

## News from the EMA

### Activities of the PDCO

During its meeting from 11-13 January 2012 the Paediatric Committee (PDCO) adopted the following opinions:

- **seven positive opinions** on paediatric investigation plans (**PIPs**) for the following products:

- Eliglustat (tartrate), from Genzyme Europe B.V. (endocrinology/gynaecology-fertility-metabolism);
- Recombinant human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13, from Baxter Innovations GmbH (haematology-hemostaseology);
- 2-Iminobiotin, from Neurophoxia B.V. (neonatology - paediatric intensive care);
- N-[3-[3-cyclopropyl-5-[(2-fluoro-4-iodophenyl)amino]-6,8-dimethyl-2,4,7-trioxo-3,4,6,7-tetrahydropyrido[4,3-D]pyrimidin-1(2H)-yl]phenyl]acetamide, dimethylsulfoxide solvate, from GlaxoSmithKline Trading Service Limited (oncology);
- Elacetytarabine, from Clavis Pharma ASA (oncology);
- Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins, from Merz Pharmaceuticals GmbH (ophthalmology / dermatology / neurology);
- Fibrinogen concentrate / thrombin preparation / aprotinin / calcium chloride, from Kedrion S.p.A. (other indication: surgical settings).

- one revised positive opinion following the re-examination of the positive opinion on a PIP adopted on 11 November 2011 for

- semuloparin sodium, from Sanofi-aventis Recherche & Développement (haematology-hemostaseology)

- **two positive opinions** for **product-specific waivers** for:

- Diltiazem (hydrochloride), from S.L.A. Pharma (UK) Ltd (gastroenterology-hepatology);
- Recombinant Porcine Factor VIII, B-Domain Deleted, from Inspiration Biopharmaceuticals EU, Ltd. (haematology-hemostaseology).

**Withdrawals:** The PDCO noted that **five applications** were withdrawn during the late stage of the evaluation (30 days or less before opinion) and **an opinion** adopted during the December PDCO meeting **for bortezomib** from Janssen-Cilag International NV (oncology), has been withdrawn **before the decision** was adopted by the EMA.

### Update of the priority list for studies into off-patent paediatric medicinal products

The PDCO adopted the revision of the priority list for studies into off-patent paediatric medicinal products in advance of the next call from the European Community through the EU's Seventh Framework Programme. Dr Alexandru-Sorin Costescu (DG RTD), updated the PDCO on the Seventh Framework Programme.

The following tables provide summaries of the current state of the applications for PIPs and waivers, the PDCO opinions and the areas covered by applications for PIPs/full waivers.

### Table 1: Applications for PIPs and waivers as of 11 January 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA <sup>1</sup>	
1161 <sup>2</sup>	865	270	26	1601
100%	75%	23%	2%	

<sup>1</sup> off patent products, which are developed specifically for children

<sup>2</sup> incl. 274 waivers

**Table 2: Overview on PDCO opinions as of 11 January 2012**

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	2	223
Positive opinions on PIPs	2	81	122	201	107	7	520
Negative opinions	0	4	13	7	3	0	27
Positive opinions on modification of a PIP	0	8	51	103	153	11	326
Negative opinions on modification of a PIP	0	0	0	4	2	0	6
Positive opinions on compliance with a PIP	0	5	8	9	9	0	31
Negative opinions on compliance with a PIP	0	0	1	0	0	0	1
Opinions on review of a granted waiver	0	0	0	2	0	0	2

**Table 3: Areas covered by applications for PIPs/full waivers**

Indications	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)
Neurology	6	4	4	11	0
Uro-nephrology	3	5	2	4	0
Gastroenterology-hepatology	3	2	1	10	1
Pneumology-allergology	6	6	41	10	4
Infectious diseases	8	9	4	15	2
Cardiovascular diseases	14	9	8	21	2
Diagnostics	1	1	1	5	0
Endocrinology-gynaecology- fertility-metabolism	15	16	5	28	3
Neonatology-paediatric intensive care	1	2	0	0	0
Immunology-rheumatology- transplantation	6	6	5	13	2
Psychiatry	3	3	2	9	0

Pain	3	6	1	2	0
Haematology- haemostaseology	5	6	4	18	1
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	2
Dermatology	3	6	3	10	1
Vaccines	6	4	2	12	0
Ophthalmology	2	2	4	8	0
Anaesthesiology	1	1	2	1	0
Nutrition	1	0	0	0	0
Other				7	2

Date of next PDCO meeting: 8-10 February 2012

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