



13 December 2002  
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## PRESS RELEASE

### 30<sup>th</sup> Meeting of the Committee for Orphan Medicinal Products

The thirtieth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 12-13 December 2002.

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

- Methotrexate toxicity
- Narcolepsy
- Gastric cancer
- Pancreatic cancer

One negative opinion on orphan medicinal product designation was adopted. This opinion will be forwarded to the sponsor, who may submit detailed grounds for appeal within 90 days of receipt of the opinion.

Two oral explanations took place during the meeting.

The status of orphan designation procedures, as of 13 December 2002, is summarised in the table below<sup>1</sup>:

| <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Applications withdrawn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> |
|--------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------------------|
| 50                             | 227                           | 61                            | 131                           | 4 <sup>2</sup>                | 121                                       |

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions<sup>3</sup>, 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 9-10 January 2003.

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 seven negative opinions adopted to date: one has been adopted at this meeting and may be subject to appeal three have resulted in final negative opinions, one has resulted in a final positive opinion following appeal, and two applications have been subsequently withdrawn.

<sup>3</sup> Summarised COMP Opinions are available on the EMA web-site (<http://www.emea.eu.int/>)  
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