# Capsulas

## Access to medicinal products and constitutional rights

*Three new judgements, two from the Supreme Court and one from the High Court of Justice of Galicia, provide new insights on this matter*

### Gutron® Case (High Court of Justice of Galicia): reimbursement of expenses and right to health protection

Judgment 756/2024 of the High Court of Justice of Galicia of 7 February 2024 deals with a request for reimbursement of expenses made by a patient to the Galician Health Service ("Sergas"). The claim was for payment of the expenses incurred in the purchase of Gurton®, a medicinal product indicated for a serious illness, but which was excluded from the pharmaceutical provision in 2005. In this case, despite being excluded from the pharmaceutical provision, the Sergas doctors prescribed the medicinal product because there was no therapeutic alternative, and they considered such product "essential for the control of the patient´s illness".

Sergas, however, refused to reimburse the costs and the patient appealed against such decision.

The ruling stands out, firstly, because it considers that the exclusion of this product from the pharmaceutical provision seems to affect the guiding principle of health protection, contained in art. 43.1 of the Spanish Constitution. In this regard, the Court points out that it can be concluded that "*if the medicinal product prescribed by SERGAS itself -without an alternative- was not administered, this would result in damage to health that could even fall under the concept of a vital emergency*".

On the other hand, the judgment recalls that the concept of "vital emergency" cannot be limited to a risk to life itself. The Court points out that the current state of social protection in health matters, derived from the constitutional mandate of the right to health protection, implies the need to consider as "vital emergency" situations of "plausible risk of loss of functionality of organs of great importance for the development of the person".

In the light of the foregoing, the appeal is upheld and Sergas is ordered to reimburse the costs.

### Translarna® case (Supreme Court): principle of equality and evidence to be presented by the patient

Much has been written about access to Translarna®. It is possible that much of what has been said needs to be revisited following the European Medicines Agency's recommendation last January not to renew the marketing authorisation for this product.

Nevertheless, we think it is relevant to comment on the Judgement 264/2024 of Supreme Court, which analyses a patient's denial of access to this product.

The case started when the family of a minor requested access to Translarna® via Royal Decree 1015/2009 on access to medicinal products in special situations. Together with the application, they provided a certification issued by the Spanish Duchenne patients' association

to prove that at that time, in Spain, there were 33 patients receiving Translarna®. The certification detailed the starting date of the treatment, the hospital where it was provided and the Autonomous Community.

The hospital refused to send the application to the Spanish Medicines Agency, arguing that it was a medicinal product with an express resolution of non-funding; and that various internal, state and regional reports casted doubts on the efficacy of the product.

The patient's family considered that the refusal was contrary to the right to equality, as they had provided sufficient proof that in other Autonomous Communities there were patients with the same conditions who were receiving the treatment.

The appeal was upheld at first instance, but the High Court of Justice of Catalonia (TSJC) subsequently overturned the ruling, stating that "*the principle of equality prohibits discrimination, but not a difference in treatment when it is based on a justification".* According to the ruling, this justification existed because *"the hospital's refusal to request authorisation (…) is based on reports issued by different institutions at state and regional level, together with the fact that the medicinal product is not available on the list of publicly financed medicinal products*".

Regarding the fact that other patients were receiving treatment with this product, the TSJC considered that the certification submitted by the minor's family was insufficient; and downplayed the relevance of this evidence by stating the following: "*there has been no comparison, there is no information on what type of patients are involved, nor under what conditions and circumstances such authorisations have been granted, there are no reports of the circumstances of each of the patients taking [Translarna®] or who have been prescribed this medicinal product, on which the possible discrimination, and therefore the violation of the right to equality, can be based*."

The Supreme Court, in cassation, considers whether or not it was correct to deny access to the product arguing that the applicant should have accredited the individualised circumstances of the patients who did receive the treatment; and concludes that the TSJC violated the right of the minor not to suffer discrimination and violated the right to equality in access to the pharmaceutical provision.

The Supreme Court does not analyse whether the requirements for the exceptional authorisation requested by the patient were met, but sympathises with the idea that it was practically impossible for the patient to prove the individual circumstances of other patients, given that he could not have access to their medical records.

That said, the Supreme Court points out that if a patient alleges infringement of the principle of equality and provides reasonable indications of discrimination, it is up to the defendant administration to rebut them. In this case, the Supreme Court considered that such reasonable evidence had been provided and that the TSJC could not justify the refusal of treatment by pointing out that the patient had not proved that his circumstances were equal to those of other patients. In this regard, it concludes that the TSJC transferred to the plaintiff the burden of an "*impossible action*", without taking into account the criteria for the distribution of the burden of proof established in the Spanish Civil Procedure Law, i.e. availability and ease of proof for each party.

## Raxone® case (Supreme Court): evidence to present when alleging a violation of the right to live

In the case of this Judgment 610/2024 of 11 April, the facts refer to the refusal of the Extremadura Health Service to supply the medicinal product Raxone® to a patient. Raxone® is a product not included in the pharmaceutical provision of the NHS.

At first instance, it was declared that preventing access to this product would violate the patient's fundamental right to life and equality. The High Court of Justice of Extremadura, however, held that there was no such violation of rights. Finally, the Supreme Court upholds the appeal and confirmed the patient's right to access to Raxone®.

As in the Translarna® case, the Supreme Court criticizes the High Court of Justice of Extremadura for having required the patient to prove that, in his case, the same circumstances were present as in other cases where access to Raxone® had been approved. The Supreme Court confirms that the patient cannot be required to prove the individualised circumstances of the other persons to whom Raxone® has been administered. Nor does it consider the mere reference to the fact that Raxone® is not financed as a sufficient objective and reasonable justification for denying access to the product®.

## Conclusion

The judgments we have discussed are a good example of how the interpretation of some constitutional provisions is evolving, when access to treatments is at stake.

The Translarna® and Raxone® judgments represent a step forward in terms of equal access to medicinal products in special situations in Spain. Recognising that the burden of proof cannot be imposed to demonstrate the circunstances under which access to certain products is being provided in other Autonomous Communities will help to reduce existing inequalities between territories. The Gutron® judgment, on the other hand, is a good example of how to interpret the guiding principle of health protection in relation to the right to life and physical integrity, especiallly in cases where there is no therapeutic alternative to treat a particular disease.

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