Amendement of Spanish law on medicines and medical devices

The Ministry of Health opens a public consultation on the first draft of the law that will amend the current laws on guaranties and rational use of medicines and medical devices

Introduction

In Spain, the procedure to elaborate a law is established in Law 50/1997 of the Government. This law states that before drafting the project of any new law, a public consultation must be carried out for the purposes of obtaining the opinion of the persons and entities that could be affected by the future legislation. The consultation must deal with the problems that the new law aims to solve, the need and opportunity of its approval, the objectives that are sought, and the possible regulatory and non-regulatory alternative solutions.

Law 50/1997 states that the public consultation must be made in such a manner that all those who may be affected by the new legislation have the possibility to issue their opinion, giving them at least 15 days calendar days to present their allegations. In this case the Ministry of Health is granting until 31 July 2022 to present such allegations.

The issues that the new law aims to solve

The document published by the Ministry of Health allows us to conclude that the reform that is being considered will have four principal axes:

a) Public financing of medicines. The document of theMinistry of Health refers to adopting new measures to rationalize pharmaceutical expenditure and promote rational use of public funds. We think it is positive that questions related to the public financing of medicines are considered as a problem to be solved. Recognizing that exists a problem is undoubtedly the first step to solve it. On the other hand, it is well known that public financing does not only raise issues in connection with the rational use of public funds. The procedures that are followed in relation with these matters are also a problem that should be addressed.

b) The experience resulting from the pandemic. Everybody knows that the pandemic has created important challenges. The more relevant ones were related to the availability of medicines and medical devices. Any measures adopted on this new legislation should consider, in a very special manner, the impact that it may have in the European industrial tissue. A legislation having as objective achieving a high level of protection of public health must necessarily aim to contribute to making the European Union an attractive space for the development and manufacturing of medicines and also of pharmaceutical active ingredients. On the other hand, the pandemic has allowed to create initiatives of great interest around the idea that home treatments have advantages and that it is interesting to keep patients away from hospitals as much as possible.

c) Impact of new technologies. It is very positive that the Ministry of Health includes these questions among those to be tackled. On the other hand, this is an area where it will be important to ensure a good alignment of the competences of the Spanish government. It will be especially important not to interfere with competences that have been assigned to the European Union (for example those related to the evaluation of safety and efficacy of medicines approved via decentralized products) nor with competences that correspond to the regions (for example in all matters that refer to medicines not as a product but as part of the healthcare assistance).

d) Implementation of European Union Law. There are various areas where this implementation is necessary. This should be made with full respect to the principles that have inspired the adoption of the European rules. Recent Spanish jurisprudence dealing with the incentives to the development and commercialization of orphan products is a good example. There are also other areas where relying on these principles will be very important. On the other hand it is not to be forgotten that European pharmaceutical legislation is at present under review. In essence, the reform of Spanish law may be a long journey subject also to questions that will be addressed during the process of adoption of new European rules.

The need and opportunity for a new law

On this issue, and when referring to medicines, the document of the Ministry of Health is mainly focused on the public financing of medicines. There are no references to the other "problems" that the new law should address. This reveals that the issues related to financing of medicines will be the main ones that will be considered in this reform of the legislation.

In connection with public financing of medicines, the document includes some interesting messages both as regards substance issues and as regards procedural issues.

As regards substance, the document insists on the idea that public healthcare centres should only use a medicine if a marketing authorization has been granted and if the product has been accepted for reimbursement by the Spanish authorities. This message, however, is qualified by stating that these conditions are necessary "in a context of ordinary use of ordinary products". Therefore, the use of medicines under special circumstances (i.e. compassionate use and other early access programmes) remains open. Another important issue that is also on the table refers to the use of products in respect of which a ruling expressly denying reimbursement has been adopted. We think it would be important to solve this question, on which a report issued by the Ministry of Health in 2019 casted some doubts. When dealing with this matter it should not be forgotten that Law 16/2003, after being amended in 2020, contemplates that the catalogue of public healthcare services fully covered by public financing includes all activities related to the diagnosis and treatment carried out in healthcare centres. On this basis, there should be no doubt about that medicines that are given to patients at public hospitals should always be covered by public funds. On the other hand, the document also refers to one of the issues which is of great relevance in this area: the conciliation between the efficacy and safety evaluation of medicines carried out by regulatory authorities and the evaluation of incremental value and cost efficacy that payers wish to carry out.

As regard the procedure, the public consultation only makes a brief reference to the Price Committee. Our experience in this area allows us to conclude that it is indispensable that the reform of the law addresses some issues that affect the price and reimbursement proceedings in Spain and that are of high relevance. Among others we could refer to the functions and competences of the Price Committee; the legal status of the therapeutic positioning reports; the various categories of prices and the role authorities can play in respect of each of them; the information to be given by companies; the applicable deadlines; how to handle transparency of the process and the decisions that are adopted; etc.

The objectives of the new law

In this chapter the document refers to specific issues on which one may expect that the Ministry of Health will concentrate its efforts.

First, the document contemplates modifying the system of co-payment of medicines with the purpose of protecting the persons that are more in need. The document does not refer to whether the co-payment system may also be used as an instrument that may help modulating the demand of certain products.

The document also contains various important ideas in connection with reference pricing. The document expressly refers to the introduction of mechanisms to increase competition; something that in Spain has not worked out very well in the past years given that the mechanisms that are currently contemplated in the law have not been used. Furthermore, such mechanisms have increased the risks of shortages of some products in the market. In this respect it will be interesting to see whether the Ministry of Health incorporates any of the proposals that the Spanish competition authority has put on the table in its last report on wholesale distribution of medicines.

In the same context of reference pricing, it is stated that the system should protect the incremental value of certain innovative solutions related to the use of medicines. This, at last, opens the door to solve the situation affecting innovative application devices or other products whose innovation did not merit any recognition. The document also announces measures of additional pressure to the industry by stating that quarterly contributions may also apply to medicines dispensed in healthcare centres. Considering the current environment of higher costs, it would be interesting to act prudently in connection with these matters.

Consolidating home delivery of hospital products and tele pharmacy appears to be another important objective. This, together with the issues of pharmaceutical depots, is a complex matter in which it will be necessary to ensure that the position of the regions is aligned with that of the central government.

The document also refers to clarifying which authorities are competent regarding the control of advertising of medicinal products, a matter on which it is important to improve as regards legal certainty.

Next steps

The process to approve this new law will be a long one. Before submitting a draft to the Spanish Parliament, a lot of work will still be required. We shall file our observations and will be happy to work on helping companies or other relevant stakeholders define their position. In addition, we shall continue monitoring the process, and keep readers of CAPSULAS up to date on this very important matter.

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