CUATRECASAS

# Draft law on medicines and medical devices.

## Analysis of the main changes of the new pharmaceutical regulation.

Spain | Legal Flash | May 2025

- On Tuesday April 8th, the Council of Ministers gave the green light to the Draft Law on medicines and medical devices (the "**Draft Law**"), which aims to modernise and significantly improve the regulatory framework in Spain. Once approved, the Draft Law will replace Royal Legislative Decree 1/2015, of July 24th, which approves the revised text of the Law on guarantees and rational use of medicines and health products.

- On Wednesday 9th of April, the period for submitting observations on the Draft Law opened and will remain open **until May 8th**. This period allows the sector to analyze the new regulation and provide any comments they deem appropriate.

Below we list the main changes proposed by this regulation:

| | |
|---|---|
| **New definitions** | New definitions are included such as biosimilar medicines, veterinary medicines, strategic medicines, first-prescription medicines, supply problems or shortages and environmental impact, among others. |
| **Veterinary drugs** | Changes are introduced in terms of pharmacovigilance of this type of products, extending the regulation on the sale of certain medicines by veterinarians and reinforcing the obligations to report suspected quality defects, among other measures. |
| **Simplified authorization processes** | Simplified authorization processes for medicines through **accelerated, conditional, and interim authorization pathways** for new medicines or new indications for existing medicines that address unmet medical needs. This facilitates faster access to innovative treatments without compromising rigorous safety and efficacy standards. |
| **Clinical trials** | Substantial changes in the **evaluation and supervision of clinical trials** and investigational medicinal products, aligning with the European regulations pending transposition. These processes will now be coordinated at the European level and will be monitored by the notifying State and the Member State responsible for the safety assessment. |
| **Selected pricing system for homogeneous drug groups**[1] | The Draft Law introduces a different reality for the selected pricing system. In this new scheme, the laboratories holding the marketing authorizations of the medications integrated into each homogeneous group included in the system must offer a price valid for six months, establishing a **triple differentiation**: (i) lowest-priced medication; (ii) medications with selected prices (within the price range of the lowest-priced medication); and (iii) the rest of the medications in that homogeneous group (non-selected medications), so that:<br>• the lowest-priced medication and the medications with selected prices will receive full funding for a period of six months; and<br>• the medications that exceed this price range will have a partial funding is up to the amount set by the lowest-priced medication.<br>Thus, the new wording allows patients to choose to pay an additional amount (avoidable payment) to obtain a specific medicine they prefer, by covering the cost that exceeds the price of the cheapest medicine in the range. This system aims, as established in the Draft Law, to promote competition within each homogeneous group of medicines, encouraging the entry of generics and biosimilars in the market. |
| **The reference price system** | The reference price system, which will remain in force, would be applied **one year after the introduction of the first generic or biosimilar drug in the market**, which indicates that this system would serve as a long-term stabilization mechanism. The reference price will continue to be the maximum amount for which the presentations of medicinal products included in each set will be financed, provided that they are prescribed and dispensed at public expense. |

[1] Homogeneous groupings constitute a classification system carried out by the AEMPS for those medicines with the same active ingredient and dosage, but not identical package/container sizes within a range or different but comparable pharmaceutical forms.

| | |
|---|---|
| | Human plasma medications and orphan drugs would be excluded from this system. Additionally, medications that objectively result in an improvement for patients or provide a strategic advantage for the National Health System could also be excluded (or have a coefficient applied to increase their price).<br><br>In the case of "strategic medicines",[2] the price of medicines included in the reference sets may be revised upwards, under certain circumstances. |
| **Environmental impact** | The prescription support systems will collect up-to-date information on the prices and environmental impact of medicines and medical devices. This includes details on the carbon footprint associated with their production and distribution, the biodegradability of their components, the impact of their waste on the environment, and the sustainability of their raw materials. This information will allow doctors, during the prescription process, to consider the economic and environmental impacts on the National Health System and apply criteria of efficiency, rational use, and environmental sustainability. |
| **Dispensing of medication and patient selection** | At the patient's choice, the pharmacist may dispense **either the prescribed medicinal product or one from its homogeneous grouping**, if available. The procedure will be as follows:<br><br>• if the patient does not express any preference, the pharmacist will dispense the lowest-priced medicine within the homogeneous grouping.<br>• if the patient selects a medicine with a selected price, they will pay the portion of the price corresponding to their contribution.<br>• if the patient opts for a medicine out of the selected pricing system, they will pay the portion of the price corresponding to their contribution for the lowest-priced medicine in the homogeneous grouping, plus the price difference between that and the chosen medicine. This includes the avoidable payment mentioned above (previously referred to in relation to the selected pricing system). |
| **Situation of shortages or urgent need** | When the prescribed medicine or any of those included in its homogeneous grouping are not available in pharmacies, the pharmacist **will be allowed to substitute it for another medicine** not included in the same homogeneous grouping in situations of shortages or urgent need. The Spanish Agency for Medicines and Medical Devices ("**AEMPS**") must publicly announce the shortage situation, specifying the duration of the exception. |
| **First prescription drugs** | The Draft Law introduces the concept of "first prescription medicines".[3] The criteria for this categorization will be determined by regulation (*reglamento*). |
| **Preventing drug shortages and** | • **Information in emergency situations**: in the event of a declaration of a public health emergency at the European level or |

[2] The Draft Law defines "strategic medicines" as those critical medicines for which it is considered necessary to adopt regulatory, economic or other measures to guarantee their survival in the market, both due to their need for health reasons and due to the vulnerability of their supply chain.

[3] The Draft Law defines "first-prescription medicine" as those medicines subject to a first prescription after a diagnosis that, due to the recurrent nature, episodic and recognisable clinical appearance of the condition they treat, can be dispensed to the patient on successive occasions without additional prescriptions for a certain period of time under the professional advice of pharmacists.

| | |
|---|---|
| **mitigating supply chain issues** | in the event of serious events, pharmaceutical laboratories, marketing companies, distribution entities, hospital pharmacy services and pharmacies will be obliged to provide the AEMPS with detailed information on stocks, sales and forecasts related to the affected medicines.<br>• **Supply prevention plans**: marketing authorization holders for medicinal products must develop and maintain plans to prevent supply problems or shortages of their products. In addition, they must notify the AEMPS of any situation that may compromise their availability.<br>• **List of strategic medicines**: the AEMPS will maintain an updated list of strategic medicines and will propose regulatory measures to ensure their continued presence on the market. These measures may include economic and fiscal incentives to ensure the availability of these essential medicines.<br>• **Repositioning of medicines**: provisions are introduced for repositioning authorized medicines in new indications that are outside the periods of patent and data protection, at the request of non-profit third parties. This measure aims to encourage the continued market presence of these drugs and avoid supply issues, promoting their use in new therapeutic indications. |
| **Pharmacotherapeutics Coordination Councils** | The creation of **Pharmacotherapeutics Coordination Councils** is established to promote the rational use of medicines in both primary care and hospital settings. These Councils will involve professionals from primary care within a Basic Health Zone. Additionally, civil society members related to the use of medicines may be included if deemed appropriate and requested by the Council coordinator. The main functions are:<br>• address and resolve deficiencies in the coordination of prescription, dispensing, and monitoring of medicines;<br>• establish effective, efficient, and relevant communication channels between agents involved in medication management within the Basic Health Zone;<br>• adapt to supply problems or difficulties that may arise with a medicine in that area;<br>• identify and address specific training needs to improve medication management. |
| **Amendments to Law 9/2017, of 8 November, on Public Sector Contracts** | The Draft Law introduces **amendments to Law 9/2017, of 8 November, on Public Sector Contracts**, to improve the bidding and purchasing processes by contracting bodies for medicines and medical devices. This amendment anticipates measures proposed by the European Union through the Critical Medicines Act and promotes joint purchasing of medicines or medical devices, inspired by the Covid-19 pandemic model. The goal is to consolidate purchases at both national and European levels in situations where centralized purchasing is more advantageous than unbundled purchasing. Centralized purchasing allows for better resource utilization, ensures more competitive prices, and facilitates a more equitable and efficient distribution of medicines and medical devices.<br>Additionally, a provision is added to enable payment by results for gene therapy medications, and a specific negotiated procedure without publicity |

| | |
|---|---|
| | is designed for medications protected by exclusive rights and without therapeutic alternatives. |
| **Contributions based on sales volume to the National Health System** | The Draft Law expands the scope of application of the Sixth Additional Provision, extending the obligation of contributions based on sales volume to **all acquisitions of medications and medical devices**, regardless of the dispensing method or whether the prescription and dispensing occurs through a pharmacy. The current text only includes this obligation for medications and medical devices that are dispensed in a pharmacy through an official prescription or dispensing order. |
| **Sanctions** | In terms of **sanctions**, the regulatory text significantly reinforces inspection actions of infringements related to medicines, medical devices, and cosmetics. Additionally, new specific offences are introduced for personal care products and narcotics. |

The text of the Draft Law is available for review **here.**

For additional information on the content of this document, you can send a message to our Life Sciences team or contact your usual contact at Cuatrecasas.