

## News from the EMA

### Activities of the PDCO

During its meeting from 7-9 December 2011 the Paediatric Committee (PDCO) adopted the following opinions:

- **13 positive opinions** on paediatric investigation plans (**PIPs**) for the following products:

- Treprostinil diethanolamine, from United Therapeutics Europe Ltd (cardiovascular diseases);
- Methyl aminolevulinate hydrochloride, from Photocure ASA (dermatology);
- Recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein from Statens Serum Institut, (diagnostic);
- Elvitegravir, from Gilead Sciences International Limited (infectious diseases);
- Bortezomib, from Janssen-Cilag International NV (oncology);
- Cyclophosphamide, from Keocyt SA (oncology - haematology);
- N-{3-[5-(2-Amino-4-pyrimidinyl)-2-(1,1-dimethylethyl)-1,3-thiazol-4-yl]-2-fluorophenyl}-2,6-difluorobenzene sulfonamide, methanesulfonate salt (GSK2118436), from GlaxoSmithKline Trading Service Limited (oncology);
- Morphine hydrochloride, from EPMC Pharma SPRL (pain / neonatology - paediatric intensive care);
- Lebrikizumab, from Roche Products Limited (pneumology – allergology);
- Atomoxetine hydrochloride, from Lilly (psychiatry);
- Diphtheria/Tetanus/Pertussis/Polio/Hib/Hepatitis B combination vaccine from Sanofi Pasteur (vaccines);
- Human Thrombin / Human Fibrinogen from Omrix Biopharmaceuticals SA (other indication: haemorrhage resulting from a surgical procedure);
- Culture expanded autologous chondrocytes, from Fidia Advanced Biopolymers S.r.l. (other indication: orthopaedics).

- **three positive opinions** for **product-specific waivers** for:

- Atorvastatin calcium / ezetimibe, from MSD (cardiovascular diseases);
- Anti-sclerostin human monoclonal antibody (AMG785), from Amgen Europe B.V (endocrinology-gynaecology-fertility-metabolism);
- Palonosetron/netupitant, from Helsinn Birex Pharmaceuticals Ltd (other indication: oncology).

- **two positive opinions** on **compliance check** for:

- Darunavir, from Tibotec (infectious disease);
- Etanercept, from Pfizer (dermatology / immunology-rheumatology-transplantation).

- an **opinion** on the a class waiver for medicinal products, used in the treatment of vulvar intraepithelial neoplasia.

**Withdrawals:** The PDCO noted that **one application** was withdrawn during the late stage of the evaluation (30 days or less before opinion).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 December 2011**

| 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> |  |
| 1144 <sup>2</sup>                                   | 850              | 268             | 26                | 1584   |
| 100%  | 74%              | 24%             | 2%                |  |

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

<sup>2</sup> incl. 271 waivers

**Table 2: Overview on PDCO opinions as of 9 December 2011**

| Number of Paediatric<br>Committee (PDCO)<br>opinions | 2007 | 2008 | 2009 | 2010 | 2011 | Total |
|--|------|------|------|------|------|-------|
| Positive opinions on full<br>waivers                 | 10   | 47   | 67   | 52   | 45   | 221   |
| Positive opinions on PIPs                            | 2    | 81   | 122  | 201  | 107  | 513   |
| Negative opinions                                    | 0    | 4    | 13   | 7    | 3    | 27    |
| Positive opinions on<br>modification of a PIP        | 0    | 8    | 51   | 103  | 153  | 315   |
| Negative opinions on<br>modification of a PIP        | 0    | 0    | 0    | 4    | 2    | 6     |
| Positive opinions on<br>compliance with a PIP        | 0    | 5    | 8    | 9    | 9    | 31    |
| Negative opinions on<br>compliance with a PIP        | 0    | 0    | 1    | 0    | 0    | 1     |
| Opinions on review of a<br>granted waiver            | 0    | 0    | 0    | 2    | 0    | 2     |

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

| Indications  | 2008<br>(%) | 2009<br>(%) | 2010<br>(%) | 2011<br>(%) |
|--|-------------|-------------|-------------|-------------|
| Neurology  | 6           | 4           | 4           | 11          |
| Uro-nephrology                                     | 3           | 5           | 2           | 4           |
| Gastroenterology-hepatology                        | 3           | 2           | 1           | 10          |
| Pneumology-allergology                             | 6           | 6           | 41          | 10          |
| Infectious diseases                                | 8           | 9           | 4           | 15          |
| Cardiovascular diseases                            | 14          | 9           | 8           | 21          |
| Diagnostics  | 1           | 1           | 1           | 5           |
| Endocrinology-gynaecology-<br>fertility-metabolism | 15          | 16          | 5           | 28          |
| Neonatology-paediatric                             | 1           | 2           | 0           | 0           |

|   |    |    |   |    |
|---|----|----|---|----|
| intensive care                          |    |    |   |    |
| Immunology-rheumatology-transplantation | 6  | 6  | 5 | 13 |
| Psychiatry                              | 3  | 3  | 2 | 9  |
| Pain                                    | 3  | 6  | 1 | 2  |
| Haematology-haemostaseology             | 5  | 6  | 4 | 18 |
| Otorhinolaryngology                     | 1  | 1  | 3 | 2  |
| Oncology                                | 12 | 11 | 8 | 19 |
| Dermatology                             | 3  | 6  | 3 | 10 |
| Vaccines                                | 6  | 4  | 2 | 12 |
| Ophthalmology                           | 2  | 2  | 4 | 8  |
| Anaesthesiology                         | 1  | 1  | 2 | 1  |
| Nutrition                               | 1  | 0  | 0 | 0  |
| Other                                   |    |    |   | 7  |

Date of next PDCO meeting: 11-13 January 2012

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for:

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