16 January 2015
EMA/CHMP/776474/2014
Procedure Management and Business Support Division

Committee for medicinal products for human use (CHMP)

Agenda of meeting to be held on 19-22 January 2015

Chair: Tomas Salmonson – Vice-chair: Pierre Demolis

19 January 2015, 13:00 – 19:30, room 2A

20 January 2015, 08:30 – 19:30, room 2A

21 January 2015, 08:30 – 19:30, room 2A

22 January 2015, 08:30 – 17:00, room 2A

Note on access to documents

Some documents mentioned in the agenda/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).

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health & safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential and therefore not disclosed. 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 CHMP are on-going and therefore are considered confidential. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available. For orphan medicinal products the applicant details are published as this information is already publicly available.

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Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Further information with relevant explanatory notes can be found at the end of this document.

For adoption

Agenda (EMA/CHMP/776474/2014 rev.4) and Annex to CHMP agenda of the CHMP plenary session to be held on 19-22 January 2015	
Timeschedule (EMA/CHMP/17260/2015 rev.3) of the CHMP plenary session to be held on 19-22 January 2015	
Minutes (EMA/CHMP/1402/2015 rev.0) of the CHMP plenary session held on 15-18 December 2014	

For information

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held on 19-22 January 2015	*See January 2015 Minutes (to be published post February 2015 CHMP meeting)*
Draft Agenda of CHMP meeting to be held on 23-26 February 2015.	

Table of contents

1. Oral explanations

1.1. Pre-authorisation procedure oral explanations

No items

1.2. Re-examination procedure oral explanation

No items

1.3. Post-authorisation procedure oral explanation

Rienso (EMEA/H/C/002215/II/0008), (ferumoxytol), MAH: Takeda Pharma A/S, Rapporteur: Harald Enzmann, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Martin Huber, "Extension of indication: all cause iron deficiency anaemia when oral therapy is ineffective or inappropriate or where there is a need for rapid iron repletion As a consequence, sections 4.1, 4.2 , 4.4, 4.8 and 5.1 of the SmPC were proposed to be updated. The Package Leaflet was proposed to be updated accordingly. The MAH took the opportunity to propose minor editorial changes to the SmPC and to propose the update of the Product Information in line with the latest version of the QRD template (9.0)" Request for Supplementary Information adopted on 20.11.2014, 26.06.2014, 25.04.2014, 24.10.2013.	Oral explanation to be held on Tuesday 20 January 2015 at 14.30.

1.4. Referral procedure oral explanation

GVK Biosciences (EMEA/H/A-31/1408)
Rapporteur: Harald Enzmann, Co-Rapporteur: Christian Schneider,
Article 31 procedure triggered by the European Commission concerning GVK Biosciences Private Limited (GVK Bio), Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India following critical GCP deficiencies reported during an inspection performed by the ANSM (Agency for Medicines and Health Products Safety, France) in May 2014.

Oral explanation held in October 2014. GVK Working Group meeting held on 8-9 December 2014.

2. Initial full applications

2.1. Initial full applications; Opinions

(EMEA/H/C/003823), (lamivudine / raltegravir), (treatment of human immunodeficiency virus (HIV-1))

List of Outstanding Issues adopted on 20.11.2014.
List of Questions adopted on 24.07.2014

(EMEA/H/C/002066), (ciclosporin), (treatment of keratitis)
List of Outstanding Issues adopted on 25.09.2014. An Oral explanation was held in December 2014.
List of Questions adopted on 25.04.2014.

(EMEA/H/C/003773), (cangrelor), (inhibitor indicated for the reduction of thrombotic cardiovascular events
Hemaxiv is a P2Y12 platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in adult patients with coronary artery disease undergoing percutaneous coronary intervention (PCI).
During the pre-operative period when oral P2Y12 therapy is interrupted due to surgery ('Bridging') Hemaxiv is also indicated to maintain P2Y12 inhibition in adult patients with acute coronary syndromes or in patients with stents who are at increased risk for thrombotic events (such as stent thrombosis) when oral P2Y12 therapy is interrupted due to surgery ('Bridging').)

List of Outstanding Issues adopted on 25.09.2014.
List of Questions adopted on 25.04.2014.

(EMEA/H/C/003785), (oritavancin), (treatment of complicated skin and soft tissue infections (cSSTI))
List of Outstanding Issues adopted on 20.11.2014.
List of Questions adopted on 26.06.2014.

(EMEA/H/C/002807), (human fibrinogen / human thrombin), (supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis)
List of Outstanding Issues adopted on 20.11.2014. List of Questions adopted on 20.03.2014.

- BWP Report: **For adoption**

(EMEA/H/C/003780), (liraglutide), (treatment of obesity)
List of Outstanding Issues adopted on 23.10.2014. An Oral explanation was held in December 2014.
List of Questions adopted on 22.05.2014.

(EMEA/H/C/002846), (tedizolid phosphate), (treatment of tissue infections (cSSTI))
List of Outstanding Issues adopted on 20.11.2014. List of Questions adopted on 26.06.2014.

2.2. Initial full applications; Day 180 List of outstanding issues

(EMEA/H/C/003728), (netupitant / palonosetron), (prevention of chemotherapy-induced nausea and vomiting (CINV))
List of Questions adopted on 22.05.2014.

(EMEA/H/C/002629), (edoxaban), (prevention of stroke; embolism and treatment of venous thromboembolism)
List of Outstanding Issues adopted on 20.11.2014.
List of Questions adopted on 26.06.2014.

(EMEA/H/C/002800), Orphan, (dinutuximab), Applicant: United Therapeutics Europe Ltd, (treatment of neuroblastoma, treatment of high-risk neuroblastoma)
List of Questions adopted on 25.04.2014.

- BWP Report: **For adoption**

2.3. Initial full applications; Day 120 List of Questions

(EMEA/H/C/003960), (cobimetinib), (treatment of metastatic melanoma)

(EMEA/H/C/003769), Orphan, (mercaptamine hydrochloride), Applicant: Orphan Europe S.A.R.L., (treatment of cystinosis)

(EMEA/H/C/003981), (duloxetine), (treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder)

(EMEA/H/C/004009), (duloxetine), (treatment in adults of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder.)

(EMEA/H/C/003935), (duloxetine), Generic, (treatment of depressive disorder, diabetic neuropathic pain, anxiety disorder)

(EMEA/H/C/003766), (evolocumab), (Hypercholesterolaemia and mixed dyslipidaemia and Homozygous familial hypercholesterolaemia)

- BWP Report: **For adoption**

(EMEA/H/C/002771), ATMP, (talimogene laherparepvec), (treatment of adults with melanoma that is regionally or distantly metastatic)

- BWP Report: **For adoption**

(EMEA/H/C/002715), (fentanyl), , (treatment of acute moderate to severe post-operative pain)

(EMEA/H/C/003727), Orphan, (lenvatinib), Applicant: Eisai Ltd, (treatment of papillary thyroid cancer, treatment of follicular thyroid cancer)

(EMEA/H/C/003840), (nivolumab), (treatment of cancer after prior chemotherapy)

- BWP Report: **For adoption**

(EMEA/H/C/003985), (nivolumab), (treatment of advanced (unresectable or metastatic) melanoma in adults)

- BWP Report: **For adoption**

2.4. Update on on-going initial full applications for Centralised procedure

(EMEA/H/C/004008), (aripiprazole), (treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder)
List of Questions adopted on 20.11.2014.
Letter from the applicant dated 19 December 2014 requesting extension of clock stop to respond to the Day 120 List of Questions: **For information**

(EMEA/H/C/003852), (human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)), (treatment of HPV diseases)
List of Outstanding Issues adopted on 18.12.2014. List of Questions adopted on 24.07.2014.

- Letter from the applicant dated 5 January 2015 requesting an extension of clock stop to respond to the List of Outstanding Issues adopted on 18 December 2014: **For information**

(EMEA/H/C/004038), Orphan, (mercaptamine hydrochloride), Applicant: Lucane Pharma, (treatment of corneal cystine deposits)
Similarity assessment report: **For adoption**

(EMEA/H/C/003702), (phenylephrine hydrochloride / ketorolac trometamol), (maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement (ILR) in adults)

List of Outstanding Issues adopted on 22.05.2014.
List of Questions adopted on 23.01.2014.

- Letter from the applicant dated 10 January 2014 requesting an extension of clock stop : **For information**

2.5. Products in the Decision Making Phase

Vantobra (EMEA/H/C/002633)
(Tobramycin), Applicant: PARI Pharma GmbH, (Management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis (CF). Consideration should be given to official guidance on the appropriate use of antibacterial agents), Hybrid application (Article 10(3) of Directive No 2001/83/EC). An Oral explanation was held in December 2014.

3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

3.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinions

Ibandronic acid Accord
(EMEA/H/C/002638/X/0006), (ibandronic acid), MAH: Accord Healthcare Ltd, Generic, Generic of Bondronat, Rapporteur: Alar Irs, “To add a new strength/potency and a new pharmaceutical form 3 mg solution for injection.”
List of Outstanding Issues adopted on 20.11.2014.
List of Questions adopted on 26.06.2014.

3.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 List of outstanding issues

Optisulin (EMEA/H/C/000309/X/0079/G), (insulin glargine), MAH: Sanofi-aventis Deutschland GmbH, Duplicate, Duplicate of Lantus, Rapporteur: Pieter de Graeff, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst, "To extend MA of Optisulin to register additional strength 300 U/ml, grouped with type IA variation to vary the invented name from Optisulin to Toujeo"
List of Questions adopted on 25.09.2014.

3.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of Questions

Suboxone (EMEA/H/C/000697/X/0029), (buprenorphine / naloxone), MAH: RB Pharmaceuticals Ltd., Rapporteur: Martina Weise, "Line extension application to add 12mg/3mg and 16mg/4mg sublingual tablets."

3.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008

Mabthera (EMEA/H/C/000165/X/0101/G), (rituximab), MAH: Roche Registration Ltd, Rapporteur: Christian Schneider, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Doris Stenver, , "Grouping of:
Line extension to add a new strength 1600 mg solution for subcutaneous injection, a new indication is proposed for this strength (different from 1400mg strength).
Type II variation to update the product information of the existing strengths as a consequence to the line extension application
Type II variation to update the RMP"

- Revised timetable for the assessment of similarity: **For information**

4. Type II variations - Extension of indication procedures according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Type II variation; Extension of indication- Opinions or Requests for supplementary information -

Abraxane (EMEA/H/C/000778/II/0067), (paclitaxel), MAH: Celgene Europe Limited, Rapporteur: Pieter de Graeff, Co-Rapporteur: Ingunn Hagen Westgaard, PRAC Rapporteur: Sabine Straus, "Extension of Indication to add a new indication for Abraxane in combination with carboplatin for the first-line treatment of non-small cell lung cancer (NSCLC) in adult patients who are not candidates for potentially curative surgery and/or radiation therapy. Consequently the MAH proposes to update sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmpC and to update the Package Leaflet accordingly.
An updated RMP version 14.0 has been provided as part of the application."
Request for Supplementary Information adopted on 25.09.2014.

Aloxi (EMEA/H/C/000563/II/0038), (palonosetron), MAH: Helsinn Birex Pharmaceuticals Ltd., Rapporteur: Patrick Salmon, Co-Rapporteur: Arantxa Sancho-Lopez, PRAC Rapporteur: Almath Spooner, "Extension of the therapeutic indication for paediatric patients 1 month of age and older for the prevention of nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy for the IV formulation, based on the paediatric studies PALO-10-14 and PALO-10-20 and update of sections 5.1 and 5.2 of the Aloxi Oral formulation to reflect those studies. The MAH took the opportunity of this variation to update the Aloxi product information annexes in line with Version 9 of the QRD template."
Request for Supplementary Information adopted on 18.12.2014, 25.09.2014.

Avastin (EMEA/H/C/000582/II/0072), (bevacizumab), MAH: Roche Registration Ltd, Rapporteur: Christian Schneider, Co-Rapporteur: Ingunn Hagen Westgaard, PRAC Rapporteur: Doris Stenver, “Extension of indication for the use of Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan in patient with persistent, recurrent, or metastatic carcinoma of the cervix. Consequently, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC and the Package Leaflet are proposed to be updated.” Request for Supplementary Information adopted on 25.09.2014.

Eylea (EMEA/H/C/002392/II/0013), (aflibercept), MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Arnaud Batz, “Update of the Product information to introduce new indication: the treatment of macular oedema following branch retinal vein occlusion (BRVO). New clinical and nonclinical data is being introduced to the SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2. The PL is being updated accordingly. Furthermore, minor editorial changes have been introduced to the PI.”
Request for Supplementary Information adopted on 25.09.2014.

Jakavi (EMEA/H/C/002464/II/0016), Orphan, (ruxolitinib), MAH: Novartis Europharm Ltd, Rapporteur: Filip Josephson, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Ulla Wändel Liminga, “Extension of Indication to add treatment of adult patients with polycythaemia vera resistant to or intolerant of hydroxyurea. As a result, the MAH proposes to update sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC. The Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to implement imnor editorial changes in the SmPC. An updated RMP version 4.0 has been provided as part of the application.”
Request for Supplementary Information adopted on 25.09.2014.

Prevenar 13 (EMEA/H/C/001104/II/0111), (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)), MAH: Pfizer Limited, Rapporteur: Kristina Dunder, Co-Rapporteur: Daniel Brasseur, PRAC Rapporteur: Qun-Ying Yue, "Extension of Indication to add "pneumonia" to the authorised indication for adults (≥18 years of age), based on data from the recently completed Community–Acquired Pneumonia Immunization Trial in Adults (CAPiTA), which studied the efficacy of Prevenar 13 in preventing vaccine-serotype pneumococcal community-acquired pneumonia (CAP) and vaccine-serotype invasive pneumococcal disease (IPD) in adults aged 65 years and older. As a consequence the MAH proposes to update sections 4.1, 4.8 and 5.1 of the SmPC and to update the Package Leaflet accordingly. The provision of the CAPiTA study addresses MEA 045." Request for Supplementary Information adopted on 23.10.2014.	
Rienso (EMEA/H/C/002215/II/0008), (ferumoxytol), MAH: Takeda Pharma A/S, Rapporteur: Harald Enzmann, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Martin Huber, "Extension of indication: all cause iron deficiency anaemia when oral therapy is ineffective or inappropriate or where there is a need for rapid iron repletion As a consequence, sections 4.1, 4.2 , 4.4, 4.8 and 5.1 of the SmPC were proposed to be updated. The Package Leaflet was proposed to be updated accordingly. The MAH took the opportunity to propose minor editorial changes to the SmPC and to propose the update of the Product Information in line with the latest version of the QRD template (9.0)" Request for Supplementary Information adopted on 20.11.2014, 26.06.2014, 25.04.2014, 24.10.2013.	

Stelara (EMEA/H/C/000958/II/0042), (ustekinumab), MAH: Janssen-Cilag International N.V., Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, PRAC Rapporteur: Julie Williams, "Extension of Indication to add treatment of moderate to severe plaque psoriasis in paediatric patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. As a consequence SmPC sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 have been updated and the Package Leaflet has been updated accordingly. A revised RMP version 12 was provided as part of the application."	
TachoSil (EMEA/H/C/000505/II/0057), (human thrombin / human fibrinogen), MAH: Takeda Austria GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication for the use of Tachosil as suture line sealing in dura mater closure. As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC and the Package leaflet are updated. The MAH also took the opportunity to make minor editorial corrections to the product information."	

4.2. Update on on-going type II variation; extension of indications

Teysuno (EMEA/H/C/001242/II/0018), (tegafur / gimeracil / oteracil), MAH: Nordic Group B.V., Rapporteur: Pieter de Graeff, PRAC Rapporteur: Sabine Straus, "Update of sections 4.1, 4.2 and 5.1 of the SmPC in order to add combination therapy of Teysuno with oxaliplatin (with or without epirubicin) with consequential updates to sections 4.3, 4.4, 4.5, 4.6, 4.8. The Package Leaflet is updated accordingly.
In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 9.0."
Request for Supplementary Information adopted on 23.10.2014.

- Letter from the MAH dated 7 January 2015 informing of the decision to withdraw the type II variation: **For information**

5. Ancillary medicinal substances in medical devices

5.1. Ancillary medicinal substances in medical devices - Opinions / List of outstanding issues / List of Questions

No items

6. Re-examination procedure (new applications) under Article 9(2) of Regulation no 726/2004

No items

7. Re-examination procedure (Type II variations) under Article Article 16 of Commission Regulation (EC) No 1234/2008 and 9(2) of Regulation (EC) No 726/2004

No items

8. Withdrawal of full initial application

No items

9. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

No items

10. Pre-submission issues

Some items in this section are considered commercially confidential or sensitive and therefore not disclosed.

11. Post-authorisation issues

Some items in this section are considered commercially confidential or sensitive and therefore not disclosed.

12. Referral procedures

12.1. Procedure for Centrally Authorised products under Article 20 Council Regulation (EC) No 726/2004

No items

12.2. Requests for CHMP Opinion under Article 5(3) and 57 (1)p of Regulation (EC) No 726/2004

Medicinal products under development for the treatment of Ebola (EMEA/H/A-5(3)/1410)

12.3. Procedure under Articles 5(2) and 10 of the Regulation (EC) No 726/2004

No items

12.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

MERISONE 50 mg and 150 mg film coated tablets and MYOSON 50 mg and 150 mg film coated tablet (EMEA/H/A-29/1411)
(tolperisone)
Meditop Pharmaceutical Co.Ltd.
, RMS: HU, CMS: DE, NL, BE, LU, Mutual recognition procedures: HU/H/0373/001-002/MR

and HU/H/0377/001-002/MR

Scope: Lack of bioequivalence studies to evaluate the food effect.

- Letter from the National Institute for Quality and Organisational Development in Healthcare and Medicines , National Institute of Pharmacy in Hungary dated 24 December 2014 notifying of an official referral under Article 29(4) and its grounds: **For information**
- Appointment of (Co)Rapporteur: **For discussion**
- List of Questions: **For adoption**
- Timetable: **For adoption**

12.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

Ikorel / Dancor and associated names (EMEA/H/A-30/1380)

(nicorandil), Sanofi-Aventis group of companies and associated companies / Merck group of companies and associated companies,
Rapporteur: Joseph Emmerich, Co-Rapporteur: Pieter de Graeff,
Ikorel / Dancor was included in the list of products for SmPC harmonisation, drawn up by the CMDh, in accordance with Article 30(2) of Directive 2001/83/EC.

- List of Outstanding Issues: **For adoption**

12.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

GVK Biosciences (EMEA/H/A-31/1408)

Rapporteur: Harald Enzmann, Co-Rapporteur: Christian Schneider,
Article 31 procedure triggered by the European Commission concerning GVK Biosciences Private Limited (GVK Bio), Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India following critical GCP deficiencies reported during an inspection performed by the ANSM (Agency for Medicines and Health Products Safety, France) in May 2014. Oral explanation held in October 2014. GVK Working Group meeting held on 8-9

December 2014
Gadolinium containing contrast agents, Gd-Cas (EMEA/H/A-31/1097), Rapporteur: Rafe Suvarna, Co-Rapporteur: Pieter de Graeff, , Discussion on the AKI to be added to the labelling of Optimark & update on the availability on the bone study results

12.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

12.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

12.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) (EC) No 1084/2003)

No items

12.10. Procedure under Article 29 Regulation (EC) 1901/2006

No items

12.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) No 1234/2008)

No items

13. Pharmacovigilance issues

Summary of recommendations and advice of PRAC meeting held on 6-9 January 2015: **For information**
Update on the Pharmacovigilance programme and the revised implementation governance: **For information**
List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for January 2015: **For adoption**

Early Notification System: January 2015 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Public: **for information**	
Rienso PSUR (EMEA/H/C/002215/PSUV/0015) (with RMP version 3.3)(ferumoxytol), MAH: Takeda Pharma A/S, Rapporteur: Harald Enzmann, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Martin Huber	

14. Inspections

14.1. GMP inspections

Request for GMP inspections: **For adoption**	*Disclosure of information related to GMP inspections will not be published as it undermines the purpose of such inspections.*
2015 EMA GMP re-inspection programme: **For adoption**	

14.2. GCP inspections

Request for GCP inspections: **For adoption**	*Disclosure of information related to GCP inspections will not be published as it undermines the purpose of such inspections.*

14.3. Pharmacovigilance inspections

Request for Pharmacovigilance inspections: **For adoption**	*Disclosure of information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections.*

14.4. GLP inspections

Request for GLP inspections: **For adoption**	*Disclosure of information related to GLP inspections will not be published as it undermines the purpose of such inspections.*

15. Innovation Task Force

15.1. Minutes of Innovation Task Force: For information

15.2. Briefing meetings (Innovation Task Force)

Disclosure of information related to briefing meetings taking place with applicants cannot be released at present time as deemed to contain commercially confidential information.

15.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

Request from EC for EMA scientific Opinion under Art. 57 (1)P of Regulation (EC) No 726/2004 • Draft report: **For comments**
Request from EDQM for EMA scientific Opinion under Art. 57 (1)J of Regulation (EC) No 726/2004 • Timetable: **For adoption**

15.4. Nanomedicines activities

No items

16. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 6-9 January 2015. Table of conclusions: **For information**	
Scientific advice letters:	*Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.*

17. Satellite Groups

17.1. Coordination Group for Mutual Recognition and Decentralised Procedures

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 19-21 January 2015: **For information**
CMDh question to CHMP (PKWP) regarding

potential risk of longer half-life of acitretin, PKWP response on the questions regarding the half –life of acitretin: **For adoption**

PKWP response on a possible extension of the post-treatment pregnancy prevention period after use of acitretin: **For adoption**

18. Other Committees

18.1. Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on 7-8 January 2015: **For information**

18.2. Committee for Herbal Medicinal Products (HMPC)

Not applicable

18.3. Paediatric Committee (PDCO)

PIPs reaching D30 at January 2015 PDCO: **For information**

Report from the PDCO meeting held on held on 14-16 January 2015: **For information**

18.4. Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 15-16 January 2015: **For information**

19. Invented name issues

No items

20. Any other business

Report from Alzheimer's disease EMA workshop: **For discussion**

Appointment of CHMP representatives to the CAT: The Co-opted members Sol Ruiz and Jean-Louis Robert need to propose their CAT alternates.

Working Parties Work plans: **For adoption**

- PCWP work plan for 2015
- HCPWP work plan for 2015

- BWP work plan for 2015
- ONCWP work plan for 2015
- CNSWP work plan for 2015
- VWP work plan for 2015
- BPWP work plan for 2015

Joint CHMP/CAT/COMP Presidency meeting in Rome.

- Minutes of the meeting: **For adoption**

PKWP position paper on specific questions:

1. Evaluation of orally inhaled medicinal products:
For adoption

2. Clarifications on the "Evaluation of the pharmacokinetics of medicinal products in patients with impaired hepatic function" guideline:
For adoption

PKWP opinion on acceptance of bioequivalence :
For adoption

Workshop on Lifecycle management to be held 28-29 October 2014: **For information**

Guidance on meetings with Applicants on the responses to questions received from EMA Scientific Committees during the evaluation within the centralised procedure

Revised framework of interaction with patients and consumers

List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 19-22 January 2015 meeting.

Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations *(section 1)*

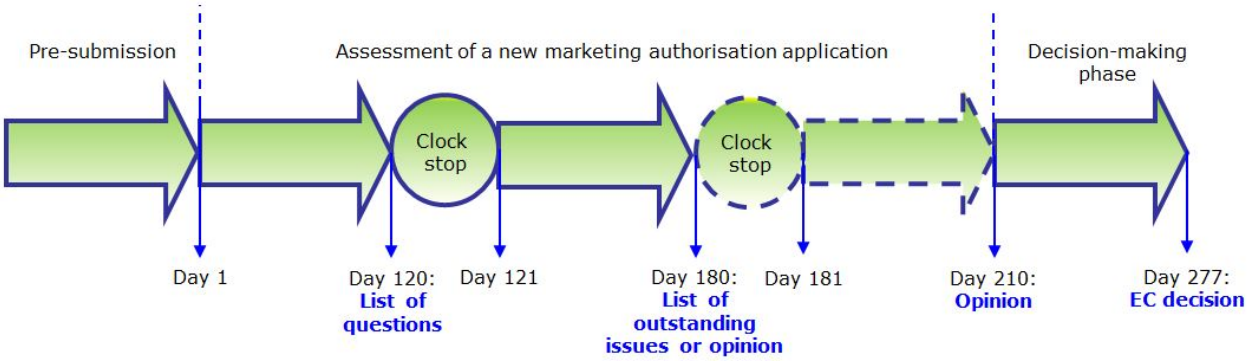
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section 12) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

New applications *(section 2)*

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 2.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 2.2 (**Day 180 List of outstanding issues**) and 2.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 2.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 2.5, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 3)*

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 4)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 3. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 5)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 6)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section 7)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 8)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 9)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 10)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 11)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 12)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 13)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 14)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 15)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 16)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 17)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 18)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.