30 March 2010
EMA/PDCO/151391/2010

Meeting highlights from the Paediatric Committee, 17-19 March 2010

Opinions on paediatric investigation plans

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

- **Perampanel**, from Eisai Ltd, in the therapeutic area of neurology;
- **Infliximab**, from Centocor B.V., in the therapeutic area of immunology-rheumatology-transplantation / dermatology / gastroenterology-hepatology;
- **Levonorgestrel**, from Bayer Schering Pharma AG, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Avotermin / human recombinant transforming growth factor beta 3 / RN1001**, from Renovo Ltd, in the therapeutic area of dermatology;
- **Taspoglutide**, from Roche Registration Limited, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Cholic acid**, from Special Products Ltd, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism / gastroenterology-hepatology;
- **Eritoran**, from Eisai Ltd, in the therapeutic area of infectious diseases.

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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Adoption of an opinion following re-examination

The PDCO adopted an opinion for the following product:

- Following the re-examination of the negative opinion for a full waiver adopted on 15 January 2010 for **esomeprazole magnesium / acetylsalisylic acid**, from AstraZeneca AB, in the therapeutic area of gastroenterology-hepatology, the PDCO adopted a positive opinion.

A re-examination of the opinion can be requested by the applicant within 30 days following receipt of the opinion of the PDCO. The grounds for the re-examination should be based only on the original information and scientific data provided in the application that were previously available to the PDCO and on which the initial opinion was based. This may include new analysis of the same data or minor protocol amendments to a previously proposed study. Significant changes to the previous plan cannot be part of the re-examination process.

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:

- **Sorafenib (as tosylate)**, from Bayer Schering Pharma AG, in the therapeutic area of oncology;
- **Diamorphine**, from IPC Pharma A/S, in the therapeutic area of psychiatry;
- **Diamorphine hydrochloride**, from Genus Pharmaceuticals Limited, in the therapeutic area of psychiatry;
- **Mometasone furoate**, from Schering-Plough Research Institute, a division of Schering Corporation, in the therapeutic area of pneumology-allergology;
- **Octocog alfa**, from Baxter AG, in the therapeutic area of haematology-hemostaseology;
- **Forodesine hydrochloride**, from Mundipharma Research Ltd, in the therapeutic area of oncology.

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.

Opinion on compliance check

The PDCO adopted a positive opinion on compliance check for **Latanoprost**, from Pfizer Global Research & Development, in the therapeutic area of ophthalmology.

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 2 applications 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 February PDCO meeting for polihexanide, from B.Braun Melsungen AG, in the therapeutic area of Other (Wound care), has been withdrawn before the decision was adopted by the Agency.

Interaction with external experts

The PDCO has regular interactions with academic experts, with a view to bringing state-of-the-art knowledge into the PDCO scientific discussions. Two experts were invited to the March meeting. With a clinical expert in paediatric malaria, the PDCO discussed the need for treatment in children from birth. With a clinical expert in paediatric oncology and haematology, the PDCO discussed unmet paediatric needs for non-Hodgkin lymphoma and a specific product.

PDCO interactions

In the course of the interaction of the PDCO with the Committee for Advanced Therapies, CAT, Dr. Sol Ruiz, Dr. Per Ljungman and Dr. Giovanni Migliaccio have participated in the meeting of the PDCO.

Informal meeting

On 4 March 2010, the PDCO held an informal meeting in Spain to review the work done and the processes put in place during its fourth year. The PDCO discussed improvements in the functioning of the PDCO, in particular timelines, summary reports, interactions with experts, learned societies and industry, and priorities in the implementation of the Paediatric Regulation.

Other issues

Update of the priority list for studies into off-patent paediatric medicinal products

The PDCO started its wave of meetings to update the priority list for studies into off-patent medicines in advance of the next call from the European Commission for funding through the EU's Seventh Framework Programme.

The updated list will comprise a number of medicines relating to various therapeutic areas. This will be a reference for applicants for funding from the European Community through the Seventh Framework Programme.

The European Commission, represented by Dr Fergal Donnelly (DG RTD), updated the PDCO on the Seventh Framework Programme.

Paediatric Rheumatology Expert Meeting

The PDCO endorsed the conclusions of the Paediatric Rheumatology Expert Meeting held in London 4 December 2009.

The next meeting of the PDCO will be held on 14-16 April 2010.

– 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/htms/human/paediatrics/decisions.htm
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 EEA, 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 'Medicines for children' section of the Agency's website.
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 2010 PDCO meeting report

	2008 (January to December)	2009 (January to December)	2010 (January to current month)	Cumulative total (2007 to 2010)
Total number of validated PIP/waiver applications	271	273	72	701[1]
Applications submitted for a product not yet authorised *(Article 7[2])*	186	191	60	476 *(68%)*
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])*	75	72	10	202 *(29%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30[2])*	10	10	2	23 *(3%)*
PIPs and full waiver indications covered by these applications	395	395	96	1057

Number of Paediatric Committee (PDCO) opinions	2008	2009	2010	Cumulative total
Positive on full waiver	48	67	10	135
Positive on PIP, including potential deferral	81	122	24	229
Negative opinions adopted	4	13	3	20
Positive opinions adopted on modification of a PIP	8	51	31	90
Positive opinions on compliance with a PIP	5	8	2	15
Negative opinions on compliance check with a PIP	0	1	0	1

[1] Of which 171 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	2008 (%)	2009 (%)	2010 (%)
Neurology	6	4	5
Uro-nephrology	3	5	0
Gastroenterology-hepatology	3	2	3
Pneumology-allergology	6	6	30
Infectious diseases	8	9	5
Cardiovascular diseases	14	9	8
Diagnostics	1	1	1
Endocrinology-gynaecology-fertility-metabolism	15	16	5
Neonatology-paediatric intensive care	1	2	0
Immunology-rheumatology-transplantation	6	6	6
Psychiatry	3	3	4
Pain	3	6	3
Haematology-haemostaseology	5	6	5
Otorhinolaryngology	1	1	1
Oncology	12	11	12
Dermatology	3	6	0
Vaccines	6	4	5
Ophthalmology	2	2	4
Anaesthesiology	1	1	3
Nutrition	1	0	0