release and receipt of batches (dates and amounts).

- They must adopt the necessary measures to guarantee the supply of the Medicinal Products, and the Minister of Health can demand they be supplied on a daily basis.

- They must give priority to the manufacture of the Medicinal Products if instructed to do so by the Minister of Health.

The above information obligations must be fulfilled through the *AEMPS website* made available for this purpose, following the instructions in the *guidelines* published by the Agency.

For additional information on the content of this document, please get in touch with your usual contact at Cuatrecasas.