

LIFE SCIENCES

AMENDMENT TO THE MEDICINES' STATUTE

Deletion of reference to the price on the labelling

VdA EXPERTISE



January 2024



**Decree-Law No. 128/2023,
of 26 December, eliminated
the obligation to mention
the maximum sales price
on the labelling of the medicine**

[Decree-Law no. 128/2023](#), of 26 December, entered into force on the 2nd of January. Amongst others, it amended the Medicines Statute, eliminating the obligation to mention the maximum sales price on the labelling of the medicine – amendment regarding which Infarmed has already issued a guidance (see [Informative Circular no. 003/CD/100.20.200](#) of 5 January 2024).

For transparency reasons, the obligation to include the maximum sales price of the medicine in the labelling was eliminated, preference being now given to other means of access to the prices of medicines, to allow the patient not only to be aware of the actual cost of purchasing the medicine, but also of the cost borne by the State.

Thus, Infarmed is now responsible for providing information on prices, namely through "*media accessible from its website and other digital tools*": at this stage, the INFOMED database, the *app Poupe na Receita* and a telephone line.

Community pharmacies, on the other hand, must provide information when dispensing the medicine and specify in the invoice (i) the maximum sales price of the medicine, (ii) the reference price (where applicable), (iii) the percentage of reimbursement, (iv) the cost borne by the State and (v) the cost borne by the patient.

The decree does not contain any transitional arrangement. Notwithstanding, Infarmed clarified that since 2 January – the date of its entry into force – packages of the same medicine with and without reference to the maximum sales price may coexist *temporarily* in the market.

Infarmed further adds that the removal of the maximum sales price does not require the submission of a variation request, and that such a change may be formalized in the next modification to the labelling. In addition, for medicines approved after 2 January 2024, there is no need to submit new labelling.

Contacts



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