



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

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PRESS RELEASE

5th Meeting of the Committee for Orphan Medicinal Products

The Committee for Orphan Medicinal Products (COMP) held its fifth meeting on 12-13 September 2000.

The Committee thanked Prof. Tilmann Ott, who is resigning his COMP membership, for his contribution and collaboration and welcomed Dr. Rembert Elbers from the Bundesinstitut für Arzneimittel und Medizinprodukte as the new German member.

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

- Acute Promyelocytic Leukaemia
- Acute Myeloid Leukaemia
- Gaucher disease
- Glioblastoma
- N-acetylglutamate synthetase (NAGS) deficiency

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

The Committee noted, that the European Commission granted the first three Decisions designating orphan medicinal products in the European Union on 8 August 2000. Details of these medicinal products (one containing somatropin and two containing alpha galactosidase A) have been entered in the Community Register of Orphan Medicinal Products which is published on the web-site of the European Commission (<http://dg3.eudra.org/register/index.htm>).

Co-ordinators and experts were appointed by the Committee for a number of upcoming applications. The status of orphan designation procedures, as of 13 September 2000, is summarised in the table below:

<i>Year</i>	<i>Intent to file Notified</i>	<i>Applications submitted</i>	<i>Positive COMP Opinions</i>	<i>Negative COMP Opinions</i>	<i>Designations granted by Commission</i>
2000	30	42	8	-	3

During this meeting the Committee discussed the principles to be taken into account when evaluating the plausibility of a condition proposed in an application for orphan medicinal product designation. It was agreed that guidance will be drafted on this subject, which once finalised by the Committee, will be incorporated into an EU Commission Guideline and released for consultation.

The Committee endorsed a 'General Information for Sponsors' document concerning orphan medicinal products (EMEA/4795/00) which will be published shortly on the EMEA web-site.

The next meeting of the COMP will be held on 26-27 October 2000.

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>

Contacts for further information:
Evaluation of Medicines for Human Use Unit

Dr. Patrick Le Courtois
Tel. (44-20) 74 18 86 49
or
Ms. Melanie Carr
Tel. (44-20) 74 18 85 75
Fax. (44-20) 75 23 70 40

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eudra.org <http://www.eudra.org/emea.html>