



REMOVAL OF THE RETAIL PRICE (PVP) FROM MEDICINE LABELLING

Decree-Law No. 128/2023, of December 26

Decree-Law no. 128/2023, of December 26 amends the legal frameworks for medicinal products for human use and workshop pharmacies.

WHAT CHANGES?

In order to strengthen the transparency of information and ensure compliance with the pricing rules applicable to all those involved in the medicinal product circuit, **the obligation to include the retail selling price ("PVP") on the packaging of medicinal products is repealed** (repeal of Article 105.º, n.º 1, of Decree-Law 176/2006 of August 30, in its current wording).

This measure is based on the need to provide clear and objective information to all market users, on the understanding that the retail price, as it appears on medicine presentations, does not, as a rule, correspond to the cost of the medicine to the citizen, taking into account a possible reimbursement, which may depend on the citizen's economic condition, as well as the application of the reference price system to medicines for which there are generics.

This measure also aims to avoid the risk of outdated information on the packaging associated with the application of the

rules for the annual price review of medicines.

This Decree-Law strengthens the information duties of INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., by giving it direct responsibility for providing information on the price of medicines, either through media accessible from its website or through other digital tools.

Further to the changes introduced by this Decree-Law, INFARMED, I.P. issued Information Circular n.º 003/CD/100.20.200, dated January 5, 2024¹, with general information on the means of accessing information on the price of medicines, namely:

- (i) On the part of dispensing pharmacies to the user at the time of dispensing the medicine;
- (ii) By consulting the Search for Medicines feature, the INFOMED database and the free "Save on Prescriptions" mobile application, which are available on the INFARMED, I.P. website;
- (iii) Through the Medicines Hotline 800 222 444.

In addition, with the removal of the price from the labeling of medicines, it is now mandatory for pharmacies to provide users with information on the price of

medicines on the invoice or receipt issued:

- a) The retail selling price (PVP);
- b) The reference price, if applicable;
- c) The percentage of the State's contribution to the PVP;
- d) The cost borne by the State;
- e) The cost borne by the user.

Finally, this Decree-Law also strengthens the maintenance of the national network of pharmacies by clarifying the application of the regime for opening and transferring pharmacies, which has undergone profound changes since 2011.

This gives greater involvement in these processes to the entities with the greatest knowledge of local realities and needs, and establishes the verification of certain requirements prior to the submission of any request to the competent regulatory authority, INFARMED, I.P., which includes the opinion of the local authorities.

To this end, article 26-A has been added to the Legal Framework for Workshop Pharmacies (Decree-Law no. 307/2007, of August 31), providing for the possibility that pharmacies located in municipalities with a capitation lower than that required, under the terms defined by ordinance, may be transferred to neighboring municipalities with a higher capitation.

¹ Available
https://www.infarmed.pt/web/infarmed/infarmed//journal_content/56/15786/9677658

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ENTRY INTO FORCE

Decree-Law no. 128/2023, of December 26 came into force on December 27, 2023, taking effect on January 2, 2024.

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