Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

[F1 Article 8

Market exclusivity

1 Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation (EEC) No 2309/93 or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down in Articles 7 and 7a of Directive 65/65/EEC or Article 9(4) of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products[1], and without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.

2 This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5. The sponsor shall provide the Agency with the information necessary for that purpose.

3 By way of derogation from paragraph 1, and without prejudice to intellectual property law or any other provision of Community law, a marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if:

a the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the second applicant, or

b the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or

c the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.

[[F2]4 The Commission is empowered to adopt delegated acts in accordance with Article 10b in order to supplement this Regulation by adopting the definitions of ‘similar medicinal product’ and ‘clinical superiority’.**]**

5 The Commission shall draw up detailed guidelines for the application of this Article in consultation with the Member States, the Agency and interested parties.**]**

Textual Amendments

F1 Regulation revoked in part (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 9 para. 1(f)** (subject to transitional provisions in S.I. 2012/1916, **Sch. 33A**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny

to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

(**1**) OJ L 147, 9.6.1975, p. 13. Directive as last amended by Council Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 141/2000 of the European Parliament and of the Council, Article 8.