European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 18-20 December 2007

First opinions on paediatric investigation plans adopted
The European Medicines Agency's (EMEA) Paediatric Committee (PDCO) adopted its first opinions on paediatric investigation plans (PIPs).
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.

The opinions on PIPs adopted by the PDCO relate to the following medicines:

- L-Asparaginase, from medac Gesellschaft fuer Klinische Spezialpraeparate mbH, in the therapeutic area of oncology;
- Tacrolimus, from Astellas Pharma GmbH, in the therapeutic area of immunology.

Six opinions on product-specific waivers adopted
The PDCO adopted opinions on six product-specific waivers, recommending that the obligation to submit data obtained through clinical studies with children be waived for the following medicinal products relating to all subsets of the paediatric population:

- Indacaterol maleate, from Novartis Europharm Ltd, in the therapeutic area of pneumology;
- Glycopyrronium bromide, from Novartis Europharm Ltd, in the therapeutic area of pneumology;
- Indacaterol maleate/ glycopyrronium bromide, from Novartis Europharm Ltd, in the therapeutic area of pneumology;
- Telmisartan/ramipril, from Boehringer Ingelheim International GmbH, in the therapeutic area of cardiology;
- Rosiglitazone maleate, from GlaxoSmithKline R&D Limited, in the therapeutic area of neurology;
- Panobinostat, from Novartis Europharm Limited, in the therapeutic area of oncology.

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 the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Decisions adopted
The EMEA has adopted decisions on product-specific waivers for three medicines. Detailed information on these waivers is available on the EMEA website at:
www.emea.europa.eu/htms/human/paediatrics/decisions.htm

Other ongoing activities
The PDCO continued to review scientific and operational issues, including:

* Annex with the overview of PIPs and waivers applications included.

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- Interaction with experts in the area of paediatric pneumology and psychiatry with a view to bringing state-of-the-art knowledge to the PDCO's scientific discussions;
- First discussion of comments received during the public consultation on the EMEA's list of class waivers, relating to conditions that are not yet included in the adopted list. Following review of the comments, the PDCO may adopt further opinions recommending the granting of waivers at a later stage.

The next meeting of the PDCO will be held on 16-18 January 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 'Medicines for children' section of the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm
2. Following an opinion adopted by the Paediatric Committee during its meeting of 21-23 November 2007, the EMEA adopted a list of conditions that occur only in adult populations. The requirement to submit a paediatric investigation plan is waived for classes of medicines intended to treat these conditions. This 'list of class waivers' is available on the 'Medicines for children' section of the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/classwaivers.htm
3. For medicinal products falling under the obligations set out in the Paediatric Regulation but which are intended for the treatment of one or more of the conditions waived, submission of a request for a product-specific waiver to the EMEA is still necessary.
4. 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 Plans (PIP) / Waiver applications[1] 85[2]

- Application submitted for a product not yet authorised (Article 7) 39 *(46%)*
- Application 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 *(53%)*
- Application 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 202

Areas covered by PIPs/waivers:	**%**
Neurology	12
Uro-nephrology	-
Gastroenterology-Hepatology	9
Pneumology – Allergology	8
Infectious Diseases	12
Cardiovascular Diseases	12
Diagnostics	-
Endocrinology-Gynaecology-Fertility-Metabolism	19
Neonatology - Paediatric Intensive Care	-
Immunology–Rheumatology-Transplantation	5
Psychiatry	5
Pain	1
Haematology-Haemostaseology	1
Oto-rhino-laryngology	-
Oncology	11
Dermatology	1
Vaccines	2
Ophthalmology	1
Anaesthesiology	-
Nutrition	1

Number of Paediatric Committee (PDCO) Opinions	
On full waiver	10
On PIPs including potential deferral	2

[1] figures including 20 December 2007 start of procedure; the figure does not include products which are currently under validation

[2] of which 14 are requests for full waiver