

News from the EMA

Activities of the PDCO

During its meeting from 5-7 September 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Human heterologous liver cells, from Cytonet (gastroenterology-hepatology);
- Certolizumab pegol, from UCB Pharma (immunology-rheumatology-transplantation);
- Ceftobiprole medocaril (sodium), from Basilea Pharmaceutica (infectious diseases);
- Dermatophagoides pteronyssinus / dermatophagoides farinae, from ALK-Abelló A/S (pneumology - allergology / oto-rhino-laryngology);
- Bitopertin, from Roche (psychiatry).

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

- Amlodipine (besylate) / candesartan (cilexetil), from Zentiva (cardiovascular diseases);
- Perindopril (tosilate) / amlodipine (besilate), from Teva Pharma (cardiovascular diseases);
- Atorvastatin / ramipril / acetyl salicylic acid, from Ferrer Internacional, S.A. (cardiovascular diseases);
- Folic acid, from Endocyte Europe B.V. (diagnostic / oncology);
- Etarfolatide, from Endocyte Europe B.V. (diagnostic / oncology);
- Fostamatinib, from AstraZeneca (immunology-rheumatology-transplantation);
- Dexketoprofen (trometamol) / tramadol (hydrochloride), from Menarini Ricerche (pain).

Following the re-examination of the **positive opinion** on a **modification** to an agreed PIP adopted on 6 July 2012 for **oseltamivir phosphate**, from Roche (infectious diseases) the PDCO **maintained** its 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 07 September 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1282 ²	964	292	26	1749
100%	75%	23%	2%	

¹ off patent products, which are developed specifically for children

² incl. 321 waivers

Table 2: Overview on PDCO opinions as of 07 September 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	31	252
Positive opinions on PIPs	2	81	122	201	107	66	579
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	125	440
Negative opinions on modification of a PIP	0	0	0	4	2	1	7
Positive opinions on compliance with a PIP	0	5	8	9	9	2	33
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	6
Uro-nephrology	3	5	2	4	4
Gastroenterology-hepatology	3	2	1	10	6
Pneumology-allergology	6	6	41	10	7
Infectious diseases	8	9	4	15	18
Cardiovascular diseases	14	9	8	21	25
Diagnostics	1	1	1	5	2
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	20
Neonatology-paediatric intensive care	1	2	0	0	2
Immunology-rheumatology-transplantation	6	6	5	13	10
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	8
Haematology-haemostaseology	5	6	4	18	7
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	16
Dermatology	3	6	3	10	12

Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	4
Anaesthesiology	1	1	2	1	2
Nutrition	1	0	0	0	0
Other				7	9

Date of next PDCO meeting: 3-5 October 2012

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for:

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