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

[F1 Article 5

Procedure for designation and removal from the register

1 In order to obtain the designation of a medicinal product as an orphan medicinal product, the sponsor shall submit an application to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation is made.

2 The application shall be accompanied by the following particulars and documents:

a name or corporate name and permanent address of the sponsor;

b active ingredients of the medicinal product;

c proposed therapeutic indication;

d justification that the criteria laid down in Article 3(1) are met and a description of the stage of development, including the indications expected.

3 The Commission shall, in consultation with the Member States, the Agency and interested parties, draw up detailed guidelines on the required format and content of applications for designation.

4 The Agency shall verify the validity of the application and prepare a summary report to the Committee. Where appropriate, it may request the sponsor to supplement the particulars and documents accompanying the application.

5 The Agency shall ensure that an opinion is given by the Committee within 90 days of the receipt of a valid application.

6 When preparing its opinion, the Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall be adopted by a majority of two-thirds of the members of the Committee. The opinion may be obtained by written procedure.

7 Where the opinion of the Committee is that the application does not satisfy the criteria set out in Article 3(1), the Agency shall forthwith inform the sponsor. Within 90 days of receipt of the opinion, the sponsor may submit detailed grounds for appeal, which the Agency shall refer to the Committee. The Committee shall consider whether its opinion should be revised at the following meeting.

[F28 The Agency shall forthwith forward the final opinion of the Committee to the Commission, which shall adopt a decision within 30 days of receipt of the opinion. Where, in exceptional circumstances, the draft decision is not in accordance with the opinion of the Committee, the decision shall be adopted in accordance with the regulatory procedure referred to in Article 10a(2). The decision shall be notified to the sponsor and communicated to the Agency and to the competent authorities of the Member States.**]**

9 The designated medicinal product shall be entered in the Community Register of Orphan Medicinal Products.

10 Each year the sponsor shall submit to the Agency a report on the state of development of the designated medicinal product.

11 To have the designation of an orphan medicinal product transferred to another sponsor, the holder of the designation shall make specific application to the Agency. In consultation with the Member States, the Agency and interested parties, the Commission shall draw up detailed guidelines on the form in which applications for transfer shall be made and the content of such applications and all the particulars of the new sponsor.

12 A designated orphan medicinal product shall be removed from the Community Register of Orphan Medicinal Products:

a at the request of the sponsor;

b if it is established before the market authorisation is granted that the criteria laid down in Article 3 are no longer met in respect of the medicinal product concerned;

c at the end of the period of market exclusivity as laid down in Article 8.**]**

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 5.