

May, 2012

**ROYAL DECREE-LAW 16/2012, OF APRIL 20, 2012, ON URGENT MEASURES TO GUARANTEE THE SUSTAINABILITY OF THE NATIONAL HEALTH SYSTEM AND IMPROVE THE QUALITY AND SAFETY OF ITS SERVICES**

## **1. INTRODUCTION**

According to the preamble of Royal Decree-Law 16/2012, the Spanish national health system, regarded as one of the greatest achievements of the Spanish welfare state, is encountering serious economic difficulties, due mainly to less efficient management of its existing resources. There is also a considerable lack of coordination between autonomous community health services, resulting in differences in the level of services available to patients. On top of this, the system is facing new challenges that will have an adverse impact on public expenditure, such as an aging population, the need to include innovative therapy in clinical treatments or the development of new medicines.

The aim of Royal Decree-Law 16/2012 is to increase the sustainability of the system, improve efficiency in its management, encourage savings and economies of scale, introduce new tools through new technologies, bring about greater cohesion among regions, coordinate health and social services and, above all, ensure equal treatment throughout Spain with a basic portfolio of common services. Against this background, the government considered that the required conditions of extraordinary and urgent need set forth in article 86 of the Spanish Constitution had been fulfilled, permitting it to approve these measures by means of a Royal Decree-Law.

In this Newsletter we will take a look at the new elements introduced by Chapter IV of Royal Decree-Law 16/2012 amending Law 29/2006, of July 26, 2006, on the safeguards for and the rational use of medicinal products and medical devices ("Medicinal Product Law"). We will also summarize other key new legislation in Royal Decree-Law 16/2012:

- 1.1 Chapter I amends Law 16/2003, of May 28, 2003, on cohesion and quality in the national health system and contains provisions on the status of insured persons, the recognition and supervision of this status, and medical assistance in special cases, such as those involving foreigners who are not registered or authorized as residents in Spain.
- 1.2 Chapter II also amends Law 16/2003, of May 28, 2003, on cohesion and quality in the national health system, by setting up categories in the portfolio of services. To that end, it creates: (i) a basic common portfolio of welfare services funded completely out

of the public purse; (ii) a supplementary common portfolio funded partly out of users' contributions; and (iii) a shared portfolio of ancillary services funded out of users' contributions or subject to reimbursement for users. Furthermore, the autonomous communities may approve their own portfolios of services which must include, at least, the three central government portfolios described.

- 1.3 In order to achieve the objectives in Chapter II and, primarily, to give all Spanish nationals equal access to health care, the Welfare Guarantee Fund has been set up, which takes the form of a specific compensation item to guarantee welfare services across the national health system. This fund will cover the activities of health services in cases where individuals with the status of insured persons in the national health system travel between autonomous communities.

## **2. KEY NEW CHANGES INTRODUCED BY CHAPTER IV**

As mentioned above, Chapter IV makes a series of changes to the Medicinal Product Law.

### **2.1 Amendment of article 85. *Prescription of medicinal products and medical devices***

Prescriptions will be issued in the most appropriate way to benefit patients whilst protecting the sustainability of the system and, to that end, a brand new classification system has been set up for acute and chronic conditions (in the latter category, a distinction is drawn between the first prescription and continuing treatment). In acute conditions and the first prescription for chronic conditions, prescriptions will, generally, be issued by active ingredient.

New provisions allow brand names to be prescribed, subject to the principle of greater efficiency for the system or where the medicinal products concerned are regarded as being non-substitutable. The general rule, however, will be to prescribe by active ingredient whereby the least expensive medicinal product within its homogeneous group will be supplied and, if the prices are the same, the appropriate generic or biosimilar medicinal product will be supplied, which is another of the key new features of the reform.

### **2.2 Addition of article 85 bis. *Information systems to support prescriptions***

The new legislation defines a joint interoperable electronic prescription system which will incorporate sub-systems to support prescriptions (including nomenclatures, treatment protocols by medical condition, costs of treatment and alternatives on the basis of efficiency parameters, or useful alerts and updates on medicinal products). These systems will gather information on the prices selected under the reduced contribution mechanism, so that at all times doctors have access to the means to assess the economic impact of prescribing medicinal products and medical devices. The competent autonomous community authorities must provide their prescribers with the same system and coordinate with the Ministry of Health to put in place basic care protocols with guidance on prescriptions and use of medicinal products.

### **2.3 Addition of article 85 ter. *Medicinal products and medical devices excluded from pharmaceutical services***

The Ministry of Health, Social Services and Equality will draw up a list of medicinal products that will be excluded from the pharmaceutical services in the national health system. The reasons for their exclusion must be based on a limited number of defined parameters (including the existence of another over-the-counter medicinal product with the same active ingredient and dosage, or because the product in question is for the treatment of minor symptoms). A procedure has been introduced requiring those responsible for the products to notify the competent authority of the prices at which the medicinal products included on the above list are to be sold. The competent authority must reply to that notification within a month of receiving it, stating whether or not it agrees to the proposed prices. If it does not agree, the authority must bring the matter before the Inter-Ministerial Committee on Medicinal Product Prices, which must decide on the case.

Until the disagreement has been resolved, the product will be sold at the maximum manufacturer price.

### **2.4 Addition of article 86, subarticle 5. *Substitution by the pharmacist***

In line with the new wording of article 85, this new subarticle provides that if the price of a medicinal product prescribed by brand name is higher than the lowest priced product in its homogeneous group, the pharmacist must substitute the prescribed product with the lower priced product and, if the prices are the same, must supply the appropriate generic or biosimilar medicinal product.

### **2.5 Amendment of article 89, subarticles 1 and 2. *Procedure for public financing***

A new provision, in Royal Decree-Law 9/2011, aimed to safeguard the rational use of medicinal products and medical devices, allowed the Ministry of Health, Social Services and Equality, on its own initiative or on the motion of the autonomous communities, to place individual restrictions on specific conditions for the prescription, supply and funding of those products and devices in the national health system.

Royal Decree-Law 16/2012 has made two amendments: (i) it does not allow the autonomous communities to unilaterally establish specific individual restrictions on the prescription, supply and funding of medicines or medical devices; and (ii) it creates a Permanent Pharmacy Committee to decide on reasoned pleas submitted by one or more autonomous communities based on their own special characteristics.

Subarticle 2 introduces the option to review categories and/or classes of medicinal product for which funding is not considered necessary to cover the basic healthcare needs of Spanish citizens.

No funding will be provided for over-the-counter medicinal products, those that are not used to treat a clearly defined condition, those used to treat minor illnesses and/or symptoms, or those that were previously authorized under the legislation in force at the time but no longer meet current treatment needs.

## **2.6 Addition of article 89 bis. *Essential criteria for inclusion in pharmaceutical services***

It will be for the government to draw up the parameters and procedures for setting prices, based not only on the appropriate cost effectiveness and budget impact studies, but also, among other parameters, on the innovative component, contribution to the sustainability of the national health system if, for the same result in health terms, there is a positive contribution to Spain's GDP, and the return mechanisms (linear discounts, price reviews) for innovative medicinal products.

## **2.7 Amendment of article 90. *Pricing***

The new wording of this article makes a number of clarifications to the previous pricing system as well as some new changes which are outlined below.

The offer of the medicinal product or medical device to the national health system must first go through the appropriate procedure before it can be marketed.

The government can determine the mechanism for pricing over-the-counter medicinal products and medical devices supplied in Spain subject to general objective and transparent rules.

Notification of the price to the Ministry will be sufficient for marketing authorization holders to be able to sell their products under the notified pricing system. The Ministry may object to the price for reasons concerning public interest.

It is expressly provided that, as a general rule, the price funded by the national health system will be lower than the manufacturer price for the medicinal product when supplied outside the national health system.

The Inter-Ministerial Committee on Medicinal Product Prices must base its decisions on the reports prepared by the new Advisory Committee on Pharmaceutical Services in the National Health System, regulated in the new article 90 bis.

## **2.8 Addition of article 90 bis. *Advisory Committee on Pharmaceutical Services in the National Health System***

This is a collective body attached to the ministerial unit with powers over pharmaceutical services, which is authorized to provide advice, evaluations and information on the appropriateness, improvement and supervision of the economic evaluation necessary to underpin the decisions of the Inter-Ministerial Committee on Medicinal Product Prices.

It will have up to 7 members, selected from among reputable professionals with established experience and careers in pharmaco-economic evaluations.

### **2.9 Addition of article 91, subarticle 6. Price review**

For the purposes of downward price reviews on request, account will only be taken of reviews entailing a reduction of at least 10% on the maximum manufacturer price in force, where the price is authorized to be publicly funded.

### **2.10 Amendment of article 93. Reference price system**

Another change made by Royal Decree-Law 16/2012 concerns the amendment to the requirement to establish groups of non-generic medicinal products. Before Royal Decree-Law 16/2012 entered into force, ten years had to have elapsed from the date on which the reference medicinal product was initially authorized in Spain or eleven years if a new remedy had been authorized. Following Royal Decree-Law 16/2012, it will be sufficient for the medicinal product or its main active ingredient to have been on sale for at least ten years in any Member State of the European Union.

Furthermore, Royal Decree-Law 16/2012 amends article 93 of the Medicinal Product Law, which previously allowed for groups and their reference prices to be determined and/or reviewed several times a year. Now, however, only one determination and/or annual review of groups and their reference prices may be carried out. In any event, the new legislation clarifies that lower prices will be reviewed quarterly.

### **2.11 Addition of article 93 bis. System of selected prices for products eligible for funding**

One of the most significant new changes made to the Medicinal Product Law by Royal Decree-Law 16/2012 is the creation of the "*selected price mechanism*," under which the Ministry of Health, Social Services and Equality, following approval from the Inter-Ministerial Committee on Medicinal Product Prices, can propose the price ceiling on funding for medicinal products eligible for funding, and these prices will be notified to suppliers so that they can state their intentions.

This mechanism entitles the Ministry of Health, Social Services and Equality to pre-determine the price ceiling for funding. The price that is ultimately decided on will be valid for two years and any medicinal products that go above that price will be excluded from public funding in the national health system.

In cases deemed to be of interest to health under the General Health Law, Royal Decree-Law 16/2012 allows this selected price mechanism to apply to medicinal products that are not funded.

## 2.12 Addition of article 94 bis. *Contributions by beneficiaries to outpatient pharmaceutical services*

One of the most controversial changes in the area of pharmaceutical services concerns the establishment of a co-payment system for outpatient pharmaceutical services.

Although it is true that the wording of article 94 of the Medicinal Product Law prior to Royal Decree-Law 16/2012 already entitled the government to regulate the circumstances under which patients would contribute to paying for medicinal products funded by the national health system, it is the new article 94 bis of the Medicinal Product Law which defines the co-payment of medicinal products funded by the national health system and purchased from pharmacies (known as "*outpatient pharmaceutical services*"). Under this article, users must contribute towards pharmaceutical services provided through pharmacies, when the medicinal product is supplied.

The size of the contribution will be determined by reference to the income recorded in the general net taxable income and savings box on the personal income tax return of insured persons, that is, of: (i) workers registered for social security purposes or with like status; (ii) pensioners in the social security system; (iii) recipients of any other periodic social security benefit; (iv) persons whose entitlement to unemployment benefit has ended and who are registered jobseekers; and (v) nationals of Spain or other EU member states, or foreigners with residence permits, provided that they do not go above certain income thresholds laid down in the legislation.

Some people, however, will be classed as "beneficiaries of the insured person" which means beneficiaries of public funding by the national health service (and, where appropriate, they must contribute part of the price of medicinal products financed by the national health service), in the following cases: (i) the spouse or spousal equivalent of the insured person; (ii) the former spouse for whom the insured person is responsible; and (iii) the descendants of the insured person for whom he/she is responsible, who are under the age of 26 or who suffer from a disability equal to or exceeding 65%.

Article 94 bis of the Medicinal Product Law provides, in this respect, that:

- (a) users and their beneficiaries whose income is equal to or greater than €100,000 must contribute 60% of the recommended retail price of medicinal products;
- (b) active insured persons and their beneficiaries whose income is equal to or greater than €8,000 must contribute 50% of the recommended retail price of medicinal products;
- (c) active insured persons and their beneficiaries not falling within the above cases must contribute 40% of the recommended retail price of medicinal products; and

- (d) pensioners in the social security system, except for those in case (a) above, must contribute 10% of the recommended retail price of medicinal products.

In order to guarantee continuity in the treatment of chronic illnesses and a high level of fairness among pensioner patients undergoing lengthy treatments, Royal Decree-Law 16/2012 places the following ceilings on users' contributions:

- (a) 10% for medicinal products belonging to the reduced contribution ATC groups;
- (b) €8/month for insured persons who are pensioners in the social security system and their beneficiaries whose income is less than €18,000;
- (c) €18/month for insured persons who are pensioners in the social security system and their beneficiaries whose income is equal to or greater than €18,000 and less than €100,000; and
- (d) €60/month for insured persons who are pensioners in the social security system and their beneficiaries whose income is greater than €100,000;

If the users' contributions exceed those thresholds, Royal Decree-Law 16/2012 allows them to be reimbursed. The reimbursement procedure involves an upfront payment by the user and subsequent reimbursement within 6 months by the "appropriate autonomous community," a period which some believe to be excessive.

However, the co-payment system exempts the following persons from the requirement to contribute to the national health system: (i) those suffering from a toxic illness or disability; (ii) recipients of social integration income; (iii) recipients of non-contributory pensions; (iv) unemployed persons who have lost their entitlement to receive unemployment benefit; or (v) those undergoing treatment arising from occupational accidents.

### **2.13 Addition of articles 94 ter and 97 bis. *Information***

The implementation of the healthcare co-payment system described above together with the increased government involvement in the area of pharmaceutical services requires the establishment of a network of systems which will have to provide information (data on the income of users, official national health service prescription revenues, etc.) to the various public authorities concerned, including the Ministry of Health, Social Services and Equality.

#### 2.14 Addition of article 97 ter. *Increased competition and competitiveness*

Lastly, it is important to note that article 97 ter of Royal Decree-Law 16/2012 suggests that further reforms will be carried out in the short term in the area of pharmaceutical services, by mentioning that to achieve the aims of efficiency and sustainability of the national health service, the appropriate administrative and regulatory measures will be implemented to encourage competition among pharmaceuticals manufacturers and prices will come down as a result.

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