

## News from the EMA

### Activities of the PDCO

During its meeting from 12-14 January 2011 the Paediatric Committee (PDCO) welcomed the new alternate from Romania, Dr Dana Gabriela Marin, who has been nominated by the Committee for Medicinal Products for Human Use, and the new alternate from France, Dr Sylvie Benchetrit, appointed by the French regulatory agency AFSSAPS and adopted the following opinions:

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

- Mipomersen sodium, from Genzyme, in the area of endocrinology-gynaecology-fertility-metabolism;
- Bucelipase alfa, from Swedish Orphan, in the area of gastroenterology-hepatology;
- Human coagulation factor X, from Bio Products Laboratory, in the area of haematology-hemostaseology;
- (1R,2S)-6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-1-naphthalenyl-beta-phenyl-3-quinolineethanol, (1R,2S)-6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-1-naphthalenyl-beta-phenyl-3-quinolineethanol (2E)-2-butenedioate(1:1) (salt), from Tibotec, in the area of infectious diseases;
- Bimatoprost, from Allergan Pharmaceuticals Ireland, in the area of ophthalmology / dermatology;
- Exon 51 specific phosphorothioate oligonucleotide, from Glaxo, in the area of neurology;
- Laquinimod sodium, from Teva Pharma GmbH, in the area of neurology;
- Monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E, from Takeda Global Research and Development Centre (Europe), Ltd, in the therapeutic area of oncology.

- a revised positive opinion following the re-examination of the positive opinion on a PIP adopted in 12 November 2010 for

- GLP-1 analogue linked to human IgG4 Fc-fragment (dulaglutide, LY2189265), from Lilly, in the area of endocrinology-gynaecology-fertility-metabolism

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

- Amlodipine besilate, atorvastatin L-lysine, from Gedeon Richter Plc, in the area of cardiovascular diseases;
- (E)-4-(2-(6-(2-(2-(2-[18F]fluoroethoxy)ethoxy)ethoxy)pyridin-3-yl)vinyl)-N-methylbenzenamine, from Avid Radiopharmaceuticals Ireland, in the area of diagnostics;
- Testosterone, from Lilly, in the area of endocrinology-gynaecology-fertility-metabolism;
- Romidepsin, from Celgene Europe Limited, in the area of oncology;
- Lenalidomide, from Celgene Europe Limited, in the area of oncology;
- HPV vaccine from ISA Therapeutics BV, in the area of oncology.

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

**Withdrawals:** The PDCO noted that **two applications** 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 14 January 2011**

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA <sup>1</sup>	
974 <sup>2</sup>	710	238	26	1385
100%	73%	24%	3%	

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

<sup>2</sup> incl. 220 waivers

**Table 2: Overview on PDCO opinions as of 14 January 2011**

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	48	67	52	6	182
Positive opinions on PIPs	2	81	122	201	8	414
Negative opinions	0	4	13	7	0	24
Positive opinions on modification of a PIP	0	8	51	103	11	173
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	1
Uro-nephrology	3	5	2	0
Gastroenterology-hepatology	3	2	1	2
Pneumology-allergology	6	6	41	2
Infectious diseases	8	9	4	1
Cardiovascular diseases	14	9	8	3
Diagnostics	1	1	1	0
Endocrinology-gynaecology- fertility-metabolism	15	16	5	3
Neonatology-paediatric intensive care	1	2	0	1
Immunology-rheumatology- transplantation	6	6	5	1
Psychiatry	3	3	2	1
Pain	3	6	1	0
Haematology-haemostaseology	5	6	4	1

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				1

Date of next PDCO meeting: 16-18 February 2011

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for:

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