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Commission Implementing Regulation (EU) 2024/2699 of 18 October laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and in vitro diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices has been published in the *Official Journal of the European Union*[1].

Pilot programme for expert panels to support the development and assessment of orphan medical devices

The European Medicines Agency has launched a pilot programme for expert panels to support the development and assessment of orphan medical devices in the European Union (i.e. those intended to be used for diseases or conditions affecting only a small number of individuals each year, not more than 12,000 individuals in the EU per year)[2]. To this end, a guidance document has been published (MDCG 2024-10 - "Clinical evaluation of orphan medical devices", June 2024[3]) that provides the criteria for determining when a medical device or an accessory for a medical device should be regarded as 'orphan device'.

[1] *Official Journal of the European Union* No. 2699 of 21 October 2024; see *here*.

[2] See *here*.

[3] See *here*.

Judgments, rulings and decisions

European Union

Exception to market exclusivity of an orphan medicinal product based on clinical superiority

The Judgment of the Court of Justice of 4 October 2024, C-237/22 P, analyses Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products and, more specifically, whether it is possible for a medicinal product similar to an orphan medicinal product to have clinical superiority over the latter, so that the exception to market exclusivity applies when the medicinal product similar to the orphan medicinal product is at the same time a generic of the medicinal product in relation to which the orphan medicinal product (whose exclusivity is excepted) is of significant benefit.

In this regard, the Court of Justice insists that the concepts of 'significant benefit' and 'clinical superiority' are not interchangeable and that they have different purposes and scope, since, while the concept of 'significant benefit' is established as a criterion for designation of a medicinal product as an orphan medicinal product, the concept of 'clinical superiority' is established as one of the criteria to derogate an orphan medicinal product from market exclusivity. It is true that the same three criteria (greater safety, greater efficacy and major contribution to patient care) can be used to assess both concepts, but this does not mean, according to the Court of Justice (confirming the interpretation of the General Court), that they are the same concept.

Accordingly, it is considered possible and appropriate in law to conclude that a medicinal product has clinical superiority over an orphan medicinal product so as to trigger the exception to market exclusivity where, at the same time, the medicinal product similar to the orphan medicinal product is a generic of the medicinal product in respect of which the orphan medicinal product is of significant benefit.

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