The European Agency for the Evaluation of Medicinal Products
Pre-authorisation evaluation of medicines for human use

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PRESS RELEASE

15th Meeting of the Committee for Orphan Medicinal Products

The Committee for Orphan Medicinal Products (COMP) held its fifteenth meeting on 17-18 July 2001.

Eight positive opinions on the designation of orphan medicinal products, were adopted by the Committee, for the following conditions:

- Acute lung injury
- Anthracycline extravasations
- Delayed graft function in organ transplant
- Indolent Non-Hodgkin's lymphoma
- Malignant mesothelioma
- Meconium aspiration syndrome
- Niemann-Pick disease, type B
- Pulmonary hypertension and chronic thromboembolic pulmonary hypertension

These opinions, will now be forwarded to the European Commission for the decision making process.

Two oral explanations took place during the meeting and three applications for orphan medicinal product designation were withdrawn by sponsors. The European Commission granted six decisions on orphan designation[1] since the last COMP meeting on 19-20 June 2001, see Annex I.

The status of orphan designation procedures, as of 18 July 2001, is summarised in the table below:

Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
58	113	19	60	1	49

The Committee appointed co-ordinators and experts for a number of upcoming applications.

Timetables for evaluation of applications for orphan designation in 2002 were agreed by the Committee. In order to synchronise each evaluation with the meetings of the COMP, validation dates (Day 1, start of the procedure) are fixed. Deadlines for submission of applications to the EMEA are provided in Annex II.

A *COMP Working Group with Interested Parties (COMP-WGIP)*, composed of EMEA/COMP members and representatives of patient organisations and the pharmaceutical industry, has been established. The COMP-WGIP, which met for the first time on 19 July 2001, will work on proposals for improving transparency on orphan activities, optimising the orphan designation procedure and delineating policy recommendations on orphan medicinal products.

The next COMP meeting will be held on 6-7 September 2001.

[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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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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Medicinal products Designated as Orphan Medicinal Products on 9 July 2001

Active substance	Betaine anhydrous
Sponsor	Orphan Europe
Orphan Indication	Treatment of homocystinuria
Opinion receipt date	28/5/01
Date of Commission Decision	9/7/01

Active substance	Thalidomide
Sponsor	Laboratoires LAPHAL
Orphan Indication	Treatment of multiple myeloma
Opinion receipt date	28/5/01
Date of Commission Decision	9/7/01

Active substance	Thalidomide
Sponsor	Laboratoires LAPHAL.
Orphan Indication	Treatment of graft versus host disease
Opinion receipt date	28/5/01
Date of Commission Decision	9/7/01

Active substance	Human $Alpha_1$-Proteinase Inhibitor (respiratory use)
Sponsor	Aventis Behring, GmbH
Orphan Indication	Treatment of emphysema secondary to congenital alpha-1-antitrypsin deficiency
Opinion receipt date	28/5/01
Date of Commission Decision	9/7/01

Active substance	Ziconotide (intraspinal use)
Sponsor	Elan Pharma International Ltd
Orphan Indication	Treatment of chronic pain requiring intraspinal analgesia
Opinion receipt date	28/5/01
Date of Commission Decision	9/7/01

Active substance	Ramoplanin
Sponsor	Biosearch Italia S.p.A
Orphan Indication	Prevention of invasive infections due to Vancomycin Resistant Enterococci (VRE) in colonised patients deemed at risk of infection
Opinion receipt date	28/5/01
Date of Commission Decision	9/7/01

Doc. Ref: EMEA/18893/01

Deadlines for Submission of Applications for Orphan Medicinal Product Designation to the EMEA

Deadline for Submission of Applications	**Start of Procedure - day 1 -** *(for validated applications)*	**COMP* Meeting** *(see note below)*
9 August 2001	24 August 2001	20 – 21 November 2001
5 September 2001	20 September 2001	17 – 18 December 2001
11 October 2001	26 October 2001	22 – 23 January 2002
15 November 2001	30 November 2001	26 – 27 February 2002
11 December 2001	4 January 2002	25-26 March 2002
16 January 2002	31 January 2002	29-30 April 2002
8 February 2002	25 February 2002	22 – 23 May 2002
8 March 2002	25 March 2002	19 –20 June 2002
5 April 2002	22 April 2002	17 – 18 July 2002
31 May 2002	17 June 2002	11 – 12 September 2002
27 June 2002	12 July 2002	8 – 9 October 2002
2 August 2002	19 August 2002	14 –15 November 2002
30 August 2002	16 September 2002	12-13 December 2002

* Committee for Orphan Medicinal Products

Note: In accordance with Article 5.5 of Regulation (EC) No 141/2000, the COMP will reach an Opinion on a valid application for orphan designation within 90 days. Please note that the dates provided above correspond to the COMP meeting falling on or just prior to day 90. Opinions may be reached earlier than day 90 if no questions are raised by COMP.
For further information on the procedure for designation please consult the *Procedure for Orphan Medicinal Product Designation – General Principles (EMEA/14222/00).*
In preparing an application for orphan designation, sponsors are requested to follow the revised draft Commission guideline *(ENTR/6283/00)* for the format and content of applications for designation as orphan medicinal products, available on the EMEA web-site.