European Medicines Agency
Press office

London, 24 September 2008
Doc. Ref. EMEA/PDCO/493761/2008

PRESS RELEASE
Meeting highlights from the Paediatric Committee, 17-19 September 2008

Representatives of patients and healthcare professionals join the Paediatric Committee

At its September 2008 meeting, the Paediatric Committee (PDCO) welcomed new members to represent the interests of patients and of healthcare professionals. The six new members, together with their alternates, were appointed by the European Commission, following a public call for expressions of interest and consultation with the European Parliament.

The new members, who will be involved in the PDCO's procedures in the same way as other members, bring additional paediatric expertise and experience to the Committee. The PDCO is the second European Medicines Agency (EMEA) scientific committee in which representatives of civil society participate as full members (the first being the Committee on Orphan Medicinal Products).

Opinions on paediatric investigation plans

The Paediatric Committee adopted positive opinions on paediatric investigation plans (PIPs) for the following medicines:

- **Aprepitant,** from Merck Sharp and Dohme Ltd, in the therapeutic area of oncology;
- **Belatacept,** from Bristol-Myers Squibb International Corporation, in the therapeutic area of immunology and rheumatology;
- **Dienogest,** from Bayer Schering Pharma AG, in the therapeutic area of endocrinology, gynaecology, fertility, metabolism;
- **Eltrombopag (Eltrombopag Olamine)**, from Glaxo Group Limited, in the therapeutic area of haematology;
- **Ipilimumab,** from Bristol-Myers Squibb International Corporation, in the therapeutic area of oncology;
- **Nalfurafine Hydrochloride,** from Toray International U.K. Limited, in the therapeutic area of dermatology;
- **Nomegestrol acetate, 17 beta-estradiol,** from NV Organon, part of Schering-Plough Corporation, in the therapeutic area of endocrinology, gynaecology, fertility, metabolism;
- **Paracetamol,** from Baxter World Trade S.A., in the therapeutic area of pain and fever;
- **Skimmed cow's milk powder,** from DBV Technologies, in the therapeutic area of diagnostic & other;
- **Vandetanib,** from AstraZeneca, in the therapeutic area of oncology.

A paediatric investigation plan 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. These data have to be submitted to the EMEA as part of an application for a marketing authorisation for new medicinal products or products covered by a patent. In some cases, a PIP may include a waiver to study one or more age groups of children, or a deferral when it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population, or when studies in the paediatric population would take longer to conduct than studies in adults.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Product-specific waivers
The PDCO adopted a negative opinion on a request for a full waiver for perflubutane, from Nycomed Danmark ApS, in the therapeutic area of cardiovascular diseases.

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

Re-examination of opinion
Following a request for re-examination of the opinion adopted on a paediatric investigation plan, including a deferral and a product-specific waiver, the PDCO confirmed its previous positive opinion and adopted a new, definitive opinion for **bevacizumab (Avastin),** from Roche Registration Limited, in the therapeutic area of oncology.

A re-examination of an opinion can be requested by the applicant within 30 days following receipt of the opinion of the PDCO. The grounds for the re-examination should be based only on the original information and scientific data provided in the application which were previously available to the PDCO and on which the initial opinion was based. This may include new analysis of the same data or minor protocol amendments to a previously proposed study. Significant changes to the previous plan cannot be part of the re-examination process.

New meeting dates adopted
PDCO meeting dates for 2010 and 2011 were adopted during the September meeting. The dates are important for applicants in planning the submission of applications for PIPs, request for waivers, requests for modification of an agreed PIP, and compliance checks. The dates will be published on the website of the European Medicines Agency shortly.

Interaction with experts
The PDCO invited two experts to discuss current trends and developments in the treatment of juvenile idiopathic arthritis.
Arthritis is the inflammation of the lining tissue of a joint. Juvenile idiopathic arthritis, the most common form of persistent arthritis in children, differs significantly from arthritis commonly seen in adults (osteoarthritis, rheumatoid arthritis), and age-appropriate treatment options are needed.

The PDCO regularly interacts and cooperates with experts in specific scientific or technical fields, to keep abreast of recent developments and be able to apply state-of-the art knowledge in its scientific assessments.

Other issues
The PDCO meeting was attended by an observer from the Japanese authorities, under the terms of the confidentiality arrangements signed between the European Commission, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare (MHLW) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), in February 2007.

The next meeting of the PDCO will be held on 15-17 October 2008.

-- ENDS --

Notes:

1. The list of PDCO members can be found at: http://www.emea.europa.eu/htms/general/contacts/PDCO/PDCO_members.html
2. The legal basis for the appointment of PDCO members to represent healthcare professionals and patient associations is Article 4(1)(c) and (d) of Regulation (EC) 1901/2006, as amended.
3. The Decision of the European Commission of 31 July 2008 appointing members and alternates of the Paediatric Committee to represent healthcare professionals and patient associations

(2008/646/EC) can be found at the website of the European Commission: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:212:0005:0005:EN:PDF

4. 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). The decisions can be found on the EMEA website: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm
5. More information about the PDCO and the Paediatric Regulation is available in the 'Medicines for children' section of the EMEA website.
6. 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

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu

OVERVIEW OF PAEDIATRIC INVESTIGATION PLAN/WAIVER APPLICATIONS

	2007 (August to December)	**2008** (January-September)	**Cumulative Total**
Total number of validated PIP / waiver applications	**85**	**208**[1]	**293**[2]
Applications submitted for a product not yet authorised *(Article 7)*	39	147	186 *(64%)*
Applications concerning a product already authorised and still under patent, submitted to obtain a variation/extension for a new indication, pharmaceutical form or route of administration *(Article 8)*	45	55	100 (*34%)*
Applications submitted for an off-patent product developed specifically for children, with an age-appropriate formulation *(Article 30)*	1	6	7 *(2%)*
PIPs and full waiver indications covered by these applications	**202**	**306**	**508**

Number of Paediatric Committee opinions	**2007**	**2008**	**Cumulative Total**
Positive opinions on full waiver	10	30	40
Positive opinions on PIPs including potential deferral	2	62	64
Negative opinions adopted	0	2	2
Positive opinions adopted on modification of a PIP	0	2	2
Positive opinions on compliance with a PIP	0	1	1

[1] Includes procedures that started on 25 September 2008 and is therefore a provisional figure as validation of these procedures is ongoing.
[2] Of which 62 are requests for full waiver.

Areas covered by PIPs/waiver applications	**2007** (%)	**2008** (%)
Neurology	12	4
Uro-nephrology	-	4
Gastroenterology-hepatology	9	4
Pneumology-allergology	8	6
Infectious diseases	12	7
Cardiovascular diseases	12	11
Diagnostics	-	1
Endocrinology-gynaecology-fertility-metabolism	19	17
Neonatology-paediatric intensive care	-	1
Immunology-rheumatology-transplantation	5	7
Psychiatry	5	3
Pain	1	3
Haematology-haemostaseology	1	5
Otorhinolaryngology	-	-
Oncology	11	12
Dermatology	1	3
Vaccines	2	7
Ophthalmology	1	3
Anaesthesiology	-	1
Nutrition	1	1