

PRESS RELEASE

The CNMC publishes its report on the Draft Royal Legislative Decree that amends the Act on Guarantees and Rational Use of Medicines' and Sanitary Products.

- The CNMC makes some recommendations under an effective competition and efficient economic regulation perspective.
- The CNMC considers that the current price setting mechanism should be replaced taking into account efficiency and more transparency criteria.

Madrid, 28 April 2015. The Spanish Markets and Competition Authority has published its report on the Draft Royal Legislative Decree (DRLD) that aims at gathering all the amendments made to the Act on Guarantees and Rational Use of Medicines' and Healthcare Products (Act 29/2006, of 26 July), derived both from the transposition of European regulations and from several measures of contention and rationalization of pharmaceutical public spending.

Even though the Draft is not subject to substantive innovation incorporations due to its structure (being an amended text), the CNMC has found several areas whose coherence and comprehension may be improved in future legal reforms.

The CNMC appraises some elements introduced such as the specific provisions on competition and competitiveness promotion, the more economic approach followed in the medicines and healthcare products' price settings and specific measures such as the promotion of generics, substitution of pharmacists or prescription by active ingredient.

Nonetheless, the CNMC would like to make some additional appreciations regarding some areas susceptible to future legal reform:

- The procedure and criteria used for the inclusion of medicines or healthcare products under public funding in the National Health System (NHS) remains very broad and discretionary, allowing discrimination based on the origin of products be made, as contribution to the GDP may be included.
- Price intervention regimes prove to be overregulated overall and sometimes unjustified for each specific case. The design of intervention mechanisms should take into account pharmacoeconomics' criteria and should be more transparent in the process setting. It is recommended that alternative demand-side intervention schemes may be investigated.

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In addition, regarding the pricing regime, the CNMC considers that:

- Should be further clarified, its rationale justified or an alternative be put in place. Medicines that are not financed are theoretically under a free market price regime but, in practice, are subject to a notified-prices scheme, with possible opposition from the Administration and are susceptible of being regulated by the Government under “transparent and objective” criteria.
- Transparency could be enhanced regarding newly marketed medicines and healthcare products subject to a fixed price scheme that has barely identified any objective criteria and that has suffered very little or no legal further development. In doing so, medicines and healthcare products’ cost-effectiveness should be accounted for, as well as their therapeutic or innovative contribution.
- The reference price system has been denatured after numerous amendments to its original conception and it now functions as a maximum price system. Under this regime, the benefits coming from enhanced competition have not been passed on to the consumers. It is therefore recommended that the system is re-thought and that the choice of consumers’ margin be amplified, together with other competition promotion mechanisms.
- The selected price system constitutes a pro-competitive mechanism that makes use of market mechanisms and, while it is therefore positively appreciated, its implementation should be carefully planned not to introduce any possible restriction to competition.
- The strict discounts and the more-than-10%-discount-only price revision limitations should be reconsidered.
- Alternative policies other than price intervention and that promote competition, (demand side measures), should be followed such as those intended for the ration use of medicines, among others, that imply an increase of price competition for consumers. Moreover, auctions and centralized public buying mechanisms are positively regarded as long as effective competition principles are taken into account.

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- The elimination of restrictions to the distribution channels of medicines and sanitary products not subject to medical prescription whether traditional or not (distant or internet sales) should be considered and, in particular, the internet sale restriction to anyone other than pharmacists.
- Regardless of what the future conclusions of the CNMC's Study on the Retail Distribution of Medicines might be (currently under elaboration), pharmacies remain heavily regulated. Reservation of activity for Technical Pharmaceutical Directors in wholesale distribution entities should be eliminated.
- The proportionality and reasonability of punishable conducts related to the replenishment guarantee might be valued. An alternative wording of those infringements more in line with Directive 2001/83 might be considered.

The CNMC is an independent markets regulator that guarantees and promotes an effective competition. This report is being done upon request of the Ministry of Health, Social Services and Equality in the exercise of CNMC's consulting competences, as regarded in the article 5.2 Law 3/2013, of 4 June, creating the CNMC.

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