The "global marketing authorisation" covers all subsequent developments of the medicinal product

Judgement of the Court of Justice of the European Union of 28 June 2017, Joined Cases C-629/15 P and C-630/15 P, Novartis vs European Commission

Background

In 2001, Novartis obtained a marketing authorization under a centralised procedure for the medicinal product Zometa® , the active substance of which is zoledronic acid and which is indicated to treat certain bone complications in patients with cancer. In 2005, Novartis obtained another marketing authorization under a centralised procedure for the medicinal product Aclasta® , which has the same active substance but its therapeutic indications are not oncological and its dosage is different from the one of Zometa® . In 2011, Teva and Hospira both submitted MA applications for their respective generic medicinal products, with zoledronic acid as active substance and using Aclasta® as a reference medicinal product. In 2012, the European Commission (EC) granted such marketing authorizations, with indications and dosages both of Aclasta® as well as Zometa® .

In 2012, Novartis appealed the granting of such MAs before the General Court of the EU alleging that the data protection period of Aclasta® which, in its opinion, was different from the one of Zometa® , had not been respected. In 2015, the General Court rejected the appeals of Novartis ruling that Aclasta® and Zometa® were included in the same "global marketing authorisation". This judgement of the Court of Justice of the European Union (CJEU) decides on the appeals of Novartis against the previous judgements of the General Court.

Position of the CJEU

In its judgement, the CJEU rejects the appeals of Novartis and values the interpretation of the concept of "global marketing authorisation" on the basis of the same principles that inspired the Generics case of 1998: when a medicinal product obtains an initial marketing authorization, any strength, pharmaceutical form, administration route and additional presentation, as well as any variations and extensions that are authorised will be considered as included in the same global marketing authorisation and there will not be an independent data protection period.

The CJEU relies on the fact that Directive 2001/83 makes no distinction between developments authorised through the grant of a separate marketing authorization and developments of the original medicinal product authorised through a variation of the initial marketing authorization. Accordingly, the CJEU states that the concept of "global marketing authorisation" covers all subsequent developments of the original medicinal product, irrespective of their authorisation procedures, namely through the variation of the initial marketing authorization for that medicinal product or through the grant of a separate marketing authorization.