# Royal Decree 177/2014, of 21 March, regulating the reference price system and the system of homogeneous groups of medicinal products in the National Health System, and certain information systems on reimbursement and prices of medicinal products and medical devices

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## CHAPTER I

## General Provisions

**Article 1.** *Subject matter and scope.*

The subject matter of this Royal Decree is to regulate:

a) The reference price system of medicinal products, applicable to medicinal products admitted for reimbursement by the National Health System.

b) The system of homogeneous groups of medicinal products, applicable to medicinal products admitted for reimbursement by the National Health System that are dispensed in pharmacies by means of official prescriptions or dispensation orders.

c) Certain information systems on reimbursement and prices of medicinal products and medical devices in the National Health System.

## CHAPTER II

## Reference price system of medicinal products

**Article 2.** *On the reimbursement of presentations of medicinal products subjected to the reference price system.*

1. Public reimbursement of medicinal products is subjected to the reference price system.

2. The purpose of the reference price system is to fix the reference price or the maximum amount of public reimbursement of the presentations of medicinal products included in the reference groups established in accordance with what is set out in article 3, whenever their prescription and dispensation are reimbursed with public funds, through the fixing of a reference ex-factory price (PVLRef) for each presentation of a medicinal product, that shall be regarded as a top limit.

In order to determine the maximum amount of public reimbursement of the presentations of medicinal products, the reference ex-factory price, calculated in

accordance with article 4, shall be increased by the relevant margins for wholesale distribution and dispensation to the public, and the applicable taxes, as the case may be.

**Article 3.** *Reference groups of medicinal products.*

1. The reference group of medicinal products is the basic unit of the reference price system and it shall be constituted by two or more presentations of medicinal products. Each reference group of medicinal products shall contain all presentations of medicinal products admitted for reimbursement by the National Health System that have the same active pharmaceutical ingredient and identical administration route.

2. Each reference group shall contain, at least, one presentation of a generic or biosimilar medicinal product. Nevertheless, in case there is no presentation of a generic or biosimilar medicinal product, the group will also be formed provided that the medicinal product or its main active pharmaceutical ingredient have been authorized in Spain or in any other Member State of the European Union for at least ten years, and there also exists a medicinal product different from the original medicinal product and its licences.

3. Independent reference groups shall be formed in the following cases:

a) Presentations of medicinal products for hospital use, meaning those presentations that, in their regular packaging, are classified as medicinal products for hospital use and also those medicinal products that without having been classified as medicinal products for hospital use, are subject to specific restrictions within the National Health System that limit their dispensation to not hospitalized patients to the hospitals' pharmacies.

b) Presentations of medicinal products in clinical packaging.

c) Presentations of medicinal products intended for paediatric treatments.

4. In order to form reference groups, presentations will only be taken into account from the effective date of their admission for reimbursement by the National Health System, according to what is established in additional provision six. Medicinal products that are in a situation of suspension, revocation or termination of commercialization, according to what is established in articles 69 and 70 of Royal Decree 1245/2007, of 11 October, regulating the Procedure of Authorization, Registration and Dispensation Conditions of Medicinal Products for Human Use Industrially Manufactured, will not be taken into account from the date of registration of such circumstance in the official Nomenclator of products admitted for reimbursement by the National Health System, according to what is established in article 12.

5. The reference groups of medicinal products shall only be deleted when they no longer comply with the abovementioned grouping requirements. Presentations of medicinal products that belong to reference groups that are deleted, but that are still admitted for reimbursement by the National Health System, will keep having as their maximum ex-

factory price the reference ex-factory price (PVLRef) that they had on the moment of the group's deletion, until such price is revised, if applicable, in accordance with what is established in article 91 of Law 29/2006, of 26 July, on Guarantees and Rational Use of Medicinal Products and Medical Devices.

**Article 4.** *Fixing of the reference prices.*

1. The reference price of each reference group of medicinal products shall be calculated on the basis of the cost/treatment/day (CTD) of the presentations of medicinal products included in such group, which will make it possible to determine the lowest cost/treatment/day that will be the reference price for the group.

To such effect, the cost/treatment/day of each presentation of medicinal product will be the result of dividing the ex-factory price at which it is being commercialized (PVL com) by the number of the defined daily doses (DDD) it contains, according to the following formula:

$$CTD = PVL\ com / number\ of\ DDD\ of\ the\ presentation$$

The defined daily doses will be the ones officially assigned by the World Health Organization Collaborating Centre for Drug Statistics Methodology or, in their absence, the ones calculated, ex officio, by the competent authority for matters on public reimbursement and price fixing of medicinal products and medical devices of the Ministry of Health, Social Services and Equality, according to the methodology used by such Centre.

2. The reference ex-factory price for each of the presentations of medicinal products included in a reference group will be the result of multiplying the lowest cost/treatment/day of the presentations grouped in it, or the reference price of the group (PRC), by the number of DDD contained in each presentation, according to the following formula:

$$PVLRef = PRC \times number\ of\ DDD\ of\ the\ presentation$$

3. In case the reference ex-factory price of a presentation of a medicinal product, determined according to the general calculation rule set forth in subarticle 2, is lower than 1.60 EUR, such amount will be fixed as the reference ex-factory price for that presentation.

Nevertheless, when the ex-factory price at which a presentation of a medicinal product is commercialized is lower than the reference ex-factory price that is applicable according to this rule, the price used for the commercialization will be fixed as the reference ex-factory price.

4. As regards the presentations of medicinal products with special doses of active pharmaceutical ingredient, used for serious diseases the prices of which have been

revised due to lack of profitability by the Inter-Ministerial Committee for Prices of Medicinal Products in the two years immediately prior to day 1 of the month of April in which the corresponding order for the yearly update of the reference price system is started to be processed, and that due to the application of the general calculation for the reference price system set forth in subarticle 2 would have an ex-factory price that does not guarantee their economic viability, a balanced reference ex-factory price (PVLRP) will be fixed, on an exceptional basis. Such balanced reference ex-factory price will be calculated on the basis of the cost/treatment/day (CTD) and on the basis of the aggregated invoicing data of the National Health System for the last 12 months, available at the moment when the corresponding order for the yearly update of the reference price system is started to be processed, according to the following formula:

> PVLRP = [Σ (CTD × number of invoiced packs of each presentation) × number of DDD of the presentation] / number of total invoiced packs of the group

Notwithstanding, when the ex-factory price at which a presentation of a medicinal product is being commercialized is lower than the balanced reference ex-factory price of such presentation, the ex-factory price used for the commercialization of such presentation will be fixed as the balanced reference ex-factory price.

**Article 5.** *Application of the reference price system.*

1. Every year and upon prior agreement of the Government Committee on Economic Affairs, the incumbent of the Ministry of Health, Social Services and Equality, through the issuance of the corresponding order, shall update the reference price system establishing new reference groups and the reference prices for the presentations of medicinal products included in them, the revision of the reference price of the presentations of medicinal products included in the existing groups and, as the case may be, the deletion of groups when they stop complying with the requirements set forth in article 3. To such effect, the drafting procedure of said order that yearly updates the system shall be initiated every year in April and using the information of the official Nomenclator of the National Health System applicable on day 1 of the month of April in which the processing of the corresponding order starts.

2. The reference price system will apply to new presentations of medicinal products admitted for reimbursement by the National Health System if according to their characteristics they can be integrated in any of the reference groups of medicinal products established through the corresponding order by means of which the yearly update of the reference price system is made. To such effect, the resolutions issued by the incumbent of the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, admitting new presentations of medicinal products for reimbursement by the National Health System, shall comprise the express declaration of inclusion of such presentations in any of the existing reference groups of medicinal products if considering their characteristics they can be included therein.

3. The reference price system will also apply to the presentations of medicinal products admitted for reimbursement by the National Health System before the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made, but whose effective admission for reimbursement by the National Health System takes place after the start of the drafting procedure of the corresponding order. To such effect, the incumbent of the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, shall ex officio include such presentations of medicinal products in any of the existing groups if considering their characteristics they can be included, with the following periods for the applicability of the corresponding new reference prices:

a) If their effective admission for reimbursement by the National Health System, according to additional provision five, takes place before the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made, the periods for the applicability of the reference prices will be the ones set forth in such order.

b) If their effective admission for reimbursement by the National Health System, according to additional provision six, takes place after the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made, the reference prices will be applicable upon their effective admission for reimbursement.

**Article 6.** *Periods for the applicability of the new reference prices.*

1. Presentations of medicinal products that are commercialized at an ex-factory price that is higher than the reference price will be supplied, by the corresponding marketing authorization holder or, as the case may be, by the local representative in Spain that is responsible for the offer to the National Health System, at the reference ex-factory price from the date of entry into force of the corresponding order by means of which yearly update of the reference price system is made.

Presentations of medicinal products in stock, that are affected by the price reductions will continue to be commercialized by the distributors at the distributor's selling price applicable prior to such reduction for a period of twenty calendar days following the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made.

Presentations of medicinal products in stock that are affected by the price reductions will continue to be commercialized by the pharmacies at the retail price applicable prior to such reduction until the last day of the first month following the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made.

2. Distributors and pharmacies can, without any additional cost, return to the corresponding marketing authorization holder or, as the case may be, to the local representative in Spain that is responsible for the offer to the National Health System, the presentations of medicinal products in stock with the price on the packaging that is previous to the reductions set forth in the corresponding order by means of which the yearly update of the reference price system is made, from the day following the termination of the periods established in the previous subarticles.

3. As regards invoices of official prescriptions to the National Health System, including the special regimes of General Insurance for Civil Government Officials (MUFACE), the Social Institute of the Armed Forces (ISFAS) and the General Judicial Insurance (MUGEJU), the former prices at which the presentations of medicinal products are being commercialized will be maintained until the last day of the first month following the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made. Invoices to the National Health System, including to the aforementioned civil servant insurances, after the first day of the second month following the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made will be paid at the new prices. To such effect, the new reference prices will be included in the official Nomenclator of products admitted for reimbursement by the National Health System that is applicable from the first day of the second month following the date of entry into force of the corresponding order by means of which the yearly update of the reference price system is made.

4. In the light of the provisions of article 10 of Royal Decree-law 8/2010, of 20 May, adopting extraordinary measures to reduce public deficit, once the new reference prices have entered into force, the presentations of medicinal products included in the reference price system will be exempted, from that moment on, from the application of the deductions regulated in articles 8 and 9 of Royal Decree-law 8/2010, of 20 May.

## CHAPTER III

## System of homogeneous groups of medicinal products

**Article 7.** *System of homogeneous groups of medicinal products.*

1. The system of homogeneous groups of medicinal products allows for the application of the conditions for dispensation and substitution set forth in articles 85 and 86 of Law 29/2006, of 26 July.

2. The system of homogeneous groups of medicinal products requires the integration of presentations of medicinal products, admitted for reimbursement by the National Health System that are to be dispensed by pharmacies upon an official prescription or dispensation order, in a homogeneous group provided that they comply with the requirements set forth in article 8. Furthermore, it determines the minor price and lowest price for the presentations of medicinal products integrated in each homogeneous group.

3. The incumbent of the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, shall, ex officio, create the homogeneous groups of medicinal products and determine the presentations of medicinal products that shall be integrated in each of them when they comply with the conditions set forth in subarticles 1, 2 and 3 of article 8, and also fix and revise, ex officio, the minor price and lowest price of each homogeneous group in accordance with what has been established in subarticles 4, 5 and 6 of article 8.

4. The information about the homogeneous groups of medicinal products, their minor prices and their lowest prices will be updated with the variations produced up until and including day 20 of the month immediately preceding the month of application, and will be published monthly, at the latest on day 25 of the month immediately preceding the month of application, on the website of the Ministry of Health, Social Services and Equality. The official Nomenclator of products admitted for reimbursement by the National Health System of the corresponding month shall take note of such information, according to the rules on its updating established in article 12.

**Article 8.** *Homogeneous groups of medicinal products, fixing and revision of the minor prices and lowest prices.*

1. Each homogeneous group of medicinal products will include the publicly reimbursed presentations of medicinal products with the same active pharmaceutical ingredient(s) as regards the dose, contents, pharmaceutical form or group of pharmaceutical form and administration route, that can be subject to substitution at the moment of dispensation.

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

2. In order to be included in homogeneous groups, presentations of medicinal products will only be taken into account as of the date of their effective admission for reimbursement by the National Health System, according to what is established in additional provision six.

Presentations of medicinal products that are in a situation of suspension, revocation or termination of commercialization, according to what is established in articles 69 and 70 of Royal Decree 1245/2007, of 11 October, regulating the Procedure of Authorization, Registration and Dispensation Conditions of Medicinal Products for Human Use Industrially Manufactured, will not be taken into account from the date of registration of such circumstance in the official Nomenclator of products admitted for reimbursement by the National Health System, according to what is established in article 12.

3. The official Nomenclator of products admitted for reimbursement by the National Health System of the corresponding month shall take note of the creation of new

homogeneous groups of medicinal products, in observance of the rules on its updating established in article 12.

4. A minor price will be fixed for each homogeneous group of medicinal products, which will correspond to the price of the presentation of medicinal product with the lowest price on the moment of its creation, and will be automatically fixed in the official Nomenclator of products admitted for reimbursement by the National Health System of the corresponding month, in observance of the rules on its updating established in article 12.

5. The lowest price for each homogeneous group of medicinal products will correspond to the price of the presentation of medicinal product with the lowest price in the official Nomenclator of products admitted for reimbursement by the National Health System of the corresponding month, in observance of the rules on its updating established in article 12.

6. The minor prices for the homogeneous groups of medicinal products will be revised quarterly within the calendar year. The new revised minor price for each homogeneous group will correspond to the price for the presentation with the lowest price on the moment of each quarterly update, and will be automatically fixed in the official Nomenclator of products admitted for reimbursement by the National Health System corresponding to the months of January, April, July and October, in observance of the rules on its updating established in article 12.

**Article 9.** *Voluntary price reductions without changes to the national code of presentations of medicinal products included in homogeneous groups of medicinal products.*

1. The marketing authorization holder or, as the case may be, the local representative in Spain that is responsible for the offer to the National Health System of each of the presentations of medicinal products included in a homogeneous group, is entitled to file a request for a voluntary reduction of the ex-factory price, without changes to the national code, to the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality.

Requests for voluntary reductions of the ex-factory price, for the purposes of minor prices, will only be taken into account if they entail, at least, a 10% reduction of the maximum ex-factory price in force for reimbursement with public funds.

2. Information on approved requests for voluntary price reductions, filed between day 5 of the previous month up until and including day 4 of the corresponding month, will be published on the website of the Ministry of Health, Social Services and Equality after day 4 of each month. They will be automatically registered in the official Nomenclator of products admitted for reimbursement by the National Health System of the next month.

3. Once this information is published, there will be a period of 3 business days in order for the marketing authorization holders or, as the case may be, the local representatives in Spain that are responsible for the offer to the National Health System, to request a voluntary reduction of the ex-factory price for their presentations of medicinal products in order to meet the lowest price of the corresponding homogeneous group.

4. Within the first 10 business days of each month, the Ministry of Health, Social Services and Equality will publish the information on the approved voluntary price reductions without changes to the national code on its website. They will be automatically registered in the official Nomenclator of products admitted for reimbursement by the National Health System of the next month.

5. As of the monthly publication on the website of the Ministry of Health, Social Services and Equality of the information related to the accepted voluntary reductions of the prices referred to in subarticles 2 and 4 above, the marketing authorization holders or, as the case may be, the local representatives in Spain that are responsible for the offer to the National Health System, will supply the presentations of medicinal products for which the requests for a voluntary reduction of the ex-factory price have been accepted at the new prices. Distributors will distribute at the new commercialization price from day 20 of that month and pharmacies will dispense at the new price from day 1 of the following month.

6. The invoice price for each presentation of medicinal product to the National Health System, including the special regimes of General Insurance for Civil Government Officials (MUFACE), the Social Institute of the Armed Forces (ISFAS) and the General Judicial Insurance (MUGEJU), will be the commercialization price listed in the corresponding official Nomenclator of products admitted for reimbursement by the National Health System of each month.

## CHAPTER IV

## Information systems on matters of reimbursement and prices of medicinal products and medical devices

*Section 1.* *The official Nomenclator of products admitted for reimbursement by the National Health System*

**Article 10.** *Definition, nature and purpose.*

1. The official Nomenclator of products admitted for reimbursement by the National Health System is the Data Base of the Ministry of Health, Social Services and Equality on matters regarding products admitted for reimbursement by the National Health System.

2. As regards the public reimbursement of medicinal products and medical devices, and without prejudice to what is established in article 17.6 of Royal Decree 1718/2010, of 17 December, on Medical Prescriptions and Dispensation Orders, the information compiled in the official Nomenclator of products admitted for reimbursement by the National Health System, created by the Directorate General of the Basic Service of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, will prevail over any other private or public source of information.

3. The dispensation and invoicing of medical prescriptions and dispensation orders for medicinal products and medical devices registered in the official Nomenclator of products admitted for reimbursement by the National Health System will be carried out in accordance with the conditions and prices listed in the Nomenclator that corresponds to the month of invoicing, not being valid otherwise.

**Article 11.** *Information to be included in the official Nomenclator of products admitted for reimbursement by the National Health System.*

1. The official Nomenclator of products admitted for reimbursement by the National Health System will include:

a) All presentations of medicinal products that are authorized for their commercialization in Spain.

b) All medical devices admitted for reimbursement by the National Health System for patients that are not hospitalized, that are to be dispensed by pharmacies upon official medical prescriptions or dispensation orders.

2. For each presentation of medicinal product registered in the official Nomenclator of products admitted for reimbursement by the National Health System, the following information shall be included, if applicable:

a) The essential characteristics for its unambiguous identification.

b) The situation of its offer in the National Health System.

c) The date of effective commercialization, suspension of the commercialization and revocation of the authorization.

d) Its maximum reimbursement price, commercialization price and notified price.

e) The reference group to which it belongs and the reference price of the presentation.

f) The homogeneous group to which it belongs, the minor price and the lowest price of the homogeneous group.

g) The deductions that apply according to articles 8, 9 and 10 of Royal Decree-law 8/2010, of 20 May.

h) The marketing authorization holder or, as the case may be, the local representative in Spain that is responsible for the offer to the National Health System.

i) Particular restrictions to the conditions for the prescription and dispensation in the National Health System.

j) The reimbursed indications, in case that only some of its therapeutic indications are reimbursed.

k) Special conditions for the prescription and dispensation in the National Health System.

l) The corresponding type of contribution.

3. As regards each medical device registered in the official Nomenclator of products admitted for reimbursement by the National Health System, the following information will be included, when applicable:

a) The essential characteristics for its unambiguous identification.

b) Its reimbursement price and notified price.

c) The reference group to which it belongs and the reference price of the device.

d) The homogeneous group to which it belongs, the minor price and the lowest price of the homogeneous group.

e) The situation of its offer in the National Health System.

f) The company responsible for the offer to the National Health System.

g) Particular restrictions to the conditions for the prescription and dispensation in the National Health System.

h) Special conditions for the prescription or dispensation in the National Health System.

i) The corresponding type of contribution.

4. The incumbent of the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality shall be responsible for determining the specific structure and contents of the information to be compiled in the official Nomenclator of products admitted for reimbursement by the National Health System according to what is established in the

previous subarticles. Notwithstanding, the health administrations of the Spanish autonomous regions, within the framework of the Permanent Pharmacy Committee of the Inter-territorial Board of the National Health System, are entitled to suggest as many modifications to the structure and contents of such information as they deem appropriate for the better management of the reimbursement plan of the National Health System.

**Article 12.** *Updating of the Official Nomenclator of products admitted for reimbursement by the National Health System.*

The official Nomenclator of products admitted for reimbursement by the National Health System will be updated every month, and the Nomenclator corresponding to the calendar month must include the variations with respect to the previous one produced up until and including day 20 of the immediately preceding month, date on which the Nomenclator will be considered as closed, without prejudice to the provisions set forth in additional provision five.

**Article 13.** *Communication, availability and access to the official Nomenclator of products admitted for reimbursement by the National Health System.*

1. The official Nomenclator of products admitted for reimbursement by the National Health System will be available through electronic procedures, and will be accessible to all Public Administrations involved in the management of the reimbursement plan of the National Health System, and also to the General Board of Official Associations of Pharmacists.

2. The communication regarding the availability of the Nomenclator of the National Health System applicable as of day 1 of each calendar month, will be made, at the latest, on day 25 of the immediately preceding month or, as the case may be, the following business day, except in events of force majeure.

3. The incumbent of the Ministry of Health, Social Services and Equality may regulate by order the conditions and the access to this information by entities and other organizations, companies and physical persons.

*Section 2.* *Information system for the support of the management of the procedures for price fixing and reimbursement decision for medicinal products and medical devices*

**Article 14.** *Information system for the support of the management of the procedures for price fixing and reimbursement decision for medicinal products and medical devices.*

1. The Ministry of Health, Social Services and Equality will have an electronic system for the management of the procedures established in articles 89 to 92 of Law 29/2006, of 26 June, on matters of public reimbursement and price fixing for medicinal products

and medical devices, that the members of the Inter-Ministerial Committee for Prices of Medicinal Products will be able to access by means of electronic procedures.

2. The incumbent of the Ministry of Health, Social Services and Equality may regulate by order the accessing to such electronic system by the marketing authorization holder or, as the case may be, by the local representative in Spain that is responsible for the offer to the National Health System, or the company responsible for the offer to the National Health System, as regards the information related to the procedures that affect their respective medicinal products and medical devices.

*Section 3.* *Information system about the use of medicinal products in the public network of hospitals of the National Health System*

**Article 15.** *Information system about the use of medicinal products in the public network of hospitals of the National Health System.*

1. All public administrations with competences in the field of management of the reimbursement plan of the National Health System shall send information regarding the number of units or packages of medicinal products, identified by their national codes, that have been used in the public network of hospitals of the National Health System to the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality. This information shall be sent monthly, and shall refer to a period that does not exceed the three months immediately prior to the date on which the information is provided. Also, the units of foreign medicinal products that have been used shall be communicated, and such shall be identified by means of an unambiguous code that will be established by the Spanish Agency of Medicinal Products and Medical Devices. The technologic procedure will be established in the way determined by the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality.

2. For the purposes of the provision above, the Ministry of Health, Social Services and Equality will have an electronic system that will make it possible to know the evolution of the use of medicinal products in the public network of hospitals of the National Health System, and public administrations with competences in the field of management of the reimbursement plan may have access, through electronic procedures, to the information of the entire National Health System.

**Additional provision one.** *Mandatory nature of the communication to the Ministry of Health, Social Services and Equality about the commercialization of a medicinal product that is a licence of an innovator medicinal product.*

1. In order to properly identify medicinal products and their licences, according to the provisions of articles 3.2 and 8.1 of this Royal Decree, the marketing authorization holder or, as the case may be, the local representative in Spain that is responsible for the offer to the National Health System of presentations of medicinal products that are

licences shall communicate and prove this situation to the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, before the decision on their admission for reimbursement by the National Health System is made. As long as this communication is not made, the relevant presentation of medicinal product cannot be considered as a licence of another medicinal product for the corresponding effects that might arise in matters of reference prices and homogeneous groups.

2. As regards presentations of medicinal products that are licences, and that were admitted for reimbursement by the National Health System before the entry into force of this Royal Decree, there is an obligation to communicate and prove such situation to the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, within the period of one month counted from the date of entry into force of this Royal Decree. In case the communication is not made within the referred period, the relevant medicinal product cannot be considered as a licence of another medicinal product in the first order that updates the system of reference prices after the entry into force of this Royal Decree.

**Additional provision two.** *Regime applicable to the presentations of medicinal products whose reference prices have been determined according to the rules set forth in subarticles 3 and 4 of article 4 and that are commercialized at a lower price in another Member State of the European Union.*

1. The marketing authorization holder or, as the case may be, the local representative in Spain that is responsible for the offer to the National Health System of a presentation of a medicinal product the reference price of which has been determined under the rules set forth in subarticles 3 and 4 of article 4 and that is commercialized in other Member State of the European Union at a price lower than the reference price fixed in the corresponding order by means of which the yearly update of the reference price system is made, shall communicate such lower price used for its commercialization in another Member State of the European Union to the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality. This communication must be made within the period of one month counted from the date of entry into force of the yearly order that updates the reference price system or from the date on which the commercialization at a lower price starts, if this takes place after the date of entry into force of the corresponding order.

Failure to comply with the communication obligation set forth in the previous paragraph will be sanctioned according to the penalty system set forth in Law 29/2006, of 26 July.

2. When the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality becomes aware that a presentation of medicinal product is being commercialized in any Member State of the European Union at an ex-factory price lower than the reference ex-factory price fixed in accordance with subarticles 3 and 4 of article 4, it will submit the issue to the next meeting of the Inter-Ministerial Committee for Prices of Medicinal Products so

that this body agrees to revise its price in order to fix the lower price at which the presentation is being commercialized in other Member State as the new maximum ex-factory price for such presentation. Said Directorate General will issue a resolution establishing the reimbursement conditions for such presentation of medicinal product with the new maximum ex-factory price fixed by the Inter-Ministerial Committee for Prices of Medicinal Products. In case that the currency of such Member State is different from the Euro, the applicable exchange rate will be the one published by the Bank of Spain applicable on day 1 of the month in which the Inter-Ministerial Committee for Prices of Medicinal Products meets.

The new maximum ex-factory price for that presentation of medicinal product will be included in the official Nomenclator of products admitted for reimbursement by the National Health System, applicable on day 1 of the month following the date of the resolution issued by the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality.

**Additional provision three.** *Reference prices for galenic innovations of therapeutic interest declared prior to the date of entry into force of Royal Decree-law 16/2012, of 29 April, adopting urgent measures to guarantee the sustainability of the National Health System and improve the quality and security of its services.*

1. Presentations of medicinal products whose galenic innovation of therapeutic interest has been declared before the date of entry into force of Royal Decree-law 16/2012, of 20 April, will be excluded from the reference price system according to the regulation under which the galenic innovation was declared. The exclusion periods from the reference price system for each presentation of medicinal product will be published as a Schedule to the consecutive orders by means of which the yearly updates of the reference price system will be made.

2. Once the exclusion period has elapsed according to the previous subarticle, the presentations of medicinal products that have been declared as galenic innovations will be automatically included in the relevant groups and will be supplied by the marketing authorization holder or, as the case may be, by the local representative in Spain that is responsible for the offer to the National Health System, at the corresponding reference ex-factory price as of the day following the elapsing of the exclusion period. These variations will be included in the official Nomenclator of products admitted for reimbursement by the National Health System of the month following the elapsing of the exclusion period.

**Additional provision four.** *Electronic communications.*

All notifications and communications derived from the application of the reference price system and the system of homogeneous groups regulated in this Royal Decree that shall be sent by the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality to

marketing authorization holders or, as the case may be, to local representatives in Spain responsible for the offer to the National Health System of presentations of medicinal products, to distributors, to the General Board of Official Associations of Pharmacists and to the rest of persons concerned, and also the interactions of all of them with such Directorate General, will be made in accordance with article 27.6 of Law 11/2007, of 22 June, on the citizens' electronic access to Public Services, through the website of the Ministry of Health, Social Services and Equality (sede.msssi.gob.es).

**Additional provision five.** *Registration of the effective commercialization date in the official Nomenclator of products admitted for reimbursement by the National Health System of presentations of medicinal products already admitted for reimbursement.*

The registration of the effective commercialization date communicated according to the provisions of Royal Decree 1345/2007, of 11 October, in the official Nomenclator of products admitted for reimbursement by the National Health System of presentations of medicinal products that have already been admitted for reimbursement prior to the entry into force date of this Royal Decree, will be made on the basis of the information sourced from the Spanish Agency of Medicinal Products and Medical Devices, and will be updated in the official Nomenclator of products admitted for reimbursement by the National Health System Health System corresponding to day 1 of the third month following the entry into force of this Royal Decree.

**Additional provision six.** *Communication of the effective commercialization date of presentations of medicinal products for their effective admission for reimbursement by the National Health System.*

1. Once the corresponding resolution about the public reimbursement of medicinal products has been issued by the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality, the admission of presentations of medicinal products for reimbursement by the National Health System will take effect according to the following rules, considering the effective commercialization date communicated by the marketing authorization holder under the provisions of article 28 of Royal Decree 1345/2007, of 11 October:

a) If the effective commercialization date of a presentation of medicinal product is fixed between days 1 and 15 of each calendar month, the admission for reimbursement by the National Health System and the registration of such situation in the official Nomenclator of products admitted for reimbursement by the National Health System will be effective on day 1 of the following month.

b) If the effective commercialization date of a presentation of medicinal product is fixed between days 16 and 31 of each calendar month, the admission for reimbursement by the National Health System and the registration of such situation in the official Nomenclator of products admitted for reimbursement by the National Health System will be effective on day 1 of the second following month.

2. For presentations of medicinal products admitted for reimbursement by the National Health System on the moment of entry into force of this Royal Decree, whose marketing authorization holder has not yet communicated the effective commercialization date under the provisions of article 28 of Royal Decree 1345/2007, of 11 October, the registration of their effective commercialization date in the official Nomenclator of products admitted for reimbursement by the National Health System will take place upon its communication according to the rules mentioned in the subarticle above.

3. Presentations of medicinal products admitted for reimbursement will not be dispensed under or invoiced to the National Health System until the registration of the communication of the effective commercialization in the official Nomenclator of products admitted for reimbursement by the National Health System takes place.

**Additional provision seven.** *Case by case revision of the presentations of medicinal products affected by the provisions of article 3.2.*

When according to article 3.2 no reference group can be formed due to the lack of, at least, one medicinal product different from the original medicinal product and its licences, the Directorate General of the Basic Service Portfolio of the National Health System and Pharmacy of the Ministry of Health, Social Services and Equality will proceed to revise, within the period of one year, on a case by case basis in accordance with article 91 of Law 29/2006, of 26 July, the price of the presentations of medicinal products admitted for reimbursement by the National Health System that have the same active pharmaceutical principle and route of administration.

**Additional provision eight.** *Dispensation regime for medicinal products.*

When the medical prescription is made by active pharmaceutical ingredient, the pharmacist must dispense the one that has the lowest price of its homogeneous group. In case of supply shortage of medicinal products or in case of urgent need, the presentations available must be dispensed starting in order of lowest price. In case that, according to the previous rules, various presentations with the same price can be dispensed, the corresponding generic or biosimilar medicinal product shall be dispensed, if there is any among them. When the medical prescription is made by commercial name, the same rules will apply only when the price of the medicinal product prescribed is higher than the minor price of the homogeneous group.

**Additional provision nine.** *Guarantee of supply of minor price medicinal products to pharmacies.*

The marketing authorization holder shall keep the market sufficiently supplied, in a proper and continued manner in order to enable compliance with the legal requirements regarding the reimbursement plan of the National Health System and guarantee the supply of medicinal products included in the homogeneous groups with the lowest price

and minor price to pharmacies and hospital pharmacy services. Non-compliance will be sanctioned according to the penalty system set forth in Law 29/2006, of 26 July.

**Transitional provision one.** *Fixing of the reference price for the presentations of medicinal products for hospital use and in clinical packaging.*

1. Transitionally and until the aggregated information on the pharmaceutical expenditure of the hospitals of the National Health System is available, as regards presentations of medicinal products for hospital use and presentations of medicinal products in clinical packaging referred to in article 3.3, and that fulfil the requirements set forth in article 4.4, the incumbent of the Ministry of Health, Social Services and Equality will establish a reference price calculated on the basis of the duration of the packaging considering the dose regime set forth in the summary of product characteristics, according to the following formula:

> PVLRef = lowest CTD × number of days of duration of the packaging considering the dose regime set forth in its summary of product characteristics

2. As soon as the aggregated information on the pharmaceutical expenditure of the hospitals of the National Health System will be available, the Balanced Reference Price referred to in article 4.4 will apply.

**Transitional provision two.** *Application of the reference prices system to medicinal products used in fluid therapy and radio-pharmaceuticals.*

Transitionally and until the aggregated information on the pharmaceutical expenditure of the hospitals of the National Health System is available, no groups of medicinal products will be formed either for medicinal products used in fluid therapy or for radio-pharmaceuticals, due to their special characteristics and their use in hospitals.

**Final provision one.** *Competence title.*

This Royal Decree is issued under the provisions of article 149.1.16 of the Spanish Constitution that attributes the exclusive competence to legislate on matters of pharmaceutical products to the Central Government.

**Final provision two.** *Development faculties.*

The incumbent of the Ministry of Health, Social Services and Equality is hereby authorized to issue the necessary provisions for the development and enforcement of this Royal Decree.

**Final provision three.** *Entry into force.*

This Royal Decree shall enter into force on the day following its publication in the Official State Journal, except for the first paragraph of article 8.2 that will enter into force on the first day of the third month following its publication in the Official State Journal.

In Madrid, 21 of March of 2014.

JUAN CARLOS R.
The Minister of Health, Social Services and Equality
ANA MATO ADROVER

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