

PRESS RELEASE

The CNMC launches a study on the market for wholesale distribution and marketing of medicines in Spain

- Potential restrictions on competition have been preliminary detected, arising from the functioning and the structure of the market, as well as from regulations in force which could restrict the access to the market and the exercise of the activity.

-A better functioning of the wholesale market for medicines is essential to the well-being of the patients, and to increase competition in the market for retail distribution of medicines.

-The report is part of the CNMC's task to promote competition and an efficient economic regulation in the Spanish markets to the benefit of consumers.

Madrid, March 17, 2017 - the CNMC (National Commission for Markets and Competition) has launched a study on the market for wholesale distribution and marketing of medicines in Spain. The report responds to detected preliminarily potential restrictions on competition, arising from the functioning and structure of the market, and from the potential regulatory restrictions on access to the market and the exercise of the activity.

The distribution and marketing of medicines is strongly regulated in Spain, which is based on the safeguarding of the individuals' health, and the protection of the public general interest. The CNMC acknowledges that the protection of the public general interest, inherent to the regulation of this market, is necessary. However, the compliance of the regulation with the principles of necessity and proportionality is also essential for the protection of the general interest. To that end, it is key to avoid introducing or maintaining unjustified restrictions to competition that prevent or make it difficult to achieve greater efficiency in the functioning of the market and the use of public resources.

During the preliminary analysis of the market, a series of potential restrictions on competition has been identified. These restrictions will be analyzed in more detail in the study. First, the companies holding patents on innovative medicines, whose protection is justified to encourage innovation, can adopt strategic behaviors, which restrict or delay the entry into the market of generic medicines.

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Occasionally, these strategic behaviors can be facilitated by rules not adjusted to the principles of necessity and proportionality of an efficient economic regulation.

Secondly, the price system and wholesale determination of margins are highly intervened. Part of these interventions could be justified by the existence of market failures which in turn could affect the overriding reasons of general interest. As a result, a careful review of the system for calculating prices and margins should be considered, as well as an analysis of each of the special price schemes.

Such an analysis will be complemented with the assessment of alternative mechanisms, such as centralized purchasing schemes and tender auctions, in order to determine their impact on prices and administrative efficiency. During the study, a thorough analysis will be conducted on the use and design of both instruments, in order to determine whether these mechanisms introduce greater competition in the sector and improve the regulation to the benefit of patients, the public administration and the economic system.

Also, the CNMC has identified, on a preliminary basis, additional potential restrictions on competition in the market, deriving from the functioning and structure of the market, as well as other regulatory restrictions on access to the market and the exercise of the activity.

In 2015, the CNMC released a study on the market for retail distribution of medicines in Spain. The study proposed to adopt a less restrictive model in order to reduce the barriers to entry and exercise to the market and to promote greater competition among pharmacies. The benefits of greater openness to competition in the segment of retail distribution of medicines would be reinforced if there is a simultaneous increase of the level of effective competition in the upstream markets. For this reason, it is appropriate to conduct a detailed analysis of the market for distribution and marketing of medicines, to propose a number of recommendations that will also strengthen the proposed measures in the retail segment. Voluntary contributions can be sent to the email address estudios@cnmc.es.

The CNMC pursuant to article 5.1 of the Law 3/2013, June 4, on the Creation of the National Commission of Markets and Competition, has among its functions the promotion of effective competition in the market, though, *inter alia*, conducting studies and market research from a competition perspective. In addition, and

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where appropriate, the CNMC could issue reports on economic sectors, including proposals for liberalization, deregulation or regulatory changes.

The Department of Competition Advocacy, in compliance to the Action Plan of the CNMC and according to the market studies' methodology, monitors the degree of competition in the Spanish markets on a permanent basis. In this framework, it has been identified, on a preliminary basis, the possible existence of a series of impediments to the development of effective competition in the market for distribution and marketing of medicines in Spain.

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