17 April 2013
EMA/232769/2013
Paediatric Committee (PDCO)

PDCO monthly report of opinions on paediatric investigation plans and other activities

10 – 12 April 2013

Opinions on paediatric investigation plans

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

- Anti Proprotein Convertase Subtilisin/Kexin Type 9 human monoclonal antibody (AMG 145), from Amgen Europe B.V, for the treatment of hypercholesterolemia and treatment of mixed dyslipidemia;
- Lacosamide, from UCB Pharma S.A., for the treatment of epilepsy with partial onset seizures, and treatment of generalised epilepsy and epileptic syndromes;
- Benralizumab, from MedImmune Ltd, for the treatment of asthma;
- Adalimumab, from AbbVie Ltd., for the treatment of hidradenitis suppurativa;
- Solifenacin (succinate), from Astellas Pharma Europe B.V., for the treatment of neurogenic detrusor overactivity;
- PaclitaxeL, from Celgene Europe Limited, for the treatment of solid malignant tumours;
- Lenvatinib, from Eisai Europe Limited, for the treatment of differentiated papillary thyroid cancer, treatment of follicular thyroid cancer, treatment of neuroblastoma.

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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 77523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 be waived in all subsets of the paediatric population, for the following medicines:

- Menotrophin, from Laboratoires Genevrier, for the treatment of female infertility;
- Valsartan / hydrochlorothiazide + rosuvastatin, from Krka, d.d., Novo mesto, for the treatment of hypertension, treatment of elevated cholesterol, treatment of dyslipidaemia and prevention of thromboembolic events;
- Rosuvastatin / ezetimibe, from EGIS Pharmaceuticals PLC, for the treatment of elevated cholesterol;
- Ivabradine (hydrochloride) / metoprolol (tartrate), from Les Laboratoires Servier, for the treatment of ischaemic coronary artery disease.

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. The PDCO adopted positive opinions, agreeing change(s), for the following products:

- Sitagliptin, from Merck Sharp and Dohme (Europe), Inc., for the treatment of type 2 diabetes mellitus;
- Aztreonam, from Gilead Sciences International Limited, for the treatment of Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis;
- Dasatinib, from Bristol-Myers Squibb Pharma EEIG, for the treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia;
- Concentrate of proteolytic enzymes in bromelain, from Teva Pharma GmbH, for the treatment of burns;
- Solifenacin (succinate), from Astellas Pharma Europe B.V., for the treatment of idiopathic overactive bladder;
- Fingolimod (hydrochloride), from Novartis Europharm Limited, for the treatment of multiple sclerosis.

Withdrawals

The PDCO noted that one application was withdrawn during the late stages of the evaluation (30 days or less before opinion).

Other matters

Until further notice and with immediate effect, the EMA will be sending PDCO opinions to applicants in hard copy via courier only. Applicants will still receive the PDCO opinions and appendixes also electronically, but this will be done together with EMA's Decision on the procedure.

The next meeting of the PDCO will be held on 15 – 17 May 2013.

– END –

Notes:

1. 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.
2. 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
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 April 2013 PDCO meeting report

	2011 (January to December)	2012 (January to december)	2013 (January to current month)	Cumulative total (2007 to present)
Total number of validated PIP/waiver applications	187	178	62	1384[1]
Applications submitted for a product not yet authorised *(Article 7[2])*	153	149	55	1054 *(76%)*
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])*	33	28	7	303 *(22%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30[2])*	1	1	0	27 *(2%)*
PIPs and full waiver indications covered by these applications	220	218	70	1872

Number of Paediatric Committee (PDCO) opinions	2011	2012	2013	Cumulative total (2007 to present)
Positive on full waiver	45	47	20	288
Positive on PIP, including potential deferral	107	87	42	642
Negative opinions adopted	3	3	1	31
Positive opinions adopted on modification of a PIP	153	165	54	534
Negative opinions adopted on modification of a PIP	2	1	2	8
Positive opinions on compliance with a PIP	9	4	4	39
Negative opinions on compliance check with a PIP	0	0	0	1
Opinions adopted under Art. 14.2	0	0	0	2

[1] Of which 361 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	2011 *(Number of areas covered)**	2012 *(Number of areas covered)**	2013 *(Number of areas covered)**
Neurology	11	11	2
Uro-nephrology	4	5	5
Gastroenterology-hepatology	10	8	5
Pneumology-allergology	10	9	2
Infectious diseases	15	19	7
Cardiovascular diseases	21	34	6
Diagnostics	5	3	2
Endocrinology-gynaecology-fertility-metabolism	28	27	7
Neonatology-paediatric intensive care	0	2	2
Immunology-rheumatology-transplantation	13	15	2
Psychiatry	9	0	3
Pain	2	9	2
Haematology-haemostaseology	18	9	5
Otorhinolaryngology	2	1	0
Oncology	19	19	12
Dermatology	10	14	5
Vaccines	12	2	2
Ophthalmology	8	5	0
Anaesthesiology	1	2	0
Nutrition	0	0	0
Other	7	16	3

* *One PIP can cover several therapeutic areas*