



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 April 2015  
EMA/PDCO/178890/2015 Corr.  
Procedure Management and Business Support Division

## Paediatric Committee (PDCO)

### Minutes of the 18-20 March 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 11-13 February 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 List of participants to be found at the end of this document.

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

Please refer to the List of participants to be found at the end of this document.

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

Please refer to the March 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 March 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 75 procedures in total<sup>1</sup>, of which:

- 34 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 4 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).

- 27 requests for modifications of an agreed paediatric investigation plan.
- 1 re-examination request.

## 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 May 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>	<p>The PDCO approved the lists of Rapporteurs and Peer Reviewers.</p>
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### IV.2 Nomination for other activities

<ul style="list-style-type: none"> <li>• Early paediatric interaction meeting</li> <li>• Appointment of PDCO representative in Cross-Committee Task Force on Registries  Dirk Mentzer</li> </ul>	<p>The Committee was informed about the progress with setting up and early interaction meeting with potential applicants to discuss paediatric strategy. Volunteers from the Committee were requested to take part in this initiative.</p> <p>Tsvetana Schyns-Liharska was nominated as PDCO representative in Cross-Committee Task Force on Registries (replacement of Viveca Odland). Marina Dimov Giusti was also nominated as additional PDCO participant in this activity.</p>
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## V Update and finalisation of opinions and requests for modification

The opinions adopted during the Paediatric Committee meeting of March 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	Active substance	Applicant	Proposed indication	Condition	Outcome
EMA-000081-PIP01-07-M07	dabigatran etexilate (Pradaxa)	Boehringer Ingelheim International GmbH	Prevention of recurrent stroke in patients with Embolic Stroke of Undetermined Source (ESUS)	Prevention of thrombo-embolic events	The applicant's request was endorsed.

## VIII Annual reports on deferrals

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMA-000311-PIP04-13	ustekinumab	Janssen-Cilag International NV	Stelara	No	No	The PDCO noted the annual report.
EMA-001115-PIP01-10	Loxapine	Alexza UK, Limited	Adasuve	No	Yes	The PDCO noted the annual report.
EMA-000469-PIP01-08	anidulafungin	Pfizer Limited	Ecalta	No	Yes	The PDCO noted the annual report.
EMA-000081-PIP01-07	dabigatran etexilate given as mesilate	Boehringer Ingelheim International GmbH	Pradaxa	No	Yes	The PDCO noted the annual report.
EMA-000170-PIP02-10	Eltrombopag	GlaxoSmithKline Trading Services Limited	Revolade	Yes	No	The PDCO noted the annual report.
EMA-000637-PIP02-10	Lanthanum carbonate hydrate	Shire Pharmaceutical Contracts Ltd	"Fosrenol" in the RMS (Sweden) and associated name "Foznol"	No	No	The PDCO noted the annual report.
EMA-000597-PIP02-10	Mirabegron	Astellas Pharma Europe B.V.	Betmiga	No	No	The PDCO noted the annual report.
EMA-001175-PIP01-11	albiglutide	GlaxoSmithKline LLC	Eperzan	No	No	The PDCO noted the annual report.
EMA-001143-PIP01-11	Cabozantinib	Exelixis, Inc.	Cometriq	Yes	No	The PDCO noted the annual report.

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMA-000087-PIP01-07	Fingolimod hydrochloride	Novartis Europharm Limited	Gilenya	No	Yes	The PDCO noted the annual report.
EMA-000718-PIP01-09	Riociguat	Bayer Schering Pharma AG	Adempas	Yes	No	The PDCO noted the annual report.
EMA-000912-PIP01-10	(1R,2S)-6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-1-naphthalenyl-benzene	Janssen Infectious Diseases BVBA	Sirturo	Yes	No	The PDCO noted the annual report.
EMA-000673-PIP01-09	Pneumo-coccal polysaccharide serotype 23F conjugated to Protein D	GlaxoSmithKline Biologicals S.A.	Synflorix	No	Yes	The PDCO noted the annual report.
EMA-000178-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05	GlaxoSmithKline Biologicals S.A.	Pumarix	No	No	The PDCO noted the report.
EMA-000817-PIP02-11	Purified antigen fractions of inactivated split virion Influenza manufactured in the Dresden plant: A/H1N1 A/H3N2 B/Victoria B/Yamagata	GlaxoSmithKline Biologicals S.A.	Influsplit Tetra and associated names	No	No	The PDCO noted the report. All studies are now completed.
EMA-000696-PIP02-10	Eslicarbazepine acetate	BIAL - Portela & Ca, SA	Exalief, Zebinix	No	Yes	The PDCO noted the report.

## IX Other topics

Guidelines	
Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis rev. 2	The Committee was informed about the latest version of the guideline and after discussion agreed to and adopted this version.
Working groups	
Formulation (FWG)	The Committee was informed about the comments the FWG provided to the SAWP.  Documents tabled for information
Non-Clinical	Documents tabled for information
D30 Products identified for the Non-Clinical Working Group  Jacqueline Carleer	Report noted
Product-related topics	
CHMP update on paediatric topics	The PDCO members were informed about 2 medicinal products with paediatric indication adopted by CHMP in February 2015.
Other topics	
Neuromyelitis Optica (NMO) workshop – conclusion on paediatrics	The Committee heard a presentation on the conclusion on Paediatric NMO from the specific workshop held on 10 October 2014.
Feedback from the Hepatitis C (HCV) Expert Meeting & next steps	PDCO was informed on the outcome of the HCV expert meeting and the discussions currently ongoing in the frame of the Infectious Disease Working Party (IDWP). Minutes from the meeting are being finalised for publication.
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)  E11 Clinical Investigation of Medicinal Products in the Paediatric Population  Revision – status update  Dirk Mentzer	The progress on the work of the E11 drafting group was presented to PDCO.

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	
Breakout sessions	
Neonatology	Follow-up discussion on the Enpr-EMA neonatology collaboration meeting held on 17 March 2015.
Paediatric oncology	The PDCO paediatric oncology working group discussed early access, inclusion of adolescents in trials with adults, plans for future activities.
Paediatric inventory	The PDCO inventory working group finalised the Inventory of paediatric therapeutic needs for Gastroenterology, which will be adopted for public consultation at the next PDCO meeting.

## Any other business

None.

The Chair thanked all participants and closed the meeting.

## List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 18-20 March 2015 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	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	To be replaced for discussions, final deliberations and voting on products when chairing the meeting	EMA-000429-PIP01-08-M04 EMA-001318-PIP01-12-M01 EMA-000178-PIP01-07-M04 EMA-000160-PIP01-07-M04 EMA-000069-PIP01-07-M03
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Violeta Iotova	Member	Bulgaria	No participation in discussions, final deliberations and voting	EMA-001441-PIP01-13 EMA-001556-PIP01-13 EMA-000496-PIP01-08-M04 <sup>2</sup>
Marina Dimov Di Giusti	Member	Croatia	No interests declared	
Georgios Savva	Member	Cyprus	No interests declared	
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Marta Granström	Alternate	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Ann Marie Kaukonen	Member	Finland	No interests declared	
Maija Pihlajamäki	Member	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Birka Lehmann	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	
Grigorios Melas	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Gylfi Oskarsson	Member	Iceland	No interests declared	

<sup>2</sup> Correction in attendance list



Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paolo Rossi	Member	Italy	No restrictions applicable to this meeting	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to this meeting	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania		
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
Herbert Lenicker	Alternate	Malta	No interests declared	
Hendrik van den Berg	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Ine Skottheim Rusten	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No restrictions applicable to this meeting	
Jolanta Witkowska-Ozogowska	Alternate	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No restrictions applicable to this meeting	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Michaela Meciakova	Member	Slovakia	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No restrictions applicable to this meeting	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMA-001716-PIP01-14

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Maria Grazia Valsecchi	Alternate	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-001654-PIP01-14 EMEA-001620-PIP01-14
Paolo Paolucci	Alternate	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-C1-000402-PIP02-11-M01 <sup>3</sup>
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussions, final deliberations and voting	EMEA-C1-001107-PIP01-10-M02 EMEA-001215-PIP01-11-M03
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Dominik Karres	Expert - in person*	United Kingdom		
Sabine Scherer	Expert - via telephone*	Germany		
Arnauld Verschuur	Expert - via telephone*	Nominated by EMA		
A representative from the European Commission attended the meeting				
For CMDh: Ad hoc experts* and 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.

<sup>3</sup> Correction in attendance list