

News from the EMA

Activities of the PDCO

During its meeting from 10-12 November 2010 the Paediatric Committee (PDCO) thanked Robert Ancuceanu for his exceptional work as he has resigned from the Committee and adopted the following opinions:

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

- Tazarotene, from Orfagen, in the area of dermatology;
- Insulin detemir, from Novo Nordisk A/S, in the area of endocrinology-gynaecology-fertility-metabolism;
- Dulaglutide, from Eli Lilly & Company, in the area of endocrinology-gynaecology-fertility-metabolism;
- 40K Pegylated recombinant blood coagulation factor IX (N9-GP), from Novo Nordisk A/S, in the area of haematology-hemostaseology;
- Recombinant human hyaluronidase, Human normal immunoglobulin, from Baxter Innovations GmbH, in the therapeutic area of immunology-rheumatology-transplantation;
- Pralatrexate, from Allos Therapeutics Limited, in the therapeutic area of oncology;
- Pazopanib, from Glaxo Group Limited, in the therapeutic area of oncology;
- Midostaurin, from Novartis Europharm Ltd, in the therapeutic area of oncology;
- Lanthanum carbonate hydrate, from Shire Pharmaceutical Contracts Ltd, in the therapeutic area of uro-nephrology;
- Dermatophagoides farinae extracts 100 %, from Allergopharma Joachim Ganzer KG, in the therapeutic area of pneumology - allergology;
- Dermatophagoides pteronyssinus extracts 100 %, from Allergopharma Joachim Ganzer KG, in the therapeutic area of pneumology - allergology;
- Dermatophagoides pteronyssinus 50 % and Dermatophagoides farinae extracts 50 %, from Allergopharma Joachim Ganzer KG, in the therapeutic area of pneumology - allergology;
- Preparation containing allergens of Birch pollen (*Betula alba/pendula/verrucosa*), from Allergopharma Joachim Ganzer KG, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata*, *Lolium perenne*, *Phleum pratense*, *Festuca pratensis*, *Secale cereale*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Phleum pratense*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Betula verrucosa*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Alnus glutinosa*, *Betula verrucosa* and *Corylus avellana*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Betula pendula*, *Corylus avellana* and *Alnus glutinosa* (33 % each), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Betula pendula*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata*, *Lolium perenne*, *Phleum pratense*, *Poa pratensis* and *Anthoxanthum odoratum* (20 % each), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata* (16%), *Lolium perenne* (16%), *Phleum pratense* (16%), *Poa pratensis* (16%), *Anthoxanthum odoratum* (16 %) and *Secale cereale* (20%), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata* (8%), *Lolium perenne* (8%), *Phleum pratense* (8%), *Poa pratensis* (8%), *Anthoxanthum odoratum* (8%), *Secale cereale* (10%), *Betula pendula* (16,7%), *Corylus avellana* (16,6%) and *Alnus glutinosa* (16,6%), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata*, *Festuca pratensis*, *Lolium perenne*, *Phleum pratense*, *Poa pratensis*, *Secale cereale*, *Betula verrucosa*, *Corylus avellana* and *Alnus glutinosa*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;

- Pollen from *Dactylis glomerata*, *Festuca pratensis*, *Lolium perenne*, *Phleum pratense*, *Poa pratensis*, *Secale cereale* and *Artemisia vulgaris*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Allergens from *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Allergen extracts of *Dermatophagoides farinae* and *Dermatophagoides pteronyssinus* (each 50%), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Allergen extracts of *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* (each 50%), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Alnus glutinosa* (33%), *Betula verrucosa* (33%) and *Corylus avellana* (33%), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Betula verrucosa*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Phleum pratense*, from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata* (16%), *Festuca pratensis* (16%), *Lolium perenne* (16%), *Phleum pratense* (16%), *Poa pratensis* (16%), *Secale cereale* (20%), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Pollen from *Dactylis glomerata*, *Festuca pratensis*, *Lolium perenne*, *Phleum pratense*, *Secale cereale* (20% each), from ALK-Abelló A/S, in the therapeutic area of pneumology - allergology;
- Adsorbed modified allergen extract of a mixture of 50% *Dermatophagoides pteronyssinus* and 50% *Dermatophagoides farinae* (subcutaneous use), from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Adsorbed modified allergen extract of a mixture of 50% *Dermatophagoides pteronyssinus* and 50% *Dermatophagoides farinae* (sublingual use), from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of a mixture of 50% *Dermatophagoides pteronyssinus* and 50% *Dermatophagoides farinae*, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of *Alnus glutinosa* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of *Corylus avellana* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of equal parts of *Betula verrucosa*, *Corylus avellana* and *Alnus glutinosa* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of equal parts of *Lolium perenne*, *Phleum pratense* and *Poa pratensis* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of 50% grass (equal parts of *Lolium perenne* pollen, *Phleum pratense* and *Poa pratensis*) and 50% *Secale cereale* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of *Phleum pratense* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Allergen extract of *Secale cereale* pollen, from HAL Allergy BV, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of birch, alder and hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of birch and hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of birch pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of *Dermatophagoides farinae*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of *Dermatophagoides pteronyssinus*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and birch pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and cereal pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;

- Modified allergen extract of grass and rye pollen (60/40), from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and rye pollen (50/50), from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of pollen from *Phleum pratense*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of rye pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of birch, alder and hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of birch and hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of birch pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of *Dermatophagoides farinae*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of *Dermatophagoides pteronyssinus*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and mugwort pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and birch pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and cereal pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass and rye pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of grass pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of pollen from *Phleum pratense*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Modified allergen extract of rye pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of birch, alder and hazel pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of birch pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of *Dermatophagoides pteronyssinus*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of grass pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of grass and cereal pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of grass and rye pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of pollen from *Phleum pratense*, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology;
- Aqueous allergen extract of grass and birch pollen, from ROXALL Medizin GmbH, in the therapeutic area of pneumology - allergology.

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

- **Interferon alpha 2b**, from Helix BioPharma Corp, in the area of infectious diseases / oncology;

- **Nalmefene HCl**, from H. Lundbeck A/S, in the area of psychiatry;
- **Ranibizumab**, from Novartis Europharm Limited, in the area of ophthalmology.

- eight positive opinions on modifications to an agreed PIP

- two opinions on the review of a granted waiver under Article 14(2) for

- opinion EMEA-000420-PIO01-08, EMA decision P/21/2010, on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for duloxetine hydrochlorid
- opinion EMEA-000249-PIP01-08, EMA decision P/101/2008, on the granting of a product specific waiver for influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B.

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

Seventh Framework Programme (FP7): The Commission representatives announced that it was probable that there would be **no funding for research into off-patent medicines for children in 2011 and 2012**. This programme was set up and included in Framework Programs based on art. 40 of the Paediatric Regulation. The PDCO regretted to hear that the very successful support for such research will be discontinued in the next FP7 calls. The three calls so far financed had a high success rate for applications, with 12 projects financed for a total of 56 million €, and the first results should be available in the near future. The discontinuation of funding might affect the groups and consortia which were recently established with a view to the development of medicines for children that are devoid of commercial interest, whilst there is no other source of funding for such medicines.

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 12 November 2010

PIPs/ waivers Total number of applications	Applications for			Indications covered by applications for PIPs/waivers
	New products	Line extensions	PUMA ¹	
941	685	232	24	1334
100%	73%	25%	2%	

¹ off patent products, which are developed specifically for children

² incl. 209 waivers

Table 2: Overview on PDCO opinions as of 12 November 2010

Number of Paediatric Committee (PDCO) opinions	2007	2008	2009	2010	Total
Positive opinions on full waivers	10	48	67	49	173
Positive opinions on PIPs	2	81	122	191	396
Negative opinions	0	4	13	6	23
Positive opinions on modification of a PIP	0	8	51	96	155

Negative opinions on modification of a PIP	0	0	0	4	4
Positive opinions on compliance with PIP	0	5	8	8	21
Negative opinions on compliance with a PIP	0	0	1	0	1
Opinions on review of a granted waiver	0	0	0	2	2

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	41
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	5
Psychiatry	3	3	2
Pain	3	6	1
Haematology-haemostaseology	5	6	4
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: 8-10 December 2010

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