European Medicines Agency
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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 16-18 January 2008

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

- Losartan, from Merck Sharp and Dohme Limited, in the therapeutic area of cardiology;
- Montelukast, from Merck Sharp and Dohme Limited, in the therapeutic area of pneumology;
- Latanoprost, from Pfizer global research and development, in the therapeutic area of ophthalmology;
- Caspofungin, from Merck Sharp and Dohme Limited, in the therapeutic area of infectious diseases.

A PIP sets out a programme for the development of a medicine in the paediatric population, which aims to generate the necessary quality, safety and efficacy data through studies in children to support the authorisation of the medicine for use in children.

Decisions adopted
The EMEA adopted a decision on a product-specific waiver for lasofoxifene tartrate. Detailed information on this waiver is available on the EMEA website at:
www.emea.europa.eu/htms/human/paediatrics/decisions.htm

Strategy for a network of paediatric networks in the EU
The PDCO welcomed the adoption by the Agency's Management Board of the implementing strategy for the network of paediatric research networks, agreed by the PDCO after a public consultation phase. The EU-wide network will bring together existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population. The objectives of the network will be to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level and to avoid unnecessary duplication of studies and testing in the paediatric population.

The implementing strategy will be published shortly on the EMEA website.

Priority lists for studies into off-patent paediatric medicinal products
The PDCO started its work to update the priority list for studies into off-patent medicines (not covered by a patent or supplementary protection certificate) in advance of the next call from the European Commission for funding through the EU's Seventh Framework Programme. The initial list was drawn up by the Paediatric Working Party (PEG), the Agency's former temporary expert working party on paediatric medicines. It helps to ensure that funds are directed into research of off-patent medicines, for which there is a high need in the paediatric population. Ultimately, the aim is that more of these medicines can be submitted to the EMEA for a paediatric-use marketing authorisation. Once updated, the list will be released for public consultation.

Procedural aspects relating to class waivers
The EMEA and the PDCO finalised guidance on how to request a waiver of the requirement to submit a PIP in respect of a medicine intended to treat one of the conditions listed in the 'list of class waivers'

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(EMEA/551894/2007) adopted by the Agency in December. These are conditions that do not affect children.

Detailed information on the procedural aspects will be published shortly on the EMEA website.

Collaboration with FDA and interaction with experts
US Food and Drug Administration (FDA) observers attended the PDCO meeting and provided updated information on the US paediatric legislation, under the terms of the principles of interaction between the EMEA and the FDA Office of Pediatric Therapeutics.
The PDCO also continued its interaction with experts to bring state-of the-art knowledge to the PDCO's scientific discussions in the areas of dermatology, endocrinology and cell therapy.

The next meeting of the PDCO will be held on 13-15 February 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). EMEA decisions on PIPs/waivers are published, after deletion of commercially confidential information, on the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm
2. The priority list for studies into off-patent medicinal products can be found at: http://www.emea.europa.eu/pdfs/human/paediatrics/19797207en.pdf
3. The paediatric-use marketing authorisation is a new type of marketing authorisation for off-patent medicines that covers the indication for children and the formulation appropriate for all paediatric age groups. The development in children will follow a paediatric investigation plan (PIP) agreed by the Paediatric Committee. Paediatric-use marketing authorisations will benefit from 10 years of data protection (intellectual-property protection) as a reward for the development in children.
4. 'Principles of Interactions: Between EMEA and FDA Pediatric Therapeutics' is available from the FDA website at: http://www.fda.gov/oia/pediatricsIP.htm
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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OVERVIEW OF PAEDIATRIC INVESTIGATION PLAN/WAIVER APPLICATIONS

Total cumulative number of validated paediatric investigation plan (PIP) / waiver applications[1] 98[2]

- Applications submitted for a product not yet authorised (Article 7) 49 *(50%)*
- 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) 48 *(49%)*
- Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation (Article 30) 1 *(1%)*

PIPs and full waiver indications covered by these applications 220

Areas covered by PIPs/waivers:	**%**
Neurology	12
Uro-nephrology	-
Gastroenterology-Hepatology	8
Pneumology – Allergology	8
Infectious Diseases	12
Cardiovascular Diseases	12
Diagnostics	-
Endocrinology-Gynaecology-Fertility-Metabolism	19
Neonatology - Paediatric Intensive Care	-
Immunology–Rheumatology-Transplantation	4
Psychiatry	5
Pain	1
Haematology-Haemostaseology	1
Oto-rhino-laryngology	-
Oncology	11
Dermatology	1
Vaccines	3
Ophthalmology	1
Anaesthesiology	-
Nutrition	2

Number of Paediatric Committee (PDCO) Opinions	
On full waiver	10
On PIPs including potential deferral	6

[1] Including applications for which procedures started on 16 January 2008.
[2] Of which 17 are requests for a full waiver (in all subsets of the paediatric population). Figure does not include applications which are currently being validated.