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Homogeneous groupings should only include marketed SKU's for which there is a real possibility of substitution

On Royal Decree-Law 9/2011 and the Judgments of the National High Court of 21 of September of 2011

Case law on groups

At the end of last year, in a Judgment of 9 December, the National High Court (Audiencia Nacional) modified its criteria on whether presentations (sku's) of products which were not effectively marketed could be taken into consideration in order to create a group and calculate the reference price.

Until then, case law had accepted the position of the administration: in order to create a group and to establish the reference price it was enough if a favorable resolution on the inclusion of the medicinal product in the pharmaceutical benefits of the National Health System (NHS) had been adopted, there was no need for such product to be effectively marketed.

In the judgment of 9 of December of 2010, the National High Court revised its criteria and ruled that Law 29/2006 should be interpreted in the sense that the reference price system requires that the presentations included in the groups be effectively launched and marketed, because only if this condition was met could the rules regarding dispensation and substitution work properly.

In this situation, and having the administration lodged appeals against these judgments before the Supreme Court, Royal Decree-Law 9/2011 was approved. The Preamble of this regulation points out that the new wording of article 93 of the Law clarifies how groups of the reference price system should be defined; and it adds (we quote literally) that this clarification was made "in order to avoid interpretative discrepancies caused by the initial lack of definition of the concept, which in the past has led to the application of different criteria by the case law".

Anyone familiar with the background could think, upon reading these words in the preamble, that the matter would be finally resolved. Well, what has happened is that the administration is coming back: under the new article 93, groups may be created as soon as there is a presentation of a generic or biosimilar medicinal product included in the pharmaceutical benefits of the NHS, and new products shall be integrated in the corresponding group from the date on which they are included in such pharmaceutical benefits, which will always happen before their launch onto the market. No effective marketing is thus required, and the reference price shall be the lowest one regardless of whether the presentation in question is available on the market or not.

Therefore, after some steps forward, it seems we have moved backwards. This becomes evident when reading the two judgments of the High Court of 21 of September of 2011, issued after the entry into force of Royal Decree-Law 9/2011. The court understands that it will have to be admitted that the creation of groups of the reference price system will not depend on the marketing or effective placing on the market of the generic medicinal product.

And what about the homogeneous groupings?

The criterion which the Court announces that it will maintain with regard to the groups of the reference price system is not necessarily applicable to the homogeneous groupings and to the system of dispensation of the product with the lowest price.

This is so because after the entry into force of Royal Decree-Law 9/2011, the reference price system shall only have a secondary relevance in relation with the prescription system and with the new rules applicable to the dispensing by pharmacists.

In this respect, we must first remember that the products included in the homogeneous groupings are not necessarily the same as those integrated in the reference price groups. In order to be included in one of the reference price groups, it is sufficient to have the same active pharmaceutical ingredient and the same route of administration. For homogeneous groupings, in addition to the same active ingredient/s, it is required the same dosage form, contents, pharmaceutical form or group of pharmaceutical form, and route of administration.

It is also required that the presentations in question are reimbursed. Furthermore, something especially important is also required that is not foreseen regarding the reference price groups: the products included in each grouping must be interchangeable in the dispensation. If there is no possibility of interchange when the patient arrives at the pharmacy with the prescription, the product in question must not be included in any homogeneous grouping.

This criterion, that the General Directorate of Pharmacy and Medical Devices has admitted with respect to original medicinal products that are not subject to generic competition because it makes no sense to create groupings of one single product, must be applied likewise in these cases. Products that are not actually marketed and with regard to which there is no real possibility of interchange should not be included in the groupings. The same criterion shall have to be used when updating the lists of homogeneous groupings.

If this criteria is not followed, we may see that, pursuant to article 86 of the Law, when a patient goes to the pharmacy and he cannot be dispensed the product with the lowest price from the grouping because it is not marketed or because there is a temporary shortage, the pharmacist shall have to dispense the product with the next lowest price. It seems simply impossible to manage this situation, from the point of view of the payments made to pharmacists. Who can decide (and how and when) that there is a shortage of supply that justifies to dispense a product with a price higher than the lowest price of the grouping? What guarantee will the pharmacist have that he will be paid for the prescriptions of these products with a higher price?

The logic of the system requires that the real possibility of the dispensing of the product is fully assessed before a product enters a grouping. For this reason, even after the entry into force of Royal Decree-Law, the criterion of the previous case law is still valid, at least with regard to the homogeneous groupings.