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The public audience and information period for the draft of Royal Decree on the funding and pricing of medical devices is open

Draft of Royal Decree regulating the public funding of medical devices for non-hospitalized patients and setting the commercialization margins

Introduction

The future Royal Decree comes to implement the provisions on these matters contained in the Consolidated Text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices and, therefore, it will regulate the procedure for the inclusion, review and exclusion of medical devices from the pharmaceutical provision of the National Health System (NHS) for non-hospitalized patients, when such medical devices are dispensed in Spain using an official prescription. Moreover, this new regulation includes the acquisition, supply and dispensation regime for these medical devices in the NHS, as well as their distribution and dispensation margins.

Once it comes into force, this new Royal Decree, will repeal Royal Decree 9/1996, of 15 January, regulating the selection of products and accessories, their public funding and their supply and dispensation regime for non-hospitalized patients.

The public audience and information period for this draft will end on 7 September. Until then, those having legitimate rights and interests affected by such draft are entitled to provide their opinion about it and to obtain information about the inputs made by other persons or companies.

Which medical devices can be publicly funded?

Medical devices for non-hospitalized patients which can be included in the pharmaceutical provision of the NHS must meet all the following requirements:

- Be serially manufactured, bear the CE Marking and comply with the regulation applicable to medical devices;

- Belong to one of the following categories: curing materials; medical devices for the collection of excretions and secretions; utensils aimed for the protection or reduction of internal injuries or malformations;

- Belong to one of the groups of medical devices having normal or reduced contribution, as contemplated in Annexes I and II of the new Royal Decree;

- Comply with the technical specifications and contrasted features set by the Ministry of Health, Consumer Affairs and Social Wellbeing based on general criteria which is objective and has been published, in particular: (i) the seriousness, duration and consequences for the pathologies for which such medical devices are intended; (ii) the specific needs of certain groups of people; (iii) the value of diagnosis, control, treatment, prevention, disability relief or compensation; (iv) the social value of the medical device and its incremental clinical benefit, taking into account its cost-effectiveness relationship; and (v) the existence of medical devices or other therapeutic alternatives for the same conditions, having a lower price or treatment cost; and

- Comply with the requirements and technical specifications set by the Ministry of Health, Consumer Affairs and Social Wellbeing, providing the corresponding certificates, if any, showing the compliance of the medical device with such technical specifications.

Prices and margins

The Ministry of Health, Consumer Affairs and Social Wellbeing will decide about the inclusion of medical devices for non-hospitalized patients in the pharmaceutical provision of the NHS by means of an express pronouncement. Such decision will include the funding conditions of the relevant medical device and its maximum ex-factory price in consideration for which companies would be entitled to sell such medical device when its dispensation is aimed to be paid with public funds.

The retail price of these products will result from adding the corresponding distribution and dispensation margins to the maximum ex-factory price. Such margins are also regulated in this draft, as follows:

- The distribution margin will be set based on the maximum ex-factory price. To such effect, if the maximum ex-factory price is set at or below 59 Eur, the distribution margin would be 6% of the wholesaler price without taxes. If the maximum ex-factory price is higher than 59 Eur, the distribution margin would be fixed at 3,77 Eur/pack.

- The dispensation margin which the pharmacies would have for these medical devices will also be set on the basis of the maximum ex-factory price. It would be 21% of the retail price if the maximum ex-factory price is set at or below 59 Eur. If the maximum ex-factory price is higher than that, the dispensation margin would be fixed at 16,69 Eur/pack.

On the other hand, if the company marketing medical devices which are funded by the NHS decides to commercialize such product at a price which is lower than the maximum ex-factory price set by the Ministry of Health, Consumer Affairs and Social Wellbeing, such company must communicate so to this Ministry. Also, in this case, the lower marketing price would become the new authorized maximum ex-factory price.

Funding inclusion and exclusion

According to this draft, the procedure for including a medical device in the pharmaceutical provision of the NHS and the procedure to set its maximum ex-factory price will be unified in a single procedure. Therefore, both matters will be subject of a single decision. This is what currently happens with medicinal products.

The funding procedure for medicinal products, which although can be initiated upon request of the interested party, is usually initiated ex officio. Contrary to this, according to the new Royal Decree, the funding procedure for medical devices can only be initiated upon request of the company who wishes to have its products included in the pharmaceutical provision of the NHS.

Along with such request, the company must provide documentation regarding the situation and price of the relevant product in other Member States of the EU in which it is being marketed. Also, if available, the company must provide information on the prices of other medical devices which have similar characteristics, and which are marketed by such company.

The procedure to exclude a medical device from the pharmaceutical provision of the NHS can, according to this draft, be initiated either ex officio or upon the request of the company. The exclusion procedure initiated by the company can only be triggered after the period of 1 year (at least) has elapsed, counted from the date on which the medical device was included in the Nomenclator, which official list of funded products. The exclusion can be approved if it does not result in a therapeutic gap and provided that it does not entail a cost increase in the pharmaceutical provision of the NHS.

Finally, this draft includes the criteria that the competent authority must consider when the exclusion procedure is initiated due to the existence of other alternatives having a lower price or the same or lower cost. The criteria to be considered by the authorities in this case are the following:

- The alternative medical device must at least have the same quality, safety and efficacy, and an equivalent effect.

- The comparison of the maximum ex-factory prices will be made only between medical devices which are comparable.

- The comparison of the cost of use will be made only between medical devices having an equivalent effect.

Special conditions

Another possibility allowed by this new regulation is that it implements the procedure for imposing special conditions to the prescription, dispensation and/or funding of medical devices within the NHS. Such special conditions will be included in the Nomenclator and can be any of the following measures:

- Requiring a prior approval for the prescription and dispensation conditions;

- Limiting the funding to certain indications of the medical device;

- Reviewing the ex-factory Price and/or the funding conditions;

- Sustainability agreements, such as agreements regarding the price-volume, maximum expenditure limits; maximum cost per patient and period; risk sharing and any other system which is similar or combines any of the previous possibilities; and

- Any other mean which is considered to be appropriate in order to assure the correct use of the medical device.

Homogeneous groups

The homogeneous groups are a system created by the NHS, according to which certain kind of products (in this case, medical devices) which are publicly funded and have the same characteristics are included in the same group. Products belonging to the same group can have different retail prices and the pharmacist dispensing the prescribed product must sell the product having the lower price of the group, instead of the prescribed one if the price of the latter is higher.

As regards the homogeneous groups system for medical devices which are funded by the NHS for non-hospitalized patients, there is a reference to the provisions of Royal Decree 177/2014 which regulates the homogeneous groups of medicinal products. Thus, the provisions applicable to medicinal product will also be deemed to be applicable to medical devices, but considering the particularities of the devices.

To such effect, the draft contemplates that each homogeneous group of medical devices will include the presentations of medical devices which are funded by the NHS and have the same characteristics, type, size and contents, for the purposes of their replacement by the pharmacist upon dispensation.

The draft also foresees that the voluntary request of the company to lower the prices of medical devices will be done in the same way as for medicinal products, as regulated in article 9 of Royal Decree 177/2014.

Replacement regime

The main rule stated in the draft of Royal Decree is that the pharmacist must dispense the medical device which have been prescribed, indicated or authorized, according to the official prescription.

If the prescribed, indicated or authorized product, according to the official prescription, has a price which is higher than the lower price of another product included in the group, the pharmacist will replace such product with the product having the lowest price of the group. Furthermore, in exceptional cases when due to shortages or urgent reasons, the prescribed, indicated or authorized medical device is not available, the pharmacist can replace the product with another one having similar characteristics and the same or lower price.

Price review

As regards the price review regime, the draft states that the company offering its medical device to the NHS, can request a review to increase the maximum ex-factory price. Such increase request can only be made if there are justifying financial, technical or health-related circumstances. The maximum ex-factory price can also be reviewed ex officio if there are financial, technical or health-related reasons or in case there are grounds to reassess its therapeutic value and, in any case, as long as at least one year has elapsed, counted from its inclusion in the pharmaceutical provision of the NHS or from the last price review procedure, as the case may be.

Transitional regime

According to the draft, those medical devices which are publicly funded when the new Royal Decree comes into force will continue to be funded by the NHS in the conditions contemplated therein, as long as such medical devices are included in the Annexes of the new Royal Decree.

In this regard, it is important to consider the first transitional provision of the draft, according to which those medical devices which are already included in the pharmaceutical provision of the NHS will have maximum ex-factory price resulting from the retail price without taxes, deducting the distribution and dispensation margins. This means that, although the retail price will not be affected by this new regulation, the maximum ex-factory price which is currently being applied by companies could be reduced because of the specific distribution and dispensation margins contemplated in the new Royal Decree. This arises doubts about the opportunity of a measure that affects the companies' rights which have been consolidated through time.

The draft also states that those medical devices which are included the pharmaceutical provision of the NHS, but which are not being marketed on the date of entry into force of this new regulation and continue having such non-marketing condition in 6 months from such date, will be excluded from the NHS.