European Medicines Agency

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 27-29 May 2009

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

- **Telavancin hydrochloride**, from Astellas Pharma Europe B.V., in the therapeutic area of infectious diseases;
- **Rituximab**, from Roche Products Ltd, in the therapeutic areas of oncology and immunology-rheumatology-transplantation;
- **Rilpivirine**, from Janssen-Cilag International N.V., in the therapeutic area of infectious diseases;
- **Brivaracetam**, from UCB Pharma SA, in the therapeutic area of neurology;
- **Recombinant human C1 inhibitor**, from Pharming Group N.V., in the therapeutic area of immunology–rheumatology-transplantation;
- **N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea** (ABT-869), from Abbott Laboratories, in the therapeutic area of oncology;
- **Nevirapine**, from Boehringer Ingelheim International GmbH, in the therapeutic area of infectious diseases;
- **Insulin glargine**, from Sanofi-Aventis Deutschland GmbH, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Fosaprepitant dimeglumine**, from Merck Sharp & Dohme Ltd., in the therapeutic area of oncology;
- **Canakinumab**, from Novartis Europharm Limited, in the therapeutic area of immunology–rheumatology-transplantation;
- **Colesevelam**, from Genzyme Europe B.V., in the therapeutic area of endocrinology-gynaecology-fertility-metabolism

The PDCO adopted an opinion on the **refusal** of a PIP for **drospirenone / ethinylestradiol (as betadex clathrate) / L-5-methyltetrahydrofolic acid, calcium salt** from Bayer Schering Pharma AG, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism.
The PDCO subsequently granted on its own motion a product-specific waiver for this medicine for all subsets of the paediatric population in the specified condition, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The PDCO adopted an opinion on the **refusal** of a PIP, including deferral, for **dienogest / estradiol valerate** from Bayer Schering Pharma AG, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism. The PDCO subsequently granted on its own motion a product-specific waiver for this medicine for all subsets of the paediatric population in the specified condition, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

* Annex of the 27-29 May 2009 PDCO meeting report has been updated

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 (EMEA), 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 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:

- **Omacetaxine mepesuccinate**, from ChemGenex Europe S.A.S., in the therapeutic area of Oncology;
- **Simvastatin / sitagliptin phosphate monohydrate**, from Merck Sharp & Dohme (Europe), Inc., in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Clostridium collagenase**, from Pfizer Limited, in the therapeutic area of immunology-rheumatology-transplantation;

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 **abatacept** from Bristol-Myers Squibb Pharma EEIG, in the therapeutic area of Immunology–Rheumatology-Transplantation.

A compliance check is performed to verify that all the measures agreed in a PIP and reflected in the EMEA 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 EMEA Procedural advice for validation of a new marketing authorisation application or extension/variation application and compliance check with an agreed PIP.

Opinion on the quality, safety or efficacy of a medicinal product
At the request of the Austrian Competent Authority, AGES, the PDCO adopted an opinion on the safety of a medicinal product for use in the paediatric population, under art. 6.(1).d of the Paediatric Regulation.

Withdrawals
The PDCO noted that 2 applications were withdrawn during the late stages of the evaluation (30 days or less before opinion).

PDCO interactions:

Interaction with external experts
The PDCO has regular interactions with academic experts, with a view to bringing state-of-the-art knowledge to the PDCO scientific discussions. Six experts were invited to the May meeting. With clinical experts in paediatric oncology, nephrology, neonatology, endocrinology, pneumologyy and child psychiatry, the PDCO discussed product-related and / or general questions on paediatric medicinal product development.

Interactions with paediatric networks
The Chair of the **Paediatric European Network for Treatment of AIDS** (**PENTA**) was invited to the meeting in order to exchange views on how to enhance the scientific collaboration with the PDCO.

PDCO ad-hoc experts group meetings:

Diabetes Expert group:
An expert group for questions on the development of medicinal products for the treatment of diabetes in children, was convened with external experts from National Competent Authorities, hospitals and Universities, in order to identify the best possible research approaches for existing and new medications in this field. A meeting report will be published on the EMEA website at a later stage.

HIV Expert group:
An expert group for questions on the development of anti-HIV medicinal products, with particular focus on different patients populations and classes of products, was convened with external experts from National Competent Authorities, hospitals and Universities in order to identify the best possible research approaches for existing and new medications in the field. A FDA representative attended the meeting. The meeting report will be published on the EMEA website at a later stage.

New meeting dates adopted
PDCO meeting dates for 2010 were adopted during the May 2009 meeting. These dates are important for applicants in planning the submission of applications for PIPs, requests for waivers, requests for modification of an agreed PIP, and requests for compliance checks. The new dates will be published on the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/pdco.htm

Other issues
The next meeting of the PDCO will be held on 24-26 June 2009.

– END –

Notes:

1. PDCO opinions on PIPs and waivers are transformed into EMEA decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the EMEA website at: http://www.emea.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 EMEA 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 EMEA website.
4. This meeting report, together with other information on the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

Enquiries only to: paediatrics@emea.europa.eu

Annex of the 27-29 May 2009 PDCO meeting report

	2007 (August to December)	**2008** (January to December)	**2009** (January to current month)	**Cumulative total**
Total number of validated PIP/waiver applications	**85**	**271**	**116**	**472**[1]
Applications submitted for a product not yet authorised *(Article 7*[2]*)*	39	186	78	303 *(64%)*
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]*)*	45	75	31	151 *(32%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30*[2]*)*	1	10	7	18 *(4%)*
PIPs and full waiver indications covered by these applications	**202**	**395**	**166**	**763**

Number of Paediatric Committee (PDCO) opinions	**2007**	**2008**	**2009**	**Cumulative total**
Positive on full waiver	10	48	35	93
Positive on PIP, including potential deferral	2	81	72	155
Negative opinions adopted	0	4	8	12
Positive opinions adopted on modification of a PIP	0	8	11	19
Positive opinions on compliance with a PIP	0	5	3	8

[1] Of which 112 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	**2007** *(%)*	**2008** *(%)*	**2009** *(%)*
Neurology	12	6	2
Uro-nephrology	-	3	4
Gastroenterology-hepatology	9	3	2
Pneumology-allergology	8	6	5
Infectious diseases	12	8	10
Cardiovascular diseases	12	14	6
Diagnostics	-	1	1
Endocrinology-gynaecology-fertility-metabolism	19	15	24
Neonatology-paediatric intensive care	-	1	1
Immunology-rheumatology-transplantation	5	6	8
Psychiatry	5	3	2
Pain	1	3	4
Haematology-haemostaseology	1	5	6
Otorhinolaryngology	-	1	-
Oncology	11	12	14
Dermatology	1	3	5
Vaccines	2	6	4
Ophthalmology	1	2	2
Anaesthesiology	-	1	-
Nutrition	1	1	-