

News from the EMA

Activities of the COMP

Results from the December meeting 2010 of the COMP

The COMP met on 7-8 December 2010 and adopted the following **six positive opinions on orphan medicinal product designation**:

- Axitinib for treatment of renal cell carcinoma, Pfizer Limited.
- Sodium thiosulphate for treatment of calciphylaxis, Promedipharma GmbH.
- Allogeneic aortic endothelial cells cultured in a porcine gelatin matrix for prevention of arteriovenous access failure in haemodialysis patients, Gregory Fryer Associates Ltd.
- Dry extract from Birch bark (DER 0.1-0.2:1), extraction solvent n-heptane 95% (V/V) for treatment of epidermolysis bullosa, Birken GmbH.
- Paclitaxel (aqueous gel) for treatment of oesophagus carcinoma, BTG International Ltd.
- Pegylated B-domain-deleted sequence-modified recombinant human factor VIII for treatment of haemophilia A, Bayer Schering Pharma AG.

The European Commission granted 14 final orphan designations.

The COMP adopted four lists of questions. Two oral hearings took place and two applications for orphan medicinal product designation were withdrawn.

The status of orphan designations/authorisations as of 8 December 2010 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submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisations since 2000
2010	167	123	2 ¹	113	48	5
2000-2009	1060	727	14	699	249	58
Total 2000-2010	1227	850	16	812	297	63

1 One negative opinion was transferred into a positive one after the sponsor's appeal.

Next COMP meeting: 11-12 January 2011

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