

News from the EMA

Activities of the PDCO

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

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

- Ixekizumab, from Lilly ((immunology-rheumatology-transplantation/oncology));
- Agomelatine, from Servier (psychiatry);
- Vonicog alfa, from BAXTER (haematology-hemostaseology);
- Anti-BAFF monoclonal antibody (LY2127399) from Lilly (immunology-rheumatology-transplantation);
- Poly (oxy-1,2-ethanediyl), α -hydro- ω -methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541), from Lilly (endocrinology-gynaecology-fertility-metabolism);
- Trisodium [3-(((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3'-methyl-2'-(pentanoyl{2''-(tetrazol-5-ylate)biphenyl-4'-ylmethyl}amino)butyrate] hemipentahydrate, from Novartis (cardiovascular diseases).

- **one opinion** on the **refusal of a PIP**, including *waiver*, for:

- Bivalirudin, from The Medicines Company UK Ltd (cardiovascular diseases).

- **three positive opinions** for a **product-specific waiver** for:

- Nifedipine / candesartan (cilexetil), from Bayer (cardiovascular diseases);
- Bimatoprost, from Allergan Pharmaceuticals Ireland (dermatology);
- Glimepiride / atorvastatin (calcium), from GSK (endocrinology-gynaecology-fertility-metabolism / cardiovascular diseases).

- **one opinion** on the **refusal** of a request for waiver for:

- Ranirestat, from Eisai Ltd (endocrinology-gynaecology-fertility-metabolism).

Withdrawals: The PDCO noted that **one application** was withdrawn during the late stage of the evaluation (30 days or less before opinion).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 13 April 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1197 ²	888	283	26	1643
100%	74%	24%	2%	

¹ off patent products, which are developed specifically for children

² incl. 286 waivers

Table 2: Overview on PDCO opinions as of 13 April 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	7	228
Positive opinions on PIPs	2	81	122	201	107	23	536
Negative opinions	0	4	13	7	3	2	29
Positive opinions on modification of a PIP	0	8	51	103	153	46	361
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	1	32
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	2
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	5
Cardiovascular diseases	14	9	8	21	12
Diagnostics	1	1	1	5	0
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	7
Neonatology-paediatric intensive care	1	2	0	0	0
Immunology-rheumatology-transplantation	6	6	5	13	6
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	0
Haematology-haemostaseology	5	6	4	18	3
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	6
Dermatology	3	6	3	10	5
Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	2
Anaesthesiology	1	1	2	1	1

Nutrition	1	0	0	0	0
Other				7	3

Date of next PDCO meeting: 14-16 May 2012

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