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

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PRESS RELEASE
2nd Meeting of the Committee for Orphan Medicinal Products

The Committee for Orphan Medicinal Products (COMP) held its second meeting on 15 May 2000.

The Committee elected Prof. Josep Torrent-Farnell (Spain) as chairperson for a term of three years, renewable once. Election of a vice-chairperson will take place at the next Committee meeting in June 2000.

During the meeting, the Fifth-Framework Programme was presented by Ms. Gwennaël Joliff-Botrel, DG Research, European Commission. Dr. Giovanni Fracchia, DG Health and Consumer Protection presented the Scientific Committees of the European Commission.

Commission Regulation (EC) No 847/2000[1] was adopted on 27 April 2000, laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'. It is now possible for sponsors to submit applications for orphan medicinal product designation in the European Union.

The Committee held an in-depth discussion on the procedure for orphan medicinal product and how to introduce the appropriate expertise into the system. The following general principles were agreed:

- Sponsors should notify the EMEA of their intention to submit an application as early as possible and at the latest two months prior to the planned submission date.
- In preparing an application for orphan medicinal product designation, sponsors are requested to follow the draft Commission guideline (ENTR/6283/00) for the format and content of applications for designation as orphan medicinal products, available on the EMEA and Commission web-site.
- Two co-ordinators (1 COMP member, 1 EMEA staff member) will be appointed for each application.
- The Committee will identify appropriate expert(s) to be involved in the evaluation and will build-up an expert network.
- The Committee may gather information from its members and patient organisations on the clinical setting for treating the condition in each of the Member States.

A document outlining the procedure was fully discussed in view of its adoption at the June meeting. This document will be made public following its adoption. To date, 10 applications for orphan medicinal product designation have been submitted to the EMEA. Co-ordinators were appointed by the Committee for each of these applications. A further 35 sponsors have informed the EMEA of their intention to apply for orphan medicinal product designation.

Meeting dates for the COMP in the year 2000 are published in Annex 1.

NOTE: This Press Release, together with other information about the work of the EMEA, may be found on the internet at the following location: http://www.eudra.org/emea.html

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[1] Official Journal of the European Communities, L103/5, 28 April 2000.

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Committee for Orphan Medicinal Products
Dates for Meetings in 2000

MONTH	DATE
June	15
July	11 - 12
September	12 - 13
October	26 - 27
December	18 - 19

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