

News from the EMEA

Activities of the PDCO

During its meeting from 14-16 July 2010 the Paediatric Committee (PDCO) adopted the following opinions:

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

- **Bosutinib (SKI-606)**, from Wyeth Europa Limited, in the area of oncology;
- **Recombinant human glutamic acid decarboxylase (rhGAD65)**, from Diamyd Medical AB, in the area of endocrinology-gynaecology-fertility-metabolism;
- **Ceftaroline fosamil**, from AstraZeneca AB, in the area of infectious diseases;
- **Emtricitabine / tenofovir disoproxil fumarate/ rilpivirine hydrochloride**, from Gilead Sciences International Limited, in the area of infectious diseases;
- **Dexamethasone**, from Allergan Pharmaceuticals Ireland, in the area of ophthalmology;
- **Chloroprocaine hydrochloride**, from Sintetica Italia S.r.l., in the area of anaesthesiology;
- **Ivabradine hydrochloride**, from Les Laboratoires Servier, in the area of cardiovascular diseases;
- **Clindamycin phosphate / tretinoin**, from MEDA Pharma GmbH & Co. KG, in the area of dermatology.

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

- **Telmisartan / hydrochlorothiazide**, from Boehringer Ingelheim International GmbH, in the area of cardiovascular diseases;
- **Indapamide / amlodipine besilate**, from Les Laboratoires Servier, in the area of cardiovascular diseases;
- **Perindopril erbumine / amlodipine besylate**, from Krka, d.d., Novo mesto, in the area of cardiovascular diseases;
- **Valsartan / amlodipine besylate**, from Krka, d.d., Novo mesto, in the area of cardiovascular diseases;
- **Vildagliptin / metformin hydrochloride**, from Novartis Europharm Limited, in the area of endocrinology-gynaecology-fertility-metabolism;
- **Insulin glargine / lixisenatide**, from Sanofi-Aventis R&D, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Bazedoxifene / conjugated estrogens**, from Pfizer Ltd, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism.

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

Withdrawals

The PDCO noted that three applications were withdrawn during the late stages of the evaluation (30 days or less before opinion).

Compliance Check

The PDCO adopted a positive opinion on compliance check for **esomeprazole sodium**, from AstraZeneca AB, in the area of gastroenterology-hepatology.

Priority list of off-patent medicines

In order to ensure that funds are directed into research of medicinal products with the highest need in the paediatric population, the PDCO has revised and, after public consultation, adopted a revised priority list of off-patent products for which studies are required as a basis for call of the FP7 programme in 2011. This list is published on the EMA website.

Table 1: Applications for PIPs and waivers as of 16 July 2010

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
886 ²	641	223	23	1262
100%	72%	25%	3%	

¹ off patent products, which are developed specifically for children

² incl. 195 waivers

Table 2: Overview on PDCO opinions as of 16 July 2010

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	Total
Positive opinions on full waivers	10	48	67	31	156
Positive opinions on PIPs	2	81	122	55	260
Negative opinions	0	4	13	5	22
Positive opinions on modification of a PIP	0	8	51	62	121
Negative opinions on modification of a PIP	0	0	0	4	4
Positive opinions on compliance with PIP	0	5	8	5	18
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	2
Gastroenterology-hepatology	3	2	1
Pneumology-allergology	6	6	46
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	2
Haematology-haemostaseology	5	6	3

Otorhinolaryngology	1	1	1
Oncology	12	11	7
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: 4-6 August 2010

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