CAPSULAS
Boletín de información jurídica

Special Edition | Faus & Moliner Abogados | January 2022

Orphan medicinal products should not be subject to reference pricing

Judgment of the National High Court of 2 December 2021

Background

This judgment, which is of utmost importance, was issued following an appeal lodged by Farmaindustria against the 2019 Reference Price Order. Farmaindustria argued that the price reduction resulting from the inclusion of orphan medicinal products in the reference price system prevents such products from benefiting from the incentives set out in Regulation 141/2000. Such incentives aim to support the research, development and marketing of orphan products.

In recent years, the Ministry of Health has shown concern about the impact of the reference price system on orphan products. A strict application of this system may result in such products ceasing to be marketed in Spain. However, in this case, the Ministry of health argued that, according to the current applicable provision, namely article 98.2 of RDL 1/2015 orphan products must be subject to reference pricing as any other product.

This judgment is crystal clear: Regulation 141/2000 prevails over national law. Article 98.2 of RDL 1/2015 must not apply to orphan products to the extent it goes against the objectives set forth in Regulation 141/2000.

Now what?

This judgment of the National High Court is not final and may be appealed before the Supreme Court. If appealed, the case could end up being heard by the Court of Justice in Luxembourg.

But setting this aside, this judgement does, in fact, grant an excellent opportunity to achieve the goals set by the Government in the Resolution of the Council of Ministers of 3 March 2020.

This Resolution recognises the need to "establish a specific economic regime to guarantee the supply of orphan medicinal products". However, the Resolution dictates that orphan medicinal products shall excluded from the reference price system only if it can be established that there is no reimbursed therapeutic alternative with the same authorised indication or, if such alternative exists, that the relevant orphan medicinal product provides a significant clinical benefit.

Furthermore, this Resolution states that the Permanent Pharmacy Commission of the Interterritorial Council of the National Health System (PPC) must assess the potential existence of a relevant clinical benefit based on the available scientific evidence and, if applicable, the Therapeutic Positioning Report. The decision of the PPC must then be ratified by the Committee for the Price of Medicines.

The conditions and procedure set out in the March 2020 Resolution are a clear example of a situation where a poorly designed "how" jeopardizes the "what".

After all, the purpose of Regulation 141/2000 was clear: to promote the research, development and marketing of orphan medicinal products. Medicinal products can only

be designated as orphans if their sponsor can establish that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. Orphan products are protected over a ten-year period, which may be extended at the end of the fifth year.

In addition, Regulation 141/2000 contemplates that protection may be lost if a similar medicinal product with the same therapeutic indication proofs to be safer, more effective or otherwise clinically superior.

If all of the above is already assessed by the authorities in charge of granting the marketing authorization, why the exemption incentive is subject to the ulterior scrutiny of the PPC and of the Price Committee?

In view of the foregoing, our opinion is that the March 2020 Resolution should be amended to state that orphan medicinal products shall unconditionally be exempted from the reference price system as required by Regulation 141/2000's primacy, over Spanish national law.

As an alternative, the Ministry of Health could, on the basis of this Judgement, decide not to include orphan medicinal products in the 2022 Reference Price Order. The case law of the Court of Justice of the EU indicates that all national authorities must respect EU law primacy at all times.

Just as article 98.2 of RDL 1/2015 should not be applied to orphan medicinal products in order to respect the provisions of Regulation 141/2000, the March 2020 Resolution should not be applied either (or at least be interpreted accordingly) to comply with Regulation 141/2000's primacy. Just as the Ministry of Health has relied on Directive 89/105/EEC to avoid reviewing the reference price of certain medicinal products, the judgment clearly explains how Regulation 141/2000 provides sufficient legal basis to avoid applying the reference price system to orphan medicinal products.

Meanwhile, and until 29 January, it is still possible to file court appeals against the 2021 Reference Price Order requesting the exclusion of orphan medicinal products from such Order.