NEW ROYAL DEGREE TO REDUCE PHARMACEUTICAL EXPENDITURE IN SPAIN

Last 3 September 2011, the decision of the Spanish Congress dated 23 August 2011 was published in the Official Gazette (BOE) ordering the publication of the Resolution approving the Royal Decree-Law 9/2011, of 19 August, on measures to improve the quality and cohesion of the National Health System, to contribute to fiscal consolidation and to increase the maximum amount of State guarantees for 2011 (hereinafter, the “RD”).

According to the Recitals of the RD, published on 20 August 2011, the legislation is required by the current economic situation, it being necessary for:

“public policies to based more than ever on scenarios of austerity and expenditure rationalisation, which make it possible to maintain an adequate level of public services without affecting the commitment to fairness and quality.”

Like the Royal Decrees published last year (RD 4/2010, of 26 May, on the rationalisation of pharmaceutical expenditure and RD 8/2010, of 20 May, on the adoption of extraordinary measures for the reduction of the public deficit), the RD’s general objective is to reduce State expenditure on pharmaceutical products by approximately 2400 million euros.

To this end, a series of measures has been taken, as set out below:

1) The Spanish Medicines and Health Products Agency (AEMPS) is given the power to decide whether a medicine must only be dispensed in hospitals under the control of the relevant staff, provided that the specific nature of the product allows this.

2) The AEMPS must review the offer of medicines within a year to ensure that the content of each package is in line with the duration of the different treatments and to avoid undesired surplus stock and expiry of medicines.

3) In the procedures for the setting of prices and including medicines within the social security system, new factors must be taken into account, such as the therapeutic and social value of the medicine or the incremental clinical benefit, while assessing the cost-effectiveness of the medicine in question. In addition, the effectiveness of these medicines must be compared with the other therapeutic alternatives which are available for the same medical conditions at a lower cost.
4) With respect to prescription on the basis of active ingredients, there are two new rules:

a) The doctor must prescribe on the basis of active ingredient using solely the international common denomination (ICD). This will apply to both medicines and health products;

b) The pharmacist must dispense the medicine or health product which is the cheapest one within a new concept called a “homogeneous grouping”, composed of those products which are considered to be equivalent for the purpose of substitution.

5) Nevertheless, in the event of therapeutic need, the doctor may prescribe by brand. In this case, the express authorisation of the doctor is required to carry out the substitution.

6) However, when the price of the medicine is the same, the pharmacist is not obliged to prescribe it.

7) With respect to setting prices, the legislation provides that groups of medicines may be created when 10 years has passed since the date on which the initial marketing of the medicine in question in Spain was authorised or 11 years with respect to a new therapeutic indication, without mentioning whether the marketing of a generic product is necessary, as the National Appeals Court (Audiencia Nacional) has held in two rulings.

8) Groups will be created when the circumstances established in the legislation are complied with (inclusion of a generic drug in the health products covered by the social security system) and not once a year, as has been the case until now.

However, there are two measures that particularly strike us as significant. The first is the special reduction of 15% for innovative medicines for which there is still no authorized generic or bio-similar product, but which have been in the market for more than 10 (or 11) years, provided that they do not have patent product protection in all of those EU Member States which, not being subject to exceptional or transitional industrial property regimes, have implemented into domestic law the corresponding Community legislation. The second measure is the penalties that the Government may apply if it considers that there is a scarcity of medicines in Spain.
due to parallel trading. In addition, pharmacies are prohibited from selling on a wholesale basis and cannot make deliveries outside of national territory.

It is clear that these last two measures - particularly the first one - will restrict the investment that the innovation-dependent pharmaceutical industry requires to ensure continued research into new therapies and medicines which are beneficial for our health.

Madrid, 5 September 2011.