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New regulation of the reference price system and of homogeneous groups in the National Health System

Royal Decree 177/2014, of 21 March 2014 also deals with information systems regarding the reimbursement and prices of medicinal products and medical devices

Introduction

After long months of negotiation this very important piece of regulation has finally been approved. The State Council, when reporting on the draft, already pointed out that this is undoubtedly a complex issue, and that therefore it would be convenient that the Preamble offered a simple and comprehensible explanation.

In this CAPSULAS Newsletter we try to explain the most relevant aspects of this regulation in terms that we hope you will find simple and easy-to-understand.

1. Reference prices

1.1. Creation of reference price groups

As to the creation of groups, the Royal Decree introduces the following novelties:

- Each group will be constituted by presentations with the same active ingredient and identical route of administration, and for which the start of their effective commercialisation has been notified.

  Products currently admitted for reimbursement but that have not yet been introduced on the market will be subject to the system as of the day on which their effective commercialisation is notified.

- Products whose marketing authorisation has been suspended or products that are no longer commercialised remain outside of the system as of the registration of such situation in the Nomenclator.

- In general, a group may also be created as of the moment on which a generic of biosimilar medicinal product starts to be commercialised in Spain.

- Groups may be created before the start of the commercialisation of a generic or a biosimilar in Spain when the medicinal product or its principal active ingredient has been authorised in Spain or in the European Union for 10 years, provided that a medicinal product different from the original medicinal product and its licences (co-marketing) exists in Spain.

  In the event that no group can be created because no such different medicinal product exists, a case-by-case price revision process will be initiated, ex officio, within one year.

- Independent groups will be created for paediatric presentations, clinical packagings, medicinal products for hospital use and medicinal products that are to be dispensed through hospital pharmacies.

- Presentations of medicinal products that obtained a declaration of galenic innovation before the date of entry into force of Royal Decree-law 16/2012 will be excluded from the system according to the regulation under which the galenic innovation was declared.

An interesting point is to what extent Law 29/2006 or the Royal Decree make it mandatory to apply the reference price system and to establish groups when all conditions to do so are met. In our opinion this is not an absolute obligation, since, for the moment, it has been decided not to create groups for medicinal products used in fluid

therapy or groups for radiopharmaceuticals, due to their particular characteristics.

1.2. Elimination of groups

Groups can be eliminated when the conditions for their creation are no longer met. Such elimination shall be done yearly and will not affect the ex-factory price of the presentations that were included in the group. Such presentations will keep their prices, until an individual price revision is made at the request of the company, if any.

1.3. Fixing of reference prices

The reference price of each group shall be the price of the presentation with the lowest daily treatment cost, which will be calculated by dividing the ex-factory price of each product by the number of defined daily doses (DDD) that it contains. It is our understanding that the ex-factory price that will be taken into account will be the price that appears in the Nomenclator and that discounts made under article 3.6 of Law 29/2006 will not be taken into account.

The reference price of a presentation will be the reference price of its group multiplied by the number of DDD it contains.

1.4. Special cases

The Royal Decree envisages two special cases:

- The reference price of a presentation cannot be lower than 1,60 Eur.

- The reference price can be calculated as a balanced price in the case of medicinal products with special doses of active pharmaceutical ingredient, medicinal products used for serious diseases or medicinal products the prices of which have been revised due to lack of profitability. Such balance will be made on the basis of the aggregated invoicing data of the National Health System of the last 12 months for all presentations included in each group. In the future, the system will apply to presentations of medicinal products for hospital use and to clinical packagings.

However, these special cases are subject to the condition that the price in Spain is never higher than the lowest price in any country of the European Union. To such effect, companies are obliged to inform the Ministry if their product is being sold in the EU at a price lower than the reference price applicable in Spain, and such lower price shall be fixed as the new ex-factory price.

In our view, the imposition of the lower EU price without taking into consideration the added costs that may be generated by the transport and marketing of a product in Spain is not compatible with applicable European Union legislation.

1.5. Coexistence periods

Pharmaceutical companies must abide by the reference prices from the date established in the corresponding annual Order (Day D of Month M).

Distributors may continue to supply their stock at the former higher price until day D+20 and pharmacies may continue to apply the higher retail price until the last day of month M+1.

Both wholesalers and pharmacies may return units of products whose labelling indicate the price applicable prior to the reductions.

Pharmacies will invoice the units dispensed at the former higher price to the National Health System until the last day of month M+1.

2. Homogeneous groups

2.1. The rules for dispensing

The system of homogeneous groups envisages that presentations that may be subject to substitute at the moment of dispensing at the pharmacy are integrated in groups for the purposes of the application of the rules for dispensing established in the Law. These rules are the following:

- If a prescription is made by commercial name, the branded product will be dispensed provided that its price is not higher than the minor price of the homogeneous group.

- If a prescription is made by active pharmaceutical ingredient, or, in the event that the price of the branded product is higher than the minor price of the group, the pharmacist must dispense the product with the lowest price of its homogeneous group. In case there are various products with the same price, a generic must be dispensed.

- In case of shortage of medicinal products or in case of urgent need, the presentations available must be dispensed starting in order of lowest price.

2.2. Creation of groups

The Directorate General of Pharmacy at the Ministry of Health will be responsible for managing the system.

Each group will include those publicly reimbursed presentations that have the same quantitative and qualitative composition of active ingredients, the same pharmaceutical form or group of pharmaceutical forms, the same route of administration, and provided that they may be substitutable at the moment of dispensing and that they are effectively being commercialised. This last rule enters into force on 1 June (Final Provision 3).

Homogeneous groups formed exclusively by one medicinal product and its licences that have the same ex-factory price will be differentiated.

2.3. Minor price and lowest price

The concept of minor price is reserved exclusively to homogeneous groups. Each time a group is created or updated, the price of the product included in the group with the lowest price will be the group's minor price. Minor prices will be updated quarterly, but lowest prices will be updated on a monthly basis.

Therefore, until minor prices are updated, different prices may coexist in each group.

The relevance of the minor price of each group is thus limited to those cases in which prescriptions are made by commercial name. In such cases, the pharmacist shall dispense the prescribed medicinal product provided that its price is not higher than the minor price, even if the price of the branded product is higher than the lowest price of the corresponding month.

2.4. Monthly adjustments of the minor price

Every month pharmaceutical companies may request voluntary price reductions without changes to the National Code.

Such requests for reductions will be published on the website as of day 5 of each month, and there will be a 3 days period in which other companies may request reductions of their prices to the same level. The final information will be published on the website of the Ministry during the first 10 working days of the month, and this information will be recorded in the Nomenclator as of the following month.

The Royal Decree establishes that "for the purposes of minor prices" only those requests that entail a 10% reduction of the previous ex-factory price will be taken into account. This wording makes it possible that voluntary price reductions are made for reductions lower than 10%, in which case such requests will be taken into consideration for the purposes of determining the lowest price but not in order to determine the minor price. This interpretation is the one that most closely adjusts to the criterion expressed by the Spanish Competition Commission.

In any case, we must not forget that the Royal Decree allows the Ministry to accept or not certain voluntary reductions, since it will only publish the ones that have been accepted.

2.5. Coexistence periods

Coexistence periods are shorter in the case of homogeneous groups. Pharmaceutical companies must supply at the new price as of day 10 of the month, and wholesalers shall invoice at the new price as of day 20. Pharmacies shall dispense at the new price as of day 1 of the following month.

3. Information systems

3.1. The Nomenclator

The Royal Decree consolidates the Nomenclator as the official data base of the Ministry regarding products admitted for reimbursement by the National Health System, but the Nomenclator will also include information on each and every medicinal product authorised in Spain, whether they are financed with public funds or not.

For each presentation the Nomenclator will include, among other information, the situation of the offer in the National Health System, the date of effective commercialisation, the maximum reimbursed price, the so-called "commercialisation price" and the notified price. We understand that the "commercialisation price" is the price notified to the Ministry and updated, if applicable, with the monthly price reductions in the homogeneous group system. The Nomenclator is updated every month.

A fundamental aspect as regards the Nomenclator is who will have access to it.

The Royal Decree envisages that the Nomenclator will be accessible to all public administrations with competences in the field of management of the reimbursement plan of the National Health System as well as to the General Board of Official Associations of Pharmacists. Such access is needed for the application of the reference price system and the system of homogeneous groups.

The access by companies shall be regulated by means of a Ministerial Order. The concerns expressed by the Competition Commission regarding the risk of market players having access to commercially sensitive information which could harm effective competition must be taken into consideration when issuing such Order.

3.2. Information during price fixing and financing decision procedures

The Royal Decree establishes that the procedures in matters of public financing and the fixing of prices of medicinal products and medical devices will be managed through a computerised system to which the members of the Inter-Ministerial Committee for Prices of Medicinal Products may have access by means of electronic procedures.

Strangely enough, the access to such computerised system by interested parties is pending to be implemented by means of a Ministerial Order. Such implementation does not necessarily have to take place, as the Royal Decree does not impose any obligation to do so.

3.3. Information on hospital consumption

The Royal Decree requires all public administrations with competences in the field of management of the reimbursement plan to send information to the Ministry regarding the number of units of medicinal products that have been used in the public network of hospitals of the National Health System. The products shall be identified by their National Codes, but it will not be necessary to notify the price at which they were purchased. The units of foreign medicinal products that have been used shall also be communicated.

The communication shall be made on a monthly basis and it is contemplated that all public administrations will have access to this information. However, the Royal Decree does not envisage the dissemination of this information to companies or other entities.