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Meeting highlights from the Paediatric Committee, 14-16 April 2010

Opinions on paediatric investigation plans

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

- **Bisoctrizole / titanium dioxide**, from Orfagen, in the therapeutic area of dermatology;
- **Clindamycin phosphate / sodium bituminosulphonate**, from ICHTHYOL -GESELLSCHAFT Cordes, Hermanni & Co. (GmbH & Co.) KG, in the therapeutic area of dermatology;
- **Anagrelide hydrochloride monohydrate**, from Shire Pharmaceutical Contracts Ltd, in the therapeutic area of haematology-hemostaseology;
- **Adalimumab**, from Abbott Laboratories Limited, in the therapeutic area of immunology-rheumatology-transplantation / dermatology / gastroenterology-hepatology;
- **Fidaxomicin**, from FGK Representative Service GmbH, in the therapeutic area of infectious diseases;
- **Boceprevir**, from SP Europe, in the therapeutic area of infectious diseases;
- **Peginterferon alfa-2a**, from Roche Registration Ltd, in the therapeutic area of infectious diseases;
- **Cediranib**, from AstraZeneca AB, in the therapeutic area of oncology;
- **Beclometasone dipropionate / formoterol fumarate dihydrate**, from Chiesi Farmaceutici S.p.A., in the therapeutic area of pneumology – allergology;
- **Solifenacin succinate**, from Astellas Pharma Europe B.V., in the therapeutic area of uro-nephrology.

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

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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 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:

- **Metformin / sitagliptin**, from Merck Sharp & Dohme (Europe), Inc., in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Vorinostat**, from Merck Sharp & Dohme Ltd., in the therapeutic area of oncology;
- **Fluocinolone acetonide**, from Campharm Ltd., in the therapeutic area of ophthalmology;

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.

Class waivers

The PDCO adopted an opinion to modify a granted class waiver, from “Primary osteoarthrosis (excluding secondary osteoarthrosis)” to “Primary and secondary osteoarthrosis”, in all subsets of the paediatric population, on the grounds that the condition occurs only in adult populations.

The opinion is transformed into an Agency’s decision.

The Agency already adopted decisions on class waivers in October 2009 for conditions that do not occur in children, or for products likely to be unsafe or ineffective in children. The list of waivers is regularly updated in light of the advance in knowledge and science in the paediatric field.

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 **Human papillomavirus1 Type 6 L1 protein / human papillomavirus1 Type 11 L1 protein / human papillomavirus1 Type 16 L1 protein / human papillomavirus1 Type 18 L1 protein**, from Sanofi Pasteur MSD, 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 were withdrawn during the late stages of the evaluation (30 days or less before opinion).

The PDCO noted that a request for modification of an agreed PIP was withdrawn before the EMEA decision.

Extrapolation working group

A working group for questions on extrapolation related to paediatric development has been set up with experts. The working group will report to the PDCO.

Other issues

The PDCO thanked Karen Aiach (Member representing patients' organisations) for her work as she has resigned from the Committee.

The next meeting of the PDCO will be held on 19-21 May 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 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 '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 April 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	122	751[1]
Applications submitted for a product not yet authorised *(Article 7[2])*	186	191	104	520 *(69%)*
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	16	208 *(28%)*
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	150	1111

Number of Paediatric Committee (PDCO) opinions	2008	2009	2010	Cumulative total
Positive on full waiver	48	67	13	138
Positive on PIP, including potential deferral	81	122	34	239
Negative opinions adopted	4	13	3	20
Positive opinions adopted on modification of a PIP	8	51	36	95
Positive opinions on compliance with a PIP	5	8	3	16
Negative opinions on compliance check with a PIP	0	1	0	1

[1] Of which 177 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	2
Gastroenterology-hepatology	3	2	2
Pneumology-allergology	6	6	40
Infectious diseases	8	9	4
Cardiovascular diseases	14	9	7
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	3
Pain	3	6	2
Haematology-haemostaseology	5	6	3
Otorhinolaryngology	1	1	1
Oncology	12	11	8
Dermatology	3	6	2
Vaccines	6	4	3
Ophthalmology	2	2	4
Anaesthesiology	1	1	2
Nutrition	1	0	0