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

[F1 Article 6

Protocol assistance

1 The sponsor of an orphan medicinal product may, prior to the submission of an application for marketing authorisation. request advice from the Agency on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of the medicinal product, in accordance with Article 51(j) of Regulation (EEC) No 2309/93.

2 The Agency shall draw up a procedure on the development of orphan medicinal products, covering regulatory assistance for the definition of the content of the application for authorisation within the meaning of Article 6 of Regulation (EEC) No 2309/93.**]**

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)**

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 6.