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PRESS RELEASE

25th Meeting of the Committee for Orphan Medicinal Products

The twenty-fifth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 27 June 2002. This meeting, originally planned to take place on 20 June 2002, was re-scheduled due to disruptions in a number of airport services.

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

- Active ulcerative colitis
- Hepatocellular carcinoma
- Ovarian cancer
- Partial deep dermal and full thickness burns
- Post transplantation graft dysfunction

Two oral explanations took place during the meeting. The COMP noted that one application for orphan medicinal product designation was withdrawn by a sponsor.

The European Commission granted 3 decisions on orphan designation¹ since the last COMP meeting on 22 May 2002, see Annex I. The status of orphan designation procedures, as of 27 June 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Applications withdrawn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>
45	191	51	110	2 ²	104

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 17-18 July 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² Of the five negative opinions adopted to date: two applications have been subsequently withdrawn, two have resulted in final negative opinions and one has resulted in a final positive opinion following appeal.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
in June 2002**

Active substance	Recombinant Human Porphobilinogen Deaminase
Sponsor	HemeBiotech A/S
Orphan Indication	Treatment of acute intermittent porphyria
Opinion receipt date	06/05/2002
Date of Commission Decision	12/06/2002

Active substance	Miltefosine
Sponsor	Zentaris Aktiengesellschaft
Orphan Indication	Treatment of visceral leishmaniasis
Opinion receipt date	06/05/2002
Date of Commission Decision	12/06/2002

Active substance	Mitotane
Sponsor	Laboratoire HRA Pharma
Orphan Indication	Treatment of adrenal cortical carcinoma
Opinion receipt date	06/05/2002
Date of Commission Decision	12/06/2002