European Medicines Agency

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# Meeting highlights from the Paediatric Committee 4-6 March 2009

**Opinions on paediatric investigation plans**
The Paediatric Committee (PDCO) adopted opinions agreeing paediatric investigation plans (PIPs) for the following medicines:

- Sieved freeze-dried allergen extract of dermatophagoides farinae / Sieved freeze-dried allergen extract of dermatophagoides pteronyssinus, from Stallergenes, in the therapeutic area of Pneumology-allergology;
- Ulipristal**,** from Laboratoire HRA Pharma, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1)**,** from GSK Biologicals, in the therapeutic area of vaccines;
- Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1)**,** from GSK Biologicals, in the therapeutic area of vaccines;
- Purified antigen fractions of inactivated split virion Influenza A/VietNam/1194/2004(H5N1)**,** from GlaxoSmithKline Biologicals S.A, in the therapeutic area of vaccines;
- Dihydroarteminsin /Piperaquine phosphate anhydride**,** from Sigma-Tau SpA, in the therapeutic area of infectious diseases;
- Sitagliptin phosphate monohydrate**,** from Merck Sharp and Dohme (Europe), Inc, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- Telcagepant from Merck Sharp and Dohme Ltd, in the therapeutic area of pain and neurology;
- Calcipotriol hydrate / hydrocortisone from LEO Pharma A/S, in the therapeutic area of dermatology;
- Mercaptopurine monohydrate from Nova Laboratories Limited, in the therapeutic area of oncology;
- Recombinant human monoclonal antibody of the IgG1 class to insulin-like growth factor-1 receptor from Roche Registration Limited, in the therapeutic area of oncology.

A 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. These data have to be submitted to the EMEA, or national competent authorities, as part of an application for a marketing authorisation for a new medicine or for one covered by a patent. In some cases, a PIP may include a waiver of the studies in one or more paediatric subsets, or a deferral.

**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:

- Pasireotide, from Novartis Europharm Ltd, in the therapeutic area of Endocrinology-gynaecology-fertility-metabolism;
- Bismuth subcitrate potassium/ Metronidazole/Tetracycline hydrochloride, from Axcan Pharma SA, in the therapeutic area of gastroenterology-hepatology;

* Note 2 on page 2 has been corrected.

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Waivers can be issued if there is evidence that the medicine 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 medicine, or the performance of trials, does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The PDCO adopted one opinion on the **refusal** of a request for waiver for:

- Bromfenac sodium sesquihydrate, from Croma Pharma GmbH, in the therapeutic area of ophthalmology.

**Opinions on modifications to an agreed PIP**
The PDCO adopts opinions on Modifications to an agreed PIP; these can be requested by the applicant, when the plan is no longer appropriate, or when there are difficulties that render the plan unworkable.

**Extrapolation working group**
A working group for devising strategy on extrapolation has been set up with members from the Committee. The first meeting was held during the March meeting and will be followed by regular interactions. The working group will report to the PDCO

**Update of the priority list for studies into off-patent paediatric medicinal products**
The PDCO started its third wave of meetings to update the priority list for studies into off-patent medicines in advance of the next call from the European Commission for funding through the EU's Seventh Framework Programme.
The initial list was drawn up by the Paediatric Working Party (PEG), the Agency's former temporary expert working party on paediatric medicines.
The updated list will comprise a number of medicines relating to various therapeutic areas.
This will be a reference for applicants for funding from the European Community through the Seventh Framework Programme.
Once the updated list is established, it will be published for comments in the 'Medicines for children' section of the EMEA website.

**Other issues**
- PDCO discussed the possible modification of the class waiver for "menopausal and other perimenopausal disorders".
- The Guideline on the investigation of medicinal products in the term and preterm neonate was reviewed by the Committee to accommodate comments from the public consultation.

The next meeting of the PDCO will be held on 1-3 April 2009.

– END –

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). The decisions can be found on the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm
2. As of 26 January 2009, applicants who submit an application for a marketing authorisation of a medicinal product, or those who submit an application for an extension of indication, a new route of administration, or a new pharmaceutical form of a medicinal product already authorised in the EEA and protected by a supplementary protection certificate or by a patent which qualifies for the granting of a supplementary protection certificate have to provide either the

results of studies in children conducted in accordance with an approved PIP, or an EMEA decision on a waiver or on a deferral.

3. More information about the PDCO and the Paediatric Regulation is available in the 'Medicines for children' section of the EMEA website.
4. This meeting report, together with other information on the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

Enquiries only to: paediatrics@emea.europa.eu

| | **2007** (August to December) | **2008** (January-December ) | **2009**- (January-March | **Cumulative Total** |
|---|---|---|---|---|
| **Total number of validated PIP / waiver applications** | **85** | **271** | **55** | **411**[1] |
| Applications submitted for a product not yet authorised *(Article 7*[2]*)* | 39 | 186 | 40 | 265 *(65%)* |
| 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*[2]*)* | 45 | 75 | 13 | 133 (*32%)* |
| Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30*[2]*)* | 1 | 10 | 2 | *13 (3%)* |
| **PIPs and full waiver indications covered by these applications** | **202** | **395** | **78** | **675** |

| **Number of Paediatric Committee (PDCO) opinions** | **2007** | **2008** | **2009** | **Total** |
|---|---|---|---|---|
| Positive on full waiver | 10 | 48 | 13 | 71 |
| Positive on PIPs including potential deferral | 2 | 81 | 39 | 122 |
| Negative Opinions adopted | 0 | 4 | 6 | 10 |
| Positive Opinions adopted on Modification of the PIP | 0 | 8 | 4 | 12 |
| Positive Opinion on Compliance with PIP | 0 | 5 | 1 | 6 |

[1] Of which 98 are requests for full waiver
[2] Applications submitted in accordance with this Article of Regulation (EC) No 1901/2006 as amended.

| Areas covered by PIPs/waiver applications: | 2007 (%) | 2008 (%) | 2009 (%) |
|---|---|---|---|
| Neurology | 12 | 6 | 2 |
| Uro-nephrology | - | 3 | 3 |
| Gastroenterology-hepatology | 9 | 3 | 3 |
| Pneumology-allergology | 8 | 6 | 3 |
| Infectious diseases | 12 | 8 | 12 |
| Cardiovascular diseases | 12 | 14 | 7 |
| Diagnostics | - | 1 | 2 |
| Endocrinology-gynaecology-fertility-metabolism | 19 | 15 | 28 |
| Neonatology-paediatric intensive care | - | 1 | - |
| Immunology-rheumatology-transplantation | 5 | 6 | 7 |
| Psychiatry | 5 | 3 | 2 |
| Pain | 1 | 3 | 5 |
| Haematology-haemostaseology | 1 | 5 | 9 |
| Otorhinolaryngology | - | 1 | - |
| Oncology | 11 | 12 | 7 |
| Dermatology | 1 | 3 | 4 |
| Vaccines | 2 | 6 | 4 |
| Ophthalmology | 1 | 2 | 2 |
| Anaesthesiology | - | 1 | - |
| Nutrition | 1 | 1 | - |