European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 6-8 May 2008

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:

- Tifacogin, from Novartis Europharm Limited, in the therapeutic area of infectious diseases;
- Pitavastatin calcium, from Kowa Pharmaceutical Europe Ltd, in the therapeutic area of endocrinology and metabolism;
- Taranabant, from Merck Sharp & Dohme (Europe) Inc., in the therapeutic area of endocrinology and metabolism;
- Tapentadol hydrochloride, from Grünenthal GmbH, in the therapeutic area of pain;
- Pneumococcal conjugate serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F vaccine, from Wyeth Lederle Vaccines S.A., in the therapeutic area of vaccines;
- Zoledronic acid, from Novartis Europharm Ltd, in the therapeutic area of endocrinology and metabolism.

The PDCO adopted a negative opinion on a PIP for risedronate sodium (hemipentahydrate), from Procter & Gamble Pharmaceuticals UK, in the therapeutic area of endocrinology and metabolism.

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 subsets of the paediatric population.

Opinions on product-specific waivers
The PDCO adopted positive opinions for product-specific waivers recommending that the obligation to submit data obtained through clinical studies with children be waived in all subsets of the paediatric population for the following medicines:

- Acetyl-(Lys)6-a-MSH acetate, from Action Pharma A/S, in the therapeutic area of nephrology;
- Dutasteride and tamsulosin hydrochloride, from Glaxo Group Ltd, in the therapeutic area of urology;
- Elocalcitol, from BioXell SpA, in the therapeutic area of urology;
- Vernakalant hydrochloride, from Cardiome UK Limited, in the therapeutic area of cardiology.

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.

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Decisions adopted
Following the adoption of opinions by the PDCO, the EMEA adopted decisions on PIPs for Meningococcal ACWY Conjugate Vaccine (meningococcal groups A, C, W-135 and Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein) and for ezetimibe. In addition, the Agency adopted decisions on a product-specific waiver in all subsets of the paediatric population for flibanserin and roflumilast.

These decisions will be published shortly on the EMEA website at:
http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm

Other ongoing activities
The PDCO continued the discussion with the Vaccines Working Party of the Agency's Committee for Medicinal Products for Human Use (CHMP) on PIPs for flu vaccines including vaccines against pandemic flu.

The next meeting of the PDCO will be held on 2-4 June 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. 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
3. 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

	2007 (August to December)	**2008 (**January-May)	**Cumulative Total**
Total number of validated PIP / waiver applications	**85**	**113**[1]	**198**[2]
Applications submitted for a product not yet authorised *(Article 7*[v1]*)*[3]	39	85	124 *(63%)*
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)*	45	23	68 (*34%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30)*	1	5	6 *(3%)*
PIPs and full waiver indications covered by these applications	**202**	**159**	**361**

Number of Paediatric Committee (PDCO) opinions	**2007**	**2008**	**Total**
Positive on full waiver	10	9	19
Positive on PIPs including potential deferral	2	25	27
Negative Opinions adopted	0	1	1

[1] figures including 8 May 2008 start of procedure; the figure does not include products which are currently under validation
[2] of which 44 are requests for full waiver
[3] applications submitted in accordance with Regulation (EC) No 1901/2006, as amended.

Areas covered by PIPs/waiver applications:	**2007 (%)**	**2008 %**
Neurology	12	3
Uro-nephrology	-	6
Gastroenterology-hepatology	9	1
Pneumology-allergology	8	3
Infectious diseases	12	8
Cardiovascular diseases	12	8
Diagnostics	-	2
Endocrinology-gynaecology-fertility-metabolism	19	22
Neonatology-paediatric intensive care	-	-
Immunology-rheumatology-transplantation	5	5
Psychiatry	5	4
Pain	1	2
Haematology-haemostaseology	1	7
Otorhinolaryngology	-	-
Oncology	11	14
Dermatology	1	2
Vaccines	2	8
Ophthalmology	1	2
Anaesthesiology	-	2
Nutrition	1	1