

News from the EMA

Activities of the PDCO

During its meeting from 8-10 December 2010 the Paediatric Committee (PDCO) elected two of its members, Dirk Mentzer and Paolo Rossi, to represent the Committee in the European paediatric research network at the EMA (EnprEMA) and welcomed the appointment of Dr Nela Vilceanu by the CHMP as the new member from Romania. The following opinions were adopted:

- **10 positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
 - (2S,3R,4R,5S,6R)-2-(4-Chloro-3-{3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyltetrahydro-pyran-3,4,5-triol, from Boehringer Ingelheim, in the area of endocrinology-gynaecology-fertility-metabolism;
 - Lixisenatide, from Sanofi-Aventis R&D, in the area of endocrinology-gynaecology-fertility-metabolism;
 - Ozenoxacin, from Ferrer Internacional, in the area of infectious diseases;
 - Amikacin Sulfate, from Transave, Inc., in the area of infectious diseases / pneumology - allergology;
 - Meropenem, from NeoMero Consortium, in the area of neonatology - paediatric intensive care / infectious diseases;
 - Pegloticase, from Savient Pharmaceuticals, in the area of immunology-rheumatology-transplantation / oncology;
 - Sotrastaurin acetate, from Novartis, in the area of immunology-rheumatology-transplantation;
 - Grass pollen allergen extract from *Dactylis glomerata* L., *Anthoxanthum odoratum* L., *Lolium perenne* L., *Poa pratensis* L. and *Phleum pratense* L., from Stallergenes, in the area of pneumology - allergology;
 - House dust mites allergen extract from *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* (50/50), from Stallergenes, in the area of pneumology - allergology;
 - Rizatriptan benzoate, from MSD, in the area of pain.

- **three positive opinions** for product-specific **waivers** in all subsets of the paediatric population for:
 - Indapamide, amlodipine besilate, perindopril arginine, from Servier, in the area of cardiovascular disease;
 - Nepafenac, from Alcon Laboratories (UK) Ltd, in the area of ophthalmology;
 - Tesamorelin, from Theratechnologies in the area of endocrinology-gynaecology-fertility-metabolism.

- **one opinion on the refusal** of a request for waiver for:
 - Recombinant human granulocyte colony stimulating factor / recombinant human albumin fusion protein, from Teva, in the area of oncology.

- **seven positive opinions on modifications to an agreed PIP**

- **two positive opinions on compliance check for:**
 - Tretinoin / clindamycin phosphate, from Meda Pharma, in the area of dermatology
 - Clopidogrel, from Sanofi Pharma BMS, in the area of cardio vascular diseases.

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

Class waivers: The PDCO adopted an opinion on the review of the current list of class waivers for medicinal products or classes of medicinal products to be used in specific conditions. The list of class waivers is updated at least once a year by the PDCO. The requirement to submit the results of studies done in accordance with a PIP should be waived, in all subsets of the paediatric population, for medicines developed for the following conditions, on the grounds that the diseases or conditions occur only in adult populations:

- Treatment of primary myelofibrosis;
- Treatment of diabetic macular oedema;
- Treatment of mesothelioma;
- Treatment of actinic keratosis.

For the following conditions a class waiver was **not** adopted: treatment of leiomyoma of uterus, treatment of pituitary gigantism, treatment of secondary myelofibrosis, treatment of myelodysplastic syndrome and treatment of hereditary amyloidosis.

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 10 December 2010

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
956 ²	696	235	25	1364
100%	73%	24%	3%	

¹ off patent products, which are developed specifically for children

² incl. 214 waivers

Table 2: Overview on PDCO opinions as of 10 December 2010

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	Total
Positive opinions on full waivers	10	48	67	52	176
Positive opinions on PIPs	2	81	122	201	406
Negative opinions	0	4	13	7	24
Positive opinions on modification of a PIP	0	8	51	103	162
Negative opinions on modification of a PIP	0	0	0	4	4
Positive opinions on compliance with PIP	0	5	8	9	22
Negative opinions on compliance with a PIP	0	0	1	0	1
Opinions on review of a granted waiver	0	0	0	2	2

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

Indications	2008 (%)	2009 (%)	2010 (%)
Neurology	6	4	3
Uro-nephrology	3	5	2
Gastroenterology-hepatology	3	2	1
Pneumology-allergology	6	6	41
Infectious diseases	8	9	4
Cardiovascular diseases	14	9	8
Diagnostics	1	1	1
Endocrinology-gynaecology- fertility-metabolism	15	16	6
Neonatology-paediatric intensive care	1	2	0
Immunology-rheumatology- transplantation	6	6	5
Psychiatry	3	3	1
Pain	3	6	1
Haematology-haemostaseology	5	6	4
Otorhinolaryngology	1	1	3
Oncology	12	11	9
Dermatology	3	6	1
Vaccines	6	4	2
Ophthalmology	2	2	4
Anaesthesiology	1	1	2
Nutrition	1	0	0

Date of next PDCO meeting: 12-14 January 2010

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for:

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