



Capsulas

Reverse distribution and exports: the Madrid Regional Authority actively monitors the activities of pharmacies

Judgment of the High Court of Justice of Madrid of 15 December 2025

Reverse distribution and parallel trade

Approximately fifteen years ago, new infringements relating to medicinal products were introduced into the Law on Medicines and Medical Devices (LGURMPS) to prevent shortages and strengthen the supervisory and inspection powers of the health authorities.

Among them, the law classified as a very serious infringement the conduct of pharmacies engaging in the distribution of medicinal products to other pharmacies, authorised wholesalers, or any unauthorised entities or individuals, as well as the export of medicinal products outside of Spain.

This case concerns the application of this sanctioning regime by the Madrid Regional Authority (“CAM”) and illustrates the enforcement actions that may be triggered in situations of reverse distribution, which have at times been highly significant in the field of parallel trade.

Dispensing of unusual quantities

The facts underlying this judgment date back to 2023, when a pharmacy dispensed 20 boxes of Progynova®. The prescription had been issued by a healthcare professional at a medical centre located outside Spain and was not made out in the name of any specific patient.

The wholesaler detected this unusually high dispensation and reported it to the CAM, which carried out an inspection at the pharmacy and subsequently initiated sanctioning proceeding.

During the proceeding, the pharmacy submitted a letter from the prescribing physician, acknowledging that the medicinal product had been intended for patients at a healthcare centre located outside Spain. The CAM considered that the pharmacy had engaged in unauthorised distribution of medicinal products and imposed a sanction of €90,001.

Position of the High Court of Justice of Madrid

The pharmacy challenged the sanction before the High Court of Justice of Madrid. In its appeal, it argued that (i) it had merely dispensed a prescribed medicinal product rather than engaged in distribution, and; (ii) the sanction was disproportionate, particularly given that the profit obtained amounted to only €111.

The Court rejects these arguments. It finds that, although the conduct was isolated, it must be classified as distribution activity. In particular, the Court emphasises that the pharmacy disregarded essential control measures: it failed to verify that the prescription included a named patient and did not check whether the person presenting it was the intended recipient, despite the large volume of Progynova® supplied.

Furthermore, the Court examines whether the facts fall within the infringement defined in the LGURMPS concerning the distribution of medicinal products to unauthorised entities or persons, which formed the basis of the sanction. The Court concludes that this classification is correct.





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In this regard, it considers it proven that the pharmacy acted negligently, noting that a considerable number of boxes of Progynova® were dispensed without the necessary safeguards, and that the medicinal products were destined for a healthcare centre outside the national territory.

As regards proportionality, the Court points out that the sanction imposed corresponds to the minimum level for very serious infringements and cannot be classified under any minor infringement provided for in the LGURMPS.

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