



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

12 May 2003
EMEA/COMP/1173/03

PRESS RELEASE
35th Meeting of the Committee for Orphan Medicinal Products

The thirty-fifth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 7-8 May 2003.

This was the first meeting of the second three-year mandate of the COMP. The composition of the Committee was renewed following the appointment of members by each Member State and by the European Commission (see list 1 attached).

The Committee re-elected Prof. J. Torrent-Farnell (Spain) as Chairman for the new 2003-2005 mandate, following a successful mandate from 2000 to 2003. The Vice-chairman will be elected at the June COMP meeting.

Observers from Accession Countries have already been appointed by their National Authorities in anticipation of full membership as of May 2004 (see list 2 attached). Two of them attended the May Meeting.

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

- Renal cell carcinoma (*2 opinions*)
- Pancreatic cancer
- Cystic fibrosis

Three explanations took place during the meeting. The COMP noted that a sponsor withdrew one application for orphan medicinal product designation. No decisions were granted by the European Commission on orphan designation¹ since the last COMP meeting on 14-15 April 2003. The status of orphan designation procedures, from January 2003 until 8 May 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Applications withdrawn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>
78	26	18	13	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Applications withdrawn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

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>)
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More than **150 positive opinions** on designations of medicinal products intended for orphan diseases have been given by the COMP. This is a clear sign of continuous interest from sponsors and a promise for more drug development for patients affected by rare diseases.

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.

The next COMP meeting will be held on 12-13 June 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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² Summarised COMP Opinions are available on the EMEA web-site.
Public EMEA/COMP/1173/03

NOMINATED MEMBERS BY EACH MEMBER STATE AND BY THE EUROPEAN COMMISSION

Member State	Name
Austria	Prof Bernd Jilma
Belgium	Dr André Lhoir
Denmark	Dr Heidrun Bosch Traberg
Finland	Dr Kalle Hoppu
France	Dr Emmanuel Héron
Germany	Dr Rembert Elbers
Greece	Dr George Stathopoulos
Ireland	To be nominated
Italy	Dr Domenica Taruscio
Luxembourg	Prof Henri Metz
The Netherlands	Dr Harrie Seeverens
Portugal	Prof Jose Manuel Gião Toscano Rico
Spain	Prof Josep Torrent-Farnell (Chairman)
Sweden	Dr Kerstin Westermark
United Kingdom	Dr Rashmi Shah
European Commission (Patient Representative)	Mrs Birthe Byskov Holm
European Commission (Patient Representative)	Mr Yann Le Cam
European Commission (Patient Representative)	Mr Alastair Kent
European Commission (EMEA Representative)	Dr Eric Abadie
European Commission (EMEA Representative)	Prof Gianmartino Benzi
European Commission (EMEA Representative)	Dr David Lyons

Observers from EFTA States	Name
Iceland	Dr Sigurdur B Thorsteinsson
Norway	Dr Lars Gramstad

**OBSERVERS FOR COMP MEETINGS NOMINATED BY ACCESSION
COUNTRIES**

Accession Country	Name
Czech Republic	Dr Milan Šmíd
Cyprus	Mr George Antoniou
Estonia	Dr Kristin Raudsepp
Hungary	Dr Judit Eggenhofer
Latvia	Ms Iveta Blodone
Lithuania	To be nominated
Malta	To be nominated
Poland	Ms Jolanta Więckowska
Slovak Republic	Prof Eva Racanska
Slovenia	To be nominated