MADRID
Castellana, 216
28046 Madrid
Tel.: (34) 91 582 91 00

BARCELONA
Diagonal, 640 bis
08017 Barcelona
Tel.: (34) 93 415 74 00

BILBAO
Alameda Recalde, 36
48009 Bilbao
Tel.: (34) 94 415 70 15

MALAGA
Marqués de Larios, 3
29015 Málaga
Tel.: (34) 952 12 00 51

VALENCIA
Gran Vía Marqués
del Turia, 49
46005 Valencia
Tel.: (34) 96 351 38 35

VIGO
Colón, 36
36201 Vigo
Tel.: (34) 986 44 33 80

BRUSSELS
Avenue Louise, 267
1050 Bruselas
Tel.: (322) 231 12 20

LONDON
Five Kings House
1 Queen Street Place
EC 4R 1QS Londres
Tel.: +44 (0) 20 7329 5407

LISBON
Avenida da Liberdade, 131
1250-140 Lisboa
Tel.: (351) 213 408 600

URGENT MEASURES TO ENSURE THE SUSTAINABILITY OF THE NATIONAL HEALTH CARE SYSTEM AND IMPROVE THE QUALITY OF ITS SERVICES (Royal Decree Law 16/2012)

Blanca Lozano
Administrative Law Department, Gómez Acebo & Pombo, Madrid

Royal Decree Law 16/2012, dated 20th April, published in the Official State Gazette on the 24th of April (hereinafter, Royal Decree Law), constitutes a bona fide *Omnibus Act* which encompasses healthcare services, pharmaceutical benefits and human resources within the National Healthcare System (Servicio Nacional de Salud, hereinafter " NHS"). The recourse to regulate by means of a Royal Decree Law is warranted by the urgent need to adopt measures which would reduce the public healthcare deficit; with these measures the Government aims to save an estimated 7 billion Euros.

The Royal Decree Law introduces a vast assortment of measures and introduces modifications in several legal regulations, emphasizing those reforms carried out in Act 16/2003, for the cohesion and quality of the National Healthcare System, Act 29/2006, on guarantees and the rational use of prescription drugs, and Act 44/2003, for the classification of healthcare professions. Following is a summary of the novelties introduced by the Royal Decree Law which are most likely to affect the pharmaceutical sector.

Prescription drug co-payment by income brackets.

Undoubtedly, one of the main innovations in the Royal Decree Law, and one of the most controversial is the implementation of a new system for the co-payment of prescription drugs set up proportionally by income brackets. This co-payement sall be applied to outpatient mobility devices (for example, wheelchairs, walkers, canes and crutches), splints, non-emergency patient transport and food supplements.

The percentage to be contributed by each user is based on the following guidelines:

a) 60% of the retail price for users and their beneficiaries whose income, based on income tax returns, is equal to or surpasses 100,000 Euros.

b) 50% of the retail price for users whose income, as declared on income tax returns, is at least 18,000 Euros but less than 100,000 Euros.

c) 40% of the retail price for those users that do not fall under sections a) or b) above (those who are not obligated to file income tax returns).

d) 10% of the retail price for those users pensioned under the Social Security program, with the exception of those users who are included in point a) above.

e) 30% of the retail price for current and retired members of the Mutual Society for State Civil Servants (MUFACE), the Society of Armed Forces and the General Law Society.

The Royal Decree Law sets monthly contribution limits for pensioners – which can be, depending of their income, 8, 18 or 60 Euros-, in order to avoid excessive medical costs for

those with chronic diseases or those requiring long-term medical care. Pensioners are required provide the full co-payment upfront and shall be reimbursed, twice a year, by the autonomous communities for any amount paid in excess..

Persons belonging to certain groups or who are receiving medical care for determined medical conditions (such as recipients of non-contributory pension plans, social welfare payments or those receiving treatment resulting from occupational accidents and occupational diseases) shall be exempt from any contribution.

The Royal Decree regulates the information to be provided regarding the cost of treatments. The patient will be informed on the cost of treatment, with specific reference made to the percentage covered by the NHS and, where appropriate, shall also be informed if there are less expensive therapeutic treatment options prior to the issuance of the official prescription.

Measures that directly affect the pharmaceutical benefit

- Possibility of brand name prescription.

  In this point, the Royal Decree, in deference to the laboratories, amends the provisions of Royal Decree Law 9/2011, which have not yet taken effect. As a general rule, under the NHS, drug prescriptions included in the reference pricing system or homogeneous groups not included in the same shall have the following scheme:

  a) For acute conditions, the prescription shall generally be issued by active ingredient.

  b) For chronic conditions, the first prescription, when treatment initially begins, will generally be prescribed by active ingredient.

  c) Chronic conditions whose prescription corresponds to the continuity of the treatment, may be prescribed by brand name, provided it is included in the reference pricing system that is the lowest price within the homogeneous group.

  But above all, it establishes, in general, "that prescriptions of brand name drugs shall be possible as long as the efficiency principle is safeguarded for the system and in the case of drugs considered non-replaceable."

  The advantages that could be obtained by laboratories due to this possibility of prescribing by brand may be, however, undermined, first by the expansion of the alleged exclusion of pharmaceutical services in the NHS, which is explained henceforth, and, furthermore, by the provision that states "when a brand name drug is prescribed, if it is priced higher than the lowest-priced medication in its homogeneous group the pharmacist shall replace the medicine prescribed for the lowest-priced drug, and, when they are priced the same, the generic or corresponding similar medicine shall be dispensed."

- Expansion of the alleged exclusion of pharmaceutical services in the NHS for medicines and medical devices. The Royal Decree adds a new provision to the law on guarantees and rational use of medicines and medical devices (85b.) whereby there are a greater number of cases which shall be excluded from receiving certain drugs as part of NHS benefits. This is one of the most controversial aspects, especially due to the possibility of excluding those drugs used in the "treatment of minor symptoms", which could ultimately affect those that are most widely used. The list of these drugs will not be known until it is approved, in the coming months, by Resolution of the Ministry of Health.

The exclusion will respond to some of following criteria: a) the establishment of selected prices (all drugs priced higher shall be excluded, as previously discussed, from NHS funding), b) non-prescription drugs are excluded in all cases as well as those that share the same active ingredient and dose (this applies to certain drugs for minor symptoms and is a proposal backed by the employers' association of non-prescription products anepf), c) over the counter drugs (OTC) within the European union d) those whose active ingredient has been proven safe and effective as sufficiently documented through years of experience and extensive use, e) those indicated in the treatment of minor symptoms (the problem can arise when the same group of drugs is used both for mild symptoms as well as others of a serious or chronic nature, such as painkillers, therefore further clarification is needed); f) those whose exclusion was envisaged in the Law (those "whose funding is neither justified nor deemed necessary", and in all cases cosmetics, dietary products, mineral waters, elixirs, toothpaste and other similar products). Similarly, drugs "that are not used for the treatment of a clearly identified disease" and "drugs indicated for the treatment of less serious symptoms" shall be excluded in all cases.

Autonomous Communities are prohibited from, except where justified due to their own particular needs, establishing specific unique reserves of prescriptions, dispensation or financing of drugs or medical devices. This is intended to stop particular initiatives by certain autonomous communities (Galicia and Andalusia) in relation to the establishment of restrictions on NHS funded drug dispensing within their respective territories. The so-called "auction" of drugs by Andalusia was introduced by Decree Law 3/2011 in this region, and its first notification has been appealed by the government explicitly invoking Article 161.2 EC, which determines the automatic suspension.

Medicines and medical devices not included in the funding can only be acquired and used by hospitals in the Public Health System prior agreement with the committee responsible for the therapeutic protocols or the equivalent body in each autonomous community.

- Novelties in the pricing system of drugs and reference prices

  The public financing of drugs remains subject to the reference pricing system (maximum amount to be financed for drug benefits included in each of the groups to be determined), but now the revision of the lowest prices within each group shall be carried out on a quarterly basis, not yearly as before.

  The main novelty in the setting of prices for NHS funding of medicines and health products for necessary prescriptions is that "the price of financing by the NHS will be less than the price of the industry drug applied when dispensed outside the NHS ", i.e., laboratories may be required to offer a discount on the authorized industrial price.

When dispensed products are not funded by the NHS, the authorization holders may sell them pursuant to the notified pricing regime, meaning that the price must be notified to the Ministry of Health, so that it can challenge the same in defence of the public interest. The industrial prices of over the counter medications may no longer be free, as the Royal Decree provides that the government "may regulate the mechanism for setting the prices of medicines and health products that do not require a prescription which are provided in Spanish territory", although the applicable regime shall, in any case, be the notified pricing regime, as previously stated. When making decisions, the Inter-ministerial Commission shall consider the reports prepared by the Advisory Committee of

the Pharmaceutical Service of the National Health System. This is a newly created body, which replaces the Committee on Cost-Effectiveness of Medicines and Health Products and is considered a state governmental body because its seven renowned experts will all be appointed by the Minister of Health (until now they were appointed by the Inter-Territorial Council of the National Health System, at the behest of the Autonomous Communities, the Society of Civil Servants and the Ministry).

As was previously done, the financial amounts for distribution and dispensing of drugs and medical devices and, where appropriate, deductions applicable to the billing thereof to the NHS, will be set by the Government, generally speaking, or by groups or sectors. Finally, the Ministry of Health will set the retail price of drugs and commodities financed by adding the authorized industrial price, which shall be considered the maximum limit, and the margins associated with the activities of distribution and dispensing to the public.

- Selected price system for drugs subject to reference prices or for drugs and products that are considered relevant to public health, through which the Ministry of Health will establish a maximum price for certain drugs, such as therapeutic groups, excluding those which exceed the funding for the NHS.

  Selected prices will be determined by taking the following into account: a) consumption of the product: b) the budgetary impact: c) the existence of at least three drugs in the group, d) no risk of shortages. During the process of price selection the suppliers shall be convened so that they can state their intentions regarding the maximum price. Once the selected price has been approved, those medications and/or products that exceed the maximum funded price will be excluded from funding by the NHS during the time period in which the selected price is applicable, which shall be at least two years.

  Laboratories holding the marketing authorization for selected drugs or vendor companies of medical devices must ensure the adequate supply of the same by express declaration to that effect. In exchange, the price, which will be communicated to suppliers, shall be maintained for a minimum of two years.

- Centralized and joint purchasing of drugs by the Autonomous Communities: The Coordinating Council ("Consejo Interterritorial") of the NHS will encourage the joint purchase of the procurement of goods which, by their nature, lend themselves to this system.

- Adaptation of packaging to meet customary guidelines and timeframes: the Ministry of Health shall adopt any necessary legislation to this effect within six months after the entry into force of the Royal Decree Law

Entry into force and measures for its effective implementation

The Royal Decree Law came into force on the day of its publication in the Official Gazette, namely, on April 24, but must now be ratified by Congress within thirty days, which may decide to process it as a Law (which is advisable, given the significant impact of many of its measures and the hasty manner in which it has been adopted).

The competent public authorities are requested to adopt all necessary measures to effectively implement the provisions of the rule and, in particular, assure that, prior to 30 June 2012, they have taken all necessary measures to enforce the new co-payment system in outpatient pharmaceutical services.