

## News from the EMA

### Activities of the COMP

#### Results from the February meeting 2012 of the COMP

The COMP met on 7-9 February 2012 and adopted the following **seven positive opinions on orphan medicinal product designation**:

- **Dipalmitoylphosphatidylcholine, 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol, sodium salt, synthetic surfactant protein C analogue and synthetic surfactant protein B analogue** for treatment of respiratory distress syndrome in premature neonates of less than 37 weeks of gestational age; Chiesi Farmaceutici S.P.A.
- **Genistein sodium salt dihydrate** for treatment of mucopolysaccharidosis type III (Sanfilippo syndrome); Axcentua Pharmaceuticals AB.
- **Melatonin** for treatment of perinatal asphyxia; Dr Nicola J. Robertson.
- **Adenovirus-associated viral vector serotype 2 containing the human RPE65 gene** for treatment of Leber's congenital amaurosis; Alan Boyd Consultants Ltd.
- **Antisense oligonucleotide targeted to the SMN2 gene** for treatment of 5q spinal muscular atrophy; Isis USA Ltd.
- **Linsitinib** for treatment of adrenal cortical carcinoma; Astellas Pharma Europe B.V.
- Sodium thiosulfate for treatment of calciphylaxis; Aptiv Solutions (UK) Limited.

Since the December meeting 2011 the European Commission granted **no more final designations as orphan medicinal product**.

The COMP adopted **five lists of questions** on initial applications.

**Six oral hearings** took place.

**Six applications** for orphan medicinal product designation were **withdrawn**.

The COMP adopted **1 opinion** recommending to the European Commission that the following **orphan medicinal product** be **kept in the EU registry** of orphan medicinal products:

- **Signifor** (pasireotide) for treatment of Cushing's disease; Novartis Europharm Limited.

The status of orphan designations/authorisations as of 08 February 2012 is given in the following table:

Year	Applications submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisations since 2000
2012	17	23	0	11	7	0
2011	166	111	2	107	45	4
2000-2010	1234	850	16	827	300	57
Total 2000-2012	1417	984	18	945	352	61

Next COMP meeting: 7-8 March 2012

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for:

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