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

[F1 Article 3

Criteria for designation

1 A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:

a that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made, or

that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment;

and

b that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

[[F2]2 The Commission shall, in accordance with the regulatory procedure referred to in Article 10a(2), adopt the necessary provisions for implementing paragraph 1 of this Article in the form of an implementing Regulation.**]]**

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 (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

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 3.