

News from the EMA

Activities of the PDCO

During its meeting from 13-15 July 2011 the Paediatric Committee (PDCO) adopted the following opinions:

- **five positive opinions** on a paediatric investigation plan (**PIPs**) for the following product:

- Lopinavir / ritonavir, from Abbott (infectious diseases);
- Eslicarbazepine (acetate), from BIAL - Portela (neurology);
- Teriflunomide, from Sanofi-aventis (neurology);
- Veliparib, from Abbott (oncology);
- Cilengitide, from Merck (oncology).

- **one opinion** for completion of a PIP (Compliance check) for:

- Rotavirus vaccine from Sanofi Pastuer (vaccines)

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

Withdrawals: The PDCO noted that **five applications**, thereof two for modification requests were withdrawn during the late stages of the evaluation (30 days or less before opinion).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 15 July 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1173 ²	789	259	26	1504
100%	73%	24%	3%	

¹ off patent products, which are developed specifically for children

² incl. 257 waivers

Table 2: Overview on PDCO opinions as of 15 July 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	28	204
Positive opinions on PIPs	2	81	122	201	61	467
Negative opinions	0	4	13	7	2	26
Positive opinions on modification of a PIP	0	8	51	103	84	246

Negative opinions on modification of a PIP	0	0	0	4	0	4
Positive opinions on compliance with a PIP	0	5	8	9	3	25
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	6
Uro-nephrology	3	5	2	1
Gastroenterology-hepatology	3	2	1	6
Pneumology-allergology	6	6	41	5
Infectious diseases	8	9	4	10
Cardiovascular diseases	14	9	8	16
Diagnostics	1	1	1	3
Endocrinology-gynaecology-fertility-metabolism	15	16	5	21
Neonatology-paediatric intensive care	1	2	0	3
Immunology-rheumatology-transplantation	6	6	5	7
Psychiatry	3	3	2	5
Pain	3	6	1	1
Haematology-haemostaseology	5	6	4	11
Otorhinolaryngology	1	1	3	0
Oncology	12	11	8	11
Dermatology	3	6	3	5
Vaccines	6	4	2	6
Ophthalmology	2	2	4	5
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				4

Date of next PDCO meeting: 10-12 August 2011

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu