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PRESS RELEASE

26th Meeting of the Committee for Orphan Medicinal Products

The twenty-sixth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 16-17 July 2002.

The Committee welcomed Prof. Bernd Jilma as the new Austrian COMP member, who will replace Prof. Hans-Georg Eichler, and Dr. Julia Dunne from the Pharmaceuticals Unit of Directorate General Enterprise at the European Commission, who will replace Ms. Emer Cooke. The Committee thanked Prof. Eichler and Ms. Cooke for their contribution and collaboration.

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

- Paroxysmal nocturnal haemoglobinuria
- Hepatocellular carcinoma
- Nonketotic hyperglycinaemia
- Adrenal cortical carcinoma

One oral explanation took place during the meeting. The COMP noted that three applications for orphan medicinal product designation were withdrawn by sponsors.

The European Commission granted one decision on orphan designation¹ since the last COMP meeting on 27 June 2002, see Annex I. The status of orphan designation procedures, as of 18 July 2002, is summarised in the table below:

<i>Intent to file notified</i>	<i>Applications submitted</i>	<i>Applications withdrawn</i>	<i>Positive COMP Opinions</i>	<i>Negative COMP Opinions</i>	<i>Designations granted by Commission</i>
47	191	54	114	2 ²	105

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions³, which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

The next COMP meeting will be held on 11-12 September 2002.

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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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>)

² Of the five negative opinions adopted to date: two applications have been subsequently withdrawn, two have resulted in final negative opinions and one has resulted in a final positive opinion following appeal.

³ Summarised COMP Opinions are available on the EMEA web-site (<http://www.emea.eu.int/>)

**Medicinal products Designated as Orphan Medicinal Products
since the June 2002 COMP Meeting**

Active substance	Carbamic acid, [[4-[[[3-[[4-[1-(4-hydroxyphenyl)-1-methyl-ethyl]phenoxy]methyl]phenyl]methoxy]-phenyl]iminomethyl]-ethyl ester
Sponsor	Boehringer Ingelheim International GmbH
Orphan Indication	Treatment of cystic fibrosis
Opinion receipt date	30/05/2002
Date of Commission Decision	26/06/2002