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

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EMEA/COMP/271/00

PRESS RELEASE

8th Meeting of the Committee for Orphan Medicinal Products

The Committee for Orphan Medicinal Products (COMP) held its eighth meeting on 18-19 December 2000.

The Committee thanked Prof. Jean-Michel Alexandre, who is resigning his COMP membership, for his contribution and collaboration. A replacement for Prof. Alexandre will be proposed early next year once the new membership of the Committee for Proprietary Medicinal Product (CPMP) has been established.

Nine positive opinions on the designation of orphan medicinal products, were adopted by the Committee, for the following conditions:

- Acromegaly
- Chronic myeloid leukaemia
- Cystic Fibrosis
- Glycogen storage disease type II (Pompe's disease)
- Haemorrhagic Fever with Renal Syndrome
- Mucopolysaccharidosis type I
- Mucopolysaccharidosis type VI
- Patent ductus arteriosus
- Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension

These opinions, will now be forwarded to the European Commission for the decision making process.

Two oral explanations took place during the meeting and two applications for orphan medicinal product designation were withdrawn by the sponsors. The status of orphan designation procedures, as of 19 December 2000, is summarised in the table below:

Year	*Intent to file Notified*	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
2000	29	71	3	26	-	8

The Committee appointed co-ordinators and experts for a number of upcoming applications.

The draft Commission guideline (ENTR/6283/00) on the format and content of applications for designation as orphan medicinal products, which was released for consultation in April 2000, has been updated to incorporate points to consider when evaluating the plausibility of a "condition", guidance on the transfer of sponsorship and comments received following the consultation period. The Committee discussed and endorsed the revised version, which will be released by the European Commission[1] for a further 3 months consultation period. In preparing an application for orphan medicinal product designation, sponsors are requested to follow the revised draft guideline.

The next meeting of the COMP will be held on 15-16 January 2001. A list of COMP meeting dates for 2001 is provided 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] ENTR/6283/00 is available on the EMEA and Commission (http://dg3.eudra.org) web-sites

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ANNEX I

Committee for Orphan Medicinal Products
Dates for Meetings in 2001

MONTH	DATE
January	15 - 16
February	8 - 9
March	20 - 21
April	9 - 10
May	22 - 23
June	11 - 12
July	17 - 18
September	6 - 7
October	25 - 26
November	20 - 21
December	17 - 18

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