

News from the EMA

Activities of the PDCO

During its meeting from 4-6 July 2012 the Paediatric Committee (PDCO) adopted the following opinions:

- **14 positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
 - Apremilast, from Celgene (dermatology);
 - Naloxegol, from AstraZeneca (gastroenterology-hepatology);
 - Human fibrinogen, from Octapharma GmbH (haematology-hemostaseology);
 - Eculizumab, from Alexion Europe SAS (immunology-rheumatology-transplantation);
 - Olokizumab, from UCB Pharma S.A. (immunology-rheumatology-transplantation);
 - Asunaprevir, from BMS (infectious diseases);
 - Daclatasvir, from BMS (infectious diseases);
 - Peginterferon lambda-1a, from BMS (infectious diseases);
 - Misoprostol, from Ferring Pharmaceuticals A/S (endocrinology-gynaecology-fertility-metabolism);
 - Pitolisant, from Bioprojet Pharma (neurology);
 - Pegylated human interferon beta-1a, from Biogen Idec Ltd. (neurology);
 - N-[6-(cis-2,6-Dimethylmorpholin-4-yl)pyridine-3-yl]-2-methyl-4'-(trifluoromethoxy) [1,1'-biphenyl]-3-carboxamide diphosphate, from Novartis Europharm Ltd (oncology);
 - MAGE-A3 recombinant protein, from GlaxoSmithKline Biologicals (oncology);
 - Ex-vivo expanded human autologous epithelium containing stem cells, from Chiesi Farmaceutici (ophthalmology);
 - Indacaterol (acetate) / mometasone (furoate), from Novartis Europharm (pneumology – allergology).

- **one opinion** on a revised **positive PIP after re-examination of a positive PIP** for:
 - turoctocog alfa, from Novo Nordisk A/S (haematology/hemostaseology).

- **seven positive opinions** for a **product-specific waiver** for:
 - Sitagliptin / atorvastatin, from MSD (endocrinology-gynaecology-fertility-metabolism);
 - Autologous tumour-derived immunoglobulin idiotype coupled to keyhole limpet haemocyanin, from Biovest Europe Ltd. (oncology);
 - [N-((2S,3R,3aS,3'R,4a'R,6S,6a'R,6b'S,7aR,12a'S,12b'S,Z)-3,6,11',12b'-tetramethyl-2',3a,3',4,4',4a',5,5',6,6',6a',6b',7,7a,7',8',10',12',12a',12b'-icosahydro-1'H,3Hspiro[furo[3,2-b]pyridine-2,9'-naphtho[2,1-a]azulene]-3'-yl)methanesulfonamide hydrochloride], from Voisin Consulting (oncology);
 - Rosuvastatin / ezetimibe, from EGIS Pharmaceuticals (cardiovascular Diseases);
 - Amlodipine (besilate) / lisinopril (dihydrate) / rosuvastatin (calcium), from Gedeon Richter Plc. (cardiovascular diseases);
 - Recombinant human antibody against activin type IIB receptors, from Novartis Europharm (neurology);
 - Co-crystal of rac-tramadol HCl / celecoxib, from Laboratorios del Dr. Esteve S.A. (pain).

Withdrawals: The PDCO noted the following withdrawals: **three applications** during the late stage of the evaluation (30 days or less before opinion) and **an opinion after re-examination** of an opinion adopted during the June PDCO meeting for ranirestat,

from Eisai Ltd (endocrinology-gynaecology-fertility-metabolism) before the decision was adopted by the Agency.

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 6 July 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1246 ²	931	289	26	1711
100%	75%	23%	2%	

¹ off patent products, which are developed specifically for children

² incl. 304 waivers

Table 2: Overview on PDCO opinions as of 6 July 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	20	241
Positive opinions on PIPs	2	81	122	201	107	56	569
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	96	411
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	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	6
Uro-nephrology	3	5	2	4	2
Gastroenterology-hepatology	3	2	1	10	2
Pneumology-allergology	6	6	41	10	5
Infectious diseases	8	9	4	15	13
Cardiovascular diseases	14	9	8	21	21
Diagnostics	1	1	1	5	2

Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	12
Neonatology-paediatric intensive care	1	2	0	0	1
Immunology-rheumatology-transplantation	6	6	5	13	8
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	6
Haematology-haemostaseology	5	6	4	18	7
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	14
Dermatology	3	6	3	10	7
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: 15-17 August 2012

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for:

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