

PRESS RELEASE

The CNMC (Spain's National Authority for Markets and Competition) publishes its report on the Draft Royal Decree Regulating the Financing and Pricing of Medicines and Sanitary Products and their inclusion in the Spanish National Health System's Pharmaceutical Provision.

- The proposal regulates the inclusion of medicines in the National Health System's pharmaceutical provision.

Madrid, 1 December 2015. The proposal made by the Ministry of Health touches upon two crucial aspects of medicines and healthcare products: its pricing and reimbursement (funding) scheme.

This regulation impacts all operators: pharmaceutical laboratories, wholesalers, pharmacies and hospitals. It also affects different sanitary administrations and citizens -as users of health services and as tax payers-.

The pharmaceutical and sanitary products' sector has been subject to special scrutiny by the CNMC, from an advocacy, enforcement and merger control perspective. The report on the Draft Royal Legislative Decree approving the Consolidated Text of the Act on Guarantees and Rational Use of Medicines' and Sanitary Products and the Study of the retail medicine distribution market in Spain can be highlighted, inter alia, from the CNMC's advocacy perspective.

The CNMC is perfectly aware of both the need to protect public health and to preserve access to affordable, safe, effective and appropriate quality medicines under equity considerations.

Particularly, it should be recalled that a public pricing policy constitutes a limitation of the Principle of Free Enterprise, recognized in the Spanish Constitution (art. 38, 1978 Constitution). The necessity and proportionality of such restraint should in any case be justified. Notwithstanding the above, economic literature and empirical evidence do not justify that price intervention is i) neither the only one nor the best available option to the Public Administration nor ii) that the pharmaceutical market should be so heavily regulated as it is in Spain, where this intervention results in direct price and margin settings. Of special concern is the extension of such settings to certain healthcare –rather than strictly sanitary-products, given its completely different nature.

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On this topic, the CNMC recommends promoting the use of measures other than price intervention, like those coming from the demand side, of a convenient extension and that present a significant pro-competitive market component. Its efficiency on reducing the pharmaceutical public spending has been proved. If price intervention is maintained, less intensity and width would be recommended. Also, intervention mechanisms should be carefully designed with special consideration to microeconomic fundamentals, especially in the pharmacoeconomics' area. A pharmacoeconomics' approach in the pricing evaluation and an increased transparency, reducing the Administration margin of discretion, would also be praised.

Additionally, the CNMC finds it pertinent to recommend:

- An effective and precise development of the financing and price fixing criteria, as foreseen in the Consolidated Text of the Act on Guarantees and Rational Use of Medicines' and Sanitary Products.
- A generalization of rigorous economic evaluations in the decision making process (*ex ante*, follow up and *ex post* evaluation). Particularly, the cost-effectiveness principle shall be developed and the introduction of the value-based pricing mechanism shall be introduced.
- Reject the current price regulation regime foreseen for sanitary products included in the pharmaceutical provision, as it extends the intense medicines' price-setting regime to some products (such as gauzes and healing materials, healthcare products for collection of excreta and secretions and others) that have different characteristics and singularities. It is therefore recommended that such regime be deployed. Especially regarding margin's regulation and the reservation of activity of dispensing them to pharmacies. An alternative scheme that takes into account competitive sourcing procedures and the expansion of homogenous group system would be more suited.
- Concretion of mandates regarding the supply of hospital medicines' billing information together with its follow-up and evaluation to take into account not only the volume of sales but also their unitary price and the volume of total spending, as it is unknown today.
- Consider alternative retribution systems other than the margins as they are not efficiency designed nor proportionate, and, thus, questionable in its rationale and design.
- Remove the limitation of discounts on medicines' prices that are not subject to medical prescription and that are published.

The CNMC report also makes a reference to the reported and selected price regimes and to the exchange of information procedures.

The CNMC is an independent markets regulator that guarantees and promotes an effective competition. This report has been approved at the request of the Ministry of Health, Social Services and Equality within the consultative remit of the CNMC with regard to the process of drawing up regulations which affect its area of jurisdiction in the sectors which it supervises, under Article 5(2) (a) of Act 3/2013, of 4 June, creating Spain's National Authority for Competition and Markets.

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