European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 12-14 March 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:

- Meningococcal groups A, C, W-135 and Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein* (MenA-CRM, MenC-CRM, MenW-CRM, MenY-CRM), from Novartis Vaccines and Diagnostics S.r.l, in the therapeutic area of vaccines;
- Ezetimibe, from MSD-SP Limited, in the therapeutic area of endocrinology.

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.

Product-specific waivers
The PDCO adopted product-specific waivers for Flibanserin, from Boehringer Ingelheim GmbH, in the therapeutic area of gynaecology, and Roflumilast, from Nycomed GmbH, in the therapeutic area of pneumology, recommending that the obligation to submit data obtained through clinical studies with children be waived in all subsets of the paediatric population.

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.

Decisions adopted
The EMEA adopted decisions on PIPs for Caspofungin, Latanoprost, Losartan and Montelukast. These decisions will be published shortly on the EMEA website at:
http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm

Consultation on registration and public access to information on paediatric clinical trials
The PDCO was informed of the launch by the European Commission of a public consultation on a draft guidance on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the EMEA. This includes information on the protocol and on the results of clinical trials for a medicine for use in the paediatric population, regardless of whether the medicine concerned has already received a marketing authorisation in the Community or not. The EudraCT database should comprise all ongoing, prematurely terminated and completed paediatric studies, whether conducted in the Community or not.

* corr. The name of the medicine has been corrected.

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The Paediatric Regulation introduced this requirement to increase the availability of information on medicines for the paediatric population and to avoid unnecessary repetition of studies in children. The draft guidance describes the roles and responsibilities of the stakeholders, as well as the scientific and organisational data to be registered. The consultation is open until 18 April 2008.

The PDCO continued its work on the update of the priority list for studies into off-patent medicines (not covered by a patent in Europe) in advance of the next call from the European Commission for funding through the EU's Seventh Framework Programme. The PDCO intends to finalise this list at its next meeting and to release it for public consultation.

The next meeting of the PDCO will be held on 9-11 April 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).
2. The draft guidance on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the EMEA can be found at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_02/guidance-eudra-ct-paediatric-clinical-trials_02-%202008.pdf
3. The priority list for studies into off-patent medicines 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. The priority list for studies into off-patent medicinal products can be found at: http://www.emea.europa.eu/pdfs/human/paediatrics/19797207en.pdf
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

Total cumulative number of validated paediatric investigation plans (PIP) / waiver applications[1] 145[2]

- Applications submitted for a product not yet authorised (Article 7)[3] 85 *(58%)*
- 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) 56 *(39%)*
- Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation (Article 30) 4 *(3%)*

PIPs and full waiver indications covered by these applications 286

Areas covered by PIPs/waivers:	**%**
Neurology	9
Uro-nephrology	-
Gastroenterology-hepatology	6
Pneumology-allergology	7
Infectious diseases	9
Cardiovascular diseases	9
Diagnostics	1
Endocrinology-gynaecology-fertility-metabolism	21
Neonatology-paediatric intensive care	-
Immunology-rheumatology-transplantation	6
Psychiatry	4
Pain	1
Haematology-haemostaseology	5
Otorhinolaryngology	-
Oncology	13
Dermatology	1
Vaccines	5
Ophthalmology	1
Anaesthesiology	1
Nutrition	1

Number of Paediatric Committee (PDCO) opinions	
On full waiver	14
On PIPs including potential deferral	11

[1] Figures including 13 March 2008 start of procedure; the figure does not include products which are currently under validation.
[2] Of which 25 are requests for full waiver.
[3] Applications submitted in accordance with Regulation (EC) No 1901/2006, as amended.