20 March 2013
EMA/PDCO/61365/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Draft minutes of the 06-08 February 2013 meeting

Chair: Daniel Brasseur

I Introduction

I.1 Adoption of the minutes from previous meeting

Adopted

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.2 Adoption of the Agenda

Adopted with modifications

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.3 Declaration of Conflict of Interest

See Annex I

I.4 External attendance

Please refer to the February PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.5 Leaving/New Members and Alternates

Please refer to the February PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

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II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

II.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

Please refer to the February PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

III Discussion of applications

The PDCO discussed 93 procedures in total[1], of which:

- 38 paediatric investigation plan applications;
- 11 product-specific waiver applications;
- 6 compliance check procedures (interim and final);
- 38 requests for modifications of an agreed paediatric investigation plan.

IV Nomination of Rapporteurs and Peer reviewers

• List of letters of intent received for submission of applications with start of procedure April 2013[1] for Nomination of Rapporteur and Peer reviewer • Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver	The PDCO approved the lists of Rapporteurs and Peer Reviewers.

V Update and finalisation of opinions and requests for modification

All opinions taken at this meeting (relating to adoption of opinions, recommendations, requests for modifications and applicability of class waivers) were made in the presence of the required quorum of members.

The opinions adopted during the Paediatric Committee meeting of February 2013 are published in the same month's meeting report published in the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab.

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition	Outcome (confirmed / not confirmed)
EMEA-66-2012	RO5314482	Treatment of advanced or metastatic breast cancer	Treatment of breast carcinoma	Confirmed

[1] The procedures discussed by the PDCO are on-going and therefore are considered confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Class waiver number	Active substance	Proposed indication	Condition	Outcome (confirmed / not confirmed)
EMEA-67-2012	RO5314482	Treatment of non-small cell lung carcinoma	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed
EMEA-68-2012	RO5537381	Treatment of advanced or metastatic breast cancer	Treatment of breast carcinoma	Confirmed
EMEA-69-2012	Onartuzumab	treatment of patients with locally advanced or metastatic Met positive NSCLC after failure of at least one prior chemotherapy regimen	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed
EMEA-70-2012	Onartuzumab	First line treatment, in combination with chemotherapy, of patients with HER2 negative, Met-positive metastatic gastrooesophageal cancer	Treatment of gastric adenocarcinoma	Not confirmed
EMEA-71-2012	Onartuzumab	Treatment of breast carcinoma	Treatment of breast carcinoma	Confirmed
EMEA-72-2012	Onartuzumab	Treatment of adenocarcinoma of the colon and rectum	Treatment of adenocarcinoma of the colon and rectum	Confirmed
EMEA-73-2012	Onartuzumab	Treatment of hepatocellular carcinoma	Treatment of liver and intrahepatic bile duct carcinoma	Confirmed
EMEA-74-2012	Sulodexide	Treatment of peripheral arterial disease	Treatment of peripheral atherosclerosis	Not confirmed
EMEA-75-2012	LY2886721	Slowing of disease progression in Patients with Prodromal Alzheimer's Disease and Mild Alzheimer's Disease	Treatment of Alzheimer's disease	Confirmed
EMEA-76-2012	Zoptarelin doxorubicin (AEZS-108)	Treatment with AEZS-108 in castration and taxane-resistant prostate cancer	Treatment of prostate cancer (excl. rhabdomyosarcoma)	Confirmed
EMEA-77-2012	Zoptarelin doxorubicin (AEZS-108)	Treatment of localized unresectable pancreatic cancer with AEZS-108 and radiation	Treatment of adenocarcinoma of the pancreas	Confirmed
EMEA-78-2012	Zoptarelin doxorubicin (AEZS-108)	Treatment with AEZS-108 in chemotherapy refractory triple negative (ER/PR/HER2-negative) LHRH-R positive metastatic breast cancer	Treatment of breast carcinoma	Confirmed

Class waiver number	Active substance	Proposed indication	Condition	Outcome (confirmed / not confirmed)
EMEA-79-2012	2-(6-(dimethylamino)benzo[d][1,3]dioxol-5-ylthio)-1-(2-(neopentylamino)ethyl)-1H-imidazo[4,5-c]pyridin-4-amine	Treatment of advanced metastatic renal cell carcinoma	Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)	Confirmed
EMEA-80-2012	MPDL3280A	Treatment of patients with locally advanced or metastatic non-small cell lung cancer that is PD-L1-positive	Treatment of lung carcinoma (small cell and non-small cell)	Confirmed
EMEA-81-2012	MPDL3280A	Treatment of patients with PD-L1 positive renal cell carcinoma	Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)	Confirmed
EMEA-82-2012	GDC-0973	Treatment, in combination with vemurafenib, of patients with unresectable or metastatic melanoma with BRAFV600 mutations	Treatment of melanoma (from 0 to less than 12 years)	Confirmed

VII Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

PIP number	Active substance	Proposed indication	Condition	Outcome (confirmed / not confirmed)
EMEA-000978-PIP01-10	Vemurafenib	Adjuvant therapy in patients with surgically resected cutaneous BRAF-mutant melanoma at high risk of recurrence.	Treatment of melanoma	Confirmed

VIII Annual reports on deferred measures

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties in progressing the PIP?	Outcome
EMEA-000176-PIP01-07-M03	Colistimethate sodium	Colobreathe	Yes	Yes	The PDCO acknowledges the rationale for the delay and welcomes the applicant's initiative to address the issues via a planned modification of the agreed PIP including advice form SA/CHMP.
EMEA-000994-PIP01-10	gadobutrol	Gadovist	No	No	N/A
EMEA-000052-PIP01-07	Vandetanib	Caprelsa	Yes	Yes	The single paediatric trial in the PIP is reported to have recruited most of the planned patients but the completion of the PIP is delayed. The PDCO is aware of other paediatric trials with the medicine.
EMEA-000978-PIP01-10	Vemurafenib	Zelboraf	No	Yes	The PDCO acknowledges the recruitment difficulties and welcome the applicant's initiatives to overcome them.
EMEA-000306-PIP01-08-M01	Corifollitropin alfa	Elonva	No	No	N/A
EMEA-000469-PIP01-08-M03	Anidulafungin	Ecalta	No	Yes	The PDCO acknowledges the justifications for the delay related to difficulties in developing an age-related formulation and is currently awaiting the planned modification of the agreed PIP with further information.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties in progressing the PIP?	Outcome
EMEA-000191-PIP01-08-M04	Voriconazole	Vfend	No	Yes	The PDCO acknowledges the justifications for the delay and is currently awaiting the planned modification.
EMEA-000311-PIP01-08-M02	Ustekinumab	Stelara	No	No	N/A
EMEA-000311-PIP03-11-M01	Ustekinumab	Stelara	No	No	N/A
EMEA-000056-PIP01-07-M01	Bevacizumab	Avastin	No	Yes	The single paediatric trial in the agreed PIP is progressing while recruiting somewhat slower than planned. The PDCO acknowledges that this is an international trial and cooperative effort.
EMEA-000056-PIP03-10-M01	Bevacizumab	Avastin	No	Yes	The single paediatric trial in the agreed PIP is progressing while recruiting slightly slower than planned. This is the first paediatric randomised controlled trial of a medicinal product in high-grade glioma. The PDCO acknowledges that this is an international trial and cooperative effort.

IX Other topics

Guidelines	
Paediatric Addendum to the guideline on clinical investigation of medicinal products to prevent development / slow progression of chronic renal insufficiency (CRI)*	The comments to the guideline were adopted by the PDCO.

Guideline on the evaluation of Medicinal Products for the treatment of Irritable Bowel Syndrome*	The comments to the guideline were adopted by the PDCO.
Paediatric Addendum* to Note for guidance on clinical investigation of medicinal products in the treatment of hypertension	In the presence of the rapporteur of the cardio-vascular working group, the PDCO discussed the revised version (draft 2 of the paediatric addendum) and is in general in agreement. With regard to the three questions raised by the cardiovascular working group the PDCO concluded that: • There is no need to be more specific in relation to assessment of end-organ damage (Q1). The need to evaluate end-organ damage every 6-12 months during the clinical studies and after study completion for additional 12 – (24) months, is considered adequately addressed in section 8 (lines 688-691). However, in order to clearly indicate the need for assessing proteinuria in paediatric patients with secondary hypertension, the wording in line 378 should be revised from "Proteinuria MAY be included as secondary endpoint" to "Proteinuria SHOULD be included as secondary endpoint", particularly in patients with secondary hypertension. • PD is adequately addressed. • Study duration is also considered to be sufficiently addressed in section 8. In addition, the following comment related to paediatric formulation was made: The PDCO very much appreciated how clearly the need for developing age appropriate formulations is addressed in this addendum. A minor change in wording is proposed because a liquid dosage form in children 1-less than 6 years of age is not necessarily "a must", as it could also be age appropriate solid formulations. Therefore the following wording is proposed by the PDCO: For children 1 to less than 6 years of age a formulation that allows adequate dosing flexibility is a must to assure ….. (Line 5310-532) Finally the PDCO recommends to change the wording in section 8, line 641 with regard to the total number of paediatric patients and to add an explanation for this number: The trial programme is expected to have a total of no less than **300 (instead of 250)** paediatric patients **for safety reasons to identify adverse reactions happening with a 1% frequency.** With incorporation of the above comments, the paediatric addendum was adopted by the PDCO.
Concept paper on the development of Medicinal products for the treatment of Autism*	The PDCO was informed that the first draft of this concept paper was now circulated by the CNS WP. A request was made for specialist paediatric psychiatrists whom could advise on the drafting of this concept paper and the subsequent guideline.

Reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use*	The PDCO was informed that this reflection paper, that they had already seen and commented a few months ago, it should soon go out for public consultation.
Working groups	
Paediatric inventory	The working group discussed the expert input provided for the area of nephro-urology.
Paediatric oncology	Topics included the revision of the list of priority studies with off-patent medicines, comments on the extrapolation concept paper, plans for model PIPs and products under assessment by the CHMP.
Indicators of public health effects of the Paediatric Regulation	The plenary and a working group collected suggestions for domains and indicators with a view to future data collection, analysis and reporting.
Revision of the standard allergen PIP	The Revision of the standard allergen PIP was discussed by a working group, including PDCO members, EMA staff and Paul-Ehrlich-Institut (PEI) representatives. It was reiterated that study designs should allow for generation of robust data demonstrating both short and long-term efficacy in children. It was agreed that only one long-term trial in adults and children will be requested for one selected allergen product per company to prove the concept. Paediatric trials with the selected product should be initiated as soon as a tolerated dose range, a dose-response relationship for clinical efficacy, short-term efficacy, safety data demonstrating no increased risk of anaphylactic reactions from adult trials (possibly including adolescents) are available. It is foreseen that one year of immunotherapy in adults will be sufficient to achieve the above mentioned goals. Afterwards the development of all other allergens will be dependent on the proposed MAA (treatment of allergic symptoms, sustained clinical effect, long-term efficacy/disease modifying effect and curing allergy). Until evidence of long-term efficacy in adults and children is available for the selected allergen product, long-term studies have to be proposed in the PIP for all allergen products with a request for a deferral.
Formulation	No non-product related issues where reported to the Committee.
Non-Clinical	No non-product related issues where reported to the Committee.
Extrapolation	The group discussed specific extrapolation issues relating to on-going PIP procedures.
Other topics	
Changes to the rules of reimbursement for delegates*	The committee was informed of the changes of rules of reimbursement for delegates.

CHMP List of Questions to be addressed by PDCO: Everolimus (Votubia)	The PDCO adopted an opinion in response to the CHMP questions to the PDCO.
Model oncology PIP acute myeloid leukaemia	The PDCO adopted the model PIP for acute myeloid leukaemia for public consultation.
Revision of the standard allergen PIP	The PDCO was informed about the proposals of the working group. The members endorsed the proposals. PDCO representatives were nominated to participate at the EMA meeting to discuss the regulatory status of allergen products in the EU member states planned for 28 February 2013.
Article 6.1(J) of the Paediatric Regulation (Communication on paediatric clinical research)	The PDCO discussed the latest version of the document on how communication should be improved on a European and national level in order to promote paediatric clinical research, which included all the comments received from members since the last plenary meeting.The committee agreed on the changes and adopted the final version of the document.
Summary of PDCO Opinion: new document and guidance*	The PDCO approved the template for the Summary of the PDCO Opinion; the Guidance document will be evaluated again in March after simplification and modification. Both documents will be published together on the EMA website after the March PDCO. The first decisions including the Summary of PDCO Opinion document are scheduled to be published in April or May.
Reflection on revocation of the EMA decision on the list of class waivers	The PDCO continued the revision of the list of class waivers. The discussion had progressed from scientific considerations that apply to several or all waivers, to scientific aspects of the individual waivers. Further discussions of the PDCO are foreseen.
Letter from European Haemophilia Consortium to Daniel Brasseur	The European Haemophilia Consortium sent a letter to the PDCO chair to discuss the obligation for applicants to complete the PIP before filing, and thus delaying the MAA of new products. Considering that haemophilia is a paediatric disease, the PDCO will invite the consortium to an up-coming plenary PDCO session to discuss the importance of studying new coagulation factors for haemophilia before marketing authorisation to avoid off-label use.
Enpr-EMA-Pharma Paediatric Type 2 diabetes mellitus meeting on 25 February 2013	The main objectives of this workshop are: • Identifying elements for agreeing Paediatric Investigation Plans (PIP) in Type 2 Diabetes Mellitus (T2DM) in line with good clinical practice and delivering conclusive outcomes. • Identifying elements to facilitate trial recruitment; approaches to enhance feasibility of paediatric T2DM trials. However, this opportunity will also be used to discuss the establishment of an Enpr-EMA Endocrinology/Diabetes Network. The participants consist of European and US experts, Industry, PDCO and CHMP members, EMA staff, members from FDA and Japanese and

	Canadian Health Authorities. Hopefully this workshop will help us further in finding more feasible solutions for the conduct of paediatric studies in T2DM patients that are in line with good clinical practise in view of the limited patient population.
How to best evaluate effect of inhaled corticosteroids on HPA axis?	This was a follow-up discussion on whether to specify the laboratory tests required in paediatric investigation plans for evaluating the effect of inhaled corticosteroids (ICS) on hypothalamo-pituitary-adrenal (HPA) axis suppression in children. The PDCO addressed two main questions: • Is there a need to test effect on HPA axis? If yes • What test? In order to address the first question, the actual risk for HPA axis suppression, induced by different ICS used for treatment of asthma should be known. One particularly relevant concern in the children is impaired growth. A study by HW Kelly et al, recently published in N Engl J Med 2012, demonstrated that asthmatic children treated with inhaled corticosteroids were on average half an inch shorter as adults compared to controls. With the evidence for a minor impact of inhaled corticosteroids on the final adult height now available, the PDCO concluded there is no longer a need to systematically require assessment of ICS effect on growth in a clinical trial setting. While an according warning should be put in the SmPC, emphasising the importance of using the lowest effective dose of ICS to control asthma symptoms, the impact on growth must be seen in the context of the undisputed beneficial effects of ICS on asthma symptoms. Severe symptomatic adrenal insufficiency during treatment with ICS is not frequently reported. Most cases of adrenal crisis resulting from ICS therapy have been associated with poor patient follow-up and inappropriately high ICS doses. However rare this complication might be in the context of the many children treated with inhaled glucocorticoids who do not experience any adverse systemic effects, adrenal insufficiency is potentially life threatening. Thus, how to best screen for this risk? With the exception of one recent publication, there is a lack of published national guidelines for adrenal suppression (AS) screening in children with asthma. Screening tests include either measurements of basal urinary or plasma cortisol levels or dynamic tests, such as ACTH or metyrapone test. The PDCO considers basal cortisol levels not sensitive enough to detect effects on the HPA axis and/or consequently differences in the potential of systemic side effects when different ICS are compared. Negative findings carry the risk of providing a false reassurance. Stimulation tests, such as the ACTH test, are considered the gold standard, but are cumbersome and increase the burden to patient/parents and staff within a clinical trial setting. In addition, the wide inter-individual

	variability in corticosteroid sensitivity limits the predictive value of test results obtained in clinical trials. In light of the lack of guidance on how to best screen for AS on one side, and the need to identify ICS with a greater potential/risk for systemic effect on the other side, the PDCO concluded that it is of the utmost importance to determine the PK and PD characteristics of any novel ICS. This is necessary to obtain information on the amount of product entering the systemic circulation, which will impact the safety profile. Although various ICS available for the treatment of asthma have been shown to have similar clinical efficacy when used at equivalent therapeutic doses, significant differences in their pharmacokinetics (PK) and pharmacodynamics (PD) exist, with consequently different risks of systemic side effects. This information should then guide determining the benefits and risks of each ICS medication and the level of clinical safety monitoring needed. If screening for AS in regulatory studies is deemed necessary, basal cortisol or glucocorticoid levels (whether in the serum, urine, saliva or other biological fluid) should not be used as they lack sensitivity to identify HPA axis suppression. While a specific test cannot be recommended over the others at present, a dynamic (stimulation) test of adrenal function should be used (for example: metyrapone stimulation test, low dose or high dose cortrosyn stimulation test).
Introduction to principles of bioequivalence and bioavailability demonstration	A presentation was given to the PDCO on the principles of bioequivalence and bioavailability studies.
Report from CHMP on paediatric topics	The PDCO members were informed about the final CHMP opinions adopted in January 2013 on medicinal products with paediatric interest.
Oseltamivir in infants	Postponed to next PDCO meeting.
PDCO survey on preferred submission method	Postponed to next PDCO meeting.

X Any other business

- Revision of the off-patent priority list for medicinal products for children:

  The PDCO was informed of the current status and requested to provide comments.

Note on access to documents

Documents marked with an asterisk* in these minutes cannot be released at present as they are currently in draft format. They will become public when adopted in their final form.

Annex I to the Minutes of the PDCO of February 2013

Documentation on Declaration of interest of members, alternates and experts

Based on the Declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of Committee members for the upcoming discussions.

In accordance with the Agency's revised Policy and Procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests).

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level DP	EMEA-001045-PIP01-10
Adriana Ceci	Restriction level DP	EMEA-001220-PIP01-11
Adriana Ceci	Restriction level XR	EMEA-000019-PIP06-09-M03
Adriana Ceci	Restriction level DP	EMEA-001371-PIP01-12
Adriana Ceci	Restriction level DP/XR	EMEA-C1-000118-PIP02-10-M01
Adriana Ceci	Restriction level XR	EMEA-001003-PIP01-10-M02
Alexandra Compagnucci	Restriction level DC	EMEA-000627-PIP01-09-M04
Alexandra Compagnucci	Restriction level DC	EMEA-000628-PIP01-09-M04
Carine de Beaufort	Restriction level XR	EMEA-001045-PIP01-10
Carine de Beaufort	Restriction level XR	EMEA-70-2012
Carine de Beaufort	Restriction level XR	EMEA-71-2012
Carine de Beaufort	Restriction level XR	EMEA-72-2012
Carine de Beaufort	Restriction level XR	EMEA-73-2012
Carine de Beaufort	Restriction level XR	EMEA-80-2012
Carine de Beaufort	Restriction level XR	EMEA-81-2012
Carine de Beaufort	Restriction level XR	EMEA-82-2012
Carine de Beaufort	Restriction level XR	EMEA-001395-PIP01-12
Christoph Male	Restriction level DP	EMEA-001296-PIP01-12
Christoph Male	Restriction level DP	EMEA-001382-PIP01-12
Dobrin Konstantinov	Restriction level XP	EMEA-C1-000468-PIP02-12

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Gerard Pons	Restriction level.DP	EMEA-000116-PIP01-07-M06
Gerard Pons	Restriction level.DP	EMEA-000332-PIP01-08-M06
Jacqueline Haddad	Restriction level XR	EMEA-001394-PIP01-12
Jacqueline Haddad	Restriction level XR	EMEA-000279-PIP01-08-M01
Jacqueline Haddad	Restriction level XR	EMEA-C1-000468-PIP02-12
Jacqueline Haddad	Restriction level XR	EMEA-000144-PIP01-07-M04
Jacqueline Haddad	Restriction level XR	EMEA-001100-PIP01-10
Jaroslav Sterba	Restriction level XP	EMEA-001372-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001392-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-C1-000468-PIP02-12
Marek Migdal	Restriction level DP	EMEA-001309-PIP01-12
Matthias Keller	Restriction level XR	EMEA-000366-PIP05-12
Michal Odermarsky	Restriction level XP	EMEA-000968-PIP02-11-M01
Michal Odermarsky	Restriction level XP	EMEA-001368-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-001288-PIP01-12
Paolo Rossi	Restriction level DP	EMEA-001289-PIP01-12
Peter Bauer	Restriction level DP	EMEA-001327-PIP01-12
Peter Szitanyi	Restriction level DP	EMEA-001100-PIP01-10
Romaldas Maciulatis	Restriction level XR	EMEA-70-2012
Romaldas Maciulatis	Restriction level XR	EMEA-71-2012
Romaldas Maciulatis	Restriction level XR	EMEA-72-2012
Romaldas Maciulatis	Restriction level XR	EMEA-73-2012
Romaldas Maciulatis	Restriction level XR	EMEA-80-2012
Romaldas Maciulatis	Restriction level XR	EMEA-81-2012
Romaldas Maciulatis	Restriction level XR	EMEA-82-2012
Tadej Avcin	Restriction level XP	EMEA-001045-PIP01-10
Tadej Avcin	Restriction level XP	EMEA-001220-PIP01-11
Tadej Avcin	Restriction level XP	EMEA-001371-PIP01-12

Note: the procedures identified in the table above are on-going and therefore considered commercially confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting

reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

No new or additional conflicts were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting.

Restriction levels:

Evaluation of the conflict of interest	
Outcome	Impact
R-P	To be replaced for the discussions, final deliberations and voting as appropriate in relation to the relevant product or a competitor product.
XP	Where Individual product involvement is declared - PRODUCT INDICATION: - No involvement with respect to procedures involving the relevant product or a competitor product in the relevant indication i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products - [Cannot act as Rapporteur for development of guidelines in concerned therapeutic area].
XC	Where cross product / general involvement is declared - COMPANY: - No involvement (as outlined above) with respect to products from the specified company. - Cannot act as Rapporteur for products from the relevant company(ies).
DP	Where Individual product involvement is declared - PRODUCT INDICATION: - Involvement in discussions only with respect to procedures involving the relevant product or a competitor product i.e. no part in final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products.
DC	Where cross product / general involvement is declared - COMPANY: - Involvement in discussions only with respect to products from the specified company. - Cannot act as Rapporteur on products from the relevant company(ies).
XR	Committee member cannot act as Rapporteur or Peer reviewer in relation to any medicinal product from the relevant company.
R-C	To be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company

Annex II to the Minutes of the PDCO of February 2013

List of Participants

Chair

Daniel BRASSEUR

Vice-chair

Dirk MENTZER

Members appointed by Member States or CHMP

Koenraad NORGA	Belgium
Dobrin KONSTANTINOV	Bulgaria
Jaroslav STERBA	Czech Republic
Marianne ORHOLM	Denmark
Irja LUTSAR	Estonia
Pirjo LAITINEN-PARKONNEN	Finland
Dirk MENTZER	Germany
Stefanos MANTAGOS	Greece
Agnes GYURASICS	Hungary
Kevin CONNOLLY	Ireland
Dina APELE-FREMIANE	Latvia
Carine de BEAUFORT	Luxembourg
John Joseph BORG	Malta
Hendrik van den BERG	The Netherlands
Siri WANG	Norway
Marek MIGDAL	Poland
Helena FONSECA	Portugal
Vlasta KAKOSOVA	Slovak Republic
Janez JAZBEC	Slovenia
Fernando DE ANDRÉS TRELLES	Spain
Marta GRANSTRÖM	Sweden
Julia DUNNE	United Kingdom

Alternates appointed by Member States or CHMP

Karl Heinz HUEMER	Austria
Jacqueline CARLEER	Belgium
Ann Marie KAUKONEN	Finland
Sylvie BENCHETRIT	France
Birka LEHMANN	Germany
Pending	Greece
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Pending	Latvia
Johannes TAMINIAU	The Netherlands
Ine Skottheim RUSTEN	Norway
Dana Gabriela MARIN	Romania
Maria Jesus FERNANDEZ CORTIZO	Spain
Viveca Lena ODLIND	Sweden
Angeliki SIAPKARA	United Kingdom

Members representing patients' organisations

Not present

Alternates representing patients' organisations

Not present

Members representing health care professionals

Not present

Alternates representing health care professionals

Paolo PAOLUCCI

Experts

Peter BAUER	Medical statistician

European Medicines Agency

Agnes SAINT RAYMOND	Head of Sector, Human Medicines Special Areas
Paolo TOMASI	Head of Section, Paediatric Medicines
Sophie OLIVIER	Scientific Administrator, Paediatric Medicines
Anne-Sophie HENRY-EUDE	Scientific Administrator, Paediatric Medicines

Almudena SAIZ HERRANZ	Scientific Administrator, Paediatric Medicines
Benjamin PELLE	Scientific Administrator, Paediatric Medicines
Chrissi Pallidis	Scientific Administrator, Paediatric Medicines
Dobromir PENKOV	Scientific Administrator, Paediatric Medicines
Elin Haf DAVIES	Scientific Administrator, Paediatric Medicines
Giovanni LESA	Scientific Administrator, Paediatric Medicines
Gunter EGGER	Scientific Administrator, Paediatric Medicines
Irmgard EICHLER	Scientific Administrator, Paediatric Medicines
Janina KARRES	Scientific Administrator, Paediatric Medicines
Peter KÁROLYI	Scientific Administrator, Paediatric Medicines
Ralf HEROLD	Scientific Administrator, Paediatric Medicines
Ralph BAX	Scientific Administrator, Paediatric Medicines
Richard VESELY	Scientific Administrator, Paediatric Medicines
Thorsten OLSKI	Scientific Administrator, Paediatric Medicines
Alessandro JENKNER	National Expert on Secondment, Paediatric Medicines
Cristina BEJNARIU	Trainee
Aurelie HERVIEU	Assistant, Paediatric Medicines
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