

## News from the EMA

### Activities of the PDCO

During its meeting from 16-18 February 2011 the Paediatric Committee (PDCO) welcomed the new member from Belgium, Prof. Koenraad Norga Dana Gabriela Marin, who has been nominated by the Belgian regulatory agency and thanked Ann Marie Kaukonen for her work. The PDCO adopted the following opinions:

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

- Recombinant human N-acetylgalactosamine-6-sulfatase (BMN110), from BioMarin Europe Limited, in the area of endocrinology-gynaecology-fertility-metabolism;
- Dimethyl fumarate (BG00012), from Biogen Idec Ltd., in the area of neurology;
- Abatacept, from Bristol-Myers Squibb Pharma EEIG, in the area of immunology-rheumatology-transplantation;
- Ciclosporin, from APT Pharmaceuticals Limited, in the area of immunology-rheumatology-transplantation;
- Bevacizumab, from Roche Registration Ltd, in the area of oncology;
- (Propane-1-sulfonic acid {3-[5-(4-chlorophenyl)-1H-pyrrolo[2,3-b]pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide), from F. Hoffmann La Roche Ltd, in the area of oncology;
- Imatinib mesilate, from Novartis Europharm Limited, in the area of cardiovascular diseases;
- Valganciclovir hydrochloride, from Roche Registration Ltd, in the area of infectious diseases;
- Human Cell Line recombinant human Factor VIII (human-cl rhFVIII), from Octapharma Pharmazeutika Produktionsges.m.b.H, in the area of haematology-hemostaseology;
- Rotavirus type G1, G2, G3, G4, P1A[8], from Sanofi Pasteur MSD, in the area of vaccines;
- Lubiprostone, from Sucampo Pharma Europe L, in the area of gastroenterology-hepatology;
- Fibrinogen (human plasma-derived), from LFB Biotechnologie, in the area of Haematology-haemostaseology;
- Azelastine hydrochloride / Fluticasone propionate, from MEDA Pharma GmbH & Co. KG, in the area of Pneumology-Allergology;

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

- Human Normal Immunoglobulin, from LFB Biotechnologies, in the area of immunology-rheumatology-transplantation;
- Perindopril tert-butylamine, Amlodipine besilate, from Gedeon Richter Plc., in the area of cardiovascular diseases;
- Flutemetamol, from GE Healthcare Limited, in the area of diagnostic;
- Rivastigmine, from Novartis Europharm Ltd., in the area of neurology;
- Iloperidone, from Vanda Pharmaceuticals Limited, in the area of psychiatry.

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

- Aciclovir, from BioAlliance Pharma, in the therapeutic area of infectious diseases.

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

**Withdrawals:** The PDCO noted that **one application** was 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 18 February 2011**

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA <sup>1</sup>	
985 <sup>2</sup>	720	239	26	1400
100%	73%	24%	3%	

<sup>1</sup> off patent products, which are developed specifically for children

<sup>2</sup> incl. 223 waivers

**Table 2: Overview on PDCO opinions as of 18 February 2011**

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	11	187
Positive opinions on PIPs	2	81	122	201	21	427
Negative opinions	0	4	13	7	1	25
Positive opinions on modification of a PIP	0	8	51	103	23	185
Negative opinions on modification of a PIP	0	0	0	4	0	4
Positive opinions on compliance with PIP	0	5	8	9	0	22
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	2
Uro-nephrology	3	5	2	0
Gastroenterology-hepatology	3	2	1	2
Pneumology-allergology	6	6	41	2
Infectious diseases	8	9	4	3
Cardiovascular diseases	14	9	8	4
Diagnostics	1	1	1	0
Endocrinology-gynaecology- fertility-metabolism	15	16	5	5
Neonatology-paediatric intensive care	1	2	0	2
Immunology-rheumatology- transplantation	6	6	5	2

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

Date of next PDCO meeting: 16-18 March 2011

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

for:

**Guide to Drug Regulatory Affairs** [www.drugregulatoryaffairs.eu](http://www.drugregulatoryaffairs.eu)

© 2011 ECV • Editio Cantor Verlag Germany