



16 April 2003
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PRESS RELEASE
34th Meeting of the Committee for Orphan Medicinal Products

The thirty-fourth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 14-15 April 2003.

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

- Pancreatic cancer (*2 opinions*)
- Congenital ichthyoses

Seven explanations took place during the meeting. The COMP noted that sponsors withdrew two applications for orphan medicinal product designation.

The European Commission granted three decisions on orphan designation¹ since the last COMP meeting on 18-19 March 2003, see Annex I. The status of orphan designation procedures, from January 2003 until 16 April 2003, is summarised below:

<i>Intent to file notified</i>	<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Applications withdrawn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>
58	26	14	12	3	0	13

Overview of orphan designation procedures

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Applications withdrawn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

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions², which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

After three years of existence this was the last meeting of the current COMP. The Committee thanked warmly Mr Moisés Abascal Alonso, Dr François Meyer, Dr. José Félix Olalla Marañón and Dr Brendan Buckley for their successful contribution to the work of the Committee. The new three-year mandate starts with the meeting in May.

The next COMP meeting will be held on 7-8 May 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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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 Summarised COMP Opinions are available on the EMEA web-site.

**Medicinal products Designated as Orphan Medicinal Products
since the March 2003 COMP Meeting**

Active substance	Bosentan
Sponsor	Actelion Registration Limited
Orphan Indication	Treatment of Systemic Sclerosis
Opinion receipt date	17/02/2003
Date of Commission Decision	17/03/2003

Active substance	Tobramycin (inhalation powder)
Sponsor	Chiron Corporation Limited
Orphan Indication	Treatment of <i>Pseudomonas aeruginosa</i> lung infection in cystic fibrosis
Opinion receipt date	17/02/2003
Date of Commission Decision	17/03/2003

Active substance	α -1-acid glycoprotein
Sponsor	Bio Products Laboratory
Orphan Indication	Treatment of tricyclic antidepressants poisoning
Opinion receipt date	17/02/2003
Date of Commission Decision	20/03/2003