



## ***New Legislation on Medicines***

### **RULES FOR PRESCRIBING AND DISPENSING MEDICINES AND HEALTH PRODUCTS**

Following the publication of Ministerial Order no. 263/2023 of 17 August and Ministerial Order no. 45/2024 of 7 February, INFARMED, I.P. and ACSS, I.P. have approved a new version (version 8.0) of the Medicines [Prescription and Dispensing Rules](#), aimed at all prescribers and community pharmacists.

The main changes in this version are the inclusion of rules aimed at ensuring that prescribing and dispensing is better adapted to the needs of users with clinically stabilised chronic pathologies, as well as simplifying access for ostomised patients and/or those with incontinence or urinary retention to medical devices adapted to their needs.

The rules are available on the [Prescription and dispensing page on INFARMED's website](#).

### **FINANCING OF THE DISPENSING OF MEDICINES IN PROXIMITY REGIME**

On 14 March, Ministerial Order no. 104/2024/1 was published in the Portuguese Official Gazette, governing the terms for financing the regime for dispensing medicines and health products in close proximity, provided for in [Decree-Law no. 138/2023](#) of 29 December.

The costs inherent to the central storage, transport and proximity dispensing of medicines and health products covered by this legal regime, **in cases where it is carried out in a pharmacy**, are subject to a **flat-rate fee of €11.96** per episode of dispensation of hospital therapy, exempt from VAT.

A dispensing episode is understood to be the act of dispensing medicines and health products to the user, regardless of the quantity dispensed.

The costs inherent to central storage, transport and dispensing are the responsibility of the hospital unit responsible for the prescription, and the funding is supported by a centralised mechanism.

The Central Administration of the Health System, I. P. (ACSS, I. P.) is responsible for managing and monitoring the centralised funding mechanism. (ACSS, I. P.).

Payment for the service is made to the pharmacy where the dispensation was made, freely selected by the user, which in turn pays the wholesale distributor, who is responsible for paying the responsible entity for central storage.

The percentage breakdown of the above fixed amount is as follows:

- a) Pharmacy selected by the user - 57.07 %;
- b) Wholesale distributor - 25.37 %;
- c) Entity responsible for the central warehouse - 17.56 %.

In terms of invoicing, the reception and control of invoices relating to the dispensing of medicines and other health products covered by this legal regime in a pharmacy is carried out through the National Health Service Control and Monitoring Centre (CCMSNS).

## **REGULATION OF DISPENSATION IN CLOSE PROXIMITY**

On 14 March, Ministerial Order no. 106/2024/1 was published in the Portuguese Official Gazette, regulating [Decree-Law no. 138/2023](#), which approved the legal regime for dispensing medicines and health products prescribed for hospital outpatients in the context of National Health Service (SNS) establishments and services.

Dispensing in proximity is characterised by the provision of medicines and health products in locations closer to the user's home, as an alternative to face-to-face dispensing in the hospital pharmaceutical services of the hospital unit responsible for the prescription or dispensation.

The procedures for implementing the regime are now set out in a regulation, to be approved by the management body of the hospital unit responsible for prescribing or dispensing the medicines, to be published on the hospital unit's official website.

This [Ordinance](#) defines the rules and criteria to be met by the regulation to be approved by the hospital unit's management body, with a view to harmonisation and fairness in the implementation of this legal regime.

### **A. Requirements for dispensing sites**

The dispensing system in close proximity depends on acceptance and fulfilment of the following requirements:

- a) Record in the user's clinical file and the user's information on dispensing in proximity;
- b) Guarantee that all storage conditions are met so that the medicine or health product maintains its quality, safety and efficacy until it is dispensed to the user, as well as the necessary information for the correct use of the medicine or health product;;
- c) Notification to the hospital pharmaceutical services (HPS) of origin of any occurrence during the use of the medicine or health product;
- d) Compliance with the regulations in force.

**Pharmacies** wishing to join the dispensing system in close proximity shall also i) register on INFARMED's licensing portal and ii) take part in specific additional training on dispensing in close proximity recognised by INFARMED or the Portuguese Pharmacists' Association.

INFARMED, I.P. publishes on its website the list of dispensing sites that participate in the dispensing in proximity regime.

## **B. Hospital dispensation regulations in close proximity**

Hospital dispensation regulations in close proximity shall include the following aspects:

- a) Identification of the INFARMED, I. P. website, which lists the places where medicines are dispensed that participate in the dispensing in proximity regime;
- b) User eligibility criteria for dispensing in close proximity;
- c) Adherence and exclusion conditions;
- d) Draft declaration of the user's option to join the dispensing system for proximity medicines;
- e) Conditions for accompanying the user and relevant contacts;
- f) Rights and duties of users included in the dispensation scheme.

Adherence to the dispensing regime in proximity depends on a **declaration of option by the user** or their legally authorised representative, preferably in writing, which can be revoked at any time.

Each hospital unit shall lay down measures to ensure effective pharmacotherapeutic monitoring and safeguard patient safety, regardless of where the medicine is dispensed.

INFARMED, I.P., whenever necessary in conjunction with other entities and with the possibility of hearing the National Pharmacy and Therapeutics Commission, may issue technical guidelines that prove necessary for the application of the law here under discussion.

This law comes into force on 13 May.

*If you have any doubts or questions on this matter, please do not hesitate to contact the Health Law team at pbb - Sociedade de Advogados, SP, RL.*

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