

News from the EMA

Activities of the PDCO

During its meeting from 3-5 October 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- (2R,3S,5R)-2-(2,5-Difluorophenyl)-5-[2,6-dihydro-2-(methylsulfonyl)pyrrolo[3,4-c]pyrazol-5(4H)-yl]tetrahydro-2H-pyran-3-amine (MK-3102), from MSD (endocrinology-gynaecology-fertility-metabolism);
- Tofacitinib citrate, from Pfizer (immunology-rheumatology-transplantation / dermatology);
- Tazobactam / ceftolozane, from Cubist Pharmaceuticals (infectious diseases);
- Dolutegravir / abacavir / lamivudine, from ViiV Healthcare (infectious diseases);
- Ponesimod, from Actelion (neurology);
- Natalizumab, from Elan Pharma (neurology);
- Regorafenib, from Bayer Pharma (oncology);
- Travoprost, from Alcon Lab. (ophthalmology);
- Levofloxacin hemihydrate, from Mpex London (pneumology – allergology).

- **eight positive opinions** for **product-specific waivers** for:

- Amlodipine besylate / valsartan, from Zentiva (cardiovascular diseases);
- Perindopril / indapamide / amlodipine, from Krka, d.d., Novo mesto (cardiovascular diseases);
- Brimonidine tartrate, from Galderma International (dermatology);
- Ezetimibe / rosuvastatin, from Zentiva (endocrinology-gynaecology-fertility-metabolism / cardiovascular diseases);
- Lopinavir / ritonavir / lamivudine, from Abbott Lab. (infectious diseases);
- N-tert-butyl-3-[(5-methyl-2-[[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino]pyrimidin-4-yl)amino]benzenesulfonamide dihydrochloride monohydrate (SAR302503), from Sanofi-Aventis (oncology-haematology);
- Icatibant, from Shire Orphan Therapies (other indications);
- Alpha1-proteinase inhibitor, from CSL Behring (pneumology – allergology and gastroenterology).

- **two opinions on completion of a compliance check** for:

- Human normal immunoglobulin, from LFB Biotechnologies (immunology-rheumatology-transplantation);
- Misoprostol, from Ferring Pharmaceuticals (other indications / endocrinology-gynaecology-fertility-metabolism).

Withdrawals: The PDCO noted the following withdrawal: **one application** 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 05 October 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1291 ²	973	292	26	1760
100%	75%	23%	2%	

¹ off patent products, which are developed specifically for children

² incl. 323 waivers

Table 2: Overview on PDCO opinions as of 05 October 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	39	260
Positive opinions on PIPs	2	81	122	201	107	75	588
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	142	457
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	4	35
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	9
Uro-nephrology	3	5	2	4	4
Gastroenterology-hepatology	3	2	1	10	6
Pneumology-allergology	6	6	41	10	7
Infectious diseases	8	9	4	15	18
Cardiovascular diseases	14	9	8	21	27
Diagnostics	1	1	1	5	2
Endocrinology-gynaecology- fertility-metabolism	15	16	5	28	22

Neonatology-paediatric intensive care	1	2	0	0	2
Immunology-rheumatology-transplantation	6	6	5	13	11
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	9
Haematology-haemostaseology	5	6	4	18	9
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	16
Dermatology	3	6	3	10	12
Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	4
Anaesthesiology	1	1	2	1	2
Nutrition	1	0	0	0	0
Other				7	10

Date of next PDCO meeting: 7-9 November 2012

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

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