



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 March 2015  
EMA/PDCO/97803/2015  
Procedure Management and Business Support Division

## Paediatric Committee (PDCO)

### Minutes of the 11-13 February 2015 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

#### Disclaimers

Some of the information contained in the PDCO minutes is considered commercially confidential or sensitive and therefore not disclosed in the present minutes. With regards to therapeutic indications listed against products it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. The procedures discussed by the PDCO are on-going and therefore certain aspects of them 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). Documents mentioned in these minutes cannot be released at present as they are currently in draft format or are classified as confidential. They will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006). Of note, this set of minutes is a working document primarily designed for PDCO members and the work the Committee undertakes.

#### Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



## **I Introduction**

### ***I.1 Adoption of the minutes from previous meeting***

The Minutes of the PDCO plenary session held on 14-16 January 2015 were adopted.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/document\\_listing/document\\_listing\\_000192.jsp&mid=WC0b01ac0580028eab](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***

The agenda was adopted with amendments.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/document\\_listing/document\\_listing\\_000192.jsp&mid=WC0b01ac0580028eab](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***

Please refer to the Annex of this document.

### ***I.4 External attendance***

Please refer to the Annex of this document.

### ***I.5 Leaving/New Members and Alternates***

Please refer to the February 2015 PDCO monthly report published on the EMA Website:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/document\\_listing/document\\_listing\\_000192.jsp&mid=WC0b01ac0580028eab](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab)

## **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 2015 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](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 86 procedures in total<sup>1</sup>, of which:

- 33 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 10 compliance check procedures (interim and final);

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<sup>1</sup> 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).

- 34 requests for modifications of an agreed paediatric investigation plan.

## IV Nomination

### IV.1 Nomination of Rapporteurs and Peer reviewers

<ul style="list-style-type: none"> <li>• List of letters of intent received for submission of applications with start of procedure April 2015<sup>1</sup> for Nomination of Rapporteur and Peer reviewer</li> <li>• Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver</li> </ul>	The PDCO approved the lists of Rapporteurs and Peer Reviewers.
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### IV.2 Nomination for other activities

<ul style="list-style-type: none"> <li>• Nomination of PDCO representative in Cross-Committee Task Force on Registries (replacement of Viveca Odling)</li> </ul>	Postponed to the March PDCO ORGAM
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## V Update and finalisation of opinions and requests for modification

The opinions adopted during the Paediatric Committee meeting of February 2015 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](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

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

PIP number	Applicant	Active substance	Proposed indication	Condition	Outcome
EMA-001207-PIP01-11	Roche Registration Limited	Obinutuzumab	Treatment of diffuse large B-cell lymphoma, of indolent non-Hodgkin's lymphoma and of small lymphocytic lymphoma	Treatment of mature B cell lymphoma	The condition covers the diseases included in the proposed indication, as already stated in the procedure leading to agreement of the PIP.

## VIII Annual reports on deferrals

Annual report based on PIP decision for	Applicant	Active substance(s)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMA-000533-PIP01-08	Gilead Sciences International Limited	Tenofovir	Viread	No	No	The PDCO noted the report.
EMA-000306-PIP01-08-M02	Merck Sharp & Dohme Limited	corifollitropin alfa	Elonva	No	No	The PDCO noted the report.
EMA-000709-PIP01-09	Eisai Ltd.	rufinamide	Inovelon	Yes	No	The PDCO noted the report.
EMA-000978-PIP01-10	Roche Registration Limited	Vemurafenib	Zelboraf	No	Yes	The PDCO noted the report and anticipates a request for modification of the agreed PIP.
EMA-000816-PIPO2-10	Ipsen Pharma	Potassium sulphate / Magnesium sulphate, heptahydrate / Sodium sulphate, anhydro	Izinova/ Eziclen	No	Yes	The PDCO noted the report and anticipates a request for modification of the agreed PIP.
EMA-001115-PIP01-10	Alexza UK Limited	Loxapine	Adasuve	No	Yes	The PDCO noted the report and anticipates a request for modification of the agreed PIP.
EMA-000878-PIPO2-11	Mitsubishi Pharma Europe Ltd	Colestilan	BindRen	No	Yes	The PDCO noted the report. The applicant is planning to

Annual report based on PIP decision for	Applicant	Active substance(s)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
						discontinue paediatric development as they intend to withdraw the marketing authorisation.
EMA-001318-PIP01-12	GlaxoSmithKline Trading Services Limited	zanamivir	Relenza	No	Yes	The PDCO noted the report and anticipates a request for modification of the agreed PIP is ongoing.
EMA-000553-PIP01-09	Shire Pharmaceutical Contracts Ltd	Lisdexamfetamine dimesylate	Venvanse	No	No	The PDCO noted the report.
EMA-001066-PIP02-11	BioAlliance Pharma	Aciclovir	Sitavir	No	No	The PDCO noted the report.

## IX Other topics

Working groups	
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	Report noted
Mandate of the joint PDCO/PRAC Working Group Dirk Mentzer	The PDCO adopted the mandate of the joint PDCO/PRAC Working Group with the nomination of an additional PDCO member (specialist in pharmacovigilance).

Product-related topics	
CHMP update on paediatric topics	The Committee noted that there were no medicinal products with paediatric indication adopted by CHMP in January 2015.
Other topics	
PDCO ORGAM dates 2015 and Minutes of the 1 <sup>st</sup> PDCO ORGAM held on 29 January 2015	The Committee adopted the PDCO ORGAM dates 2015 and the minutes of the 1 <sup>st</sup> PDCO ORGAM held on 29 January 2015.
PDCO White Paper Koenraad Norga	The Committee endorsed the current draft of the PDCO White Paper.
PDCO class waiver list review Koenraad Norga	The Committee was informed about steps for finalising the review of the class waiver list.
PDCO - COMP and IMI-2 Activities Koenraad Norga	The Committee was informed about IMI2 and invited to propose paediatric related research topics for this initiative.
Involvement of PDCO in Art. 46 procedures and MAA procedures - BI report	The PDCO members were informed of their possible involvement in Art. 46 procedures and MAA procedures starting at CHMP.
Update on Enpr-EMA activities: <ul style="list-style-type: none"> <li>Nomination of PDCO member within Enpr-EMA coordination group;</li> <li>European Strategy Forum on Research Infrastructure - call for projects</li> </ul>	<ul style="list-style-type: none"> <li>Expressions of interest for representing PDCO within Enpr-EMA coordination group were received from Christoph Male and Angeliki Siapkara. The Committee nominated both PDCO members as new PDCO representatives to the Enpr-EMA coordinating group for the mandate of 3 years.</li> <li>European Strategy Forum on Research Infrastructure (ESFRI) - call for projects: The Committee was informed that several Enpr-EMA members are preparing a bid for a paediatric entry on ESFRI roadmap focusing on sustainable paediatric research infrastructure for paediatric drug trials at individual sites. The application aims to show pan-European interest in the project. To this end contact persons within EU member states and EEA are needed.</li> </ul>

Outcome of Scientific Advice / Protocol Assistance with paediatric questions	Selected SAWP procedures were discussed by the PDCO.
Discussion of 1 <sup>st</sup> reports	
Discussion following a discussion meeting with companies	
Modelling and Simulation Working Group report and workplan	PDCO welcomed the workplan and the work to be carried out by the Modelling and Simulation Working Group on PIPs procedures.
Standard allergen PIP	The Committee adopted the 4 <sup>th</sup> revision of the Standard Allergen PIP.
Breakout sessions	
Neonatology	The attendees focused on the preparation of the upcoming Enpr-EMA neonatal meeting in March 2015.
Paediatric oncology	The participants discussed the recent international meeting on progressing medicine development for children with cancer and the next steps.
Inventory	The Chair of the inventory group informed the PDCO that the draft inventories for gastroenterology and endocrinology had been finalised and would be circulated to the Committee members with the post-mail for a 1-month consultation.

### **Any other business**

The Chair thanked all participants and closed the meeting.

## Annex to the Minutes of the PDCO of February 2015

The List of participants includes any restrictions with respect to the involvement of members / alternates / experts following evaluation of declared interests for the meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	Full involvement	
Karl-Heinz Huemer	Member	Austria	Full involvement	
Christoph Male	Alternate	Austria	Full involvement	
Koenraad Norga	Member	Belgium	Full involvement	
Jacqueline Carleer	Alternate	Belgium	Full involvement	
Violeta Iotova	Member	Bulgaria	No participation in discussions, final deliberations and voting	EMA-000783-PIP01-09-MO2 EMA-001441-PIP01-13 EMA-001324-PIP01-12-MO1 EMA-001030-PIP01-10-MO3 EMA-000694-PIP02-14 EMA-000470-PIP01-08-MO9 EMA-001556-PIP01-13 EMA-000828-PIP02-14
Marina Dimov Di Giusti	Member	Croatia	Full involvement	
Jaroslav Sterba	Member	Czech Republic	Full involvement	
Peter Sztanyi	Alternate	Czech Republic	Full involvement	
Marianne Orholm	Member	Denmark	Full involvement	
Marta Granström	Alternate	Denmark	Full involvement	
Irja Lutsar	Member	Estonia	Full involvement	
Ann Marie Kaukonen	Member	Finland	Full involvement	
Maija Pihlajamäki	Member	Finland	Full involvement	
Sylvie Benchetrit	Member	France	Full involvement	
Birka Lehmann	Member	Germany	Full involvement	
Immanuel Barth	Alternate	Germany	Full involvement	
Grigorios Melas	Member	Greece	Full involvement	
Ágnes Gyurasics	Member	Hungary	Full involvement	
Brian Aylward	Member	Ireland	Full involvement	
Francesca Rocchi	Alternate	Italy	Full involvement	
Dina Apele-Freimane	Member	Latvia	Full involvement	
Kristine Supe	Alternate	Latvia	Full involvement	
Romaldas	Member	Lithuania	Full involvement	



Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Mačiulaitis			Connected via teleconference for EMEA-000078-PIP01-07-M06	
Carola de Beaufort	Member	Luxembourg	Full involvement	
Herbert Lenicker	Alternate	Malta	Full involvement	
Hendrik van den Berg	Member	Netherlands	Full involvement	
Siri Wang	Member	Norway	Full involvement	
Ine Skottheim Rusten	Alternate	Norway	Full involvement	
Marek Migdal	Member	Poland	No participation in final deliberations and voting	EMEA-001713-PIP02-14 EMEA-000018-PIP01-07-M09 EMEA-001635-PIP02-14
Jolanta Witkowska-Ozogowska	Alternate	Poland	Full involvement	
Helena Fonseca	Member	Portugal	Full involvement	
Hugo Tavares	Alternate	Portugal	Full involvement	
Dana Gabriela Marin	Member	Romania	Full involvement	
Michaela Meciakova	Member	Slovakia	Full involvement	
Stefan Grosek	Member	Slovenia	Full involvement	
Fernando de Andrés Trelles	Member	Spain	Full involvement	
Maria Jesús Fernández Cortizo	Alternate	Spain	Full involvement	
Ninna Gullberg	Member	Sweden	Full involvement	
Angeliki Siapkara	Member	United Kingdom	Full involvement	
Martina Riegl	Alternate	United Kingdom	Full involvement	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	Full involvement	
Maria Grazia Valsecchi	Alternate	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-001654-PIP01-14
Paolo Paolucci	Alternate	Healthcare Professionals' Representative	Full involvement	
Johannes Taminiau	Member	Healthcare Professionals' Representative	Full involvement	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-C1-000402-PIP02-11-M01 EMEA-C-000127-PIP01-07-M03
Paola Baiardi	Alternate	Patients' Organisation Representative	Full involvement	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	Full involvement	
Kerry Leeson-Beevers	Alternate	Patients' Organisation Representative	Full involvement	
Nasir Hussain	Expert - in person*	United Kingdom	Full involvement	
Dominik Karres	Expert - in person*	United Kingdom	Full involvement	
Juliana Min	Expert - in person*	United Kingdom	Full involvement	
Kerstin Westermark	Expert - in person*	Sweden	Full involvement	
Caroline Auriche-Benichou	Expert - via telephone*	France	Full involvement	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

\* Experts were only evaluated against the product(s) they have been invited to talk about.