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PRESS RELEASE

Meeting highlights from the Paediatric Committee, 2-4 July 2008

The Paediatric Committee (PDCO) celebrated its first anniversary at its 2-4 July 2008 meeting. Established as the fifth scientific committee within the European Medicines Agency (EMA), the Committee's main task is to provide scientific opinions on the development of medicines for use in children. Working in cooperation with Member States and EU partners, and in conjunction with learned societies and industry, the PDCO successfully prepared the groundwork to fulfil its responsibilities stemming from the Paediatric Regulation in its first year of operation,

Highlighting the achievements of the PDCO, the EMA Executive Director, Thomas Lönngren, said, "Together with our partners in the European medicines network and our stakeholders, the Paediatric Committee has made a major contribution to the challenge of providing better medicines for children in Europe. The establishment of the PDCO was the most significant achievement of the Agency in 2007. The PDCO has met the high expectations by performing strongly in its core tasks and in a number of activities of public health value as a result of the implementation of the Paediatric Regulation."

Daniel Bresseur, chair of the PDCO, added, "Thanks to the impressive dedication of its members, constantly supported by the EMA Paediatric Team, the PDCO succeeded in looking at more than 200 Paediatric investigation plans (PIP) corresponding to about twice as many indications, delivering already more than 70 decisions. Since nearly two-third of the opinions were issued for non registered products still in their conceptual phase, such PIP decisions will undoubtedly have a dramatic impact on future drug development, both for children and adults. Ethical considerations and safe research leading to age appropriate formulations addressing more specifically child diseases remain the top priorities of a very keen body of paediatric experts."

A full report on the first year of the activity of the PDCO can be found [here](#).

Positive opinions on paediatric investigation plans adopted

The PDCO adopted positive opinions on paediatric investigation plans for the following medicines:

- **Ribavirin (Rebetol)** from Schering-Plough Europe, in the therapeutic area of gastroenterology and hepatology;
- **Peginterferon alfa-2b (PegIntron)**, from Schering-Plough Europe, in the therapeutic area of gastroenterology and hepatology;
- **Tiotropium bromide**, from Boehringer Ingelheim International GmbH, in the therapeutic area of pneumology;
- **Eplivanserin hemifumarate**, from SanofiAventis Recherche & Développement, in the therapeutic area of psychiatry;
- **Bevacizumab (Avastin)**, from Roche Registration Ltd, in the therapeutic area of oncology.

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 age groups of children.

Adoption of a revised opinion

Following a request for re-examination of the positive opinion adopted in May 2008, the PDCO adopted a revised positive opinion on a PIP for **Tapentadol hydrochloride**, from Grünenthal GmbH, in the therapeutic area of neurology.

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 is 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.

Opinions on product-specific waivers

The PDCO adopted a product-specific waiver, 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:

- **Pioglitazone hydrochloride and metformin hydrochloride (Competact / Glubrava)**, from Takeda Global Research and Development Centre (Europe) Ltd, in the therapeutic area of endocrinology and metabolism;
- **Balaglitazone**, from Rheoscience A/S, in the therapeutic area of endocrinology and metabolism;
- **Dexamethasone**, from Allergan Pharmaceuticals Ireland, in the therapeutic area of ophthalmology;
- **Aciclovir and hydrocortisone**, from Medivir AB, in the therapeutic area of infectious 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 specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Opinion on class waiver

The PDCO, having reviewed the decision on class waivers of 3 December 2007 and 21 April 2008, adopted an opinion to change the class waiver for the condition of treatment of melanoma. The PDCO recommends maintaining the waiver for the age range from 0 to less than 12 years and revoking the waiver for the subset of the paediatric population from 12 to less than 18 years. The opinion will be forwarded to the EMEA to issue a decision within 10 days.

In accordance with the Paediatric Regulation, if a class waiver is revoked, the requirements set out in Articles 7 and 8 of the Paediatric Regulation shall not apply to this condition for the subsets of the paediatric population from 12 to less than 18 years for 36 months from the date of the removal from the list of waivers, i.e. until 14 July 2011.

Update of the priority list for off-patent medicines

The PDCO reviewed the comments made on the draft of the revised priority list for studies into off-patent medicines (not covered by a patent in Europe), after a public consultation phase. This list will be finalised in advance of the next call from the European Commission in September 2008 for funding through the EU's Seventh Framework Programme.

Informal meeting

On 1 July, the PDCO held an informal meeting to review the work done and the processes put in place during its first year. The PDCO discussed improvements in the functioning of the PDCO, in particular

timelines, summary reports, interactions with experts, learned societies and industry, and priorities in the implementation of the Paediatric Regulation.

The next meeting of the PDCO will be held on 29-31 July 2008.

-- ENDS --

Notes:

1. [Regulation \(EC\) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended by Regulation \(EC\) No 1902/2006.](#)
2. 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 at <http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm>.
3. Further information on the re-examination procedure for paediatric investigation plan and/or waiver opinions by the Paediatric Committee (PDCO) can be found at <http://www.emea.europa.eu/htms/human/paediatrics/2360408en.pdf>
4. Article 7 and article 8 of the Paediatric Regulation refer to the obligation for pharmaceutical companies to submit the results of all studies performed in compliance with an agreed Paediatric investigation plan, a decision of the Agency granting a product-specific waiver or a class waiver, or a decision of the Agency granting a deferral at the time of the submission of an application for a marketing authorisation for an unauthorised medicine or for a medicine already authorised and still under patent.
5. 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>
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- July)	Cumulative Total
Total number of validated PIP / waiver applications	85	148¹	233²
Applications submitted for a product not yet authorised (<i>Article 7</i>) ³	39	104	143 (61%)
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 (<i>Article 8</i>)	45	39	84 (36%)
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation (<i>Article 30</i>)	1	5	6 (3%)
PIPs and full waiver indications covered by these applications	202	221	423

Number of Paediatric Committee (PDCO) opinions	2007	2008	Total
Positive on full waiver	10	21	31
Positive on PIPs including potential deferral	2	37	39
Negative Opinions adopted	0	1	1
Positive Opinions adopted on Modification of the PIP	0	1	1
Positive opinion on Compliance with PIP	0	1	1

¹ figures including 1 July 2008 start of procedure; the figure does not include products which are currently under validation

² of which 49 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	-	5
Gastroenterology-hepatology	9	1
Pneumology-allergology	8	4
Infectious diseases	12	7
Cardiovascular diseases	12	12
Diagnostics	-	2
Endocrinology-gynaecology-fertility-metabolism	19	21
Neonatology-paediatric intensive care	-	-
Immunology-rheumatology-transplantation	5	5
Psychiatry	5	3
Pain	1	3
Haematology-haemostaseology	1	6
Otorhinolaryngology	-	-
Oncology	11	14
Dermatology	1	2
Vaccines	2	8
Ophthalmology	1	2
Anaesthesiology	-	1
Nutrition	1	1