

News from the EMA

Activities of the PDCO

During its meeting from 12-14 October 2011 the Paediatric Committee (PDCO) adopted the following opinions:

- **six positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
 - Human normal immunoglobulin, from Octapharma Pharmazeutika (immunology-rheumatology-transplantation);
 - Delamanid, from Otsuka (infectious diseases);
 - Alemtuzumab, from Genzyme (neurology);
 - Iron(III)-oxyhydroxide from Vifor (uro-nephrology);
 - Dopamine (hydrochloride), from BrePco Biopharma (neonatology- paediatric intensive care);
 - Budesonide, from Neurosis Consortium, (neonatology – paediatric intensive care);
- **one positive opinion** for a **product-specific waiver** for:
 - Icosapent, from S.L.A. Pharma (gastroenterology-hepatology).

Withdrawals: The PDCO noted that **four applications** were withdrawn during the late stages of the evaluation (30 days or less before opinion) of which one was a modification to an agreed PIP and one a request for a compliance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

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 14 October 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1112 ²	822	264	26	1549
100%	74%	24%	2%	

¹ off patent products, which are developed specifically for children

² incl. 263 waivers

Table 2: Overview on PDCO opinions as of 14 October 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	47	67	52	40	216
Positive opinions on PIPs	2	81	122	201	84	490
Negative opinions	0	4	13	7	3	27
Positive opinions on modification of a PIP	0	8	51	103	128	290

Negative opinions on modification of a PIP	0	0	0	4	2	6
Positive opinions on compliance with a PIP	0	5	8	9	5	27
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	9
Uro-nephrology	3	5	2	1
Gastroenterology-hepatology	3	2	1	8
Pneumology-allergology	6	6	41	8
Infectious diseases	8	9	4	11
Cardiovascular diseases	14	9	8	19
Diagnostics	1	1	1	5
Endocrinology-gynaecology-fertility-metabolism	15	16	5	26
Neonatology-paediatric intensive care	1	2	0	0
Immunology-rheumatology-transplantation	6	6	5	10
Psychiatry	3	3	2	7
Pain	3	6	1	1
Haematology-haemostaseology	5	6	4	14
Otorhinolaryngology	1	1	3	1
Oncology	12	11	8	17
Dermatology	3	6	3	6
Vaccines	6	4	2	11
Ophthalmology	2	2	4	6
Anaesthesiology	1	1	2	1
Nutrition	1	0	0	0
Other				6

Date of next PDCO meeting: 9-11 November 2011

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu