

News from the EMA

Activities of the PDCO

During its meeting from 6-8 June 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Serelaxin, from Novartis Europharm Ltd (cardiovascular diseases)
- Ethanol, from Orfagen (dermatology);
- Migalastat (hydrochloride), from Glaxo Group Limited (endocrinology-gynaecology-fertility-metabolism);
- Apremilast, from Celgene Europe Limited (immunology-rheumatology-transplantation);
- Potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol, from Swiss Cardio Technologies AG (cardiac surgery);
- Brexpiprazole, from Otsuka (psychiatry);
- Lurasidone (hydrochloride), from Takeda (psychiatry);
- Trivalent, seasonal, recombinant influenza hemagglutinin vaccine, from Protein Sciences Europa (vaccines / infectious diseases)

- **one negative opinion after re-examination of a negative opinion for a full waiver** for:

- ranirestat, from Eisai Ltd (endocrinology-gynaecology-fertility-metabolism)

- **one negative opinion after -examination of the negative opinion for a PIP and waiver** for:

- bivalirudin, from The Medicines Company UK Ltd (cardiovascular diseases).

- **three positive opinions** for a **product-specific waiver** for:

- Ezetimibe / simvastatin, from MSD-SP Limited (cardiovascular diseases);
- Ezetimibe, from from MSD-SP Limited (cardiovascular diseases);
- Tafluprost / timolol, from Santen Oy (ophthalmology)

- **one opinion** on the **refusal** of a request for waiver for:

- Tivantinib, from Daiichi Sankyo Development Limited (oncology)

- **one opinion** on the **refusal** of modifications to an agreed PIP for:

- Zoledronic acid, from Novartis (endocrinology-gynaecology-fertility-metabolism).

Withdrawals: The PDCO noted that **two applications** were withdrawn during the late stage of the evaluation (30 days or less before opinion).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 8 June 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1232 ²	918	288	26	1695
100%	75%	23%	2%	

¹ off patent products, which are developed specifically for children

² incl. 293 waivers

Table 2: Overview on PDCO opinions as of 8 June 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	13	234
Positive opinions on PIPs	2	81	122	201	107	41	554
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	83	398
Negative opinions on modification of a PIP	0	0	0	4	2	1	7
Positive opinions on compliance with a PIP	0	5	8	9	9	1	32
Negative opinions on compliance with a PIP	0	0	1	0	0	0	1
Opinions on review of a granted waiver	0	0	0	2	0	0	2

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

Indications	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)
Neurology	6	4	4	11	4
Uro-nephrology	3	5	2	4	2
Gastroenterology-hepatology	3	2	1	10	2
Pneumology-allergology	6	6	41	10	5
Infectious diseases	8	9	4	15	12
Cardiovascular diseases	14	9	8	21	18
Diagnostics	1	1	1	5	0
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	11
Neonatology-paediatric intensive care	1	2	0	0	1
Immunology-rheumatology-transplantation	6	6	5	13	8
Psychiatry	3	3	2	9	0

Pain	3	6	1	2	2
Haematology- haemostaseology	5	6	4	18	5
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	12
Dermatology	3	6	3	10	5
Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	3
Anaesthesiology	1	1	2	1	1
Nutrition	1	0	0	0	0
Other				7	6

Date of next PDCO meeting: 4-6 July 2012

Exclusively reported by Dr. Siegfried Throm, German Association of Research-Based Pharmaceutical Companies (e-mail: s.throm@vfa.de)

for:

Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu

© 2012 ECV • Editio Cantor Verlag Germany