

News from the EMA

Activities of the PDCO

During its meeting from 15-17 June 2011 the Paediatric Committee (PDCO) adopted the following opinions:

- **one positive opinion** on a paediatric investigation plan (**PIPs**) for the following product:

- Gadobutrol, from Bayer Schering Pharma (diagnostics)

- **one negative opinion** for a PIP for

- Rubidium Rb-82 chloride, form DRAXIMAGE (diagnostic)

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

- Valsartan/amlodipine besilate, from Gedeon Richter (cardiovascular diseases);
- Amlodipine besylate/perindopril erbumine, from KBM Pharma (cardiovascular diseases);
- Florbetaben, from Bayer Schering Pharma (diagnostic);
- Vitamin D3/strontium ranelate, from Servier (immunology-rheumatology-transplantation)
- Teriparatide, from Lilly (endocrinology-gynaecology-fertility-metabolism);
- Recombinant salmon calcitonin, from Novartis Europharm (endocrinology-gynaecology)
- Aflibercept, from Bayer Schering Pharma, (ophthalmology).

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

- Azelastine hydrochloride/fluticasone from MEDA Pharma (pneumolgy-allergology)

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

Withdrawals: The PDCO noted that **three applications**, thereof one for a modification request were withdrawn during the late stages of the evaluation (30 days or less before opinion).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 17 June 2011

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
1056 ²	775	255	26	1481
100%	73%	24%	3%	

¹ off patent products, which are developed specifically for children

² incl. 250 waivers

Table 2: Overview on PDCO opinions as of 17 June 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	28	204
Positive opinions on PIPs	2	81	122	201	56	462
Negative opinions	0	4	13	7	1	25
Positive opinions on modification of a PIP	0	8	51	103	66	228
Negative opinions on modification of a PIP	0	0	0	4	0	4
Positive opinions on compliance with a PIP	0	5	8	9	2	24
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	6
Uro-nephrology	3	5	2	1
Gastroenterology-hepatology	3	2	1	6
Pneumology-allergology	6	6	41	3
Infectious diseases	8	9	4	8
Cardiovascular diseases	14	9	8	13
Diagnostics	1	1	1	3
Endocrinology-gynaecology-fertility-metabolism	15	16	5	17
Neonatology-paediatric intensive care	1	2	0	3
Immunology-rheumatology-transplantation	6	6	5	7
Psychiatry	3	3	2	4
Pain	3	6	1	0
Haematology-haemostaseology	5	6	4	10
Otorhinolaryngology	1	1	3	0
Oncology	12	11	8	9
Dermatology	3	6	3	2
Vaccines	6	4	2	6
Ophthalmology	2	2	4	4
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				4

Date of next PDCO meeting: 13-15 July 2011

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for:

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