

## News from the EMA

### Activities of the PDCO

During its meeting from 6-8 October 2010 the Paediatric Committee (PDCO) welcomed the new alternate from Romania, Ms Nela Vilceanu, who has been nominated by the Committee for Medicinal Products for Human Use (CHMP) and thanked Dr Sophie Fornairon for her outstanding work and very active participation during her mandate, as she has resigned from the Committee. The PDCO adopted the following opinions:

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

- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract from the pollen of *Betula alba*, from LETI Pharma GmbH, in the area of pneumology - allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of birch, alder and hazel pollen (1/3 each), from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix) and Birch, Alder and Hazel pollen (Tree-Mix) (50/50) in nonbuffered 0.5 % phenol saline solution, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix) and Birch pollen (50/50) in non-buffered 0.5 % phenol saline solution, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix) and *Secale cereale* (Cultivated Rye) pollen (75/25), from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix) and *Secale cereale* (Cultivated Rye) pollen (50/50), from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of *Phleum pratense* pollen and *Secale cereale* (Cultivated Rye) pollen (50/50), from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix) (1/5) each, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of *Phleum pratense* pollen, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch pollen, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of *Phleum pratense* pollen, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix), from LETI Pharma GmbH, in the area of pneumology – allergology.
- Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of *Phleum pratense*, *Dactylis glomerata*, *Festuca elatior*, *Lolium perenne* and *Poa pratensis* pollen (Grasses-Mix) and *Secale cereale* (Cultivated Rye) pollen (50/50), from LETI Pharma GmbH, in the area of pneumology – allergology.
- Mixture of Birch, Hazel and Alder allergen extracts, from LETI Pharma GmbH, in the area of pneumology – allergology.
- *Betula alba* allergen extract, from LETI Pharma GmbH, in the area of pneumology – allergology.

- Dermatophagoides pteronyssinus allergen extract, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Mixture of Dermatophagoides pteronyssinus and Dermatophagoides farinae allergen extracts, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis allergen extracts, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis (Grasses-Mix) and Secale cereale (50/50) allergen extracts, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis (Grasses-Mix) and Secale cereale (75/25) allergen extracts, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Mixture of Phleum pratense and Secale cereale allergen extracts, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Phleum pratense allergen extract, from LETI Pharma GmbH, in the area of pneumology – allergology.
- Recombinant Bet v1 folding variant (rBet v1-FV), from Allergopharma Joachim Ganzer KG, in the area of pneumology – allergology.
- Partially purified bromelain, from Teva Pharma GmbH, in the area of dermatology.
- [(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl} methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875), from Takeda Global Research and Development Centre (Europe) Ltd., in the area of endocrinology-gynaecology-fertility-metabolism.
- Teduglutide ([gly2] recombinant human glucagon-like peptide), from Nycomed Danmark ApS, in the area of gastroenterology-hepatology.
- Anti-BAFF monoclonal antibody, from Eli Lilly & Company Limited, in the area of immunology-rheumatology-transplantation / oncology / neurology.
- Atazanavir sulphate, from Bristol-Myers Squibb Pharma EEIG, in the area of infectious diseases.
- Aztreonam, from Gilead Sciences International Limited, in the area of infectious diseases.
- Recombinant human monoclonal antibody to human Interleukin (IL)-17A, from Novartis Europharm Limited, in the area of ophthalmology.
- Pixantrone, from CTI Life Sciences Ltd, in the area of oncology.
- Fentanyl citrate, from EPMC Pharma SPRL, in the area of pain / neonatology - paediatric intensive care.

- **one opinion after re-examination**, on a request for modification of an agreed PIP

- **one positive opinion** for a product-specific **waiver** in all subsets of the paediatric population for:

- **ocriplasmin**, from ThromboGenics, in the area of ophthalmology

- **one opinion** on the **refusal** of a request for waiver for:

- **4-hydroxy-n-(2-hydroxyethyl)-butyramide**, from Dr. Franz Köhler Chemie GmbH, in the area of anaesthesiology / neurology.

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

**Withdrawals:** The PDCO noted that five applications one of which was a modification to an agreed PIP 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 8 October 2010**

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA <sup>1</sup>	
927	674	230	23	1306
100%	70%	28%	2%	

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

<sup>2</sup> incl. 205 waivers

**Table 2: Overview on PDCO opinions as of 8 October 2010**

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	Total
Positive opinions on full waivers	10	48	67	45	169
Positive opinions on PIPs	2	81	122	113	318
Negative opinions	0	4	13	6	23
Positive opinions on modification of a PIP	0	8	51	88	147
Negative opinions on modification of a PIP	0	0	0	4	4
Positive opinions on compliance with PIP	0	5	8	7	20
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	42
Infectious diseases	8	9	4
Cardiovascular diseases	14	9	8
Diagnostics	1	1	1
Endocrinology-gynaecology- fertility-metabolism	15	16	6
Neonatology-paediatric intensive care	1	2	0
Immunology-rheumatology- transplantation	6	6	5
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	2
Nutrition	1	0	0

Date of next PDCO meeting: 10-12 November 2010

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for:

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