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EMEA/COMP/177/04

PRESS RELEASE
Committee for Orphan Medicinal Products
April 2004 Meeting

The forty-fifth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 14 April 2004.

The Committee welcomed Dr. Veijo Saano as the new Finnish COMP member, who will replace Dr. Kalle Hoppu. The Committee thanked Dr. Hoppu for his contribution and collaboration.

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

- Functional gastro-entero-pancreatic endocrine tumours
- Hyperphenylalaninemia

Of these two opinions, one was adopted on day 59 of the procedure, well before the 90-day deadline for the Committee's opinion following receipt of a valid application.

The COMP noted that one application for orphan medicinal product designation was withdrawn by a sponsor in the validation phase of the procedure.

The status of orphan designation procedures, to date for 2004, is summarised below:

<i>Applications submitted</i>	<i>Positive COMP Opinions</i>	<i>Applications withdrawn</i>	<i>Appeals ongoing</i>	<i>Final negative COMP Opinions</i>	<i>Designations granted by Commission</i>
33	15	7	-	-	12

An overview of orphan designation procedures for 2000-2003 is provided in Annex 1.

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions¹, which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

A training session for new COMP members nominated from the accession countries was held at the EMEA on 13 April 2004. Decisions on Orphan Medicinal Product designation, which have been granted by the European Commission prior to May 2004, will automatically extend to the acceding countries on the day of accession. Further information for sponsors of orphan medicinal products on the practical issues arising from EU enlargement (EMEA/COMP/177/04) is available on the EMEA's web-site.

The Committee look forward to officially welcoming ten COMP members from the new Member States at its May meeting, which will be held on 13-14 May 2004.

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 These documents are available on the EMEA web-site.

**Overview of Procedures for Orphan Medicinal Product Designation
for 2000-2003**

<i>Year</i>	<i>Applications submitted</i>	<i>Positive COMP Opinions</i>	<i>Applications withdrawn²</i>	<i>Final negative COMP Opinions</i>	<i>Designations granted by Commission</i>
2003	87	54	41	1	55
2002	80	43	30	3	49
2001	83	64	27	1	64
2000	72	26	6	0	14

² These figures have been updated to include withdrawals from the validation phase of the designation procedure