European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 2-4 June 2008

Positive opinions on paediatric investigation plans adopted
The European Medicines Agency's (EMEA) Paediatric Committee (PDCO) adopted positive opinions on paediatric investigation plans for the following medicines:

- **Atorvastatin calcium** (trihydrate), from Pfizer Limited, in the therapeutic area of metabolism;
- **Nicotinic acid/laropripant**, from Merck Sharp and Dohme (Europe), Inc., in the therapeutic area of metabolism;
- **Rabeprazole sodium**, from Eisai Limited, in the therapeutic area of hepatology and gastroenterology;
- **Mepolizumab**, from Glaxo Group Limited, in the therapeutic area of immunology and gastroenterology;
- **Darunavir** (as ethanolate), from Janssen-Cilag International NV, in the therapeutic area of infectious diseases.
- **Zoledronic acid anhydrous**, from Novartis Europharm Limited, in the therapeutic area of metabolism;

A paediatric investigation plan (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. In some cases, a PIP may include a waiver to study one or more age groups of children.

Adoption of a revised opinion
Following a request for re-examination of the positive opinion adopted in April 2008, the PDCO adopted a revised positive opinion on a PIP for **Dalbavancin**, from Pfizer Limited, in the therapeutic area of infectious diseases.

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 which were previously available to the PDCO and on which the initial opinion is 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 a product-specific waiver, 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:

* The information concerning zoledronic acid anhydrous has been corrected: the PDCO adopted a positive opinion on a PIP for this medicine and not a product-specific waiver.
+ The number of positive opinions including potential deferrals has been changed in the annex.

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- **Epoetin theta** (recombinant human erythropoietin), from CT Arzneimittel GmbH, in the therapeutic area of haematology;
- **Glucosamine hydrochloride/Chondroitin sulfate**, from Bioiberica S.A., in the therapeutic area of rheumatology;
- **Valsartan/Amlodipine/Hydrochlorothiazide**, from Novartis Europharm Ltd, in the therapeutic area of cardiology.

Waivers can be issued if there is evidence showing that the medicinal product 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 specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

First decision on PIP modification adopted

The EMEA adopted the first decision on the modification of an agreed PIP, for caspofungin, from Merck Sharp and Dohme (Europe), Inc., in the therapeutic area of infectious diseases, following the adoption of the PDCO opinion during its May 2008 meeting.

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

Concept paper on formulation

The PDCO endorsed a concept paper on paediatric formulation which addresses the different approaches needed by the different subsets of the paediatric population (from pre-term newborn infants to adolescents) in the context of the development of a medicine.

The document has been drafted jointly with the Committee for Medicinal Products for Human Use (CHMP) and the Committee on Herbal Medicinal Products (HMPC), and will be further discussed by both Committees.

The PDCO has scheduled an informal meeting on 1 July 2008 to discuss organisational matters in the light of the review of the first year of implementation of the Paediatric Regulation and to address strategic aspects of the paediatric development.

The next meeting of the PDCO will be held on 2-4 July 2008.

-- ENDS --

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 at http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm.
2. Further information on the re-examination procedure for paediatric investigation plan and/or waiver opinions by the Paediatric Committee (PDCO) can be found at http://www.emea.europa.eu/htms/human/paediatrics/2360408en.pdf
3. EMEA decisions on the list of class waivers can be found at http://www.emea.europa.eu/htms/human/paediatrics/classwaivers.htm
4. More information about the PDCO and the Paediatric Regulation is available in the 'Medicines for children' section of the EMEA website: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm
5. 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

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OVERVIEW OF PAEDIATRIC INVESTIGATION PLAN/WAIVER APPLICATIONS

	2007 (August to December)	**2008** (January-June)	**Cumulative Total**
Total number of validated PIP / waiver applications	**85**	**129**[1]	**214**[2]
Applications submitted for a product not yet authorised *(Article 7)*[3]	39	94	133 *(62%)*
Applications submitted for a product already authorised still under patent in view of a submission of a variation/extension for a new indication, pharmaceutical form or route of administration *(Article 8)*	45	30	75 (*35%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30)*	1	5	6 *(3%)*
PIPs and full waiver indications covered by these applications	**202**	**194**	**396**

Number of Paediatric Committee (PDCO) opinions	**2007**	**2008**	**Total**
Positive on full waiver	10	14	24
Positive on PIPs including potential deferral	2	33	35
Negative Opinions adopted	0	1	1
Positive Opinions adopted on Modification of the PIP	0	1	1
Positive opinion on Compliance with PIP	0	1	1

[1] Figures including 5 June 2008 start of procedure; the figure does not include products which are currently under validation.
[2] Of which 46 are requests for full waiver.
[3] Applications submitted in accordance with Regulation (EC) No 1901/2006, as amended.

Areas covered by PIPs/waiver applications:	**2007 (%)**	**2008 %**
Neurology	12	3
Uro-nephrology	-	5
Gastroenterology-hepatology	9	1
Pneumology-allergology	8	3
Infectious diseases	12	7
Cardiovascular diseases	12	11
Diagnostics	-	2
Endocrinology-gynaecology-fertility-metabolism	19	22
Neonatology-paediatric intensive care	-	-
Immunology-rheumatology-transplantation	5	5
Psychiatry	5	4
Pain	1	2
Haematology-haemostaseology	1	8
Otorhinolaryngology	-	-
Oncology	11	14
Dermatology	1	1
Vaccines	2	9
Ophthalmology	1	1
Anaesthesiology	-	1
Nutrition	1	1