

News from the EMA

Activities of the PDCO

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

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

- Selexipag, from Actelion (cardiovascular diseases);
- Secretin, from Repligen (diagnostic);
- Lixivaptan, from Cardiokine Biopharma (endocrinology-gynaecology-fertility-metabolism)
- Lorcaserin, from Arena Pharmaceutical (endocrinology-gynaecology-fertility-metabolism);
- Recombinant fusion protein linking human coagulation factor IX with human albumin, from CSL Behring (haematology-hemostaseology);
- Aciclovir, from BioAlliance Pharma (infectious diseases);
- A peptide, acetate salt, from Circassia (pneumology-allergology);
- (1R, 4S, 5S, 6S)-4-[[(2s)-2-Amino-4-(methylthio)-1-oxobutyl]amino]-2-thiabicyclo[3.1.0]hexane-4,6-dicarboxylic acid,2,2-dioxide, monohydrate (LY2140023), from Lilly (psychiatry);
- Furosemide, from KidzPharma (uro-nephrology);

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

- Acetylsalicylic acid / clopidogrel (bisulphate), from TEVA Pharma (cardiovascular diseases);
- Metformin / (2S,3R,4R,5S,6R)-2-(4-Chloro-3-{ 3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyltetrahydro-pyran-3,4,5-triol, from Boehringer Ingelheim (endocrinology-gynaecology-fertility-metabolism);
- Linagliptin / (2S,3R,4R,5S,6R)-2-(4-Chloro-3-{ 3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyltetrahydro-pyran-3,4,5-triol, from Boehringer Ingelheim (endocrinology-gynaecology-fertility-metabolism);
- Pancreas powder, from Eurand Pharmaceuticals (gastroenterology-hepatology).
- Temsirolimus, from Wyeth Europa (oncology);
- Brinzolamide / brimonidine tartrate, from Alcon Lab (ophthalmology);
- 4-[[9-[(3S)-tetrahydro-3-furanyl]-8-[(2,4,6-trifluorophenyl)amino]-9H-purin-2-yl]amino]-transcyclohexanol (CC-930), from Celgene (pneumology-allergology);

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

- Infliximab, from Janssen Biologics (immunology-rheumatology-transplantation / dermatology / gastroenterology-hepatology)
- Rizatriptan (benzoate), from MSD (pain).
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Withdrawals: The PDCO noted that **four applications** were withdrawn during the late stages of the evaluation (30 days or less before opinion) and one application for request for modification of an agreed PIP before the EMA decision.

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 2011

PIPs/ waivers Total number	Applications for	Indications covered by
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of applications	New products	Line extensions	PUMA ¹	applications for PIPs/waivers
1103 ²	814	263	26	1535
100%	74%	24%	2%	

¹ off patent products, which are developed specifically for children

² incl. 261 waivers

Table 2: Overview on PDCO opinions as of 9 September 2011

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	2011	Total
Positive opinions on full waivers	10	47	67	52	39	215
Positive opinions on PIPs	2	81	122	201	78	484
Negative opinions	0	4	13	7	3	27
Positive opinions on modification of a PIP	0	8	51	103	115	277
Negative opinions on modification of a PIP	0	0	0	4	1	5
Positive opinions on compliance with a PIP	0	5	8	9	5	27
Negative opinions on compliance with a PIP	0	0	1	0	0	1
Opinions on review of a granted waiver	0	0	0	2	0	2

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

Indications	2008 (%)	2009 (%)	2010 (%)	2011 (%)
Neurology	6	4	4	8
Uro-nephrology	3	5	2	1
Gastroenterology-hepatology	3	2	1	8
Pneumology-allergology	6	6	41	7
Infectious diseases	8	9	4	10
Cardiovascular diseases	14	9	8	17
Diagnostics	1	1	1	5
Endocrinology-gynaecology-fertility-metabolism	15	16	5	25
Neonatology-paediatric intensive care	1	2	0	0
Immunology-rheumatology-transplantation	6	6	5	10
Psychiatry	3	3	2	6
Pain	3	6	1	1
Haematology-	5	6	4	13

haemostaseology				
Otorhinolaryngology	1	1	3	1
Oncology	12	11	8	16
Dermatology	3	6	3	6
Vaccines	6	4	2	9
Ophthalmology	2	2	4	6
Anaesthesiology	1	1	2	0
Nutrition	1	0	0	0
Other				5

Date of next PDCO meeting: 12-14 October 2011

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