



# Capsulas

## What point in time must be considered when defining the reference group?

*The Administrative Chamber of the National High Court provides an answer in an interesting judgment*

### Timings in the processing of OPRs

On 6 September, the Ministry of Health published the 2022 update of the reference price system order for medicinal products covered by the NHS, which, in turn, opened the period for allegations.

This Draft Order is based on the information available in the official Nomenclator of the NHS dated 1 April of the relevant year. However, a medicinal product included in the Nomenclator on 1 April may very well not be registered on the date on which the Reference Price Order (“OPR” by its Spanish Acronym) comes into force. The judgment of the Administrative Chamber of last January addresses how to proceed in these cases.

### The position of the National High Court

The 2017 OPR included the medicinal product “Bluepharma Weekly Alendronic Acid” in Group C5. This product was already being marketed at the start of the PRO process, but ceased to be by the date of approval of the OPR. Therefore, the question is which point in time must be considered when defining the reference group. The Court is clear on this subject: this medicinal product was not marketed at the time of approval of the 2017 OPR, and hence should not be included in Group C5 nor taken into account for the purposes of setting the reference price of that particular group.

### Conclusions

Obtaining either one or both reductions does not prevent the offender from appealing in court. As explained in the Supreme Court judgment of 18 February 2021, it is possible to appeal before the Court without losing the right to the reduction, as article 85(3) of the Law no. 39/2015 only requires a waiver of actions in administrative proceedings.

The products that, for any reason, are not included in the Nomenclator on any of these dates cannot be included in the reference groups. Therefore, these products cannot create a group nor be taken into account for the purposes of reference price setting. Otherwise, the corresponding OPR may be contested by means of an administrative appeal (*recurso de reposición*) to the Minister of Health within one month, or an appeal to the Administrative Chamber of the National High Court within two months. Both periods start counting on the day following publication of the OPR in the Official State Gazette.

