The seventy-fifth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 9-10 January 2007. The Committee was delighted to officially welcome two COMP members from the new Member States. An updated list of COMP membership is provided in Annex 1.

**COMP Opinions**

The Committee adopted 6 positive opinions on orphan medicinal product designation during this meeting:

- Artesunate, from ACE Pharmaceuticals BV, for **treatment of malaria** (review time: day 62)
- Autologous dendritic cells pulsed with autologous cell lysate, from Dorian Regulatory Affairs BV, for **treatment of glioma** (review time: day 62)
- Ex-vivo cultured adult human mesenchymal stem cells, from Quintiles UK Limited, for **treatment of Graft-versus-Host disease** (review time: day 62)
- HLA class I/II binding tumour associated peptides (ADF-APO-CCN-GUC-K67-MET-MMP-MUC-RGS), from Immatics Biotechnologies GmbH, for **treatment of renal cell carcinoma** (review time: day 62)
- Idebenone, from Santhera Pharmaceuticals (Deutschland) AG, for **treatment of Leber's hereditary optic neuropathy** (review time: day 90)
- Recombinant human C1-inhibitor, from Pharming Group N.V., for **prevention of delayed graft function after solid organ transplantation** (review time: day 90)

Four oral explanations on orphan medicinal product designation took place during the meeting.

**Withdrawals of Orphan Medicinal Product Applications**

The COMP noted that four applications for orphan medicinal product designation were withdrawn by the sponsor during evaluation phase of the procedure.

**Overview of orphan designation procedures**

The European Commission granted four positive decisions on orphan designation\(^1\) since the last COMP meeting on 5-6 December 2006 (see Annex 2).

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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://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm)
The status of orphan designation procedures, to date for 2007, is summarised below:

<table>
<thead>
<tr>
<th>Applications submitted</th>
<th>Positive COMP Opinions</th>
<th>Applications withdrawn</th>
<th>Appeals ongoing</th>
<th>Final negative COMP Opinions</th>
<th>Designations granted by Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>6</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

An overview of orphan designation procedures for 2000-2006 is provided in Annex 3.

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions\(^2\), which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

**Applications for Marketing Authorisation for Orphan Medicinal Products**
Details of those designated orphan medicinal products that have been the subject of a centralised application for marketing authorisation since the last COMP meeting are provided in Annex 4.

**Date of next COMP meeting**
The next COMP meeting will be held on 6-7 February 2007.

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.europa.eu](http://www.emea.europa.eu).

For further information, please contact:
Martin Harvey Alchurch, EMEA press officer
Tel. (+44-20) 74 18 84 27, E-mail: press@emea.europa.eu.

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\(^2\) These documents are available on the EMEA web-site.
Composition of the Committee for Orphan Medicinal Products

Chair: Kerstin Westermark
EMEA contact: Agnès SAINT RAYMOND

Members
- Brigitte BLÖCHL-DAUM (Austria)
- Andrew BORG (Malta)
- Heidrun BOSCH TRABERG (Denmark)
- Birthe BYSKOV HOLM (patients’ organisation representative) (vice-chairman)
- Yann LE CAM (patients’ organisation representative)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Julia DUNNE (EMEA representative)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Pauline EVERS (patients’ organisation representative)
- Lars GRAMSTAD (Norway)
- Emmanuel HÉRON (France)
- Detelina IVANOVA (Bulgaria)
- Ioannis KKOLOS (Cyprus)
- Kateřina KUBÁČKOVÁ (Czech Republic)
- Magdaléna KUŽELOVÁ (Slovakia)
- André LHOIR (Belgium)
- David LYONS (EMEA representative)
- Greg MARKEY (United Kingdom)
- Aušra MATULEVIČIENĖ (Lithuania)
- Henri METZ (Luxembourg)
- Martin MOŽINA (Slovenia)
- Kristina PAVLOVSKA (Latvia)
- Veijo SAANO (Finland)
- Patrick SALMON (Ireland)
- Miranda SIOUTI (Greece)
- Daniela STANCIU (Romania)
Orphan Medicinal Product Designations received since the December 2006 COMP Meeting

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Sponsor</th>
<th>Orphan Indication</th>
<th>Opinion receipt date</th>
<th>Date of Commission Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,7,10,13,16,19-docosahexaenoic acid</td>
<td>Jose Manuel Cela Lopez</td>
<td>Treatment of retinitis pigmentosa</td>
<td>17 October 2006</td>
<td>3 November 2006</td>
</tr>
<tr>
<td>Forodesine hydrochloride</td>
<td>Napp Pharmaceuticals Research Limited</td>
<td>Treatment of acute lymphoblastic leukaemia</td>
<td>20 November 2006</td>
<td>18 December 2006</td>
</tr>
<tr>
<td>Paclitaxel (micellar)</td>
<td>Oasmia Pharmaceutical AB</td>
<td>Treatment of ovarian cancer</td>
<td>20 November 2006</td>
<td>18 December 2006</td>
</tr>
<tr>
<td>Tazarotene</td>
<td>Orfagen</td>
<td>Treatment of congenital ichthyoses</td>
<td>20 November 2006</td>
<td>18 December 2006</td>
</tr>
</tbody>
</table>
Overview of Procedures for Orphan Medicinal Product Designation for 2000-2006

<table>
<thead>
<tr>
<th>Year</th>
<th>Applications submitted</th>
<th>Positive COMP Opinions</th>
<th>Applications withdrawn</th>
<th>Final negative COMP Opinions</th>
<th>Designations granted by Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>104</td>
<td>81</td>
<td>20</td>
<td>2</td>
<td>80</td>
</tr>
<tr>
<td>2005</td>
<td>118</td>
<td>88</td>
<td>30</td>
<td>0</td>
<td>88</td>
</tr>
<tr>
<td>2004</td>
<td>108</td>
<td>75</td>
<td>22</td>
<td>4</td>
<td>72</td>
</tr>
<tr>
<td>2003</td>
<td>87</td>
<td>54</td>
<td>41</td>
<td>1</td>
<td>55</td>
</tr>
<tr>
<td>2002</td>
<td>80</td>
<td>43</td>
<td>30</td>
<td>3</td>
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<tr>
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<td>2000</td>
<td>72</td>
<td>26</td>
<td>6</td>
<td>0</td>
<td>14</td>
</tr>
</tbody>
</table>
Overview of Designated Orphan Medicinal Products that have been the subject of a Centralised Application for Marketing Authorisation
- update since the last COMP meeting on 6-7 December 2006 -

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Sponsor/applicant</th>
<th>EU Designation Number &amp; Date of Orphan Designation</th>
<th>Designated Orphan Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>gusperimus trihydrochloride (Spanidin)</td>
<td>Euro Nippon Kayaku GmbH</td>
<td>EU/3/01/034 29/03/2001</td>
<td>Treatment of Wegener’s granulomatosis</td>
</tr>
</tbody>
</table>