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

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PRESS RELEASE
38th Meeting of the Committee for Orphan Medicinal Products

The thirty-eight meeting of the Committee for Orphan Medicinal Products (COMP) took place on 9-11 September 2003. Due to the increase in the number of applications of the Committee, the COMP held a three-day meeting for the first time.

Seven positive opinions on the designation of orphan medicinal products were adopted by the Committee during this meeting, for the following conditions:

- Chronic idiopathic myelofibrosis
- Paroxysmal nocturnal haemoglobinuria
- Hematopoietic cell transplantation
- Dermatomyositis
- Polymyositis
- Ovarian cancer
- Wilson's disease

Of these seven opinions, five were adopted on day 58 of the procedure, well before the 90-day deadline for the Committee's opinion following receipt of a valid application.

No negative opinions on orphan medicinal product designation were adopted. Five oral explanations took place during the meeting. The COMP noted that sponsors withdrew five applications for orphan medicinal product designation. Two sponsors submitted a letter of intention to appeal after the negative opinions adopted in July 2003. Detailed grounds for appeal must be submitted within 90 days of receipt of the opinion.

The European Commission on orphan designation granted no decisions[1] since the last COMP meeting on 29-30 July 2003. The status of orphan designation procedures, from January 2003 until 11 September 2003, is summarised below:

Intent to file notified	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
79	63	41	26	2	0	32

Overview of orphan designation procedures

Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*
2000	72	26	3	0	14
2001	83	64	25	1	64
2002	80	43	24	3	49

[1] Details of all orphan designations granted to date by the European Commission are entered in the Community Register of Orphan Medicinal Products (http://pharmacos.eudra.org/F2/register/index.htm)

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Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions[2], which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

The Committee was updated on the revision of Annex I of Directive 2001/83/EC and on the publication of the Communication from the Commission on Regulation (EC) No 141/2000 of the European Parliament and the Council on orphan medicinal products as adopted on 29 July 2003 (2003/C 178/02). The Communication from the Commission sets out its interpretation on certain matters relating to the implementation of the designation and market exclusivity provisions. It provides also additional clarifications in order to avoid a departure from the spirit of the Regulation. These documents are available on the web site of the European Commission, DG Enterprise (http://pharmacos.eudra.org/F2/pharmacos/docs.htm#news).

The next COMP meeting will be held from 9 to 10 October 2003.

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.emea.eu.int

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[2] Summarised COMP Opinions are available on the EMEA web-site.