

News from the EMA

Activities of the PDCO

During its meeting from 7-9 November 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Posaconazole, from MSD (infectious diseases);
- Faldaprevir, from Boehringer Ingelheim (infectious diseases);
- (S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphorylamino)-Propanoate (GS-7977), from Gilead Sciences (infectious diseases);
- Chimeric anti-disialoganglioside (GD2) monoclonal antibody (NSC764038), from United Therapeutics (oncology);
- Spheroids of human autologous matrix-associated chondrocytes, from co.don AG (transplantation);
- Dextran, 3 [(2-aminoethyl)thio]propyl 17-carboxy-10,13,16-tris(carboxymethyl)-8-oxo-4-thia-7,10,13,16-tetrazaheptadec-1-yl 3-[[2-[[1-imino-2-(D-mannopyranosylthio)ethyl]amino]ethyl]thio]propyl ether, from Navidea Biopharmaceuticals (diagnostics);
- Meningococcus ABCWY vaccine, from Novartis Vaccines (vaccines);
- Human normal immunoglobulin (LFB-IgSC), from LFB Biotechnologies (immunology-rheumatology-transplantation).

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

- Ivermectin, from Galderma (dermatology);
- Expanded autologous bone marrow-derived osteoblastic cells, from Bone Therapeutics (other: musculoskeletal diseases);
- Elagolix, from AbbVie (endocrinology-gynaecology-fertility-metabolism);
- Skeletal muscle derived cells, from Innovacell Biotechnologie (uro-nephrology).

Withdrawals: The PDCO noted that **two applications** were withdrawn during the late stage of the evaluation (30 days or less before opinion).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 09 November 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1310 ²	989	294	27	1789
100%	76%	22%	2%	

¹ off patent products, which are developed specifically for children

² incl. 332 waivers

Table 2: Overview on PDCO opinions as of 09 November 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	44	265
Positive opinions on PIPs	2	81	122	201	107	83	596
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	148	463
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	4	35
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	11
Uro-nephrology	3	5	2	4	4
Gastroenterology-hepatology	3	2	1	10	6
Pneumology-allergology	6	6	41	10	8
Infectious diseases	8	9	4	15	19
Cardiovascular diseases	14	9	8	21	33
Diagnostics	1	1	1	5	2
Endocrinology-gynaecology- fertility-metabolism	15	16	5	28	26
Neonatology-paediatric intensive care	1	2	0	0	2
Immunology-rheumatology-	6	6	5	13	13

transplantation					
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	9
Haematology- haemostaseology	5	6	4	18	9
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	17
Dermatology	3	6	3	10	13
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	13

Date of next PDCO meeting: 5-7 December 2012

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for:

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