

## News from the EMA

### Activities of the PDCO

During its meeting from 8-10 February 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Rubidium (82Rb) chloride, from Advanced Accelerator Applications (diagnostics);
- Rubidium (82Rb) chloride, from Jubilant DraxImage Inc (diagnostics);
- ALX-0081, anti-von Willebrand Factor Nanobody, from Ablynx NV (haematology-hemostaseology);
- Ustekinumab, from Janssen-Cilag International NV (immunology-rheumatology-transplantation);
- Hepatitis B (rDNA) surface antigen (adjuvanted), from Dynavax International BV (vaccines);
- Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox), from Bavarian Nordic A/S (vaccines);
- Nitisinone, from Swedish Orphan Biovitrum International AB (endocrinology-gynaecology-fertility-metabolism);
- Anakinra, from Swedish Orphan Biovitrum AB (immunology-rheumatology-transplantation)

- **one positive opinion** for a **product-specific waiver** for:

- Deoxycholic acid, from Intendis GmbH (dermatology).

**Withdrawals:** The PDCO noted that **two applications** were withdrawn during the late stage of the evaluation (30 days or less before opinion).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 10 February 2012**

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA <sup>1</sup>	
1172 <sup>2</sup>	873	273	26	1612
100%	75%	23%	2%	

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

<sup>2</sup> incl. 279 waivers

**Table 2: Overview on PDCO opinions as of 10 February 2012**

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	3	224
Positive opinions on PIPs	2	81	122	201	107	15	528

Negative opinions	0	4	13	7	3	0	27
Positive opinions on modification of a PIP	0	8	51	103	153	21	336
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	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	2
Cardiovascular diseases	14	9	8	21	5
Diagnostics	1	1	1	5	0
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	5
Neonatology-paediatric intensive care	1	2	0	0	0
Immunology-rheumatology-transplantation	6	6	5	13	4
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	3
Dermatology	3	6	3	10	3
Vaccines	6	4	2	12	1
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: 7-9 March 2012

Exclusively reported by Dr. Siegfried Throm, German Association of Research-Based Pharmaceutical Companies (e-mail: [s.throm@vfa.de](mailto:s.throm@vfa.de))  
for:

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