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Some medicines containing the same active substance may not be the same medicinal product (… in terms of reference price)

The Judgement of the General Court of 22 March, in Case T-80/16 Shire, brings light into this delicate issue

Background

This case refers to the position taken by the European Medicines Agency ("EMA") in relation to an application filed by Shire to obtain orphan designation for Idursulfase-IT. The EMA rejected to validate such application on the grounds that Idursulfase-IT contained the same active substance ("API") as that of Elaprase® , another medicinal product for which Shire had previously obtained orphan designation and a marketing authorization.

The EMA did not give value to the fact that Idursulfase-IT had been developed so that it would be possible to deliver its API directly into the cerebrospinal fluid through intrathecal administration. This new route of administration, according to Shire, met an unsatisfied clinical need for treatment of some patients with Hunter Syndrome: the ones suffering from a severe form of that disease with cognitive disorders. Shire considered that the medical condition that Idursulfase-IT could treat was different from the common Hunter Syndrome.

Court's position and local consideration

In its judgement, the Court departs from the idea that the sole fact that both Idursulfase IT and Elaprase® contain the same API does not necessarily mean that they are the same medicinal product. The API, the Court says, is the main constituent of a medicinal product but it must not be confused with the medicinal product itself.

In order to assess the differences between two medicinal products, the Court understands it is necessary and reasonable to take into account their methods of administration and the therapeutic effects that may be achieved using one or the other. In this case, the Court argues that the intrathecal administration of Idursulfase-IT allows the API to be delivered directly into the cerebrospinal fluid, and this results in the possibility of treating the cognitive disorders exhibited by some of the patients suffering from Hunter Syndrome. Considering this, the Court concludes that the EMA should not have refused to validate the application for the orphan designation because at least in respect of the route of administration it does not seem that Idursulfase-IT should be considered the same medicinal product as Elaprase ® .

As a local consideration, in our opinion these ideas of the Court should inspire new rules on reference prices in Spain. At present, products containing the same API are included in the same reference price group and their price is determined only taking into account the unitary price of the API of the product having the lowest price in the group. This is known as the reference price system.

The products for which a new route of administration has been developed that may result in a significant clinical benefit for the patient deserve special treatment, and their price should not be determined only taking into account the unitary price of the API of the product having the lowest price in the group.

Otherwise, companies may be bound not to market some of the products, and research on improvements which may be beneficial to patients may be unfairly harmed.