EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/PDCO/213115/2011

Monthly report

Paediatric Committee (PDCO)

16-18 March 2011

Opinions on paediatric investigation plans

The Paediatric Committee (PDCO) adopted opinions agreeing paediatric investigation plans (PIPs) for the following medicines:

- Tadalafil, from Eli Lilly and Company Limited, in the therapeutic area of cardiovascular diseases;
- Darbepoetin alfa, from Amgen Europe B.V, in the therapeutic area of cardiovascular diseases / oncology / uro-nephrology;
- Ataluren, from Genzyme Europe B.V., in the therapeutic area of endocrinology-gynaecology-fertility-metabolism / pneumology – allergology;
- Linaclotide, from Almirall S.A., in the therapeutic area of gastroenterology;
- Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-methoxy-133 ester with granulocyte colony-stimulating factor [methionyl,133-[O-[2-(acetylamino]-6-O-[N-[N-carboxyglycyl)amino]-alpha neuraminosyl]-2-deoxy-alpha-D-galactopyranosyl]-L-threonine]] (human), from Ratiopharm GmbH, in the therapeutic area of oncology;
- Aripiprazole, from Otsuka Pharmaceutical Europe Ltd, in the therapeutic area of psychiatry;
- Autologous cartilage derived cultured chondrocytes, from Genzyme Europe BV, in the therapeutic area of other (orthopaedics).

A PIP sets out a programme for the development of a medicine in the paediatric population. The PIP aims to generate the necessary quality, safety and efficacy data through studies to support the authorisation of the medicine for use in children of all ages. These data have to be submitted to the European Medicines Agency, or national competent authorities, as part of an application for a marketing authorisation for a new medicine, or for one covered by a patent. In some cases, a PIP may include a waiver of the studies in one or more paediatric subsets, or a deferral.

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Opinions on product-specific waivers

The PDCO adopted positive opinions for product-specific waivers, recommending that the obligation to submit data obtained through clinical studies with children will be waived in all subsets of the paediatric population, for the following medicines:

- Ezetimibe / simvastatin, from MSD-SP Limited, in the therapeutic area of cardiovascular diseases;
- Amlodipine besylate / atorvastatin calcium, from Miklich Laboratorios, S.L., in the therapeutic area of cardiovascular diseases;
- Delafloxacin, from Rib-X Therapeutics Ltd, in the therapeutic area of infectious diseases.

Waivers can be issued if there is evidence that the medicine concerned is likely to be ineffective or unsafe in the paediatric population, or that the disease or condition targeted occurs only in adult populations, or that the medicine, or the performance of trials, does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Opinions on modifications to an agreed PIP

The PDCO also adopts, every month, opinions on modifications to an agreed PIP, which can be requested by the applicant when the plan is no longer appropriate or when there are difficulties that render the plan unworkable.

Withdrawals

The PDCO noted that 4 applications, of which one was a request for a modification to an agreed PIP, were withdrawn during the late stages of the evaluation (30 days or less before opinion).

Other issues

The PDCO welcomed the new alternate from Finland, Anne Paavola.

The PDCO thanked Ine Blankenberg Skottheim, former alternate from Finland, for her work as she has resigned from the Committee.

The next meeting of the PDCO will be held on 18-20 April 2011.

– END –

Notes:

1. PDCO opinions on PIPs and waivers are transformed into Agency's decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/pip_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d129

2. As of 26 January 2009, pharmaceutical companies that submit an application for a marketing authorisation for a medicinal product, or those that submit an application for an extension of indication, a new route of administration, or a new pharmaceutical form of a medicinal product already authorised in the European Union, have to provide either the results of studies in children conducted in accordance with an approved PIP, or an Agency's decision on a waiver or on a deferral.

3. More information about the PDCO and the Paediatric Regulation is available in the Regulatory section of the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000023.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cd

4. This meeting report, together with other information on the work of the Agency's, can be found on the Agency's website: http://www.ema.europa.eu

Enquiries only to: paediatrics@ema.europa.eu

Annex of the March 2011 PDCO meeting report

	2009 (January to December)	2010 (January to December)	2011 (January to current month)	Cumulative total (2007 to 2010)
Total number of validated PIP/waiver applications	273	326	47	1003[1]
Applications submitted for a product not yet authorised *(Article 7[2])*	191	280	39	735 *(73%)*
Applications submitted for a product already authorised and still under patent, in view of a submission of a variation/extension for a new indication, pharmaceutical form or route of administration *(Article 8[2])*	72	43	7	242 *(24%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30[2])*	10	4	1	26 *(3%)*
PIPs and full waiver indications covered by these applications	395	403	56	1420

Number of Paediatric Committee (PDCO) opinions	2009	2010	2011	Cumulative total
Positive on full waiver	67	52	14	190
Positive on PIP, including potential deferral	122	201	28	434
Negative opinions adopted	13	7	1	25
Positive opinions adopted on modification of a PIP	51	103	33	195
Negative opinions adopted on modification of a PIP	0	4	0	4
Positive opinions on compliance with a PIP	8	9	0	22
Negative opinions on compliance check with a PIP	1	0	0	1
Opinions adopted under Art. 14.2	0	2	0	2

[1] Of which 228 have been requests for a full waiver.
[2] Applications submitted in accordance with the referenced article of Regulation (EC) No 1901/2006, as amended.

Areas covered by PIPs/waiver applications	2009 *(%)*	2010 *(%)*	*(Number of areas covered)**
Neurology	4	3	2
Uro-nephrology	5	2	0
Gastroenterology-hepatology	2	1	2
Pneumology-allergology	6	41	3
Infectious diseases	9	4	4
Cardiovascular diseases	9	8	8
Diagnostics	1	1	0
Endocrinology-gynaecology-fertility-metabolism	16	6	7
Neonatology-paediatric intensive care	2	0	2
Immunology-rheumatology-transplantation	6	5	3
Psychiatry	3	1	3
Pain	6	1	0
Haematology-haemostaseology	6	4	6
Otorhinolaryngology	1	3	0
Oncology	11	9	3
Dermatology	6	1	1
Vaccines	4	2	4
Ophthalmology	2	4	1
Anaesthesiology	1	2	0
Nutrition	0	0	0
Other			2

** One PIP can cover several therapeutic areas*