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What is going on in Spanish pharmaceutical law?

A commentary on the most relevant aspects of Royal Decree-law 16/2012 which affect pharmaceutical and medical devices' companies

You have undoubtedly heard a lot about Spain lately. Debt crisis, public deficit, bailout or financial assistance to some Spanish banks (call it as you like) are some of the issues that have been on the news every day during the last months; and will probably continue so during some time.

In this situation, the Spanish government has taken several measures which have a direct impact on the internal pharmaceutical market. At the end of April, the Spanish government decided to use again the mechanism of a Royal Decree-law to adopt such new measures. A Royal Decree-law is a tool that allows the government to legislate on matters normally reserved to Parliament, and which may be used in case of urgency. The Spanish Constitutional Court has ruled in several instances that an economic situation requiring a rapid response from the government is a valid ground to use a Royal Decree-law. Royal Decree-law 16/2012 was ratified by Congress on May 17th. On the eve of this ratification by Parliament, the Spanish Official Journal published a "correction of errors". This is a procedure that Spanish law allows for amending a legal text that has been published in order to take account of minor typographical errors which may be discovered after the initial publication. In this case, the "correction of errors" went a little beyond this, and introduced some changes in the legislation. Because we expected this to happen, we decided to wait some time before devoting one of our CAPSULAS to the new measures. On the other hand, as days and weeks passed by, many doubts arose on how the rules were going to be implemented in practice. Not that we now have answers to all the questions, but having let some time pass allows us to provide this general commentary with some more comfort.

Objectives of the new legislation

The preamble of this Royal Decree-law signals the relevance of this piece of legislation. The aim of the government is to carry out a deep structural reform of the National Health System with the objective of making it sustainable.

On the other hand, a very important novelty of this Royal Decree-law, when compared with other measures adopted by the government in recent months, is that for the first time it directly affects patients and their rights and duties in connection with access to medicines. As of July, the amount that patients shall have to pay for their drugs shall be higher than before. The implementation of this increase in co-payment is raising difficulties because the system relies on information held by regional governments and also on the level of income of each individual.

Economic measures by regions

The Preamble of Royal Decree-law 16/2012 states that it also aims to ensure that no differences appear as regards the degree of protection that citizens receive in each of the 17 autonomous communities or regions which are part of Spain. This has been an objective of the various governments during the last months, be-

cause the fact that the regions are the ultimate payers of health expenditure (although they are not competent to decide on price and reimbursement of medicinal products) has resulted in a variety of measures aiming to cut expenses and creating differences on how drugs may be prescribed and also paid for in each region. The rule is now clear in the sense that the regions shall not be entitled to establish local measures restricting the prescription, dispatching or financing of medicines or devices which have been accepted for reimbursement at national level.

However, we anticipate that some issues shall still remain in this area, because the law allows regional authorities to put in place systems that doctors shall have to follow when writing prescriptions, and how these systems are designed has indeed an impact on prescription patterns.

New rules on selective financing and pricing

The times when virtually any product which received a marketing authorization in Spain was selected for reimbursement are likely to be over, and companies must be ready to face more strict criteria regarding reimbursement decisions.

In this area, in addition to classical criteria such as the social and therapeutic value of the drug, the government is ready to give first priority to cost-efficiency analysis and to the impact of each product in the public budget. This shall apply both to pharmacy products and to hospital use products.

As regards the process for price fixing, an important novelty is that all products, before launch, must be offered to the National Health System so that the Ministry of Health may decide whether they shall be financed or not and at what price. If the product is not financed, then the company shall still be obliged to notify its selling price, and the government may oppose to it on grounds of public interest.

Innovation shall still be an asset, and an interesting, and maybe controversial provision of Royal Decree-law 16/2012 is the one which states that Spanish authorities shall take into account innovation efforts and also the contribution that a product may make to the sustainability of the Spanish National Health System, which is said to be measured considering the positive contribution of such product to Spanish GDP. It shall be necessary to wait and see how this is put into practice.

Last, but not least, the government seems determined to increase price competition and it seems clearly open to new systems and mechanisms to fix prices. In this respect, it is important to see that Royal Decree-law 16/2012 expressly mentions that return mechanisms such as discounts or price reviews shall be taken into account for innovative products. Risk sharing agreements and other forms of collaboration may well fit into this concept.

New measures on how to write prescriptions, homogeneous groups

Under Royal Decree-law 16/2012, doctors may prescribe using the trademark instead of the INN for follow-on prescriptions in chronic treatments provided that the price of the branded product is not higher than the lowest within the homogeneous group where the product is included, or provided that the product is subject to reference pricing. In all other cases, prescriptions must be written using

the INN, and pharmacists must dispatch the product which has the lowest price. If a branded product and a generic share the same lowest price, the pharmacist must dispatch the generic. This is one of the areas of the law which is raising more controversy now that it has become operational.

The system works around the concept of "Homogeneous Groups". Each of these comprises products having the same characteristics and which are basically interchangeable when dispatched. These are no "jumbo" groups where therapeutic equivalence may be assessed. The rule, as it stands now, is that the Ministry of Health shall each month publish the list of the groups with the actual prices for each product, as these may be notified by companies. The practice has been, and it seems it shall continue being so, to allow companies whose product is priced above the lowest in the group to have a period of 2-3 days to reduce their price and thus match the lowest price in the group. Once the lists are closed, only products having the lowest price may be dispatched.

The system has become operative, and has already received a lot of criticism because of its various side effects. Among others, risks of shortages have been identified in groups where companies offering the lowest price have limited capacity to serve all the needs of the market. On the other hand, the fact that these reviews shall take place monthly creates a lot of uncertainty and makes it very difficult to plan any production activity.

We will therefore not be surprised if we see changes in this system in the near future.

Reference pricing still exists

The Homogeneous Groups system mentioned above relies on the idea that products included in each group are substitutable when dispatched. The price of other products such as biological ones facing competition from biosimilars, could therefore not be tackled through this system. The same could happen with products that have no generic competition. In this situation, the rule now is that any product for which a generic or a biosimilar exists, even if it is not substitutable, and also products which have no generic competition and have been in the market for more than 10 years may be subject to reference pricing, which basically means that their price shall be lowered to the level of the lowest comparable product. These reference prices shall be revised annually.

Selected price and 2 year tenders

On the other hand, the Homogeneous Group mechanism may well evolve into what Royal Decree-law 16/2012 calls a selected price system. Under this, the Ministry of Health may organize a sort of tender for some products. The tender process is somewhat curious, and companies shall have to be vigilant on how it is run in practice. It shall start by means of a motivated ruling by the Ministry of Health fixing a maximum price for the affected products, all of which shall belong to the same class. Here one may expect "jumbo" groups including products which have a major budget impact or maybe even more reduced groups where the government intends to increase price competition.

After having fixed this price, the law says that it shall be notified to the companies so that they may "express their intentions". The language used by the law is not very clear, and whether

the process shall be a truly competitive on remains to be seen, because the law is silent on what the authorities will do when they know about these intentions. The process should then finalize with some products selected for reimbursement and others which would be delisted, and this ruling shall be valid for two years.

Prices for delisted products may be controlled

Royal Decree-law 16/2012 contemplates that the Ministry of Health shall be entitled to control the price of medicines which are not reimbursed. This aims, apparently, to secure that once the government decides to delist products for minor syndromes whose retail price is rather low (in many cases under 3 Eur), companies shall not raise their prices sharply in an attempt to compensate the situation as regards reimbursed products. On 27 June the government announced that 426 products shall be excluded from reimbursement and that it expects savings for this delisting to be in the region of 450 Mio Eur.

The law is not explicit on how the government may exercise the power to control the price of delisted products, it simply states that it may oppose to price increases by reasons of public interest.

Hospitals may manipulate products

In recent years, some controversy has arisen in Spain as to whether and under what conditions hospital pharmacies could manipulate drugs in the interest of improving the efficiency in their usage and ultimately cutting costs.

Those who have fiercely opposed to this shall not encounter some additional hurdles, because Royal Decree-law 16/2012 states that, in order to be more efficient, the health authorities of the Autonomous Communities may approve that hospital pharmacies carry out activities involving fractioning, dosage personalization, and also "other operations of remanipulation and transformation of medicines". The approval process shall be monitored to secure that the general quality standards to be set up by the Ministry of Health are respected. Still, whether this is compatible with the rule that any manufacturing operation requires a manufacturing license, as set forth in EU Directives, remains to be seen.

Final comments

Royal Decree-law 16/2012 has impact on some other areas, and its implementation shall raise issues during the next months, so we shall probably keep referring to it. At present, it is fair to say that it represents a major change in the rules of the game in Spain, and that the legal scenario is likely to become complex, with a higher degree of administrative intervention.

On the other hand, times being hard as they are, one may expect increased concern by the government as regards financing some products, but this recently approved law still provides tools to foster innovation, which is also a matter of public interest. Finally, it is important to mention that the government has taken some measures aiming to reduce the impact that price cuts may have on parallel trade originating in Spain. Instruction 2/2012 from the Spanish Medicines Agency deals with this, and we shall comment on it in one of our next CAPSULAS.