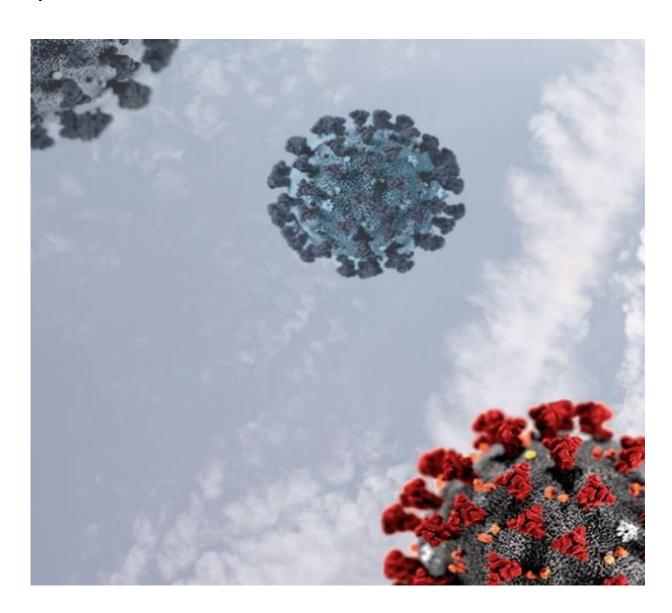


Impact of COVID-19 legislative changes: conditions for dispensing and administering medicinal products within the National Health System

Legal flash

March 30, 2020

Order SND/293/2020, of March 25, setting out conditions for dispensing and administering medicinal products within the National Health System, in view of the public health crisis caused by COVID-19.



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Under <u>Order SND/293/2020</u>, published on Friday, March 27, the Spanish Ministry of Health has adopted a set of measures to ensure the availability of medicinal products within the Spanish National Health System and to reduce the exposure of patients to potential infection.

First, hospital pharmacy dispensaries are not allowed to supply medicinal products dispensed in hospitals for longer than two months' treatment, and the Spanish Agency of Medicinal Products and Medical Devices (AEMPS) may reduce this term to one month in cases involving essential medicinal products.

Along the lines of the AEMPS's <u>Informative Note MUH 4/2020</u>, of March 16, this limit does not apply where medication is dispensed in clinical trials, in which case it is advisable to provide patients with quantities covering a longer period of treatment than normal.

Second, the Ministry has authorized the competent bodies and authorities of each Autonomous Region to implement the following exceptional measures:

- Medicinal products dispensed and used in hospitals may be dispensed outside the hospital grounds.
- Medicinal products may be dispensed to the domiciles of patients undergoing clinical trials. The Autonomous Regions' competent bodies may entrust the management of the logistics to the clinical trial sponsors, under the supervision of the corresponding Pharmacy Service and the principal investigator of the clinical trial in question.

Therefore, the Ministry leaves to each Autonomous Region to determine which medicinal products can be dispensed outside hospitals and the procedure to follow through resolutions, provisions and interpretative guidelines.

These measures will remain in force until the end of the state of emergency.

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