

News from the EMA

Activities of the PDCO

During its meeting from 10-12 August 2011 the Paediatric Committee (PDCO) adopted the following opinions:

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

- **Potassium sulphate / magnesium sulphate, heptahydrate / sodium sulphate, anhydrous**, from Ipsen Pharma (gastroenterology-hepatology);
- **Octenidine dihydrochloride / prednicarbate**, from Almirall Hermal GmbH, (dermatology);
- **Mepolizumab**, from Glaxo, (pneumology – allergology);
- **Loxapine**, from Alexza UK Ltd (psychiatry);
- **Vatreptacog alfa (activated)**, from Novo Nordisk A/S, (haematology-haemostaseology);
- **Deferasirox**, from Novartis, (haematology-haemostaseology);
- **Eltrombopag**, from GSK, (haematology-haemostaseology);
- **Colestilan**, from Mitsubishi Pharma Europe Ltd. (uro-nephrology);

- **four positive opinions** for **product-specific waivers** for:

- **Quinidine sulphate / dextromethorphan hydrobromide**, from Avanir Pharm. (neurology);
- **Vildagliptin**, from Novartis (endocrinologygynaecology-fertility-metabolism);
- **Progesterone**, from Teva Pharmaceuticals (endocrinology-gynaecology-fertility-metabolism);
- **Metformin hydrochloride / dapagliflozin**, from BMS / AstraZeneca (endocrinology-gynaecology-fertility-metabolism);

- **one opinion** on the **refusal** of a request for waiver for:

- **Antithrombin alfa**, from GTC Biotherapeutics UK Ltd (haematology-haemostaseology).

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

Withdrawals: The PDCO noted that **two applications** were withdrawn during the late stages of the evaluation (30 days or less before opinion).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 12 August 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1087 ²	800	261	26	1516
100%	74%	24%	2%	

¹ off patent products, which are developed specifically for children

² incl. 259 waivers

Table 2: Overview on PDCO opinions as of 12 August 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	32	208
Positive opinions on PIPs	2	81	122	201	69	475
Negative opinions	0	4	13	7	3	27
Positive opinions on modification of a PIP	0	8	51	103	97	259
Negative opinions on modification of a PIP	0	0	0	4	1	5
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	7
Uro-nephrology	3	5	2	1
Gastroenterology-hepatology	3	2	1	6
Pneumology-allergology	6	6	41	6
Infectious diseases	8	9	4	10
Cardiovascular diseases	14	9	8	16
Diagnostics	1	1	1	4
Endocrinology-gynaecology-fertility-metabolism	15	16	5	23
Neonatology-paediatric intensive care	1	2	0	3
Immunology-rheumatology-transplantation	6	6	5	9
Psychiatry	3	3	2	6
Pain	3	6	1	1
Haematology-haemostaseology	5	6	4	11
Otorhinolaryngology	1	1	3	0
Oncology	12	11	8	14
Dermatology	3	6	3	5
Vaccines	6	4	2	8
Ophthalmology	2	2	4	6
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				4

Date of next PDCO meeting: 7-9 September 2011

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for:

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