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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 7-9 January 2009

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

- **Anastrozole**, from AstraZeneca, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells**, from Baxter AG, in the therapeutic area of vaccines;
- **Asenapine maleate**, from N.V. Organon, in the therapeutic area of psychiatry;
- **Iron, aqua carbonate hydroxy oxo starch sucrose complex**, from Novartis Europharm Ltd, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Methoxy polyethylene glycol - epoetin beta**, from Roche Products Ltd, in the therapeutic area of uro-nephrology;
- **Modified grass pollen extract,** from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
- **N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide**, from Vertex Pharmaceuticals Inc, in the therapeutic area of pneumology-allergology;
- **PEGylated recombinant Factor VIIa**, from Novo Nordisk A/S, in the therapeutic area of haematology;
- **Plerixafor**, from Genzyme Europe B.V., in the therapeutic area of oncology;
- **Sunitinib malate**, from Pfizer Ltd, in the therapeutic area of oncology;
- **Ustekinumab**, from Janssen-Cilag International NV, in the therapeutic area of dermatology.

The PDCO adopted an opinion on the refusal of a PIP, including waiver and deferral, for **ethinylestradiol (as betadex clathrate) / drospirenone**, 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.

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 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 modification of an agreed PIP
The PDCO adopted an opinion on the modification of an agreed PIP for **latanoprost**, from Pfizer Global Research & Development, in the therapeutic area of ophthalmology, following the adoption of the PDCO opinion on the original PIP during its January 2008 meeting.

Modifications to an agreed PIP can be requested by the applicant when the plan is no longer appropriate or there are difficulties that render the plan unworkable.

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:

- **Aliskiren hemifumarate / hydrochlorothiazide**, from Novartis Europharm Ltd, in the therapeutic area of cardiovascular diseases;
- **Lapatinib ditosylate monohydrate**, from Glaxo Group Ltd, in the therapeutic area of oncology;
- **Pemetrexed disodium**, from Eli Lilly & Company, in the therapeutic area of oncology.

The PDCO adopted an opinion on the refusal of a request for waiver for **Velaglucerase alfa**, from Shire Human Genetic Therapies AB, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism.

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 does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Class waivers
The PDCO adopted an opinion on the confirmation of the current list of class waivers for conditions that do not affect children, or for classes of medicinal products to be used in specific conditions, and for which the requirement to submit a PIP can therefore be waived. The list of class waivers is updated at least annually by the PDCO.

Interaction with experts
The PDCO has regular interaction with academic experts with a view to bringing state-of-the-art knowledge to the PDCO scientific discussions. Two medical experts on Gaucher's disease participated in the January 2009 PDCO meeting, as did the Executive Director of the UK Gaucher's Association.

Other issues
The PDCO welcomed the new alternate member from Romania, Dr Raluca Cirstea, who has been nominated from within the Committee for Medicinal Products for Human Use.

The next meeting of the PDCO will be held on 4-6 February 2009.

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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 July 2008, pharmaceutical companies that submit an application for a marketing authorisation for a medicine 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. This will also apply, from 26 January 2009, for medicines that are already authorised, and for which a company is submitting an application for an extension of indication, or for a new route of administration, or for a new pharmaceutical form.
3. More information about the PDCO and the Paediatric Regulation is available in the 'Medicines for children' section of the EMEA website.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu

	2007 (August-December)	**2008** (January-December)	**2009** (January)	**Cumulative Total**
Total number of validated PIP / waiver applications	**85**	**271**[1]	**16**	**372**[2]
Applications submitted for a product not yet authorised *(Article 7*[3]*)*	39	186	9	234 *(63%)*
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*[3]*)*	45	75	6	126 (*34%)*
Applications submitted for an off-patent product developed specifically for children, with an age-appropriate formulation *(Article 30*[3]*)*	1	10	1	12 *(3%)*
PIPs and full waiver indications covered by these applications	**202**	**395**	**19**	**616**

Number of Paediatric Committee (PDCO) opinions	**2007**	**2008**	**2009**	**Cumulative Total**
Positive on full waiver	10	48	5	63
Positive on PIPs including potential deferral	2	81	11	94
Negative opinions adopted	0	4	1	5
Positive opinions adopted on modification of a PIP	0	8	1	9
Positive opinion on compliance with a PIP	0	5	0	5
Withdrawals prior to EMEA decision	0	0	1	1

[1] Figures including 8 January 2009 start of procedure.
[2] Of which 88 were requests for a full waiver.
[3] Applications submitted in accordance with this Article of Regulation (EC) No 1901/2006 as amended.

Areas covered by PIPs/waiver applications	**2007** (%)	**2008** (%)	**2009** (%)
Neurology	12	6	6
Uro-nephrology	-	3	6
Gastroenterology-hepatology	9	3	6
Pneumology-allergology	8	6	0
Infectious diseases	12	8	11
Cardiovascular diseases	12	14	0
Diagnostics	-	1	0
Endocrinology-gynaecology-fertility-metabolism	19	15	41
Neonatology-paediatric intensive care	-	1	0
Immunology-rheumatology-transplantation	5	6	6
Psychiatry	5	3	6
Pain	1	3	0
Haematology-haemostaseology	1	5	6
Otorhinolaryngology	-	1	0
Oncology	11	12	0
Dermatology	1	3	6
Vaccines	2	6	6
Ophthalmology	1	2	0
Anaesthesiology	-	1	0
Nutrition	1	1	0