

The CNMC publishes a study on the wholesale distribution market for medicines in Spain

- The study analyses restrictions on the marketing and distribution of medicines.
- It detects a lack of competition in the case of competing drugs (originator brand/generics and biologicals/biosimilars).
- It suggests improvements to the remuneration of medicine wholesale and retail distributors, so that consumers benefit from competition.
- It proposes measures to improve efficiency and competition in this market, to benefit both patients and the sustainability of the health system.

Madrid, June 22, 2022 - The CNMC has published the "Market Study on Wholesale Distribution for Medicines in Spain." (E/CNMC/002/17).

This study continues the work begun in 2015 with the publication of the Market Study on Retail Medicine Distribution in Spain. At that time, the CNMC recommended removing restrictions on the opening and operation of pharmacies and allowing the dispensing of non-prescription medicines in other establishments, as well as their online sale, while respecting safety criteria and guarantees for public health.

The recently published study focuses on the wholesale distribution channel. It identifies numerous barriers to competition in the distribution of medicines imposed by current regulations. It also offers recommendations to the competent authorities aimed at improving efficiency in the marketing and distribution of medicines, without undermining current levels of public health protection.

Conclusions of the study

The analysis results in a series of conclusions:

- Innovative medicines (those protected by patent, where no ٠ competition is possible). There is scope for improvement in the process of pharmacoeconomic evaluation, which could lead to more efficient pricing.
- Off-patent drugs. Competition is possible in these medicine markets, since they are no longer protected by patents and generic and biosimilar

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medicines may emerge. However, the regulations do not sufficiently encourage competition. In the study, a comparative analysis of international experiences offers guidelines for introducing greater competition to benefit both consumers and the Spanish National Health System through price reductions.

Inefficiencies in wholesale and retail distribution remuneration systems. Currently, the design of the remuneration system is oriented towards the product rather than service to the patient, and does not allow discounts applied in the distribution channel to also benefit the Spanish National Health System.

CNMC recommendations

The CNMC makes the following recommendations to improve the functioning of the sector for the benefit of consumers and public health:

- Strengthen therapeutic positioning reports (TPRs) as complete and . transparent reference documents to support financing and pricing decisions for innovative medicines, especially with regard to pharmacoeconomic evaluation.
- Continuously evaluate the therapeutic effectiveness of medicines, • taking advantage of new technologies and big data.
- Implement a more flexible reference pricing system that allows greater competition in the price of medicines set by pharmaceutical companies.
- Strengthen the analysis and focus on evidence regarding the interchangeability of biosimilars with biological medicines and to establish a formal stance on this issue.
- Modify prescribing and dispensing policies to encourage competition between originator (name brand) and generic medicines, promoting patient choice.
- Substitute the current system of price-proportional distribution margins for another related to the services provided to patients, and introduce a clawback system. Under this system, part of the discounts offered in the distribution channel would be passed on as lower costs to the Spanish National Health System.

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Further develop informative and health education campaigns on generic and biosimilar medicines.

The CNMC is the independent market regulator that guarantees and promotes the existence of effective competition that benefits consumers. This study was conducted within the framework of the institution's competition advocacy functions.

(E/CNMC/002/17)

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