European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 21-23 November 2007

List of class waivers
The European Medicines Agency's (EMEA) Paediatric Committee (PDCO) adopted an opinion on a list of class waivers for condition(s) that do not affect children and for which the requirement to submit a paediatric investigation plan (PIP) can therefore be waived.

The list, which was released for public consultation, includes 17 symptomatic conditions relating, 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, menopausal disorders, etc.).

The list refers to waivers for the treatment of these conditions and does not include waivers for medicines used for their prevention or diagnosis. The Agency will take a final decision on the PDCO opinion on the list of class waivers within 10 days. Once approved, the list of waivers will be regularly updated in light of the advance of knowledge and science in the paediatric field.

Product-specific waiver
The PDCO adopted a product-specific waiver for lasofoxifene tartrate, from Pfizer Limited, in the area of bone diseases. It means that in the waived condition, the applicant is not required to conduct clinical trials to develop this medicinal product in the paediatric population. This is the fourth product-specific waiver issued by the PDCO.

Other ongoing activities
The PDCO continued discussing operational issues in the framework of its responsibilities, in particular:

- The PDCO recommendation to the European Commission on a symbol for medicinal products with a paediatric indication;
- Update on the implementation of the Paediatric Regulation in dialogue with the European Commission;
- Update on the renewal of the US legislation on paediatrics;
- Interaction with academic experts with a view to bring state-of-the-art knowledge to the PDCO scientific discussions in the area of epilepsy and seizures in children, including in neonates.

The next meeting of the PDCO will be held on 18-20 December 2007.

-- ENDS --

Notes:
1. As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children, and so a paediatric investigation plan (PIP) will not be required by the Paediatric Committee; the requirement for a PIP will therefore be waived in these cases.

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2. The list of class waivers will be published on the Agency's website (www.emea.europa.eu) once a final decision on the list is given by the EMEA.
3. For medicinal products falling under the obligations set out in the Paediatric Regulation (Regulation (EC) No 1901/2006 as amended) 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. 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 will be published on the EMEA website, after deletion of commercially confidential information.
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 (PIP)/WAIVER APPLICATIONS

Total number of validated applications[1] for PIPs and waivers	71[2] (100%)
Applications submitted for a product not yet authorised (Article 7 of Regulation (EC) No 1901/2006)	27 *(38%)*
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 of Regulation (EC) No 1901/2006)	43 *(61%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation (Article 30 of Regulation (EC) No 1901/2006)	1 *(1%)*

PIPs and full waiver indications covered by these applications 182

Areas covered by PIPs/waivers:	**%**
Neurology	12
Uro-nephrology	-
Gastroenterology-Hepatology	10
Pneumology-Allergology	8
Infectious Diseases	11
Cardiovascular Diseases	14
Diagnostics	-
Endocrinology-Gynaecology-Fertility-Metabolism	18
Neonatology-Paediatric Intensive Care	-
Immunology-Rheumatology-Transplantation	4
Psychiatry	3
Pain	2
Haematology-Haemostaseology	-
Oto-rhino-laryngology	-
Oncology	11
Dermatology	-
Vaccines	3
Ophthalmology	2
Anaesthesiology	-
Nutrition	2

Number of Paediatric Committee (PDCO) opinions	
On full waiver	4
On PIPs (including potential deferral of PIPs)	0

[1] Figures as of 22 November 2007 (the figures do not include products that are currently under validation).
[2] Of which 11 are requests for a full waiver (in all subsets of the paediatric population).