

News from the EMEA

Activities of the PDCO

During its meeting from 9-11 June 2010 the Paediatric Committee (PDCO) adopted the following opinions:

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

- **Vedolizumab (MLN0002)**, from Takeda, in the area of gastroenterology-hepatology;
- **Bosentan monohydrate**, from Actelion, in the area of cardiovascular diseases;
- **Synthetic erythropoietin (EPO) receptor agonist**, from Takeda, in the area of haematology-hemostaseology;
- **Coagulation Factor IX (recombinant)**, from Inspiration Biopharmaceuticals, in the area of haematology-hemostaseology;
- **Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class**, from Novartis, in the area of immunology-rheumatology-transplantation;
- **(3R,4R)-4-methyl-3-(methyl-1H-pyrrolo[2,3-d]pyrimidin-4-ylamino)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy- 1,2,3-propanetricarboxylate (1:1) (CP-690,550)**, from Pfizer, in the area of immunology-rheumatology-transplantation.

- three opinions on the **refusal** of a PIP for

- **4-O-(β -D-galactopiranosyl)-D-xylopyranose**, from Lactest SL, in the area of diagnostic / gastroenterology-hepatology;
- **Omalizumab**, from Novartis, in the area of pulmonology;
- **lidocaine, tetracaine**, from ZARS Pharma, in the area of anaesthesiology.

The PDCO subsequently granted on its own motion product-specific complete waivers for these products since these do not represent a significant therapeutic benefit over existing treatments for paediatric patients.

- **five positive opinions** for product-specific **waivers** in all subsets of the paediatric population for the following medicines:

- **Perindopril tert-butylamine, Amlodipine besilate**, from Gedeon Richter, in the area of cardiovascular diseases;
- **Ramipril, amlodipine**, from EGIS Pharmaceuticals, in the area of cardiovascular diseases;
- **Dexamethasone**, from Allergan Pharmaceuticals Ireland, in the area of ophthalmology;
- **Tafamidis meglumine**, from FoldRx Pharmaceuticals, in the area of neurology;
- **Levonorgestrel, ethinylestradiol**, from Teva Pharma, in the area of endocrinology-gynaecology-fertility-metabolism.

- **a negative opinion** for the **requested waiver** for

- **Human normal immunoglobulin**, from Bio Products Laboratory, in the area of immunology-rheumatology-transplantation / haematology-hemostaseology.

Opinions on modifications to an agreed PIP

The PDCO adopted 15 positive opinions and three negative opinions on the request for modification of an agreed PIP.

Withdrawals

The PDCO noted that one application was withdrawn during the late stages of the evaluation (30 days or less before opinion).

Table 1: Applications for PIPs and waivers as of 11 June 2010

| PIPs/ waivers Total number of applications | Applications for | | | Indications covered by applications for PIPs/waivers |
|---|------------------|-----------------|-------------------|--|
| | New products | Line extensions | PUMA ¹ | |
| 857 ² | 615 | 219 | 23 | 1229 |
| 100% | 72% | 25% | 3% | |

¹ off patent products, which are developed specifically for children

² incl. 189 waivers

Table 2: Overview on PDCO opinions as of 11 June 2010

| Number of Paediatric Committee (PDCO) opinions | 2007 | 2008 | 2009 | 2010 | Total |
|--|------|------|------|------|-------|
| Positive opinions on full waivers | 10 | 48 | 67 | 24 | 149 |
| Positive opinions on PIPs | 2 | 81 | 122 | 46 | 251 |
| Negative opinions | 0 | 4 | 13 | 5 | 22 |
| Positive opinions on modification of a PIP | 0 | 8 | 51 | 58 | 117 |
| Negative opinions on modification of a PIP | 0 | 0 | 0 | 4 | 4 |
| Positive opinions on compliance with PIP | 0 | 5 | 8 | 4 | 17 |
| Negative opinions on compliance with a PIP | 0 | 0 | 1 | 0 | 1 |

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

| Indications | 2008 (%) | 2009 (%) | 2010 (%) |
|--|----------|----------|----------|
| Neurology | 6 | 4 | 4 |
| Uro-nephrology | 3 | 5 | 1 |
| Gastroenterology-hepatology | 3 | 2 | 1 |
| Pneumology-allergology | 6 | 6 | 50 |
| Infectious diseases | 8 | 9 | 3 |
| Cardiovascular diseases | 14 | 9 | 9 |
| Diagnostics | 1 | 1 | 1 |
| Endocrinology-gynaecology-fertility-metabolism | 15 | 16 | 6 |
| Neonatology-paediatric intensive care | 1 | 2 | 0 |
| Immunology-rheumatology-transplantation | 6 | 6 | 4 |
| Psychiatry | 3 | 3 | 2 |
| Pain | 3 | 6 | 2 |
| Haematology-haemostaseology | 5 | 6 | 2 |
| Otorhinolaryngology | 1 | 1 | 1 |
| Oncology | 12 | 11 | 6 |
| Dermatology | 3 | 6 | 2 |
| Vaccines | 6 | 4 | 2 |
| Ophthalmology | 2 | 2 | 3 |
| Anaesthesiology | 1 | 1 | 1 |
| Nutrition | 1 | 0 | 0 |

Date of next PDCO meeting: 14-16 July 2010

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