



Capsulas

New regulation for home delivery of medicines and other changes to the Madrid Pharmacy Law

On the approval of the new Law 13/2022, of 21 December, on Pharmaceutical Management and Care in the Community of Madrid

Home delivery of medicinal products

The regulation of home delivery was one of the novelties that has sparked the most debate in the process of adopting the regulation. This new regulation consolidates the veto on platforms and entities outside the pharmacy office to conduct home delivery of medicinal products. According to Article 13 of the Law, the presence of a pharmacist from the pharmacy office is an essential requirement for the act of dispensing. In addition, the act of delivery itself must be conducted by qualified pharmacy personnel.

This mandate is in line with the ruling of the High Court of Justice of Madrid, in its judgment of 16 September 2022. The Court upheld the sanction imposed by the AEMPS on the “Telefarmacia App” platform for intermediation in the sale of medicines, including prescription medicines. In this ruling, the Court recalled that the different elements of dispensing (patient advice, delivery of the medicine and sale, as a commercial act) can be separated, which (unless prohibited) allows delivery outside the pharmacy premises. This was already recognised by the Supreme Court in its now famous judgment of 2 November 2021.

However, in the case of “Telefarmacia App”, the High Court of Justice of Madrid indicated that the requirement of the necessary intervention of the pharmacist in advising the patient was violated, as an intermediary (Telefarmacia) managed the order, payment and collection of the medicine.

Despite this new regulation, it will be necessary to wait for the necessary regulatory development for home delivery to become a reality in Madrid, as the standard requires compliance with procedures and control systems that are yet to be developed.

In the case of medicinal products to be dispensed by hospital pharmacy services, article 40(j) of the Law sets out the possibility of home delivery, although this is not subject to subsequent regulatory development. According to this provision, which refers to the functions of hospital pharmacy services, they may adopt measures to allow the dispensing of medicines away from the patient’s home, including home delivery or collection from another authorised establishment close to the patient’s home.

Advertising of pharmacies and free choice of pharmacy office

As a novelty, the Law regulates the advertising of pharmacies, stating that only pharmacies may advertise the authorised activities and services they provide. It also specifies the places where advertising may take place (inside, on the façade of the pharmacy office and on the company website), but always with reference to the health authorisation of the services advertised.

The aim of this regulation is to safeguard the patient’s right to choose his pharmacy by prohibiting any advertising, incentives or similar



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mechanisms, the result of which may condition the exercise of this right.

Register of pharmaceutical establishments

Article 10 of the Law creates the public register of pharmaceutical establishments and services, which will serve as an informative directory for users, although its operation will require further regulatory development.

Dosing systems

On the other hand, article 14 of the Law allows pharmacists, after dispensing the medicinal product, to provide personalised dosage systems to patients who request them, in order to improve the adherence, effectiveness and safety of their treatments. The pharmacist will be required to submit a declaration of responsibility to the regional ministry (Consejería). Again, the provision of this service will require further regulatory development to establish the necessary technical and health requirements.

New sections in the pharmacy

Finally, the nutrition and dietetics section has been added to the list of healthcare activities that can be provided in pharmacies, according to article 16 of the Law. This section is added to those already foreseen for optical, hearing, orthopaedics and clinical analysis services, all of which are subject to administrative authorisation. Despite the authorisation, the development of these activities is not linked to the owner of the establishment, allowing a margin of flexibility in the organisation of these services and incentivising the professional opportunities related to these activities.

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