



Dispensing Medicines in proximity

At the end of the year, on 29 December, Decree-Law 138/2023 was approved, which establishes the proximity dispensing system for medicines and other health products prescribed for hospital outpatients, within the scope of NHS establishments and services.

The purpose of the proximity dispensing scheme is to facilitate the user's access to medicines and other health products at locations of their choice, as an alternative to their face-to-face dispensation at the Hospital Pharmaceutical Services (HPS) of the hospital unit responsible for monitoring the user.

According to the new regime, medicines can be dispensed in NHS hospital establishments other than the one where the patient is followed, in pharmacies and, in exceptional situations, in primary care centres.

It is up to the user to choose the regime that suits them, as well as the sites of dispensation available, in the case of the proximity dispensing regime.

A. Eligibility

The user's eligibility for access to the proximity dispensing system requires stabilisation of the prescribed therapy, medical and pharmaceutical validation and verification of the following conditions:

- a) Guarantee of the patient's clinical stability, according to the assessment made by the prescribing doctor, duly evidenced in the clinical file;*
- b) Validation in the pharmaceutical consultation of the patient's ability to autonomously comply with the therapeutic protocol and/or, if applicable, the caregiver's ability to ensure compliance, as well as monitoring any adverse drug reactions with the intervention of the HPS pharmacist and the dispensing sites, ensuring communication and sharing of relevant information between all professionals throughout the process;*
- c) Patient adherence to therapy and hospital care, namely by attending scheduled medical and pharmaceutical appointments;*
- d) Compliance with the procedures defined in the Hospital Regulations for Proximity Dispensing (provided for in article 9 of this decree-law).*

B. Medicines dispensing sites

Proximity dispensing can take place at the following locations:

- a) NHS establishments and services responsible for ensuring the provision of hospital care, which may be different from the place of prescription;*
- b) Pharmacies;*
- c) Other dispensing sites, in exceptional and duly substantiated situations.*

INFARMED, I.P., will have an up-to-date list of all the places available for dispensing in close proximity on its website.

Workshop pharmacies wishing to join the list of proximity dispensing sites must register on INFARMED's Licensing+ Portal.

Proximity dispensing is always carried out by or under the supervision of a pharmacist.

If the existence of a pharmaceutical technical directorate is ensured, proximity dispensing can also be carried out in NHS establishments and services that guarantee the provision of primary healthcare, namely in the context of Local Health Units.

C. Hospital pharmaceutical consultation and monitoring by health professionals

Users who are part of the proximity dispensing scheme are monitored through a hospital pharmaceutical consultation, without prejudice to the necessary monitoring in medical consultations and interventions by the pharmacist at the dispensing sites. The main objectives of the pharmaceutical consultation are to provide general information about the disease and the medicine, clarify any doubts and validate the prescription and dosage regimen.

D. Distribution of medicines

The distribution of medicines at dispensing points is carried out by a wholesale distributor in a fleet suitable for transporting medicines, and the provisions of the Medicines Statute, approved by Decree-Law no. 176/2006, of 30 August, in its current wording, and the Good Distribution Practices for Medicines for Human Use, apply, with the necessary adaptations.

The verification and deactivation of the unique identifier of medicines equipped with safety devices must be carried out, respectively, at the hospital unit responsible for the prescription, at the Central Warehouse (made available by the hospitals' common use service) or, when dispensed in close proximity, at the place of dispensation, by qualified professionals.

E. Associated costs

Proximity dispensing does not entail any costs for the user, the hospital unit responsible for the prescription being responsible for the costs. However, the costs of central storage, transport and dispensation, in cases where this is carried out in a pharmacy, are borne by a centralised cost mechanism, to be defined by order of the members of the Government responsible for the areas of finance and health, within 30 days of 29 December.

F. Information and monitoring system

The dispensing circuit for proximity medicines will be supported by a technological system that allows the team of health professionals involved in the entire proximity dispensing process to share the necessary clinical information on the user, without prejudice to compliance with the rules on personal data protection.

The technological system must guarantee the traceability of the medicine from prescription to dispensation, as well as fraud prevention at all stages of the circuit, and must include mechanisms for recording and controlling access.

G. Data Protection

The processing of personal data for the purposes of implementing the proximity medicines dispensing scheme must comply with the provisions of the applicable legislation, and the role of data controller is assumed by the hospital unit responsible for the prescription, which will keep the data for as long as is necessary to fulfil the purpose of the processing, which must be appropriate and relevant.

This regime came into force on 30 December and the list of medicines and health products that make up the proximity dispensing regime will be approved by order of the member of the government responsible for health, and will be reviewed annually.

Finally, it should be noted that the implementation of this regime will also be monitored by a team that must include a representative from each of the following organisations: INFARMED, I. P., DE-SNS, I. P., SUCH, ACSS, I. P. and SPMS, E. P. E. E.

If you have any questions on this subject, please do not hesitate to contact the Health Law team at pbbr - Sociedade de Advogados, SP, RL.

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