The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

London, 9 February 2001
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Appeal Procedure for Orphan Medicinal Product Designation

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 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 negative 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.

Appeal Procedure

- Upon adoption of a negative opinion on orphan medicinal product designation, the EMEA will forward the opinion to the sponsor together with a copy of the COMP Assessment Report.
- The sponsor will be requested to inform the Agency of any intent to appeal, within 15 days of receipt of the opinion, by giving written notice to the EMEA.
- The COMP may decide to appoint a new COMP co-ordinator and/or a new EMEA co-ordinator for the appeal procedure, accompanied, if necessary, by additional experts.
- In case of appeal, 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 EMEA (3 paper copies + 1 electronic copy).
- The EMEA will refer the grounds for appeal to the COMP at their next meeting. Copies of the grounds for appeal will be provided to all COMP members and appointed expert(s) by the EMEA.
- The sponsor will be invited to an oral explanation before the COMP at the following meeting.
- An ad-hoc expert meeting may be convened, as necessary.
- The EMEA co-ordinator, in association with the COMP co-ordinator, will update the COMP assessment report. The revised assessment report will be circulated for comments to COMP members and appointed expert(s) by the EMEA, at least one week before the meeting.
- The COMP, at the first meeting following its referral by the EMEA, 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 EMEA 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.
- Upon a favourable Decision by the Commission, the designated medicinal product shall be entered in the Community Register of Orphan Medicinal Products.

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