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Some ideas for the new Royal Decree on prices and public financing of medicines in Spain

Summary of the conference given at the Seminario CEFI on Public Procurement of Medicines held on 12 November 2013

Now that the publication of the long expected new Royal Decree on pricing and reimbursement of medicines in Spain is near, I was kindly invited by the CEFI Foundation to speak about this matter at a Seminar on Public Procurement of Medicines held in Madrid on 12 November. My speech, which is summarised in this Capsulas Newsletter, was an attempt to put forward some ideas which, in my opinion, could be taken into account by the persons responsible for drafting the new regulation.

Initial remarks

First of all, I think that those of us who may collaborate, in one way or another, with the persons in charge of drafting the new rules, or who may have to analyze or apply the text that will be approved, must take into due account the complexity of the legal, economic and social environment in which the new Royal Decree shall be passed.

As regards the legal environment, the new rules shall have to respect European Union laws and also some Spanish legislation which is higher in rank. At the same time, they shall have to reconcile the interests of the Spanish central government with those of the regions, who shall be the ones ultimately responsible for public financing of medicines.

The economic and social environment is also important. The new rules shall have a material impact on the industry; they shall have also a direct effect on those who work on research and development, on healthcare professionals, on hospital managers and on the patients. These rules shall be approved at a time when public authorities face, as never before, the need to take priorities and to make the best of their resources. In this context, on the other hand, it shall be very difficult, if at all possible, that citizens accept direct cuts in the basic contents of public pharmaceutical coverage.

All of the above leads us to suggest patience and serenity in the debate which must take place prior to the approval of the new rules. The current regulation was passed in 1990. If it has taken 23 years to replace it with a new one, it would be good not to hurry. It is important to make things well.

In addition to serenity, we also need finesse. In the recent past, many rules on pricing and reimbursement have been approved using urgency procedures. The Ministry of Health has now the opportunity to bring clarity to some issues that are creating undesired confusion precisely because the legal texts were drafted too rapidly and were not adequately revised.

In this line, and speaking about the contents and the scope of the new Royal Decree, we think it would be convenient, before starting to draft the rules, to make a "back to basics" exercise, to focus on what are the issues that the government wants to cover. In my opinion, the new Royal Decree should limit itself to give an answer to four questions: (i) which products are reimbursed products under the public system?

(ii) which process shall the government follow to decide on this matter? (iii) what price shall the government be willing to pay for a product? and (iv) what are the legal consequences of public financing of a given product. We think that if the Ministry of Health intends to go beyond these issues, the risk of inconsistencies with other laws increases very much.

Procedure and delays

As regards procedural issues, a first idea that comes up, linked to what will be established by the future Transparency Directive, is that companies should be given the right to initiate the process for pricing and reimbursement of their own motion at any time. It would be good, we think, to facilitate early contacts between the company and the authorities, this is something that the new Directive shall most likely contemplate. The main objective has to be securing that approved products reach patients, through ordinary channels, as soon as possible after they have received a marketing authorization.

As regards the timing on which the process has to be completed, the new text may keep the negative silence rule, meaning that if the company has not received an express answer within 180 days from the filing date, then it may consider that the government has decided not to reimburse the product. European case law dealing with this matter has established that each EU member state is free to decide about the effects of administrative silence. Still, we think it is wise to recall that the trends in modern administrative law would advocate for a revision of this matter. We think it would be advisable to change the rule so that, if the applicant has not received an answer within 180 days from filing, the drug would be reimbursed at the price requested by the applicant. On the other hand, the Ministry of Health should not forget that the upcoming Directive shall require member states to secure that applicants have access to rapid and effective remedies in case of non-compliance with the time limits.

Avoid duplication

European rules shall also prohibit duplication in the procedures. The decisions related to pricing and reimbursement of medicines should be taken by a single authority at national level, and under a single process. This rule applies to all public authorities, which means that those who are not competent to adopt a ruling on this matter should not act *ultra vires* and should therefore not take any action that may affect pricing and reimbursement of medicines.

When drafting the Royal Decree it would also be also advisable to explain better what article 88 of Law 29/2006 establishes. Under this provision, the maximum approved ex-factory price for a product "cannot be modified or subject to a bonus, unless this modification or bonus consists in a percentage discount which applies in all the national territory". I suggest that this provision is developed in the regulation making it clear that it imposes an obligation on public authorities but that it does not preclude pharmaceutical companies from offering different prices in public procurement procedures, or from offering risk sharing agreements or other return mechanisms.

On the other hand, the Transparency Directive shall also prohibit that the authorities in charge of deciding on pricing and reimbursement of medicines carry out a new assessment of the quality, efficacy, safety or bioequivalence of a product. On these issues, it is for the European Medicines Agency or for the national evaluation agencies to decide. In Spain, this matter shall require continuous surveillance, because many public authorities, even after the approval of a new product and of its price, feel themselves

competent to put into question the efficacy or safety of the product. By doing this they are in fact limiting the ability of patients to have access to treatment with these products.

Criteria for price approval

The Ministry of Health, in the new Royal Decree, must indicate which are the criteria that will be used in order to decide on price applications. It is important to establish a difference between these criteria and those which apply in order to decide whether a product is accepted for reimbursement or not. One of the issues that the authorities have to take into account in order to decide if a product is reimbursed, as a matter of fact, is the price at which the new product might be offered by the company in comparison with other alternative products. The persons in charge of drafting the new Royal Decree, therefore, shall have to decide whether prices in Spain shall continue to be determined using a cost plus profit system or if other criteria shall be taken into account.

In any event, the new Royal Decrees must continue contemplating that these criteria shall have to be objective, verifiable and shall not discriminate between companies. This means that administrative decisions in this area shall have to be duly motivated. In recent times, the motivation of decisions related to the price of medicines has not been frequent. Normally the initial application has been followed by an individual negotiation after which the authorities have requested companies to file a new application with the price resulting from the negotiation. Only in very few cases the authorities have approved decisions motivating a ruling different from what the applicant had requested. In the future it is foreseeable that this will change. Those in charge of drafting the Royal Decree should take this into account and contemplate proper procedural measures which will help them in front of those who may wish to appeal any of these decisions. Dealing with the criteria that have to be used by the authorities, it is important to request prudence as regard the assessment of contributions to GDP (Gross Domestic Product). We all know that all authorities in the world, including those of EU member states, look after the interests of their local economies. In the European Union, however, regulations and directives prohibit governments to adopt measures that may go against the free movement of goods, persons, services and capitals. Freedom of movement is the result of European integration and therefore companies have the right to establish their production or research centers where they consider this to be more appropriate. When drafting the new rules we should be careful not to use wording that could be considered against these principles. It would be more interesting to devote efforts to create the underlying conditions so that companies will want to establish their operations in Spain or carry out clinical research in our country.

Another very important issue regarding the criteria that shall be used to adopt decisions on pricing and reimbursement is the documentation that authorities may request the companies. Law 29/2006 grants the Ministry of Health very wide powers in this respect. The new Royal Decree, when establishing how these powers may be used, should make sure that the rules are easy to comply with and that the authorities have the proper resources to assess the documentation that may be provided to them.

Price amendments

The modification of prices shall also be one of the issues on which the new Royal Decree shall have to set up some rules. Law 29/2006 establishes that the price of a drug may be modified when changes in the economic,

technical, or health circumstances so avail. It also establishes that a change may be the result of an assessment of therapeutic utility. The new Royal Decree should make these criteria a little bit more clear, and also establish procedural rules for the review of prices. When doing so, it would be advisable to establish a period during which pricing decisions should not be modified. One year would be, in my opinion, a reasonable term during which prior pricing decisions should not be revised.

Notified prices

As regards the regime applicable to notified prices, on which so much has been said lately, the analysis of this issue must be framed within the general principle of limitation of public intervention on pricing. In Spain after some years, nobody doubts that the administrative intervention on pricing of medicines is limited to those units of products that are publicly financed, so that nothing is against the idea that one same product may be available in the market at an alfa price (the maximum price accepted for reimbursement by the government); and at a beta price (the price that the company establishes for all the units which are bought outside the public system). If public administration intervention must be limited to units that are financed with public funds, nothing should impede that, once a product has received a marketing authorization, and even prior to the date on which it is decided if the government shall reimburse that product or not, this product may be available in the market at the beta price freely established by the company. The Royal Decree would respect basic principles of modern administrative law, which are the ones inspiring the above mentioned ideas, if clarity was given on this issue. On the other hand, and also in relation with notified price, the Royal Decree should focus on regulating precisely the system for exchange of information which shall effectively allow the marketing of products at beta price, and reimbursements to pharmacy offices of the corresponding part of the alfa price.

Selected prices

My speech at the CEFI seminar finished with some comments on selected prices. The 16 paragraphs of article 93 bis of Law 29/2006 (introduced through Royal Decree-Law 16/2012) raise many questions. Because of this I think that when developing this article the Ministry of Health should work calmly. First of all, it shall be necessary to make it clear to which products may the system of selected prices apply. Once this first issue is clear, the Royal Decree should deal with the procedure that suppliers shall have to follow. The Law, in this regard, refers to the authorities contacting suppliers so that they may "inform about their intentions". We think that when regulating this procedure, the principles of transparency, publicity and not discrimination, which are well established in the rules applicable to contracts in the public sector, must be duly respected. We think that the Royal Decree should also regulate with special finesse the obligation to supply that selected companies shall have, and parallel to this, the rights that interested parties may have in forcing administrative action in the event of breach of this obligation.

Final comment

The issues that the new Royal Decree shall have to cover are clearly many. My last comment is that it would be advisable that those in charge of drafting the new rules take into account that obtaining economic benefits in the short term is always desirable, but it should be reconciled with the protection of the quality of the public coverage of medicines that has been achieved with so many efforts of so many people.