



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Monthly report

Paediatric Committee (PDCO)

13-15 July 2011

Opinions on paediatric investigation plans

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

- Lopinavir / ritonavir, from Abbott Laboratories Limited, in the therapeutic area of infectious diseases;
- Eslicarbazepine (acetate), from BIAL - Portela & Ca, SA, in the therapeutic area of neurology;
- Teriflunomide, from Sanofi-aventis recherche & développement, in the therapeutic area of neurology;
- Veliparib, from Abbott Laboratories Ltd, in the therapeutic area of oncology;
- Cilengitide, from Merck KGaA, in the therapeutic area of oncology.

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.

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.



Opinion on compliance check

The PDCO adopted a positive opinion on compliance check for rotavirus serotype G2 / rotavirus serotype P1A[8] / rotavirus serotype G4 / rotavirus serotype G1 / rotavirus serotype G3, from Sanofi Pasteur MSD SNC, in the therapeutic area of vaccines.

A compliance check is performed to verify that all the measures agreed in a PIP and reflected in the Agency's decision have been conducted in accordance with the decision, including the agreed timelines. Compliance is one of several prerequisites for obtaining the rewards and incentives provided for in Articles 36 to 38 of the Paediatric Regulation.

Before the submission of a request for a compliance check, applicants are encouraged to consult the [Agency's Procedural advice](#) for validation of a new marketing authorisation application or extension/variation application and compliance check with an agreed PIP.

Withdrawals

The PDCO noted that 5 applications, of which 2 were requests for modification to an agreed PIP, were withdrawn during the late stages of the evaluation (30 days or less before opinion).

The PDCO also noted that an opinion adopted during the June PDCO meeting for Rb-82 Chloride, from DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc, in the therapeutic area of diagnostics, has been withdrawn before the decision was adopted by the Agency.

Other issues

The next meeting of the PDCO will be held on 10-12 August 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>

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Annex of the July PDCO meeting report

	2009 (January to December)	2010 (January to December)	2011 (January to current month)	Cumulative total (2007 to 2011)
Total number of validated PIP/waiver applications	273	326	118	1075 ¹
Applications submitted for a product not yet authorised (<i>Article 7²</i>)	191	280	93	790 (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 (<i>Article 8²</i>)	72	43	24	259 (24%)
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation (<i>Article 30²</i>)	10	4	1	26 (3%)
PIPs and full waiver indications covered by these applications	395	403	140	1504

Number of Paediatric Committee (PDCO) opinions	2009	2010	2011	Cumulative total
Positive on full waiver	67	52	28	204
Positive on PIP, including potential deferral	122	201	61	467
Negative opinions adopted	13	7	2	26
Positive opinions adopted on modification of a PIP	51	103	84	246
Negative opinions adopted on modification of a PIP	0	4	0	4
Positive opinions on compliance with a PIP	8	9	3	25
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 257 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 (%)	2011 (Number of areas covered)*
Neurology	4	3	6
Uro-nephrology	5	2	1
Gastroenterology-hepatology	2	1	6
Pneumology-allergology	6	41	5
Infectious diseases	9	4	10
Cardiovascular diseases	9	8	16
Diagnostics	1	1	3
Endocrinology-gynaecology-fertility-metabolism	16	6	21
Neonatology-paediatric intensive care	2	0	3
Immunology-rheumatology-transplantation	6	5	7
Psychiatry	3	1	5
Pain	6	1	1
Haematology-haemostaseology	6	4	11
Otorhinolaryngology	1	3	0
Oncology	11	9	11
Dermatology	6	1	5
Vaccines	4	2	6
Ophthalmology	2	4	5
Anaesthesiology	1	2	0
Nutrition	0	0	0
			4

* One PIP can cover several therapeutic areas