25 May 2011
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**Monthly report**

# Paediatric Committee (PDCO)

18-20 May 2011

## Opinions on paediatric investigation plans

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

- Chlorhexidine gluconate / isopropyl alcohol, from 3M Health Care Limited, in the therapeutic area of dermatology;
- Canagliflozin, from Johnson & Johnson Pharmaceutical Research & Development, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- Recombinant fusion protein consisting of Human Coagulation Factor VIII attached to the Fc domain of Human IgG1 (rFVIIIFc), from Biogen Idec Ltd., in the therapeutic area of haematology-haemostaseology;
- Ocrelizumab, from Roche Registration Limited, in the therapeutic area of neurology;
- A derivative of Octahydro-4-hydroxy-4-[phenylethynyl]-1H-indole-1-carboxylic acid ester (AFQ056), from Novartis Europharm Ltd, in the therapeutic area of neurology;
- Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae), from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;
- Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae), from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;
- Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae), from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;

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- Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis, from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;
- Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis, from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;
- Chemically modified extract of trees pollen from Birch and Alder, from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;
- Chemically modified extract of trees pollen from Birch and Alder, from Granzer Regulatory Consulting & Services, in the therapeutic area of pneumology - allergology / oto-rhino-laryngology;
- Influenza virus type A, H1N1 / influenza virus type A, H3N2 / influenza virus type B, yamagata lineage / influenza virus type B, victoria lineage, from MedImmune Limited, in the therapeutic area of vaccines;
- Risperidone, from Wockhardt UK Ltd, in the therapeutic area of psychiatry.

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 European Medicines Agency, 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 is waived in all subsets of the paediatric population, for the following medicines:

- Pravastatin sodium, acetylsalicylic acid, from Teva Pharma B.V., in the therapeutic area of cardiovascular diseases;
- Progesterone, from IBSA Farmaceutici Italia Srl, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- Alogliptin (benzoate) / metformin (hydrochloride), from Takeda Global Research and Development Centre (Europe) Ltd, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- Ciclosporin, from Allergan Pharmaceuticals Ireland, in the therapeutic area of ophthalmology.

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.

## Opinions on modifications to an agreed PIP

The PDCO also adopts, every month, opinions on modifications to an agreed PIP, which can be requested by the applicant when the plan is no longer appropriate or when there are difficulties that render the plan unworkable.

## Opinion on compliance check

The PDCO adopted a positive opinion on compliance check for meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM), meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM), meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM), meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM), from Novartis Vaccines and Diagnostics S.r.L, in the therapeutic area of vaccines.

A compliance check is performed to verify that all the measures agreed in a PIP and reflected in the Agency's decision have been conducted in accordance with the decision, including the agreed timelines. Compliance is one of several prerequisites for obtaining the rewards and incentives provided for in Articles 36 to 38 of the Paediatric Regulation.

Before the submission of a request for a compliance check, applicants are encouraged to consult the Agency's Procedural advice for validation of a new marketing authorisation application or extension/variation application and compliance check with an agreed PIP.

## Withdrawals

The PDCO noted that seven applications were withdrawn during the late stages of the evaluation (30 days or less before opinion).

## PDCO interactions

A delegation of the European Organisation for Rare Diseases attended the meeting of the PDCO in order to gain a better understanding of the PDCO activities and enhance the scientific collaboration between the two groups.

## Other issues

The next meeting of the PDCO will be held on 15-17 June 2011.

## – END –

## Notes:

1. PDCO opinions on PIPs and waivers are transformed into Agency's decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/pip_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d129

2. As of 26 January 2009, pharmaceutical companies that submit an application for a marketing authorisation for a medicinal product, or those that 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 European Union, have to provide either the results of studies in children conducted in accordance with an approved PIP, or an Agency's decision on a waiver or on a deferral.

3. More information about the PDCO and the Paediatric Regulation is available in the Regulatory section of the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000023.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cd

4. This meeting report, together with other information on the work of the Agency's, can be found on the Agency's website: http://www.ema.europa.eu

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# Annex of the May PDCO meeting report

| | 2009 (January to December) | 2010 (January to December) | 2011 (January to current month) | Cumulative total (2007 to 2010) |
|---|---|---|---|---|
| Total number of validated PIP/waiver applications | 273 | 326 | 76 | 1033[1] |
| Applications submitted for a product not yet authorised *(Article 7[2])* | 191 | 280 | 60 | 757 *(73%)* |
| Applications submitted for a product already authorised and 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])* | 72 | 43 | 15 | 250 *(24%)* |
| Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30[2])* | 10 | 4 | 1 | 26 *(3%)* |
| PIPs and full waiver indications covered by these applications | 395 | 403 | 93 | 1457 |

| Number of Paediatric Committee (PDCO) opinions | 2009 | 2010 | 2011 | Cumulative total |
|---|---|---|---|---|
| Positive on full waiver | 67 | 52 | 21 | 197 |
| Positive on PIP, including potential deferral | 122 | 201 | 55 | 461 |
| Negative opinions adopted | 13 | 7 | 1 | 25 |
| Positive opinions adopted on modification of a PIP | 51 | 103 | 60 | 222 |
| Negative opinions adopted on modification of a PIP | 0 | 4 | 0 | 4 |
| Positive opinions on compliance with a PIP | 8 | 9 | 1 | 23 |
| Negative opinions on compliance check with a PIP | 1 | 0 | 0 | 1 |
| Opinions adopted under Art. 14.2 | 0 | 2 | 0 | 2 |

[1] Of which 243 have been requests for a full waiver.
[2] Applications submitted in accordance with the referenced article of Regulation (EC) No 1901/2006, as amended.

| Areas covered by PIPs/waiver applications | 2009 ( % ) | 2010 ( % ) | *2011 (Number of areas covered)** |
|---|---|---|---|
| Neurology | 4 | 3 | 5 |
| Uro-nephrology | 5 | 2 | 0 |
| Gastroenterology-hepatology | 2 | 1 | 4 |
| Pneumology-allergology | 6 | 41 | 3 |
| Infectious diseases | 9 | 4 | 7 |
| Cardiovascular diseases | 9 | 8 | 12 |
| Diagnostics | 1 | 1 | 2 |
| Endocrinology-gynaecology-fertility-metabolism | 16 | 6 | 11 |
| Neonatology-paediatric intensive care | 2 | 0 | 2 |
| Immunology-rheumatology-transplantation | 6 | 5 | 5 |
| Psychiatry | 3 | 1 | 3 |
| Pain | 6 | 1 | 0 |
| Haematology-haemostaseology | 6 | 4 | 7 |
| Otorhinolaryngology | 1 | 3 | 0 |
| Oncology | 11 | 9 | 7 |
| Dermatology | 6 | 1 | 2 |
| Vaccines | 4 | 2 | 5 |
| Ophthalmology | 2 | 4 | 4 |
| Anaesthesiology | 1 | 2 | 0 |
| Nutrition | 0 | 0 | 0 |
| Other | | | 3 |

** One PIP can cover several therapeutic areas*