Access to medicinal products authorised but not included in public pharmaceutical provision

Judgment of the High Court of Justice of the Canary Islands of 21 October 2024

Background

This judgment analyses whether the refusal of the Canary Islands Health Service (SCS) to fund and provide individual access to a medicinal product authorised but not included in the pharmaceutical provision of the National Health System (SNS by its Spanish acronym) is contrary to the principle of equality recognised in art. 14 of the Spanish Constitution. The case raises concerns about the principle of equality as patients in other Spanish regions have received the same treatment at public expense.

Neither the High Court's approach nor its conclusion is new (the Court recognises the existence of discrimination), but the judgement offers illustrative insights on access to medicinal products in special situations.

Right to equality

The High Court assesses the judgments of the Supreme Court of 19 February and 11 April 2024, key judgments in the matter at hand. According to the Court, the Supreme Court judgments should be read in the sense that "the principle of equal treatment in access to medicinal products applies even to cases of medicinal products not included in the public pharmaceutical provision".

This interpretation establishes that the appropriate basis for comparison is at the national level, rather than at the regional level. This assessment is relevant because, as far as we know, it is the first time that a High Court establishes that the above-mentioned Supreme Court judgments should be interpreted in the sense that there is a subjective right to equality outside the public pharmaceutical provision.

Authorisation to access as a regulated act

The High Court also warns that the authorisation to access non-marketed medicinal products according to Royal Decree 1015/2009 does not allow for discretion by AEMPS. This point is very important because it reinforces the message that the AEMPS, when faced with a request for access to a medicinal product in special situations, must only review whether the criteria set out in Royal Decree 1015/2009 are met, without making any additional considerations.

Competence levels

Finally, the Court raises an issue of competence that had already been observed in similar judgments (e.g. judgment of the Madrid High Court of 9 May 2024). The Court considers that the AEMPS, and not regional health authorities, is the one competent to authorise the supply of a medicinal product that is not yet available in Spain.

On this basis, the Court the SCS to initiate the authorisation process with the AEMPS. In addition, the Court rules that if AEMPS decides favourably, the SCS must offer the medicinal product to the patient at public expense.

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Our conclusions

We welcome the High Court's conclusion that, if the AEMPS authorises exceptional access to a medicinal product, regional authorities should not oppose its provision at public expense. We believe this conclusion aligns with the general principle that patients should have access to prescribed treatment without financial barriers.

However, we are also aware that section 6 of art. 17 of Royal Decree 1718/2010 (incorporated by Royal Decree-Law 16/2012) establishes that the acquisition of non-funded medicinal products by SNS hospitals requires the prior authorisation of the corresponding regional commission of therapeutic protocols; and that a conclusion such as the one reached by the High Court could be questioned from this perspective.

Therefore, we consider it urgent to clarify the relation between Royal Decree 1015/2009 and Royal Decree 1718/2010 in order to provide a clear legal framework that offers certainty to all interested parties.

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