

News from the EMA

Activities of the PDCO

During its meeting from 18-20 May 2011 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Chlorhexidine gluconate / isopropyl alcohol, from 3M Health Care (dermatology);
- Canagliflozin, from Johnson & Johnson (endocrinology-gynaecology-fertility-metabolism);
- Recombinant fusion protein consisting of Human Coagulation Factor VIII attached to the Fc domain of Human IgG1 (rFVIII-Fc), from Biogen Idec (haematology-haemostaseology);
- Ocrelizumab, from Roche (neurology);
- derivative of Octahydro-4-hydroxy-4-[phenylethynyl]-1H-indole-1-carboxylic acid ester (AFQ056), from Novartis (neurology);
- three applications for chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae), from Granzer Regulatory Consulting & Services (pneumology - allergology / oto-rhino-laryngology);
- two applications for chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis, from Granzer Regulatory Consulting & Services (pneumology - allergology / oto-rhino-laryngology);
- two applications for chemically modified extract of trees pollen from Birch and Alder, from Granzer Regulatory Consulting & Services (pneumology - allergology / oto-rhino-laryngology);
- Influenza vaccine (type A, H1N1 / type A, H3N2 / type B, yamagata lineage and victoria lineage) from MedImmune (vaccines);
- Risperidone, from Wockhardt UK (psychiatry).

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

- Pravastatin sodium / acetylsalicylic acid, from Teva (cardiovascular diseases);
- Progesterone, from IBSA Farmaceutici Italia (endocrinology-gynaecology-fertility-metabolism);
- Alogliptin (benzoate) / metformin (hydrochloride), from Takeda (endocrinology-gynaecology-fertility-metabolism);
- Ciclosporin, from Allergan Pharmaceuticals (ophthalmology).

- **one opinion** for completion of a PIP (Compliance check) for:

- Meningitis vaccine from Novartis Vaccines

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

Withdrawals: The PDCO noted that **seven applications** were withdrawn during the late stages of the evaluation (30 days or less before opinion).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 May 2011

PIPs/ waivers Total number	Applications for	Indications covered by
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of applications	New products	Line extensions	PUMA ¹	applications for PIPs/waivers
1033 ²	757	250	26	1457
100%	73%	24%	3%	

¹ off patent products, which are developed specifically for children

² incl. 243 waivers

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

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	21	197
Positive opinions on PIPs	2	81	122	201	55	461
Negative opinions	0	4	13	7	1	25
Positive opinions on modification of a PIP	0	8	51	103	60	222
Negative opinions on modification of a PIP	0	0	0	4	0	4
Positive opinions on compliance with a PIP	0	5	8	9	1	23
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	5
Uro-nephrology	3	5	2	0
Gastroenterology-hepatology	3	2	1	4
Pneumology-allergology	6	6	41	3
Infectious diseases	8	9	4	7
Cardiovascular diseases	14	9	8	12
Diagnostics	1	1	1	2
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	7
Dermatology	3	6	3	2

Vaccines	6	4	2	5
Ophthalmology	2	2	4	4
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				3

Date of next PDCO meeting: 15-17 June 2011

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for:

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