CAPSULAS
Boletín de información jurídica

Number 224 | Faus & Moliner Abogados | February 2022

# Are orphan drugs subject to reference pricing?

*Judgment of the Supreme Court of 3 February 2022*

## Background

On 3 March 2020, a Resolution of the Council of Ministers excluded orphan medicinal products from the reference price system under two conditions: that no "therapeutic alternative" exists or, otherwise, that the relevant orphan medicinal product provides a "significant clinical benefit". According to this Resolution, the Permanent Pharmacy Commission (PPC) is the body in charge of approving the existence of such "significant clinical benefit". The decision of the PPC must be ratified by the Committee for the Price of Medicines (CIPM). The Resolution also provides that the price of medicinal products may be reviewed downwards if "they are found to be economically viable" or if the conditions of article 96 of RDL 1/2015 are met. The legal basis of the Resolution is article 3(3) of RDL 1/2015. Its premise is that there exists a need to "establish a specific economic regime to guarantee the supply of orphan medicinal products".

On 2 December 2021, the National High Court (*Audiencia Nacional*) issued an important judgment on this matter following an appeal lodged by Farmaindustria against the 2019 Order updating the reference price system. The ruling was clear: Regulation 141/2000 on orphan medicinal products prevails over national regulation; article 98(2) of RDL 1/2015 is an obstacle to the fulfilment of the objectives of European regulation; therefore, article 98(2) of RDL 1/2015 should not be applied with respect to orphan medicinal products. Article 98(2) of RDL 1/2015 provides that "all presentations of reimbursed medicinal products with the same level 5 of the ATC classification and identical route of administration" are subject to the reference price system. This article lists a set of exceptions and conditions, but does not make any reference to orphan medicinal products.

The judgment of the National High Court does not mention the Resolution of 3 March 2020. However, and with all necessary caveats, it seems reasonable to state that, according to the judgment, orphan medicinal products should be excluded from the reference price system unconditionally, as required by Regulation 141/2000's primacy over Spanish national law.

In this context, the Supreme Court issued an interesting judgment on 3 February 2022 following an appeal lodged by Laboratorios Servier against the Resolution of 3 March 2020. The applicant argued that the conditions for excluding orphan medicinal products from the reference price system set out in the Resolution violated Regulation 141/2000 and "rendered EU incentives ineffective". According to Servier, the Resolution should "exclude orphan medicinal products from the reference price system without qualification or reservation and should not grant itself the power to force downward price revisions".

## Position of the Supreme Court

Although the appeal was partially upheld on formal grounds, the Supreme Court did not support the arguments of the applicant and reached several conclusions that deserve to be

highlighted. Firstly, it is incorrect to argue that the principle of primacy of EU law and Regulation 141/2000 enable the non-application of article 98 of RDL 1/2015 for orphan medicinal products (Points of Law, par 3). According to the Supreme Court, orphan medicinal products are subject to the reference price system by virtue of article 98(2) of RDL 1/2015, which does not contravene Regulation 141/2000.

Secondly, considering that orphan medicinal products are subject to the reference price system, the government may approve "incentives" for this type of product by virtue of article 9 of Regulation 141/2000, which allows Member States to adopt additional incentives "to promote research, develop and make available orphan medicinal products". The Supreme Court further states that "if the Government is empowered to agree on the benefit, it is also empowered to set out the conditions of access to such benefit". The Resolution of 3 March 2020 is considered to be one such incentives.

Thirdly, it cannot be argued that the PPC and the CIPM are not competent to assess the existence of "therapeutic alternatives" or of a "significant clinical benefit" because such issues fall under the exclusive competence of the European Commission (EC). According to the Supreme Court, the EC intervenes with the purpose of declaring and registering a medicinal product as orphan. Considering that the competences attributed to the PPC and the CIPM do not seek to question such qualification, but are merely limited to assessing the possible exclusion of a medicinal product from the reference price system, they do not encroach upon the competences of the EC.

Fourthly, for the same reasons above, the Supreme Court also points out that, as set out in the Resolution, the possibility of reviewing the price of orphan medicinal products downwards, if "proven to be economically viable" or if the conditions of article 96 of RDL 1/2015 are met, is acceptable and in accordance with the law.

In the end, the Supreme Court partially upheld Servier's appeal and agreed to modify the wording of the Resolution. According to the Supreme Court, the exception contained in Section 1 of the Resolution, which states that the exemption shall not apply if there is a "therapeutic alternative", should be completed by adding "with the same authorised indication". The reason for this change is formal: although the recitals of the Resolution included "with the same authorised indication", its operative provisions did not. Therefore, the Supreme Court decided to amend the Resolution to remedy this inconsistency in the interest of legal certainty.

## Conclusions

The economic regime for orphan medicinal products in Spain has been overturned once again: according to the Supreme Court, orphan medicinal products are, from the outset, subject to the reference price system. Only those that meet the conditions of the Resolution of 3 March 2020 (i.e., no authorised therapeutic alternative exists or, if such alternative exists, they provide a "significant clinical benefit" in the opinion of the PPC and the CIPM in the light of the available evidence and the IPT) may be excluded.