

## News from the EMA

### Activities of the PDCO

During its meeting from 8-9 September 2010 the Paediatric Committee (PDCO) elected Dr Daniel Brasseur as its Chair for a second term of three years, and Dr Dirk Mentzer as Vice-Chair and adopted the following opinions:

- **17 positive opinions** on paediatric investigation plans (**PIPs**) for the following products:
  - Riociguat, from Bayer Schering Pharma AG, in the therapeutic area of cardiovascular diseases;
  - Prucalopride succinate, from Movetis NV, in the therapeutic area of gastroenterology-hepatology;
  - Everolimus, from Novartis Europharm Limited, in the therapeutic area of immunology-rheumatology-transplantation;
  - Eculizumab, from Alexion Europe SAS, in the therapeutic area of immunology-rheumatology-transplantation;
  - Efavirenz, from Bristol-Myers Squibb Pharma EEIG, in the therapeutic area of infectious diseases;
  - Pagibaximab, from Biosynexus, Incorporated, in the therapeutic area of neonatology-paediatric intensive care;
  - L-asparaginase encapsulated in erythrocytes, from ERYtech Pharma, in the therapeutic area of oncology;
  - 12 Grass Pollen Extract and Cultivated Rye Pollen Extract (oromucosal solution), from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - 12 Grass Pollen Extract and Cultivated Rye Pollen Extract (suspension for injection), from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Dermatophagoides farinae and Dermatophagoides pteronyssinus extracts (oromucosal solution), from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Dermatophagoides farinae and Dermatophagoides pteronyssinus extracts (suspension for injection), from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Birch, hazel and alder pollen extracts, from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Birch pollen extract, from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Birch / alder / hazel pollen extract, from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Grass pollen extract, cultivated rye pollen extract and birch pollen extract, from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Grass pollen extract, cultivated rye pollen extract and birch/alder/ hazel pollen extract, from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology;
  - Grass pollen extract, cultivated rye pollen extract and mugwort pollen extract, from Allergy Therapeutics (UK) Ltd, in the therapeutic area of pneumology-allergology.
  
- **seven positive opinions** for product-specific **waivers** in all subsets of the paediatric population for the following medicines:
  - **Ingenol mebutate**, from LEO Pharma A/S, in the therapeutic area of dermatology/oncology;

- **Tropicamide, Phenylephrine hydrochloride, Lidocaine hydrochloride**, from Laboratoires THEA, in the therapeutic area of ophthalmology;
- **1H-Indole-6-carboxylic acid, 2,3-dihydro-3-[[[4-[methyl[(4-methyl-1-piperazinyl)acetyl] amino]phenyl]amino]phenylmethylene]-2-oxo-, methyl ester, (3Z)-, monoethanesulfonate**, from Boehringer Ingelheim International GmbH, in the therapeutic area of pneumology–allergology;
- **Phentermine/topiramate**, from Vivus BV, in the therapeutic area of endocrinology-gynaecologyfertility-metabolism;
- **Dronabinol**, from Bionorica AG, in the therapeutic area of pain;
- **Fampridine**, from Acorda Therapeutics Inc, in the therapeutic area of neurology;
- **Derivative of 4,4'-(1-methylene)-bisbenzotrile**, from Novartis Europharm Limited, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism.

**- 13 positive opinions on modifications to an agreed PIP.**

**Withdrawals**

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

The following tables provide summaries of the current state of the applications for PIPs and waivers, the PDCO opinions and the areas covered by applications for PIPs/full waivers.

**Table 1: Applications for PIPs and waivers as of 9 September 2010**

| PIPs/ waivers<br>Total number<br>of<br>applications | Applications for |                 |                   | Indications<br>covered by<br>applications<br>for<br>PIPs/waivers |
|---|------------------|-----------------|-------------------|--|
|   | New products     | Line extensions | PUMA <sup>1</sup> |  |
| 912   | 690              | 229             | 23                | 1290   |
| 100%  | 72%              | 25%             | 3%                |  |

<sup>1</sup> off patent products, which are developed specifically for children

<sup>2</sup> incl. 199 waivers

**Table 2: Overview on PDCO opinions as of 9 September 2010**

| Number of Paediatric<br>Committee (PDCO) opinions | 2007 | 2008 | 2009 | 2010 | Total |
|---|------|------|------|------|-------|
| Positive opinions on full waivers                 | 10   | 48   | 67   | 43   | 167   |
| Positive opinions on PIPs                         | 2    | 81   | 122  | 80   | 285   |
| Negative opinions                                 | 0    | 4    | 13   | 5    | 22    |
| Positive opinions on<br>modification of a PIP     | 0    | 8    | 51   | 82   | 141   |
| Negative opinions on modification<br>of a PIP     | 0    | 0    | 0    | 4    | 4     |
| Positive opinions on compliance                   | 0    | 5    | 8    | 7    | 20    |

|  |   |   |   |   |   |
|--|---|---|---|---|---|
| with PIP                                   |   |   |   |   |   |
| Negative opinions on compliance with a PIP | 0 | 0 | 1 | 0 | 1 |

**Table 3: Areas covered by applications for PIPs/full waivers**

| <b>Indications</b>                             | <b>2008 (%)</b> | <b>2009 (%)</b> | <b>2010 (%)</b> |
|--|-----------------|-----------------|-----------------|
| Neurology                                      | 6               | 4               | 4               |
| Uro-nephrology                                 | 3               | 5               | 1               |
| Gastroenterology-hepatology                    | 3               | 2               | 1               |
| Pneumology-allergology                         | 6               | 6               | 45              |
| Infectious diseases                            | 8               | 9               | 4               |
| Cardiovascular diseases                        | 14              | 9               | 8               |
| Diagnostics                                    | 1               | 1               | 1               |
| Endocrinology-gynaecology-fertility-metabolism | 15              | 16              | 5               |
| Neonatology-paediatric intensive care          | 1               | 2               | 0               |
| Immunology-rheumatology-transplantation        | 6               | 6               | 4               |
| Psychiatry                                     | 3               | 3               | 2               |
| Pain   | 3               | 6               | 1               |
| Haematology-haemostaseology                    | 5               | 6               | 3               |
| Otorhinolaryngology                            | 1               | 1               | 3               |
| Oncology                                       | 12              | 11              | 8               |
| Dermatology                                    | 3               | 6               | 3               |
| Vaccines                                       | 6               | 4               | 2               |
| Ophthalmology                                  | 2               | 2               | 4               |
| Anaesthesiology                                | 1               | 1               | 1               |
| Nutrition                                      | 1               | 0               | 0               |

Date of next PDCO meeting: 6-8 October 2010

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