8 May 2013
EMA/2677/01 Rev.2[1]
Orphan Medicines

Procedural advice on appeal procedure for orphan medicinal product designation or review of orphan designation criteria at the time of Marketing Authorisation

Legal basis

In accordance with Article 5(7), Regulation (EC) No 141/2000 of 16 December 1999, where the opinion of the Committee for Orphan Medicinal Products (COMP) is that an application does not satisfy the criteria for orphan medicinal product designation, the Agency shall forthwith inform the sponsor. Within 90 days of the receipt of the opinion, the sponsor may submit detailed grounds for appeal, which the Agency shall refer to the COMP. The Committee shall consider whether its opinion should be revised at the following meeting.

Appeal procedure

- Upon adoption of an opinion on orphan medicinal product designation or on the review of orphan designation criteria at the time of Marketing Authorisation, the EMA will forward the opinion to the sponsor together with a copy of the COMP Summary Report.
- The sponsor may inform the Agency of any intent to appeal, without delay after receipt of the opinion, by giving written notice to the EMA.
- The COMP will appoint a new COMP co-ordinator for the appeal procedure. If necessary, the COMP may appoint additional experts.
- Detailed grounds for appeal must be submitted by the sponsor within 90 days of receipt of the opinion. The grounds for appeal should be submitted to the EMA via Eudralink to orphandrugs@ema.europa.eu.
- The EMA will refer the grounds for appeal to the COMP immediately after receipt.
- The sponsor will be invited to an oral explanation before the COMP at the meeting following the receipt of the grounds.
- An ad-hoc expert meeting may be convened, as necessary.

[1] Paper and CD submission of ground for appeal was replaced by electronic only submission via Eudralink

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- The EMA co-ordinator, in association with the COMP co-ordinator, will update the COMP Summary Report. The revised Summary Report will be circulated for comments to COMP members and appointed expert(s) by the EMA.
- The COMP, at the first meeting following the sponsor's submission of the grounds for appeal, having reviewed the detailed grounds for appeal and having heard the oral explanation of the sponsor, will consider whether its opinion should be revised and will adopt a final COMP opinion. Where possible the expert(s) involved in the application will be invited to attend the COMP discussion.
- The EMA will forward the final opinion to the Commission and the sponsor.
- The decision will be adopted by the Commission, within 30 days of its receipt of the final opinion. Once the decision has been issued, a public summary of opinion will be published on the EMA website.
- Upon a favourable decision by the Commission, the designated medicinal product shall be entered in the EU Register of Orphan Medicinal Products.