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Is it possible to challenge no reimbursement decisions?

Judgment of the High Court of Justice of Madrid of 11 February 2022, and Judgment of the Supreme Court of 17 February 2022

Background

The Directorate-General of Pharmacy (DGP) is the competent body to rule on the reimbursement of medicinal products. Reimbursement decisions must be based on the "general, objective and published" criteria listed in article 92 of Royal Legislative Decree 1/2015. Among such criteria, the incremental clinical benefit of the new product, cost-effectiveness factors, and the existence of therapeutic alternatives at a lower cost are the ones more frequently used by the Ministry of Health (MOH) to support its rulings. According to data from the MOH (February 2022), over 70% of 2021 no reimbursement rulings of orphan drugs were based on such criteria.

Once a decision of no reimbursement has been received, can it be challenged in court?

Traditionally, the main obstacle when it comes to challenging any such decision has been the so called "technical discretion" of the DGP. Such "technical discretion" was based on two main ideas. Firstly, the company cannot seek the judicial review of the assessment carried out by the DGP within the scope of its technical and specialised competences (Royal Decree 735/2020), because the opinion of the DGP following the examination of the documentation in the file must prevail. Secondly, except in case of formal defects, breach of the right of defence, arbitrariness or misuse of power, the courts cannot replace the assessment made by the administration with their own opinion.
The foregoing often hinders companies from challenging no reimbursement rulings of the DGP; even when such companies have adequate evidence to support their positions.

What options are left?

A few years ago, the Supreme Court stated that the administration cannot seek to construct indeterminate legal concepts, such as "therapeutic interest", "significant therapeutic benefit" or "therapeutic alternative", by using its technical discretion. In the judgment of the Supreme Court of 23 February 2011 highlighted that the reasons provided by an expert appointed by the company were more convincing than those of the administration; and this resulted in the Court annulling the contested acts.

Both judgments mentioned in this article support this idea and allow us to conclude that, in the case of non-reimbursement rulings, it is indeed possible to file a successful appeal if one can prove that the decisions of the DGP contain serious errors.

The Octaplasmalg case

On 5 April 2019, the DGP decided not to reimburse Octaplasmalg on the basis of "cost-effectiveness and budgetary criteria, and the existence of alternatives at a lower cost".

Octapharma appealed this ruling of the DGP on the grounds that it lacked sufficient statement of reasons, as it did not explain which studies had been conducted leading to the conclusions, nor did it provide cost-effectiveness data.

In support of its claims, Octapharma requested the Court to appoint an independent expert. The expert's opinion concluded that Octaplasmalg "is a unique, and (...) innovative product" and constitutes a "more beneficial alternative to plasma". Plasma was the lower-priced therapeutic alternative on which the DGP relied to deny reimbursement for Octaplasmalg.

The Court assesses the expert report as required by law (in accordance with the logical and reasonable rules of evaluation) and concludes that its reasoning is convincing. As a result, the judgement considers that Octaplasmalg is "innovative and unique" and provides "greater safety" and "significant therapeutic benefits" when compared to plasma. As stated by the Court, it is clear "that the proposed product outperforms plasma".

The Court also questions the cost-effectiveness data used by the DGP to deny reimbursement for Octaplasmalg: the DGP worked on the assumption that Octaplasmalg and plasma are therapeutic alternatives; an assumption that, in view of the Expert Report, is incorrect.

On the basis of the above, the Court rules that the DGP must re-examine Octaplasmalg's dossier considering Octaplasmalg's "innovative" and "more beneficial alternative to plasma" conditions.

The *"Fin de Jornada" painting case*

This case, which is totally unrelated to the pharmaceutical sector, was the subject of the judgment of the Supreme Court of 17 February 2022. Its interest lies in how the Court analyses the value of reports issued by civil servants as opposed to that of expert reports submitted by companies or individuals. In this case, based on internal reports, the administration refused to grant a temporary authorization to export a painting on the grounds that it was considered a work of exceptional value according to the Law on the Spanish Historical Heritage. The appellant submitted expert reports concluding that "although the merits of the painting are undeniable, they are not exceptional in the context of the artist's work".

In its judgment, the Supreme Court provides a number of interesting ideas that may fully apply to non-reimbursement of medicinal products cases.

Firstly, the Court recalls that the administration's technical discretion "is not discretion in its strict definition and, therefore, the administration may not adopt decisions based on criteria of pure expediency or convenience".

Secondly, the judgment admits that certain civil servants and technicians that serve the Administration may, due to their training and recruitment process, have specialized knowledge that may be relevant to prove facts that can only be accredited by experts. However, whenever a court assesses the reports issued by these civil servants, it must state the reasons leading the court to either accept or reject their conclusions. This must be done in accordance with the logical and reasonable rules of evaluation. In addition, this judgment states that, whenever a dispute arises between a company and the Administration, the report issued by a civil servant is not per se impartial given that it is issued in the interest of one of the parties. Therefore, the court should not rule in favour of the Administration only on

the basis of such a report without analysing its content and making a comparative analysis of the arguments contained in other reports and opinions that may have been provided, including those of experts appointed by the company. The judgement must also examine the robustness of all expert opinions considering their respective sources of information, lines of reasoning and the professional reputation of the expert.

In short, according to the Supreme Court, it is not correct to assume that the reports issued by the Administration must always prevail above those subscribed by private experts. Reports issued by civil servants must also be examined critically, without automatically giving them greater credit simply because they are issued by the Administration.

Conclusions

The Administration cannot resort to "technical discretion" in an indiscriminate manner. Whenever solid and substantiated data support different conclusions to those reached by the DGP, companies may rely on such data to defend their position both before the administration and the courts.

These data should be introduced in the relevant proceedings by way of expert reports, which may be issued by experts appointed by the court (as in the Octaplasmalg case) or by a party (as in the Fin de Jornada case). The former can only be requested within judicial proceedings and have a greater appearance of impartiality and independence. However, the *Fin de Jornada* case proves that courts are also willing to consider party-appointed expert reports issued by recognized experts in the field. These party-appointed expert reports may be submitted in administrative proceedings and also before the court. What do we recommend? It is advisable to always consider the possibility of submitting a party-appointed expert report in the context of administrative proceedings, preferably signed by a recognized expert in the field. If the matter ends up being discussed in court, it may be worthwhile to request the judge to appoint an independent expert, with whom it is also possible to share the party-appointed expert report submitted within the administrative proceedings.

Finally, we note that Courts cannot rule on the reimbursement of a medicinal product. For this reason, the effect of the Octaplasmalg judgment is the recommencement of the reimbursement proceeding before the DGP. This having said, it is important to highlight that the DGP, when re-examining the case, is bound by the Court ruling and the DGP is therefore not allowed to deviate from the Court's considerations and conclusions.