Capsulas

Reference price groups without generics and with different active substances

Order of the Supreme Court of 11 February 2026

The underlying issue

Can a reference price group be formed comprising two medicinal products with different active substances, both authorised for more than ten years and sharing the same ATC level 5 classification, where no generics or biosimilars exist? This is the question the Supreme Court will address after admitting, by Order of 11 February 2026, a cassation appeal concerning the 2021 Reference Price Order.

The case arises in the context of the regulatory reform introduced in 2021, which abandoned the traditional active-substance identity criterion and adopted the ATC Level 5 classification as the basis for the establishment of reference price groups. The case under consideration concerns a reference price group comprising presentations of two originator medicinal products: Sinemet (levodopa + carbidopa) and Madopar (levodopa + benserazide). Both products share the same ATC Level 5 classification, have no generic or biosimilar equivalents, and were authorised in the European Union more than ten years ago. Under the applicable regulations, reference price groups may be formed without generics or biosimilars provided that "a medicinal product different from the originator and its licensees exists." The central issue in dispute is the interpretation of this requirement.

The "different medicinal product" requirement

On one hand -as argued by the Ministry of Health and upheld in the first-instance judgment- the requirement may be considered satisfied on a reciprocal basis: Sinemet would constitute a "different medicinal product" from Madopar, and vice versa. Their coexistence within the same ATC level 5 classification would therefore suffice to meet the regulatory conditions to create the reference price group.On the other hand, the claimant advocates a stricter interpretation: for both originators, or at least for one of them, there must exist another medicinal product distinct from that originator and its licensees, but with the same composition. Under this interpretation, the mere coexistence of two originators with different active substances would not be sufficient to justify the formation of a reference price group. The Supreme Court expressly acknowledges the controversial nature of the issue, the absence of prior case law, and the existence of interest in establishing legal doctrine.

Final comment

This case once again highlights the tensions arising from the shift from an active-substance-based approach to an ATC level 5 classification system. In recent years, problematic situations have emerged, such as the inclusion within the same reference price group of medicinal products with different active substances where only one had generic versions, while the other remained protected by exclusivity rights. Such scenarios are difficult to reconcile with the underlying rationale of the legislation, as they may result in a de facto erosion of exclusivity periods. Although the issue now under consideration is different, it stems from the same regulatory shift.Clarity will ultimately depend on the forthcoming judgment of the Supreme Court. In the meantime, the debate is particularly relevant in the context of the future Law on Medicinal Products and Medical Devices, currently under preparation, which could usefully address these issues to enhance legal certainty.