

News from the EMA

Activities of the PDCO

During its meeting from 5-7 December 2012 the Paediatric Committee (PDCO) adopted the following opinions:

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

- Apixaban, from BMS/Pfizer (cardiovascular diseases);
- Human dermal fibroblasts cultured on bioresorbable polygalactin mesh (ABH001), from TMC Pharma (dermatology);
- Dobutamine (hydrochloride), from Proveca Ltd (neonatology – paediatric intensive care);
- Everolimus, from Novartis Europharm (uro-nephrology / neurology)

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

- Amlodipne besilate / Indapamide / Perindopril erbumine, from Billev Pharma Aps (cardiovascular diseases);
- Atorvastatin calcium / Amlodipine besilate, from Billev Pharma ApS (endocrinology-gynaecology-fertility-metabolism / cardiovascular diseases).
- Oxycodone hydrochloride / morphine sulfate, from QRxPharma Inc (pain).

Withdrawals: The PDCO noted that **eight applications** were withdrawn during the late stage of the evaluation (30 days or less before opinion).

Review of the Paediatric Regulation: Mr Florian Schmidt, Legal Officer in the Medicinal Products-Authorisations Unit of the Directorate General for Health and Consumers (European Commission), presented an initial feedback on the number and type of responses received during the public consultation on the Paediatric Regulation.

Inventory of therapeutic needs

The PDCO adopted the inventory for cardiovascular diseases adopted the inventory for infectious diseases for public discussion.

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 07 December 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1322 ²	999	299	27	1802
100%	76%	22%	2%	

¹ off patent products, which are developed specifically for children

² incl. 339 waivers

Table 2: Overview on PDCO opinions as of 07 December 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full waivers	10	47	67	52	45	47	268
Positive opinions on PIPs	2	81	122	201	107	87	600
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	165	480
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	11
Uro-nephrology	3	5	2	4	5
Gastroenterology-hepatology	3	2	1	10	8
Pneumology-allergology	6	6	41	10	9
Infectious diseases	8	9	4	15	19
Cardiovascular diseases	14	9	8	21	34
Diagnostics	1	1	1	5	3
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	27
Neonatology-paediatric intensive care	1	2	0	0	2
Immunology-rheumatology-transplantation	6	6	5	13	15
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	19
Dermatology	3	6	3	10	14
Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	5
Anaesthesiology	1	1	2	1	2
Nutrition	1	0	0	0	0
Other				7	16

Date of next PDCO meeting: 9-11 January 2013

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

for:

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