

News from the EMA

Activities of the PDCO

During its meeting from 14-16 May 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Ulimorelin, from Norgine Ltd (gastroenterology-hepatology);
- Tafluprost, from MSD (Europe) Inc., (ophthalmology);
- Azithromycin (monohydrate), from Ixodes AG (infectious diseases / dermatology);
- Odanacatib, from MSD (Europe), Inc. (immunology-rheumatology-transplantation);
- Cabozantinib (S)-malate, from Exelixis, Inc. (oncology);
- Ponatinib, from Ariad Pharma, Ltd. (oncology);
- Lumacaftor, from Voisin Consulting SARL (pneumology-allergology);
- Melatonin, from RAD Neurim Pharmaceuticals EEC Ltd (neurology);
- Albiglutide, from GlaxoSmithKline LLC (endocrinology-gynaecology-fertility-metabolism);
- Golimumab, from Janssen Biologics B.V. (immunology-rheumatology-transplantation/gastroenterology-hepatology).

- **one opinion** on a revised **positive PIP after re-examination of a positive PIP** for:

- Liraglutide, from Novo Nordisk A/S (endocrinology-gynaecology-fertility-metabolism)

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

- Amlodipine (besilate) / valsartan, from Synthon B.V. (cardiovascular diseases);
- Alisporivir, from Novartis Europharm Ltd (infectious diseases);
- Masitinib (mesylate), from AB Science (oncology).

Withdrawals: The PDCO noted that **four applications**, of which three were requests of modifications to agreed PIPs, were withdrawn during the late stage of the evaluation (30 days or less before opinion).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 16 May 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1219 ²	907	286	26	1682
100%	74%	24%	2%	

¹ off patent products, which are developed specifically for children

² incl. 293 waivers

Table 2: Overview on PDCO opinions as of 16 May 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	231
Positive opinions on PIPs	2	81	122	201	107	23	546
Negative opinions	0	4	13	7	3	2	29
Positive opinions on modification of a PIP	0	8	51	103	153	46	376
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	4
Uro-nephrology	3	5	2	4	2
Gastroenterology-hepatology	3	2	1	10	2
Pneumology-allergology	6	6	41	10	4
Infectious diseases	8	9	4	15	9
Cardiovascular diseases	14	9	8	21	15
Diagnostics	1	1	1	5	0
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	10
Neonatology-paediatric intensive care	1	2	0	0	1
Immunology-rheumatology-transplantation	6	6	5	13	6
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	2
Haematology-haemostaseology	5	6	4	18	3
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	11
Dermatology	3	6	3	10	5
Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	3
Anaesthesiology	1	1	2	1	1
Nutrition	1	0	0	0	0
Other				7	6

Date of next PDCO meeting: 6-8 June 2012

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for:

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