

News from the EMA

Activities of the PDCO

During its meeting from 9-11 November 2011 the Paediatric Committee (PDCO) adopted the following opinions:

- **eleven positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
 - Deferiprone, from Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF), (haematology-hemostaseology);
 - Nonacog alfa (recombinant coagulation factor IX), from Baxter Innovations GmbH, (haematology-hemostaseology);
 - Human monoclonal antibody against IL-6 (CNTO 136), from Janssen-Cilag International NV (rheumatology-transplantation);
 - Macitentan, from Actelion Registration Ltd (immunology-rheumatology-transplantation / cardiovascular diseases / pneumology-allergology);
 - Purified antigen fractions of inactivated split virion Influenza manufactured in the Dresden plant: A/H1N1 A/H3N2 B/Victoria B/Yamagata, from GlaxoSmithKline Biologicals S.A. (vaccines);
 - Lomitapide, from Aegerion Pharmaceuticals (endocrinology-gynaecology-fertility-metabolism);
 - (1-(3-chloro-5-{[4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid monomaleate), from Eisai Limited (haematology-hemostaseology);
 - Chimeric monoclonal anti-Shiga toxin (Stx) antibodies caStx1 and caStx2, from LFB Biotechnologies (infectious diseases);
 - Recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein, from Teva GmbH (oncology / haematology-hemostaseology);
 - Afamelanotide, from Clinuvel (UK) Limited (dermatology).
- **two positive opinions** for **product-specific waivers** for:
 - Liraglutide / Insulin degludec, from Novo Nordisk A/S (endocrinology-gynaecology-fertility-metabolism);
 - Esketamine, from Auris Medical Limited (oto-rhino-laryngology).
- **one positive opinion** on **compliance check** for:
 - insulin glargine, from Sanofi-Aventis Deutschland GmbH (endocrinology-gynaecology-fertility-metabolism)

- an **opinion** on the **confirmation of the current list of class waivers**.

Withdrawals: The PDCO noted that **one application** was withdrawn during the late stage of the evaluation (30 days or less before opinion).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 11 November 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1127 ²	837	264	26	1564
100%	74%	24%	2%	

¹ off patent products, which are developed specifically for children

² incl. 268 waivers

Table 2: Overview on PDCO opinions as of 11 November 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	47	67	52	42	218
Positive opinions on PIPs	2	81	122	201	94	500
Negative opinions	0	4	13	7	3	27
Positive opinions on modification of a PIP	0	8	51	103	139	301
Negative opinions on modification of a PIP	0	0	0	4	2	6
Positive opinions on compliance with a PIP	0	5	8	9	7	29
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	10
Uro-nephrology	3	5	2	4
Gastroenterology-hepatology	3	2	1	9
Pneumology-allergology	6	6	41	8
Infectious diseases	8	9	4	14
Cardiovascular diseases	14	9	8	20
Diagnostics	1	1	1	5
Endocrinology-gynaecology-fertility-metabolism	15	16	5	26
Neonatology-paediatric intensive care	1	2	0	0
Immunology-rheumatology-	6	6	5	10

transplantation				
Psychiatry	3	3	2	8
Pain	3	6	1	2
Haematology- haemostaseology	5	6	4	17
Otorhinolaryngology	1	1	3	1
Oncology	12	11	8	18
Dermatology	3	6	3	7
Vaccines	6	4	2	12
Ophthalmology	2	2	4	6
Anaesthesiology	1	1	2	1
Nutrition	1	0	0	0
Other				6

Date of next PDCO meeting: 7-9 December 2011

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for:

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