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The Ministry of Health works on the review of the rules on the use of medicines in special situation

Summary of our contribution in the process that may lead to new legislation replacing Royal Decree 1015/2009

Background

At the end of 2020, the Spanish Ministry of Health triggered a public consultation process within the context of its works to replace Royal Decree 1015/2009 with new legislation that will govern the use of products that are in special situations. This will affect early access of products to the Spanish market prior to price and reimbursement process being completed as well as the terms under which products may be prescribed of label.

State and Regional Competences

Article 24 of Law 1/2015 of Medicines is the one that offers legislative coverage for these matters. Royal Decree 1015/2009 developed this Article and granted the Spanish Medicines Agency the main responsibilities to handle these situations in accordance with Article 149 of the Spanish Constitution, which states that central government agencies have exclusive competence on legislation of pharmaceutical products. Spanish jurisprudence, however, has also stated that the exclusive competence of the central authorities in this matter refers to drugs insofar as products, but not to the rules that refer to the drug as part of healthcare coverage by the national health system.

In this sense, the rules adopted by the central government and which relate to how patients may access drugs (for instance those referred to prescription and dispensation of medicines) are basic norms that establish the common ground within the whole of Spain but they are without prejudice of rules that may be established by regions in their territories.

In our opinion the modification of Royal Decree 1015/2009 must be very careful regarding these matters. Ensuring equity in access to approved medicines is very important and already complex. In our view, it may even be more difficult to regulate access to drugs in special situations. In this area it is prudent to ensure that there are little differences between regions.

Access to approved products that are not yet commercially available in Spain

The Ministry of Health considers it necessary to differentiate between access to drugs that are not approved and access to drugs that are approved but are not effectively marketed in Spain yet. We think that establishing this difference is appropriate. It is advisable that the access regime for unapproved drugs be very rigorous, but the procedures to access drugs that are approved but not yet commercially available may be more flexible.

At present Royal Decree 1015/2009 contemplates that AEMPS will handle access to drugs that are approved but not marketed in the same manner as if they were not yet approved. According to our experience there may be different reasons why this happens, and the following scenarios may be highlighted:

a) Products approved by the European Commission after their assessment by the EMA, which therefore already have a valid marketing authorization in Spain, but which may not be yet marketed in Spain because a price and reimbursement decision is pending.

b) Products that have been approved but which are not marketed because of lack of interest of the marketing authorization holder . This situation may appear when the Ministry of Health decides not to include these products in the list of reimbursed drugs or in cases where even if the product is reimbursed, the holder decides to cease the commercialization.

c) Approved products in respect to which there is a shortage situation.

We think it is fair that the Spanish Medicines Agency wonders what its role should be in these cases, and whether access to drugs could be handled as part of the health care provision system rather than as part of the approval process. This would allow more intervention of hospitals or regional authorities. In our opinion, the role of the Spanish Medicines Agency in these cases must continue being relevant because this is guarantees that the units to which Spanish patients will have access are acceptable from their quality point of view. In these cases, we understand that the Spanish Medicines Agency should at least keep a role similar to the one it plays when there is parallel import into Spain of products that are marketed in other Member States.

On the other hand, because we are talking about approved products, we think it will not be necessary to keep a system of individualized access (named patient basis) and that the procedures could be simplified and be replaced by a system of self-responsible declaration.

The use of data obtained for research purposes

The new rule will probably contemplate some conditions under which data obtained in connection with the use of a drug in special situations may be used. This raises various questions. First we may wonder whether the use of drugs in special situations must be subject to specific obligations different from the ones that generally apply in the context of pharmacovigilance. Setting up certain obligations in this respect may have advantages but also inconveniences. The situation should be analyzed taking into account the interest of the different stakeholders in particular those of the patient, but also those of the prescriber, the healthcare center where the treatment is being carried out, the administration and also the ones of the marketing authorization holder. The use of drugs in special situations, in our opinion, should not be considered equal to the use of drugs within a clinical trial, but one could study options in favor of observational studies in relation to these products.

The use of magistral formulas in special situations

In connection with this issue, we think that it is important to state that European and Spanish Pharmaceutical Law understand that magistral formula is something that should cover special needs of individual patients. The use of a magistral formula to treat a pathology is per se a special situation which we think is not compatible with the reiterated and generalized manufacturing of these preparations. This, we think, which should be avoided when there exists a product approved to treat a given pathology.