

News from the EMA

Activities of the PDCO

During its meeting from 15-17 August 2012 the Paediatric Committee (PDCO) adopted the following opinions:

- **five positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
 - Pegylated B-domain-deleted sequence-modified recombinant human factor VIII, from Bayer Pharma (haematology-hemostaseology)
 - Split influenza vaccine with four components from Sanofi Pasteur MSD (vaccines)
 - Ioforninol, from GE Healthcare (diagnostic medicines)
 - Recombinant single chain coagulation factor VIII, from CSL Behring (haematology-haemostaseology)
 - Glycopegylated recombinant coagulation Factor VIII, from Novo Nordisk (haematology-haemostaseology)
- **four positive opinions** for a **product-specific waiver** for:
 - Acetylsalicylic acid / rosuvastatin, from EGIS Pharmaceuticals (cardiovascular diseases)
 - Chlortalidone / azilsartan medoxomil, from Takeda (cardiovascular diseases)
 - Icosapent Ethyl, from Amarin Pharmaceuticals (cardiovascular diseases)
 - Lapatinib ditosylate monohydrate, from Glaxo Group (oncology)
- **one opinion on completion of a compliance check for:**
 - Tiotropium bromide (monohydrate), from Boehringer Ingelheim (pneumology-allergology).

With regard to the inventory of paediatric therapeutic needs the PDCO adopted a list of products in the therapeutic area of cardiovascular diseases.

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 17 August 2012

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1266 ²	948	292	26	1732
100%	75%	23%	2%	

¹ off patent products, which are developed specifically for children

² incl. 313 waivers

Table 2: Overview on PDCO opinions as of 17 August 2012

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	2012	Total
Positive opinions on full	10	47	67	52	45	24	245

waivers							
Positive opinions on PIPs	2	81	122	201	107	61	574
Negative opinions	0	4	13	7	3	3	30
Positive opinions on modification of a PIP	0	8	51	103	153	110	425
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	2	33
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	6
Uro-nephrology	3	5	2	4	3
Gastroenterology-hepatology	3	2	1	10	4
Pneumology-allergology	6	6	41	10	7
Infectious diseases	8	9	4	15	18
Cardiovascular diseases	14	9	8	21	24
Diagnostics	1	1	1	5	2
Endocrinology-gynaecology-fertility-metabolism	15	16	5	28	14
Neonatology-paediatric intensive care	1	2	0	0	2
Immunology-rheumatology-transplantation	6	6	5	13	9
Psychiatry	3	3	2	9	0
Pain	3	6	1	2	7
Haematology-haemostaseology	5	6	4	18	7
Otorhinolaryngology	1	1	3	2	1
Oncology	12	11	8	19	16
Dermatology	3	6	3	10	9
Vaccines	6	4	2	12	2
Ophthalmology	2	2	4	8	3
Anaesthesiology	1	1	2	1	2
Nutrition	1	0	0	0	0
Other				7	8

Date of next PDCO meeting: 5-7 September 2012

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for:

Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu

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