



# Capsulas

## New developments in the reimbursement of non-hospital medical devices

*Royal Decree 90/2026, of 11 February, on the selective reimbursement of medical devices under the pharmaceutical provision of the Spanish National Health System (NHS) for non-hospitalised patients*

### Background

Thirty years ago, Royal Decree 9/1996 regulated the selection of medical devices and accessories, their reimbursement, and their supply and dispensing to non-hospitalised patients. Under that framework, the Ministry of Health determined the retail price, including commercial margins.

Subsequently, Law 29/2006 updated the criteria and reimbursement procedure. Since then, the Interministerial Commission on Medicine Prices (CIPM) has been responsible for deciding on the inclusion of medical devices in the pharmaceutical provision, with the retail price (PVP) subject to prior regulation of distribution and dispensing margins. The absence of updated regulations in this regard blocked in fact the reimbursement of new medical devices.

The new Royal Decree addresses this regulatory gap by establishing the reimbursement procedure and setting distribution and dispensing margins.

### Requirements for financing

For a medical device to be eligible for reimbursement, it must be included in the pharmaceutical provision through an express decision of the Directorate-General for the Common Portfolio of Services of the NHS and Pharmacy (DGCC), which sets the reimbursement conditions and the applicable price within the NHS.

Reimbursement may be granted for medical devices intended for non-hospitalised patients falling within one of the following categories:

- wound care materials;
- products for the administration of medicines;
- products for the collection of excreta and secretions; and
- devices intended to protect or reduce internal injuries or malformations.

In addition, reimbursement is conditional upon the products being mass-produced, complying with the criteria set out in Article 92.6 of Law on Medicines and Medical Devices (LGURMPS), meeting the technical specifications established by the Ministry of Health, bearing CE marking, and not being subject to advertising directed at the general public.

### Reimbursement procedure

The procedure is always initiated at the request of the interested party and must include a description of the product; a reasoned proposal for a maximum price; projected sales for the first three years; the CE declaration of conformity and other documentation evidencing quality, usability and comparative improvements over other products.

Applicants must also provide information on budgetary impact; justification of price differences compared to reimbursed alternatives; production costs; and the status and pricing of the product in EU Member States where it is marketed.

At the request of the DGCC or on the initiative of the applicant, additional documentation may be submitted, including economic studies, clinical use studies, or any other relevant evidence.



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Once the information has been received, the evaluation process begins and it will finish with a technical report issued by the DGCC. This report will include, among other information, the product's positioning within the NHS, its degree of innovation, effectiveness, conditions of use, and comparison with other products, and may also include a cost-effectiveness analysis.

The DGCC must issue a decision within six months from the date of application. If no express decision is adopted within that period, the application will be deemed rejected.

### Setting of the ex-factory price

The CIPM is responsible for setting the ex-factory price (PVL) for reimbursed medical. In doing so, it considers the reimbursement criteria established in LGURMPS, as well as any reports issued by the Advisory Committee for the Pharmaceutical Provision.

The retail price (PVP) is calculated by adding the corresponding wholesale distribution and retail dispensing margins to the PVL.

If an applicant company decides to market a medical device at a price lower than the PVL, it must notify the Ministry of Health so that the applicable margins can be recalculated accordingly.

### Effects of the decision

Following a favourable decision, the applicant company must notify the Ministry of Health of the effective marketing of the medical device within a maximum period of one year. Failure to do so will result in the product being excluded from the reimbursement.

In the event of a negative decision, a new application may not be submitted until at least one

year has elapsed, unless new grounds of general interest or public health -unassessed in the previous procedure- arise.

Once the product has been placed on the market, the company is required to ensure continuity of supply. Any interruption must be authorised in advance by the DGCC, which may grant or refuse such authorisation on public health grounds.

### Exclusion procedure

The exclusion procedure may be initiated ex officio or at the request of the applicant company.

Ex officio exclusion may occur where alternative medical devices exist that are equal or superior for the same indications at a lower price or with an equal or lower cost of use. In such cases, the applicant company may propose modifications, which will be taken into account in determining whether exclusion is appropriate.

Procedures initiated at the request of the company may only be submitted one year after the product has been financed. The DGCC may only authorise exclusion if it does not result in the absence of suitable alternatives with the same indications, characteristics, and conditions of use.

The procedure has a maximum duration of six months. If no decision is adopted within that period, ex officio procedures will lapse, whereas procedures initiated at the request of a party will be deemed rejected.

### Price reviews

The applicant company may request an upward revision of the PVL where there have been changes in economic, technical or healthcare circumstances or in the assessment of the device's utility.



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The decision is taken by the CIPM, with the formal resolution issued by the DGCC. The review procedure must be completed within six months. If no express decision is adopted within that period, the application will be deemed upheld where initiated at the request of a party. In ex officio procedures, the lapse of time results in expiry.

### Specific reservations

The DGCC, ex officio or at the proposal of the CIPM or the regions through the Interterritorial Council of the NHS, may subject the reimbursement of medical devices to specific reservations.

These may include: prior authorization requirements (visado); limitation to specific indications; periodic review of the maximum PVL; and other measures such as expenditure caps, maximum cost per patient, or risk-sharing agreements.

### What about medical devices already included in the pharmaceutical provision?

By way of exception, the Royal Decree provides that medical devices already reimbursed will be automatically excluded if they are not marketed within one year of the entry into force of the Royal Decree.

### Information for analysis by the health authority

For the purpose of analysing the evolution of prices and margins of medical devices, the Ministry of Health may require applicant companies and distributors to provide information on prices and sales volumes, including details of any discounts applied.

The Ministry may also establish standardised formats, timelines, and criteria for the submission of such information, ensuring the protection of commercially sensitive data and compliance with the principles of necessity, proportionality, and administrative efficiency.

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