

## News from the EMA

### Activities of the PDCO

During its meeting from 7-9 March 2012 the Paediatric Committee (PDCO) adopted the following opinions:

- **two positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
  - Liraglutide, from Novo Nordisk (endocrinology-gynaecology-fertility-metabolism);
  - Rituximab, from Roche ((immunology-rheumatology-transplantation/oncology)
- **one positive opinion** for a **product-specific waiver** for:
  - Acetyl salicylic acid / Clopidogrel (hydrogen sulfate) from Sandoz (cardiovascular diseases)
- **one positive opinion on compliance check** for:
  - Imatinib (meylete) form Novartis (oncology).

**Withdrawals:** The PDCO noted that **four applications** were withdrawn during the late stage of the evaluation (30 days or less before opinion).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 09 March 2012**

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA <sup>1</sup>	
1180 <sup>2</sup>	879	275	26	1621
100%	75%	23%	2%	

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

<sup>2</sup> incl. 281 waivers

**Table 2: Overview on PDCO opinions as of 09 March 2012**

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	4	225
Positive opinions on PIPs	2	81	122	201	107	17	530
Negative opinions	0	4	13	7	3	0	27
Positive opinions on modification of a PIP	0	8	51	103	153	33	348

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	1
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	3
Cardiovascular diseases	14	9	8	21	6
Diagnostics	1	1	1	5	0
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	6
Neonatology-paediatric intensive care	1	2	0	0	0
Immunology-rheumatology-transplantation	6	6	5	13	5
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	5
Dermatology	3	6	3	10	4
Vaccines	6	4	2	12	1
Ophthalmology	2	2	4	8	0
Anaesthesiology	1	1	2	1	1
Nutrition	1	0	0	0	0
Other				7	2

Date of next PDCO meeting: 11-13 April 2012

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for:

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