

News from the EMA

Activities of the PDCO

During its meeting from 18-20 April 2011 the Paediatric Committee (PDCO) thanked Alexandra Soldatou, former alternate from Greece, for her work as she has resigned from the Committee. The PDCO adopted the following opinions:

- **13 positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
 - Octocog alfa (recombinant coagulation factor VIII), from Bayer Schering, in the area of haematology-hemostaseology;
 - Human normal immunoglobulin, from Bio Products Laboratory, in the area of immunology-rheumatology-transplantation / haematology-hemostaseology;
 - Treosulfan, from medac Gesellschaft für klinische Spezialpräparate, in the area of immunology-rheumatology-transplantation / oncology;
 - 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (Lu AA21004), from Lundbeck A/S, in the area of psychiatry;
 - Cobicistat, from Gilead Sciences, in the area of infectious diseases;
 - Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil (as fumarate), from Gilead Sciences International Limited, in the area of infectious diseases;
 - Perflubutane, from Granzer Regulatory Consulting & Services, in the area of diagnostic / cardiovascular diseases;
 - Ipilimumab, from Bristol-Myers Squibb, in the area of oncology;
 - Ombrabulin, from Sanofi-Aventis, in the area of oncology;
 - (S)-3'-(OH)-desazadesferrithiocin-polyether, magnesium salt (FBS0701), from FerroKin BioSciences, Ltd, in the area of haematology-hemostaseology;
 - Recombinant fusion protein consisting of Human Coagulation Factor IX attached to the Fc domain of Human IgG1 (rFIXFc), from Biogen Idec Ltd., in the area of haematology-hemostaseology;
 - Autologous oral mucosal epithelial cells, from CellSeed Europe S.A.R.L., in the area of ophthalmology;
 - Edoxaban tosylate, from Daiichi Sankyo, in the area of cardiovascular diseases.

- **three positive opinions** for product-specific **waivers** in all subsets of the paediatric population for:

- Canagliflozin/Metformin, from Johnson & Johnson Pharmaceutical Research & Development, in the area of endocrinology-gynaecology-fertility-metabolism;
- Gallium [68 Ga] Chloride / Germanium [68 Ge] Chloride, from Eckert & Ziegler Radiopharma GmbH, in the area of other (Radiopharmaceuticals);
- Rivastigmine, from Novartis Europharm Ltd., in the area of Neurology.

- **one opinion** after re-examination, on a request for modification of an agreed PIP

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

Withdrawals: The PDCO noted that **four applications**, of which one was for a modification of an agreed PIP, 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 20 April 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1022 ²	750	246	26	1444
100%	73%	24%	3%	

¹ off patent products, which are developed specifically for children

² incl. 240 waivers

Table 2: Overview on PDCO opinions as of 20 April 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	17	193
Positive opinions on PIPs	2	81	122	201	41	447
Negative opinions	0	4	13	7	1	25
Positive opinions on modification of a PIP	0	8	51	103	42	204
Negative opinions on modification of a PIP	0	0	0	4	0	4
Positive opinions on compliance with PIP	0	5	8	9	0	22
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	4
Uro-nephrology	3	5	2	0
Gastroenterology-hepatology	3	2	1	3
Pneumology-allergology	6	6	41	3
Infectious diseases	8	9	4	7
Cardiovascular diseases	14	9	8	10
Diagnostics	1	1	1	1
Endocrinology-gynaecology- fertility-metabolism	15	16	5	11
Neonatology-paediatric intensive care	1	2	0	2
Immunology-rheumatology- transplantation	6	6	5	5
Psychiatry	3	3	2	3
Pain	3	6	1	0
Haematology-haemostaseology	5	6	4	7

Otorhinolaryngology	1	1	3	0
Oncology	12	11	8	4
Dermatology	3	6	3	2
Vaccines	6	4	2	5
Ophthalmology	2	2	4	3
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				2

Date of next PDCO meeting: 18-20 May 2011

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