Capsulas

What news may we expect in Spain's pharmaceutical policy in the next few months?

Some notes on the intervention of the Secretary of State for Health in Congress on October 14

Last Monday, Javier Padilla appeared before the Health Commission of Congress to report on the general lines of action of the Ministry of Health. Among other functions, the Secretary of State for Health is responsible for developing and executing the national pharmaceutical policy, updating the National Health System's common portfolio of services. The comnpetence of his department also includes price and reimbursement of medicines. The Secretary of State's speech is undoubtedly an important moment in the legislature, providing insight into the issues on which the Ministry of Health will focus its efforts.

New provisions in the Law on Guarantees and Rational Use of Medicinal products and Medical Devices

The process to amendment of the Law on Guarantees and Rational Use of Medicinal products and Medical Devices (LGURMPS) was triggered in July 2022 by launching a public consultation. Since then, there has been much speculation about the potential changes. The Secretary of State announced that the public hearing phase of the new law is expected to open in mid-November. Padilla highlighted the following ideas on new provisions in the upcoming regulation:

1. Modification of the reference price system

Price differentiation between generic and innovator medicinal products will be proposed. According to the Secretary of State, the fact that a generic product is differentiated by a lower price does not necessarily mean that the reference product must also reduce its price.

2. Charge backs

The willingness to extend the current charge back to products for hospital use and products that are only dispensed at hospitals is confirmed, but Padilla announced the possibility of exceptions. The case law on the protection of orphan products suggests that these could benefit from some special treatment.

3. New funding criteria

Environmental criteria will be considered when ruling on reimbursement, in order to "prioritise socially desirable aspects within our system".

4. Substitution by pharmacists

It is proposed to give pharmacists greater substitution power in situations where problems of supply of certain medicinal products may appear. The Spanish Medicines Agency, on the other hand, will retain power to approve substitution protocols.

5. Prescription by nurses

The law will include provisions giving greater legal certainty to prescription by nurses, currently regulated in Royal Decree 954/2015. The law will contemplate the approval and implementation of protocols or clinical practice guidelines.

Royal Decrees

Padilla also referred to the four Royal Decrees currently under discussion:

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1. Health Technology Assessment

The idea that companies should provide information on the volume and origin of funds (public and private) for research and manufacturing of their products is maintained. The current regulation already foresees that these costs are a relevant factor when fixing prices, but it is possible that the new Royal Decree will reinforce this issue.

2. Price and reimbursement of medical devices for non-hospital use

At present, this issue is still governed by a Royal Decree approved in 1996. The Ministry of Health understands that the current rules are very rigid and as a result its capacity to address special situations such as shortages has been affected. The new regulation should provide for a more agile price and reimbursement process for these products.

3. Selective financing of medicinal products

The need of renewing the current regulation governing this matter (a Royal Decree from 1990) is confirmed. The new regulation will contunue circling around the concept of "selective funding" in order to prioritise the medicinal products that provide the most value to the NHS. It is expected that the public consultation will be launched at the end of 2024 and its approval is foreseen for 2025.

4. Magistral formulae of standardised cannabis preparations

A public consultation is now open and the publication of a monograph is announced. These formulations may only be prescribed by specialists. For the time being, these formulae will only be dispensed at hospital pharmacy services.

Other new developments

The Secretary of State also announced other relevant measures.

1. Transparency

Padilla confirmed that, as of this month, fact sheets will be published for each medicinal product/indication for which the Price Committee recommnends reimbursement. The sheets will include information on the indications for which reimbursement was requested, the assessment considered in the decision, the final decision and the reasoning behind it.

On the issue of transparency of unit prices the Secretary of State announced that the Ministry of Health will respect the industry's right to define its market strategies, and its willingness to preserve the Ministry of Health's negotiation power. It finally seems that the Ministry is aware of the advantages of maintaining confidentiality of unit prices.

On the other hand, Padilla confirmed the Administration's commitment to providing more information on overall amounts spending for reimbursed medicinal products grouped by therapeutic groups.

2. Early access data

Information on early access will be published, showing how patients have accessed the product before the reimbursement process was completed. Additionally, timelines from obtaining regulatory approval to the initiation and completion of the price and reimbursement process will be reported.