Capsulas

The AEMPS publishes its guidance note on foreign trade of medicinal products

Instruction 1/2025 sets out the criteria for handling authorisations and notifications related to foreign trade of medicinal products

The new Instruction 1/2025 addresses the need to update and clarify various issues that have arisen in practice over recent years. It also introduces specific provisions related to foreign trade, such as the procedures applicable in cases of returns or donations for humanitarian purposes.

These procedures apply to companies that import or export medicinal products to or from countries outside the European Economic Area (EEA). As the Instruction 1/2025 reminds, this includes operations involving Switzerland, Andorra, or the United Kingdom.

Below, we highlight some of the most relevant updates concerning medicinal products for human use.

Definition of "registered medicinal product"

One issue that created legal uncertainty was the lack of clarity around the term "registered medicinal product", as neither the previous version nor Royal Decree 824/2010 provided a definition. According to Royal Decree 1345/2007, a registered medicinal product is one that has received marketing authorisation and is entered into the AEMPS medicinal product registry. However, doubts have arisen as to whether this includes products that are authorised but not yet registered, pending pricing/reimbursement decision, or with suspended authorisation.

Instruction 1/2025 clarifies that a medicinal product will be considered "registered" if it has the same active substance and excipients, the same pharmaceutical form, and the same manufacturers (both of the active substance and the finished product) as a product registered in Spain; regardless of differences in trade name, presentation, packaging format, or marketing authorisation holder (MAH) in the destination country. The Instruction also explicitly confirms that products with suspended marketing authorisation still qualify as registered medicinal products.

Our view, based on these clarifications, is that the reimbursement status of a product in the National Health System is irrelevant for the purposes of considering it a registered medicinal product.

Importation

The previous version of the Instruction did not clearly define the roles of different entities involved in the import/export process. This created confusion around which entities could physically carry out these operations and which were authorised to request the relevant approvals or submit notifications to AEMPS.

The new Instruction clarifies these roles.

For the importation of finished medicinal products, intermediates, or bulk products, only authorised importers (as defined in Royal Decree 824/2010) or the MAH may carry out the import. For investigational medicinal products, importation must be carried out by an authorised importer.

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On the other hand, the request for prior authorisation for each import - which is granted per shipment and for a specific quantity of product - may be submitted by other entities, depending on the type of product:

- Finished medicinal products (excluding plasma derivatives, which follow a separate procedure): by authorised importers, the MAH, or – as newly recognised by the Instruction - the MAH's local representative in Spain.

- Intermediates or bulk products: by the authorised importers or the MAH.

- Investigational medicinal products: by the authorised importers or the clinical trial sponsor.

These authorisations are valid for one year, during which multiple shipments may be made up to the approved total quantity; unless the conditions that led to the authorisation change.

Exportation

Exportation may be carried out by authorised manufacturers, the MAH, or distributors.

Instruction 1/2025 clarifies that for registered finished medicinal products, the export notification may be submitted by the MAH, the manufacturer or the distributor. For bulk products, only the manufacturer may submit the notification.

In the case of products with suspended authorisation, the exporter must inform the recipient of the suspension. Exports must take place within two months from the date of that notification.

The export of investigational medicinal products for use in clinical trials conducted in other countries participating in a clinical trial authorised in Spain remains unchanged from the 2015 Instruction. It still requires prior authorisation from AEMPS and may involve multiple shipments until the authorised quantity is reached.

Likewise, prior authorisation is required from AEMPS for the export of unregistered medicinal products in Spain; their intermediates or bulk forms; and investigational medicinal products intended for clinical trials not authorised in Spain, whether for another EU country or a third country. Where such products are manufactured in Spain for export, a manufacturing authorisation issued by AEMPS is required. As a new development, this authorisation is now valid for three years (previously two). It also includes the issuance of an export certificate for the destination country.

Additionally, for unregistered medicinal products intended for other EEA countries, only one manufacturing authorisation will now be required, and it will be valid across all EEA countries.

Samples

Instruction 2/2025 maintains the position that the import or export of samples does not require prior authorisation from AEMPS. However, it strengthens the conditions for their use.

The interested company must provide documentation to the Pharmaceutical Inspection Services at AEMPS justifying the intended use of the samples. As a new requirement, the Instruction requires that: the sample size must be consistent with the declared purpose, the intended use must be clearly justified, and any unused quantities must be destroyed through a licensed waste disposal company.

Only authorised importers or manufacturers may import samples; unless the destination is a preclinical or research study, in which case universities, hospitals, research centres, or pharmaceutical companies may also carry out the import.

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Returns

The new Instruction includes a section on returns.

It states that the import of previously exported medicinal products requires prior authorisation from AEMPS. The information provided in the import request must match the details recorded in the corresponding export authorisation or notification.

By contrast, the return of active substances for human use does not require prior authorisation, but it is subject to pharmaceutical border control.

Humanitarian donations

Finally, Instruction 1/2015 sets out the procedure for exporting medicinal products as humanitarian donations, a subject of increased relevance during recent emergencies such as the COVID-19 pandemic or armed conflicts.

All such exports require prior authorisation from the Department of Inspection and Control of Medicinal Products at the AEMPS. The authorisation is valid for three months and must be requested through Labofar or the AEMPS electronic registry.

The authorisation may only be requested by pharmaceutical companies, distributors, hospitals, NGOs, or humanitarian aid foundations that comply with applicable regulations. In every case, the applicant is responsible for the export.

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