

News from the EMA

Activities of the PDCO

During its meeting from 16-18 March 2011 the Paediatric Committee (PDCO) welcomed the new alternate from Finland, Anne Paavola and thanked Ine Blankenberg Skottheim, former alternate from Finland, for her work as she has resigned from the Committee. The PDCO adopted the following opinions:

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

- Tadalafil, from Eli Lilly and Company Limited, in the therapeutic area of cardiovascular diseases;
- Darbepoetin alfa, from Amgen Europe B.V, in the therapeutic area of cardiovascular diseases / oncology / uro-nephrology;
- Ataluren, from Genzyme Europe B.V., in the therapeutic area of endocrinology-gynaecologyfertility-metabolism / pneumology – allergology;
- Linaclotide, from Almirall S.A., in the therapeutic area of gastroenterology;
- Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-methoxy-133 ester with granulocyte colonystimulating factor [methionyl,133-[O-[2-(acetylamino)-6-O-[N-[N-carboxyglycyl)amino]-alpha neuraminosyl]-2-deoxy-alpha-D-galactopyranosyl]-L-threonine]] (human), from Ratiopharm GmbH, in the therapeutic area of oncology;
- Aripiprazole, from Otsuka Pharmaceutical Europe Ltd, in the therapeutic area of psychiatry;
- Autologous cartilage derived cultured chondrocytes, from Genzyme Europe BV, in the therapeutic area of other (orthopaedics).

- **three positive opinions** for product-specific **waivers** in all subsets of the paediatric population for:

- Ezetimibe / simvastatin, from MSD-SP Limited, in the area of cardiovascular diseases;
- Amlodipine besylate / atorvastatin calcium, from Miklich Lab., in the area of cardiovascular diseases;
- Delafloxacin, from Rib-X Therapeutics Ltd, in the area of infectious diseases.

- **ten positive opinions on modifications to an agreed PIP.**

Withdrawals: The PDCO noted that **four applications**, of which one was for a modification of an agreed PIP, were withdrawn during the late stages of the evaluation (30 days or less before opinion).

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 18 March 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1003 ²	735	242	26	1420

100%	73%	24%	3%	
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¹ off patent products, which are developed specifically for children

² incl. 228 waivers

Table 2: Overview on PDCO opinions as of 18 March 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	14	190
Positive opinions on PIPs	2	81	122	201	28	434
Negative opinions	0	4	13	7	1	25
Positive opinions on modification of a PIP	0	8	51	103	33	195
Negative opinions on modification of a PIP	0	0	0	4	0	4
Positive opinions on compliance with PIP	0	5	8	9	0	22
Negative opinions on compliance with a PIP	0	0	1	0	0	1
Opinions on review of a granted waiver	0	0	0	2	0	2

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

Indications	2008 (%)	2009 (%)	2010 (%)	2011 (%)
Neurology	6	4	4	2
Uro-nephrology	3	5	2	0
Gastroenterology-hepatology	3	2	1	2
Pneumology-allergology	6	6	41	3
Infectious diseases	8	9	4	4
Cardiovascular diseases	14	9	8	8
Diagnostics	1	1	1	0
Endocrinology-gynaecology-fertility-metabolism	15	16	5	7
Neonatology-paediatric intensive care	1	2	0	2
Immunology-rheumatology-transplantation	6	6	5	3
Psychiatry	3	3	2	3
Pain	3	6	1	0
Haematology-haemostaseology	5	6	4	6
Otorhinolaryngology	1	1	3	0
Oncology	12	11	8	3
Dermatology	3	6	3	1
Vaccines	6	4	2	4
Ophthalmology	2	2	4	1
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				2

Date of next PDCO meeting: 18-20 April 2011

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for:

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