European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 24-26 October 2007

First opinions for product-specific waivers
The first opinions for three product-specific waivers were adopted by the European Medicines Agency's (EMEA) Paediatric Committee (PDCO) at its fifth meeting, on 24-26 October 2007 at the EMEA. The product-specific waivers, issued within the 60-day period set out by the regulation on paediatric medicines, relate to the following medicinal products:

- **Everolimus**, from Novartis Europham Ltd, in the therapeutic area of oncology;
- **Atacand Plus** (candesartan cilexetil/hydrochlorothiazide), from AstraZeneca, in the therapeutic area of cardiology;
- **Blopress Comp/Comp Forte** (candesartan cilexetil/hydrochlorothiazide), from Takeda Global Research & Development Centre Ltd, in the therapeutic area of cardiology.

Obtaining a waiver means that the applicant does not need to establish a paediatric investigation plan (PIP) for development of these medicinal products in the paediatric population.

Unless the applicant requests a re-examination of a PDCO opinion within 30 days, the opinion becomes final. This final opinion is then transformed into an EMEA decision, within 10 days. EMEA decisions on PIPs/waivers are published in the 'Medicines for children' section of the EMEA website, after deletion of commercially confidential information.

The PDCO continued its interaction with academic experts. The aim of such interaction is to ensure that a PDCO opinion on a PIP or waiver reflects the state-of-the-art knowledge in the different paediatric fields (e.g. cardiovascular, ophthalmology, bone diseases).

List of needs in gastroenterology
The Committee released for six-months' public consultation a list of paediatric needs for gastroenterology, building on the work done by the Paediatric Working Party – the former EMEA temporary expert working party on paediatric medicines.

Guidance on the data to be collected by Member States
The Paediatric Committee adopted guidance on the content and the format of data to be collected by Member States on all existing uses of medicinal products in the paediatric population, which should be completed by the end of 2008 and must be communicated to the Agency. The data will be used by the PDCO to establish an inventory of paediatric needs.

Review of the feedback on the list of class waivers
The PDCO further reviewed the comments received on a list of class waivers referring to symptomatic conditions that do not affect children and for which a PIP will not be required. The class waivers relate, for example, to different types of cancer (lung cancer, basal cell carcinoma, breast and ovarian cancer, multiple myeloma, etc.), neurodegenerative conditions (Alzheimer's disease, Parkinson's disease), and other conditions that occur only in the adult population (age-related macular degeneration, chronic obstructive pulmonary disease, etc.). An opinion on the list of class waivers is expected to be adopted at the next PDCO meeting, to be transformed into a further decision by the Agency.

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The next meeting of the PDCO will be held on 21-23 November 2007.

-- ENDS --

Notes:

1. The Paediatric Regulation (Regulation (EC) No 1901/2006 as amended) states that waivers can be issued, in particular, if there is evidence showing that the specific medicinal product or class of medicinal products concerned is likely to be ineffective or unsafe in the paediatric population (or part of the paediatric population), or that the disease or condition for which the medicinal product is intended occurs only in adult populations, or the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.
2. The list of paediatric needs for gastroenterology will be available for consultation on the EMEA's 'Medicines for children' web pages.
3. 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 number of validated Paediatric Investigation Plans (PIP) / Waiver applications[1]	57[2]
▪ Application submitted for a product not yet authorised (Article 7)	23 *(40%)*
▪ 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)	33 *(58%)*
▪ Application submitted for an off-patent product developed specifically for children with an age-appropriate formulation (Article 30)	1 *(2%)*
PIPs and full waiver indications covered by these applications	148

Areas covered by PIPs/waivers:	**%**
Neurology	10
Uro-nephrology	-
Gastroenterology-Hepatology	5
Pneumology – Allergology	10
Infectious Diseases	10
Cardiovascular Diseases	18
Diagnostics	-
Endocrinology-Gynaecology-Fertility-Metabolism	16
Neonatology - Paediatric Intensive Care	-
Immunology–Rheumatology-Transplantation	4
Psychiatry	4
Pain	2
Haematology-Haemostaseology	-
Oto-rhino-laryngology	-
Oncology	14
Dermatology	-
Vaccines	3
Ophthalmology	2
Anaesthesiology	-
Nutrition	2

Number of Paediatric Committee (PDCO) Opinions	
On full waiver	3
On PIPs including potential deferral	0

[1] figures as of 25 October 2007; the figure does not include products which are currently under validation
[2] of which 11 are requests for full waiver