

LIFE SCIENCES

ORDER NO. 235/2023 OF AUGUST 1
SPECIFIC MEASURES FOR CRITICAL
MEDICINES

VdA EXPERTISE



August 2023



Amongst the criteria set out to determine which medicines should be considered “critical”, we would highlight the essentiality of the medicine for the health system, the existence of an history of shortages, the identification of vulnerabilities in the manufacturing and distribution chain, as well as the existence of a reimbursement or a prior evaluation contract.

For medicines considered as “critical”, the Order determines that a set of specific measures can be applied, including the following:

- (a) For the purposes of setting the maximum price, the selling price to wholesalers may reach the highest price in the reference countries or, if the medicine doesn't exist in those countries, the price of the medicine in other EU countries;
- (b) Waiver of the rules, criteria, deadlines and other procedures governing price revision for a maximum period of five years;
- (c) Possibility of using the exceptional price revision procedure, with the price of these medicines being exempt from price reductions resulting from the annual price review for a period of five years;
- (d) Possibility of applying different measures in public procurement contracts and acquisition procedures conducted and executed by SPMS.

On August 1, [Order no. 235/2023, of July 27](#) (“Order”) entered into force.

The Order defines the applicable criteria for determining which essential medicines should be considered as “critical” to justify specific measures being applied to ensure market access and availability, and further defines such measures.

Infarmed may also, in duly substantiated cases, propose to the Minister of Health the application of other measures considered necessary to maintain the medicines on the market, given the need to ensure the provision of basic healthcare.

MA holders of medicines subject to specific measures are nevertheless obliged to fulfil “minimum” obligations - which seems to suggest that additional measures may also be imposed.

Such obligations include:

- (a) Maintenance of a permanent stock level in order to ensure adequate, regular and continuous supply of the market for a minimum period of four months of consumption - contrary to the general rule of two months; and
- (b) Setting forth a real-time stock reporting mechanism to Infarmed.

Infarmed is responsible for drawing up the list of medicines considered as “critical”, having already done so through [Decision no. 054/CD/2023, of July 27](#). This list should be reviewed whenever deemed necessary, or, at least, annually.

Infarmed will also be responsible for defining the additional guidelines needed to implement the Order.

Contacts



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