



The European Agency for the Evaluation of Medicinal Products  
*Evaluation of Medicines for Human Use*

London, 23 November 2000  
EMEA/COMP/249/00

## **PRESS RELEASE**

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

The Committee for Orphan Medicinal Products (COMP) held its seventh meeting on 21 November 2000.

The Committee thanked Ms. Mariette Backes-Lies, who is resigning her COMP membership, for her contribution and collaboration and welcomed Dr. Henri Metz as the new Luxembourg member. An updated list of COMP members is provided in Annex I.

One oral explanation took place during the meeting and one application for orphan medicinal product designation was withdrawn by the sponsor. Three positive opinions on the designation of orphan medicinal products, were adopted by the Committee, for the following conditions:

- Amyotrophic lateral sclerosis
- Acute promyelocytic leukaemia
- Acute respiratory distress syndrome

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

The status of orphan designation procedures, as of 21 November 2000, is summarised in the table below:

| <i>Year</i> | <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Applications withdrawn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> |
|-------------|--------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------------------|
| 2000        | 32                             | 59                            | 1                             | 17                            | -                             | 8                                         |

The Committee appointed co-ordinators and experts for a number of upcoming applications and noted that, to date, a total of sixty-six experts have been included in the expert network on rare disease which is being built up by the EMEA.

With a view to increasing transparency and communication in the field of rare diseases and orphan medicinal products, the Committee further discussed proposals for identifying and liaising with interested parties and in particular patient organisations, the scientific community (including health professionals and independent researchers) and the pharmaceutical sector. These proposals will be presented during the Transparency Workshop which will be held at the EMEA on 23 November 2000.

The next meeting of the COMP will be held on 18-19 December 2000.

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.eudra.org/emea.html>

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**Members of the Committee for Orphan Medicinal Products 2000-2003**

**Chairman - Prof. Josep TORRENT-FARNELL (España)**

**Vice-Chairman - Mr. Yann LE CAM (Representative of Patient Organisation)**

|                                        |                                                           |
|----------------------------------------|-----------------------------------------------------------|
| België/Belgique/Belgien                | Dr. André LHOIR                                           |
| Danmark                                | Dr. Jan RENNEBERG                                         |
| Deutschland                            | Dr. Rembert ELBERS                                        |
| Ελλάδα                                 | Dr. George STATHOPOULOS                                   |
| France                                 | Dr. François MEYER                                        |
| Ireland                                | Dr. Brendan BUCKLEY                                       |
| Italia                                 | Dr. Domenica TARUSCIO                                     |
| Luxembourg/Luxemburg                   | Dr. Henri METZ                                            |
| Nederland                              | Dr. H.J.J. SEEVERENS                                      |
| Österreich                             | Prof.Dr. Hans Georg EICHLER                               |
| Portugal                               | Dr. José Manuel Gião TOSCANO RICO                         |
| Suomi/Finland                          | Dr. Kalle HOPPU                                           |
| Sverige                                | Dr. Kerstin WESTERMARK                                    |
| United Kingdom                         | Dr. Rashmi SHAH                                           |
| EMA Representative                     | Prof. Jean-Michel ALEXANDRE                               |
| EMA Representative                     | <i>(Replacement for Dr. Mary Teeling to be nominated)</i> |
| EMA Representative                     | Prof. Gianmartino BENZI                                   |
| Representative of Patient Organisation | Mr. Abascal ALONSO                                        |
| Representative of Patient Organisation | Mr. Alastair KENT                                         |