



5 November 2001  
EMA/COMP/498/01

**PRESS RELEASE**  
**17<sup>th</sup> Meeting of the Committee for Orphan Medicinal Products**

The seventeenth meeting of the Committee for Orphan Medicinal Products (COMP) was held on 26 October 2001.

The Committee welcomed back Dr. Rashmi Shah, as UK representative to the COMP, and thanked Dr. Alex Nicholson for his contribution and collaboration.

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

- Cutaneous T-cell lymphoma
- Mucopolysaccharidosis, type II (Hunter syndrome)
- *Pseudomonas aeruginosa* infections in patients with cystic fibrosis
- Short bowel syndrome
- Systemic sclerosis

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

Two applications for orphan medicinal product designation were withdrawn by sponsors.

The European Commission granted eight decisions on orphan designation<sup>1</sup> since the last COMP meeting on 6-7 September 2001, see Annex I. The status of orphan designation procedures, as of 26 October 2001, 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Applications withdrawn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>
52	139	24	78	1 <sup>2</sup>	60

The next COMP meeting will be held on 20-21 November 2001.

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NOTE: This Press Release, together with other information about the work of the EMA, may be found on the internet at the following location: <http://www.emea.eu.int/>

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<sup>1</sup> 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>)

<sup>2</sup> Of the four negative opinions adopted to date, one is ongoing. Two applications have been subsequently withdrawn and one has resulted in a final positive opinion following appeal.

**Medicinal products Designated as Orphan Medicinal Products  
in September 2001**

<b>Active substance</b>	Pemetrexed disodium
<b>Sponsor</b>	Eli Lilly Nederland B.V.
<b>Orphan Indication</b>	Treatment of malignant mesothelioma
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	17/9/01

<b>Active substance</b>	Beraprost sodium
<b>Sponsor</b>	Aventis Pharma SA
<b>Orphan Indication</b>	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	18/9/01

<b>Active substance</b>	Sinapultide, dipalmitoylphosphatidylcholine, palmitoyl-oleoyl phosphatidylglycerol and palmitic acid
<b>Sponsor</b>	Discovery Laboratories Inc.
<b>Orphan Indication</b>	Treatment of Meconium Aspiration Syndrome
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	19/9/01

<b>Active substance</b>	Cladribine (subcutaneous use)
<b>Sponsor</b>	Lipomed GmbH
<b>Orphan Indication</b>	Treatment of indolent non-Hodgkin's lymphoma
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	18/9/01

<b>Active substance</b>	Recombinant human acid sphingomyelinase
<b>Sponsor</b>	Genzyme B.V.
<b>Orphan Indication</b>	Treatment of Niemann-Pick Disease, type B
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	19/9/01

<b>Active substance</b>	Porcine lung surfactant
<b>Sponsor</b>	Leo Pharmaceutical Products
<b>Orphan Indication</b>	Treatment of acute lung injury
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	19/9/01

<b>Active substance</b>	Repertaxin L-lysine salt
<b>Sponsor</b>	Dompé s.p.a.
<b>Orphan Indication</b>	Prevention of delayed graft function in organ transplant
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	19/9/01

<b>Active substance</b>	Dexrazoxane
<b>Sponsor</b>	TopoTarget A/S
<b>Orphan Indication</b>	Treatment of anthracycline extravasations
<b>Opinion receipt date</b>	25/7/01
<b>Date of Commission Decision</b>	19/9/01