28 November 2013
EMA/PDCO/714542/20133
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 04-06 December 2013 meeting

Chair: Dirk Mentzer

I Introduction

I.1 Adoption of the minutes from previous meeting

I.2 Adoption of the Agenda

I.3 Declaration of Conflict of Interest

Based on the Declaration of Interest submitted by the Committee members, alternates and experts, the Committee Secretariat identified, based on the topics listed in the Agenda of the current Committee meeting, the following restricted involvement of Committee members for the upcoming discussions:

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-000380-PIP02-09-M01
Adriana Ceci	Restriction level DP	EMEA-001371-PIP01-12
Alexandra Compagnucci	Restriction level XC	EMEA-000380-PIP02-09-M01
Alexandra Compagnucci	Restriction level XC	EMEA-001371-PIP01-12
Carine de Beaufort	Restriction level XR	EMEA-001425-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001434-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-000128-PIP03-13
Jaroslav Sterba	Restriction level XP	EMEA-001493-PIP01-13
Jean-Pierre Aboulker	Restriction level XC	EMEA-000380-PIP02-09-M01

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Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Jean-Pierre Aboulker	Restriction level XC	EMEA-001371-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-001460-PIP01-13
Michal Odermarsky	Restriction level XP	EMEA-001442-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-000128-PIP03-13
Paolo Rossi	Restriction level DP	EMEA-000872-PIP02-13
Paolo Rossi	Restriction level XR	EMEA-001442-PIP01-13
Tadej Avcin	Restriction level XP	EMEA-001371-PIP01-12

Members of the Committee are kindly requested to review the list and state any changes, omissions or errors to the already declared interests.

Note: the procedures identified in the table above are on-going and therefore considered confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting reports webpage (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

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

I.4 External attendance

Florian Schmidt, European Commission.

I.5 Leaving / New Members and Alternates

The PDCO welcomes Vessela Boudinova in her new role as an alternate nominated to represent Bulgaria.

The PDCO would like to thank Margarita Guizova for her work following the end of her mandate.

II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

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

III Discussion of applications

97 current procedures in total[1], of which:

- 41 paediatric investigation plan applications;
- 10 product-specific waiver applications;
- 7 compliance check procedures (interim and final);
- 39 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 February 2014[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.

[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).

V Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of December are published in the same month's meeting report published in the EMA website

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition
Golvatinib	Treatment of carcinoma of the liver	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
Golvatinib	Treatment of squamous cell carcinoma of the head and neck	Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lympho-epithelioma)
Lesinurad	Treatment of adult patients with chronic gout in combination with a xanthine oxidase inhibitor where additional therapy is warranted and as monotherapy in patients with intolerance to a xanthine oxidase inhibitor	Treatment of primary gout (excluding Lesch Nyhan syndrome and other secondary forms of gout)

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

PIP number	Active substance	Proposed indication	Condition
Not applicable	Not applicable	Treatment of axial spondyloarthritis without radiographic evidence of ankylosing spondylitis	Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000689-PIP01-09	Exenatide	BYETTA	No	Yes
EMEA-000237-PIP01-08	Azilsartan medoxomil	Not available at present	No	Yes
EMEA-000410-PIP01-08	Regadenoson	Not available at present	No	Yes
EMEA-000567-PIP01-09	Dasatinib	SPRYCEL	Yes	No

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000282-PIP01-08	Clevidipine butyrate	CleviprexTM (clevidipine butyrate injectable emulsion)	No	No
EMEA-000147-PIP01-07	Dienogest	Not available at present	No	Yes
EMEA-000599-PIP01-09	Influenza virus surface antigens (haemagglutinin and neuraminidase)* of H5N1 st...	Focetria and associated names, Aflunov and associated names	No	Yes
EMEA-000036-PIP01-07	Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate / Pneumoc...	Not available at present	No	No
EMEA-000317-PIP01-08	Rilpivirine	Not available at present	No	No
EMEA-000774-PIP01-09	Rilpivirine (as hydrochloride) / emtricitabine / tenofovir disoproxil (as fumara...	Not available at present	No	Yes

IX Other topics

Guidelines	
Draft guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia*	For information
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Extrapolation	For discussion
Formulation	For information
Non-Clinical	For information
Other topics	
CHMP update on paediatric topics	For information
Journal articles on topics related to Paediatric Regulation	For information
Update on Enpr-EMA activities	For information

Communication from the European Commission	For information
Call for interest for participation at a teleconference with the International Pediatric Multiple Sclerosis Study Group (IPMSSG) on 'Paediatric MS trials'	For discussion
Draft proposal for establishment of the joint PDCO/COMP working group*	For discussion
ECDC-EMA Workshop on Vaccine schedules in PIPs-Preliminary programme *	For information
Draft Agenda Training session for patients and consumers involved in EMA activities (10 December 2013)*	For information
Draft Agenda PCWP meeting with all eligible organisations (11 December 2013)*	For information

Any other business

Note on access to documents

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