

News from the EMA

Activities of the PDCO

During its meeting from 4-6 August 2010 the Paediatric Committee (PDCO) adopted the following opinions:

- **nine positive opinions** on paediatric investigation plans (PIPs) for the following products:
 - **Artemether / lumefantrine**, from Novartis, in the area of infectious diseases;
 - **Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent**, from Abbott, in the area of infectious diseases;
 - **Entecavir**, from Bristol-Myers Squibb Pharma EEIG, in the area of infectious diseases;
 - **Romiplostim**, from Amgen Europe B.V, in the area of haematology-haemostaseology;
 - **Rufinamide**, from Eisai Ltd, in the area of neurology;
 - **CAT-354, a neutralising human IgG4 monoclonal antibody with specificity for human interleukin-13 (IL-13)**, from MedImmune Ltd, in the area of pneumology - allergology;
 - **Glycinamide, L-cysteinyl-L-phenylalanyl-L-isoleucyl-6-oxo-L-lysyl-L-asparaginyll-cysteinyl-L-prolyl-N5-(1-methylethyl)-L-ornithyl-, cyclic(1 → 6)-disulfide acetate (FE 202158 acetate)**, from International PharmaScience Center, Ferring Pharmaceuticals A/S, in the area of cardiovascular diseases;
 - **Guanfacine hydrochloride**, from Shire Pharmaceutical Contracts Ltd, in the therapeutic area of psychiatry;
 - **Mirabegron**, from Astellas Pharma Europe B.V., in the therapeutic area of uro-nephrology.
- **five positive opinions** for product-specific **waivers** in all subsets of the paediatric population for the following medicines:
 - **(R)-3(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrilephosphate**, from Novartis Europharm Ltd, in the area of oncology;
 - **Copper [64 Cu] Chloride**, from Sparkle, in the area of ophthalmology;
 - **Pasireotide**, from Novartis Europharm Ltd, in the area of endocrinology-gynaecology-fertility-metabolism;
 - **Amlodipine camsylate / losartan potassium**, from Hanmi Europe Limited, in the area of cardiovascular diseases;
 - **Afamelanotide**, from Clinuvel (UK) Limited, in the area of dermatology.
 -
- **seven positive opinions on modifications to an agreed PIP and one opinion after re-examination of the vote on an application for a modification.**

Withdrawals

The PDCO noted that four applications were withdrawn during the late stages of the evaluation (30 days or less before opinion). One request for a modification was withdrawn before the EMA decision.

Compliance Check

The PDCO adopted the following two positive opinions on compliance checks for:

- **midazolam (as hydrochloride)**, from ViroPharma SPRL, in the area of neurology and
- **nevirapine**, from Boehringer Ingelheim International GmbH, in the therapeutic area of infectious diseases.

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 August 2010

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
907	655	229	23	1283
100%	72%	25%	3%	

¹ off patent products, which are developed specifically for children

² incl. 198 waivers

Table 2: Overview on PDCO opinions as of 6 August 2010

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	Total
Positive opinions on full waivers	10	48	67	37	161
Positive opinions on PIPs	2	81	122	64	269
Negative opinions	0	4	13	5	22
Positive opinions on modification of a PIP	0	8	51	69	128
Negative opinions on modification of a PIP	0	0	0	4	4
Positive opinions on compliance with PIP	0	5	8	7	20
Negative opinions on compliance with a PIP	0	0	1	0	1

Table 3: Areas covered by applications for PIPs/full waivers

Indications	2008 (%)	2009 (%)	2010 (%)
Neurology	6	4	4
Uro-nephrology	3	5	1
Gastroenterology-hepatology	3	2	1
Pneumology-allergology	6	6	45
Infectious diseases	8	9	4
Cardiovascular diseases	14	9	8
Diagnostics	1	1	1
Endocrinology-gynaecology- fertility-metabolism	15	16	5

Neonatology-paediatric intensive care	1	2	0
Immunology-rheumatology-transplantation	6	6	4
Psychiatry	3	3	2
Pain	3	6	1
Haematology-haemostaseology	5	6	3
Otorhinolaryngology	1	1	3
Oncology	12	11	8
Dermatology	3	6	3
Vaccines	6	4	2
Ophthalmology	2	2	4
Anaesthesiology	1	1	1
Nutrition	1	0	0

Date of next PDCO meeting: 8-9 September 2010

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