25 September 2015
EMA/CHMP/620116/2015 Rev. 1
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 21-24 September 2015

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

21 September 2015, 13:00 – 19:30, room 3A

22 September 2015, 08:30 – 19:30, room 3A

23 September 2015, 08:30 – 19:30, room 3A

24 September 2015, 08:30 – 16:00, room 3A

Health and 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 or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes 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. 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.

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

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of 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).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

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 21-24 September 2015. See September 2015 CHMP minutes (to be published post October 2015 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 21-24 September 2015

1.3. Adoption of the minutes

CHMP minutes for 20-23 July 2015.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - mepolizumab - EMEA/H/C/003860

treatment of asthma

Scope: Oral Explanation

Action: Oral Explanation to be held on Tuesday 22 September 2015 at 11:00

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.03.2015.

See also 3.1.10

BWP Report

2.1.2. - recombinant l-asparaginase - Orphan - EMEA/H/C/002661

medac Gesellschaft fuer klinische Spezialpraeparate mbH; combination therapy for B/T cell lymphoblastic leukaemia (ALL) or B/T cell lymphoblastic lymphoma (LBL)

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 23 September 2015 at 11.00.

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 25.04.2014.

2.2. Re-examination procedure oral explanations

2.3. Post-authorisation procedure oral explanations

2.3.1. TECFIDERA - Dimethyl Fumarate - EMEA/H/C/002601/WS0689/G; NAPs included in WS: Fumaderm, Fumaderm Intial

Biogen Idec Ltd,

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber,

Scope: Oral explanation and Opinion

Action: Oral explanation to be held on Tuesday 22 September 2015 at 14.00

Update of sections 4.4 of the SmPC in order to add a recommendation to consider interruption of treatment in patients with low lymphocyte counts (<0.5 x 109/L) persisting for more than six months and to monitor lymphocyte counts until recovery. Update of section 4.8 of the SmPC with information on observed low lymphocyte counts in clinical studies with tecfidera and PML (Progressive multifocal leukoencephalopathy) occurrence in the setting of severe and prolonged lymphopenia. Furthermore, the due dates of two commitments as part of the RMP have been revised."

Request for Supplementary information adopted on 26.02.2015, 23.04.2015, 23.07.2015. SAG Neurology held on 11 June 2015.

See also 9.1.5

2.3.2. TachoSil - human thrombin / human fibrinogen - EMEA/H/C/000505/II/0057

Takeda Austria GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Oral explanation and Opinion

"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."

Action: Oral explanation to be held on Tuesday 22 September 2015 at 17.00.

Request for Supplementary Information adopted on 21.05.2015, 22.01.2015.

2.4. Referral procedure oral explanations

2.4.1. IOGOL and associated names soft capsules, 25 / 50 mg - diclofenac epolamine - EMEA/H/A-29/1414

Regiomedica GmbH

Rapporteur: Martina Weise, Co-Rapporteur: Concepcion Prieto Yerro,

Scope: Oral explanation and Opinion

Disagreements regarding the demonstration of bioequivalence with the reference product

See also 10.4.1.

Action: Possible oral explanation to be held on Tuesday 22 September 2015 at 09.00.

RMS: DE, CMS: AT, BE, CZ, EL, ES, HU, IT, PL, SK, UK, Decentralised procedure number: DE/H/3633/002-003/DC

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - aripiprazole - EMEA/H/C/004021

treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 18.12.2014.

3.1.2. - blinatumomab - Orphan - EMEA/H/C/003731

Amgen Europe B.V.; treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.02.2015.

BWP Report

3.1.3. - pemetrexed - EMEA/H/C/003788

Treatment of malignant pleural mesothelioma and non-small cell lung cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.02.2015.

3.1.4. - cobimetinib - EMEA/H/C/003960

treatment of metastatic melanoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2015. List of Questions adopted on 22.01.2015.

3.1.5. - efmoroctocog alfa - Orphan - EMEA/H/C/003964

Biogen Idec Ltd; Treatment of Haemophilia A

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.02.2015.

BWP Report

3.1.6. - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042

Treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 23.04.2015.

3.1.7. - fentanyl - EMEA/H/C/002715

treatment of acute moderate to severe post-operative pain

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 22.01.2015.

3.1.8. - carfilzomib - Orphan - EMEA/H/C/003790

Amgen Europe B.V.; treatment of multiple myeloma

Scope: Opinion

Action: For adoption

List of Questions adopted on 25.06.2015.

3.1.9. - levodopa / carbidopa - EMEA/H/C/002611

treatment of Parkinson's disease

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.03.2015.

3.1.10. - mepolizumab - EMEA/H/C/003860

treatment of asthma

Scope: Oral explanation or Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.03.2015.

BWP Report

Possible Oral Explanation – see 2.1.1.

3.1.11. - lumacaftor / ivacaftor - Orphan - EMEA/H/C/003954

Vertex Pharmaceuticals (U.K.) Ltd.; treatment of cystic fibrosis

Scope: Possible Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.03.2015.

3.1.12. - pemetrexed - EMEA/H/C/003970

treatment of malignant pleural mesothelioma and non-small cell lung cancer (excluding predominantly squamous cell histology)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.02.2015.

3.1.13. - pemetrexed - EMEA/H/C/003905

Treatment of malignant pleural mesothelioma and non-small cell lung cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2015. List of Questions adopted on 26.02.2015.

3.1.14. - idarucizumab - EMEA/H/C/003986

Prevention and treatment of dabigatran associated haemorrhage

Scope: Opinion

Action: For adoption

List of Questions adopted on 23.07.2015. Accelerated assessment.

BWP Report

3.1.15. - glycerol phenylbutyrate - Orphan - EMEA/H/C/003822

Horizon Therapeutics Limited; treatment of patients with urea cycle disorders

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2015. List of Questions adopted on 23.10.2014.

3.1.16. - dapagliflozin / metformin - EMEA/H/C/004162

Diabetes mellitus, type 2

Scope: Opinion

Action: For adoption

3.1.17. - dapagliflozin - EMEA/H/C/004161

Diabetes mellitus, type 2

Scope: Opinion

Action: For adoption

3.1.18. - cinacalcet - EMEA/H/C/004014

treatment of secondary hyperparathyroidism and hypercalcaemia

Scope: Opinion

Action: For adoption

List of Questions adopted on 21.05.2015.

3.1.19. Kolbam – Cholic Acid - Orphan - EMEA/H/C/002081

Retrophin Europe Ltd, treatment of inborn errors of primary bile acid synthesis

Rapporteur: Robert James Hemmings, Co-Rapporteur: Patrick Salmon

Scope: Revised opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - brivaracetam - EMEA/H/C/003898

treatment of partial-onset seizures

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

3.2.2. - mercaptamine - Orphan - EMEA/H/C/004038

Lucane Pharma; treatment of corneal cystine deposits

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

3.2.3. sacubitril / valsartan - EMEA/H/C/004062

treatment of heart failure (NYHA class II-IV)

Scope: Day 180 list of outstanding issue

Action: For adoption

3.2.4. - eptifibatide - EMEA/H/C/004104

prevention of early myocardial infarction

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

3.2.5. - ferric maltol - EMEA/H/C/002733

treatment of iron deficiency anaemia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

3.2.6. - octocog alfa - EMEA/H/C/004147

Treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency), Treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of haemophilia A

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

BWP Report

3.2.7. - octocog alfa - EMEA/H/C/003825

Treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency), Treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of haemophilia A, treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

BWP Report

3.2.8. - dexamethasone acetate - Orphan - EMEA/H/C/004071

LABORATOIRES CTRS; treatment of symptomatic multiple myeloma in combination with other medicinal products.

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 18.12.2014.

3.2.9. - parathyroid hormone - Orphan - EMEA/H/C/003861

NPS Pharma Holdings Limited; treatment of hypoparathyroidism

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

BWP Report

3.2.10. - betulae cortex dry extract (5-10 : 1); extraction solvent: n-heptane 95% (w/w) - EMEA/H/C/003938

treatment of partial thickness wounds

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

3.2.11. - opicapone - EMEA/H/C/002790

Parkinson's disease and motor fluctuations

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

3.2.12. - pemetrexed - EMEA/H/C/004072

unresectable malignant pleural mesothelioma
metastatic non-small cell lung cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

3.2.13. - pemetrexed - EMEA/H/C/004109

Treatment of malignant pleural mesothelioma and non-small cell lung cancer.

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.06.2015.

3.2.14. - necitumumab - EMEA/H/C/003886

treatment of squamous non-small cell lung cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

BWP Report

3.2.15. - etanercept - EMEA/H/C/004007

treatment of arthritis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

BWP Report

3.2.16. - selexipag - Orphan - EMEA/H/C/003774

Actelion Registration Ltd.; treatment of pulmonary arterial hypertension (PAH; WHO Group I)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

3.2.17. - human fibrinogen / human thrombin - EMEA/H/C/003914

supportive treatment for improvement of haemostasis and as a suture support in vascular surgery

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015, 23.04.2015.

BWP Report

3.2.18. - talimogene laherparepvec - ATMP - EMEA/H/C/002771

treatment of adults with melanoma that is regionally or distantly metastatic

Scope: 2nd Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 25.06.2015. List of Questions adopted on 22.01.2015.

BWP Report

3.3. Initial applications; Day 120 list of questions

3.3.1. - docetaxel - EMEA/H/C/004086

treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, head and neck cancer

Scope: Day 120 list of questions

Action: For adoption

3.3.2. - eluxadoline - EMEA/H/C/004098

for the treatment of irritable bowel syndrome with diarrhoea

Scope: Day 120 list of questions

Action: For adoption

3.3.3. - emtricitabine / tenofovir alafenamide - EMEA/H/C/004094

treatment of HIV

Scope: Day 120 list of questions

Action: For adoption

3.3.4. - lutetium (177 lu) chloride - EMEA/H/C/003999

radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - dinutuximab beta - Orphan - EMEA/H/C/003918

APEIRON Biologics AG; treatment of neuroblastoma

Scope: Day 120 list of questions

Action: For adoption

BWP Report

3.3.6. - chlormethine - Orphan - EMEA/H/C/002826

Actelion Registration Ltd.; treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)

Scope: Day 120 list of questions

Action: For adoption

3.3.7. - irinotecan - Orphan - EMEA/H/C/004125

Baxter Innovations GmbH; treatment of pancreatic cancer

Scope: Day 120 list of questions

Action: For adoption

3.3.8. - palonosetron - EMEA/H/C/004129

prevention of nausea and vomiting associated with cancer chemotherapy

Scope: Day 120 list of questions

Action: For adoption

3.3.9. - palonosetron - EMEA/H/C/004069

prevention of nausea and vomiting associated with cancer chemotherapy

Scope: Day 120 list of questions

Action: For adoption

3.3.10. - saxagliptin / dapagliflozin - EMEA/H/C/004057

treatment of type 2 diabetes

Scope: Day 120 list of questions

Action: For adoption

3.3.11. - autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human ada cdna sequence - Orphan - ATMP - EMEA/H/C/003854

GlaxoSmithKline Trading Services; severe combined immunodeficiency

Scope: Day 120 list of questions

Action: For adoption

Accelerated assessment.

BWP Report

3.3.12. - ixekizumab - EMEA/H/C/003943

treatment of moderate to severe plaque psoriasis

Scope: Day 120 list of questions

Action: For adoption

BWP Report

3.3.13. - ceftazidime / avibactam - EMEA/H/C/004027

treatment of cIAI, cUTI, nosocomial pneumonia

Scope: Day 120 list of questions

Action: For adoption

3.4. Update on on-going initial applications for Centralised procedure

3.4.1. - amikacin - Orphan - EMEA/H/C/003936

Insmed Limited; treatment of Pseudomonas aeruginosa lung infection/colonisation in cystic fibrosis patients, treatment of nontuberculous mycobacterial lung infection

Scope: Similarity assessment

Action: For adoption

Letter from the applicant dated 21 August 2015 informing of the decision to withdraw the indication for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 6 years and older."

3.4.2. - glycopyrronium bromide - EMEA/H/C/003883

treatment of sialorrhoea

Scope: Letter from the applicant dated 7 August 2015 requesting an extension of clock stop to submit the responses to the Day 120 list of questions .

Action: For adoption

List of Questions adopted on 25.06.2015.

3.4.3. - drisapersen - Orphan - EMEA/H/C/003846

BioMarin International Limited; treatment of Duchenne muscular dystrophy (DMD)

Scope: Similarity assessment

Action: For adoption

3.4.4. - sirolimus - Orphan - EMEA/H/C/003978

Santen Oy; treatment of chronic non-infectious uveitis of the posterior segment of the eye

Scope: Letter from the applicant dated 8 September 2015 requesting an extension of clock stop to respond to Day 120 list of questions adopted on 25.06.2015.

Action: For adoption

3.4.5. - miglustat - EMEA/H/C/004016

treatment of Gaucher disease

Scope: Letter from the applicant dated September 2015 requesting an extension of clock stop to respond to Day 120 list of questions adopted on 23.07.2015.

Action: For adoption

3.4.6. - mercaptamine - Orphan - EMEA/H/C/003769

Orphan Europe S.A.R.L.; treatment of cystinosis

Scope: Letter from the applicant dated September 2015 requesting to postpone the planned oral explanation to CHMP plenary to be held on 19-22 October 2015.

Action: For information

List of Outstanding Issues adopted on 25.06.2015. List of Questions adopted on 22.01.2015.

3.4.7. - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: Timetable for assessment of similarity

Action: For adoption

3.4.8. - pancreas powder - EMEA/H/C/002070

treatment in exocrine pancreatic insufficiency

Scope: Letter from the applicant dated 10 July 2015 requesting an extension of clock stop to respond to Day 120 list of questions adopted on 25.06.2015.

Action: For adoption

3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004

3.5.1. Heparesc - human heterologous liver cells - Orphan - ATMP - EMEA/H/C/003750

Cytonet GmbH&Co KG; treatment of urea cycle disorders (UCD)

Scope: Provisional timetable

Action: For information

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

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

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

4.1.1. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/X/0034/G

Vertex Pharmaceuticals (U.K.) Ltd.

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Miguel-Angel Macia

Scope: "Line extension to the Marketing Authorisation to include a new pharmaceutical form (granules) in two new strengths (50 mg and 75 mg unit doses) to enable administration of Kalydeco to patients aged 2 to less than 6 years of age. Changes to SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.2 to provide clarity and relevant updates in line with the proposed paediatric extension application. Consequential changes are made to the Package Leaflet."

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 26.02.2015.

4.1.2. Suboxone - buprenorphine / naloxone - EMEA/H/C/000697/X/0029

RB Pharmaceuticals Ltd.

Rapporteur: Martina Weise

Scope: "Line extension application to add 12mg/3mg and 16mg/4mg sublingual tablets."

Letter from the MAH dated September 2015 informing of the decision to withdraw the application 12mg/3 mg strength sublingual tablets.

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 22.01.2015.

4.1.3. Emend - aprepitant - EMEA/H/C/000527/X/0049/G

Merck Sharp & Dohme Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "The MAH has submitted a type II variation classified as C.I.6 to extend the

indication for chemotherapy-induced nausea and vomiting (CINV) in adults to paediatric patients (12 to 17years) for the 80mg and 125mg hard capsules. SmPC section 4.2 and 5.3 of the 165mg hard capsule label, which is consequential to the outcome of this grouped procedure, will be updated under the scope of type II variation classified as C.I.6.
In addition to this, an application for an addition of a new pharmaceutical form (powder for oral suspension) has been submitted for 125mg strength as part of this grouping.
The MAH has also submitted a type II variation classified as C.I.4 to reflect the paediatric results for prevention of post-operative nausea and vomiting (PONV) in the clinical sections of 40mg hard capsules label, thus updating sections 5.1 and 5.2 of the SmPC.
The Package Leaflet has been proposed to be updated accordingly."

Action: For adoption

List of Questions adopted on 23.04.2015.

4.1.4. Pyramax - pyronaridine / pyronaridine phosphate / artesunate - EMEA/H/W/002319/X/0008/G

Shin Poong Pharmaceutical Co., Ltd.

Rapporteur: Joseph Emmerich, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Arnaud Batz

Scope: "Line Extension to add a new paediatric formulation PYRAMAX 60 mg/20 mg Granules for Oral Suspension.
The PI for Pyramax 180 mg/60 mg Film Coated Tablets has also been updated with data submitted for the line extension."

Action: For adoption

List of Questions adopted on 26.02.2015.

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

4.2.1. Iclusig - ponatinib - Orphan - EMEA/H/C/002695/X/0023

ARIAD Pharma Ltd

Rapporteur: Rafe Suvarna,

Scope: "Addition of a new strength of 30 mg film-coated tablets to the approved strengths of 15 mg and 45 mg film-coated tablets.

Editorial changes have been introduced to the quality information of the existing strengths."

Action: For adoption

4.2.2. Lojuxta - lomitapide - EMEA/H/C/002578/X/0016

Aegerion Pharmaceuticals Limited

Rapporteur: Pieter de Graeff,

Scope: “The applicant has submitted an application for a line extension to include 30 mg, 40 mg and 60 mg hard capsules.”

Action: For adoption

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

4.3.1. Reyataz - atazanavir / atazanavir sulfate - EMEA/H/C/000494/X/0094/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Joseph Emmerich, Co-Rapporteur: Rafe Suvarna, PRAC Rapporteur: Arnaud Batz

Scope: “An extension application covering a new pharmaceutical form (oral powder), a new strength for the oral powder presentation (50mg), and a new paediatric indication (patients from 3 months of age and weighing at least 5kg); a type II variation (C.1.6) to updated Reyataz capsules in light of new paediatric data; a type IB (C.I.11) variation to make minor revisions to the RMP with regards to nephrolithiasis, following PRAC's assessment of RMP version 7.3.”

Letter from the applicant dated 18 September 2015 requesting an extension of clock stop to respond to the Request for Supplementary Information adopted in July 2015.

Action: For adoption

4.4. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

5.1.1. Abilify - aripiprazole - EMEA/H/C/000471/II/0110

Otsuka Pharmaceutical Europe Ltd

Rapporteur: Bruno Sepodes,

Scope: “Extension of Indication to include treatment of schizophrenia in adolescents between 13 – 15 years of age based on paediatric studies 31-09-266 and 31-09-267 submitted according to Article 46 of the paediatric regulation. As a consequence sections 4.1, 4.2 and 4.8 of the SmPC have been updated and the Package Leaflet has been updated

accordingly."

Action: For adoption

5.1.2. CYRAMZA - ramucirumab - Orphan - EMEA/H/C/002829/II/0003

Eli Lilly Nederland B.V.

Rapporteur: Pieter de Graeff, Co-Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include new indication for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with progression after platinum-based chemotherapy for CYRAMZA.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, one minor typographical error was corrected in section 4.2 of the SmPC.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 21.05.2015.

5.1.3. CYRAMZA - ramucirumab - Orphan - EMEA/H/C/002829/II/0004

Eli Lilly Nederland B.V.

Rapporteur: Pieter de Graeff, Co-Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include a new indication for Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to correct minor editorial mistakes."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015.

5.1.4. Eylea - aflibercept - EMEA/H/C/002392/II/0021

Bayer Pharma AG

Rapporteur: Pierre Demolis, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Arnaud Batz

Scope: "Extension of Indication to include a new indication for adult for the treatment of visual impairment due to myopic choroidal neovascularisation(myopic CNV).
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated. The Package Leaflet is updated in accordance.

In addition, some editorial changes are proposed in section 5.1 of the SmPC, in the Annex II and in the PL."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015.

5.1.5. Gilenya - fingolimod - EMEA/H/C/002202/II/0034

Novartis Europharm Ltd

Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, Scope: "Extension of Indication to update the Gilenya indication in second line use to 'patients with active disease defined by clinical or imaging features despite treatment with at least one disease modifying therapy' As a consequence, section 4.1 of the SmPC is updated.
In addition, the applicant took the opportunity to relocate documents from section 5.3.5.1 to 5.3.5.2."

Action: For adoption

Request for Supplementary Information adopted on 23.07.2015.

5.1.6. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/II/0027

Vertex Pharmaceuticals (U.K.) Ltd.

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Miguel-Angel Macia

Scope: "Extension of indication for Kalydeco to include the treatment of cystic fibrosis in patients aged 18 years and older who have a R117H mutation in the CFTR gene. Consequently, changes are proposed to sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and to the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015, 26.02.2015, 23.10.2014.

5.1.7. Opdivo - nivolumab - EMEA/H/C/003985/II/0001

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults (in line with the Nivolumab BMS MAA, procedure EMEA/H/C/003840). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been revised accordingly. Further, Annex II has been updated to include a post-authorisation efficacy study as a new obligation in line with the agreed Annex II for Nivolumab BMS. In addition, the MAH took the opportunity to make editorial changes in the SmPC, Annex II, labelling and Package Leaflet. A revised RMP version 2.0 was provided as part of the application."

Action: For adoption

5.1.8. Pyramax - pyronaridine / pyronaridine phosphate / artesunate - EMEA/H/W/002319/II/0002

Shin Poong Pharmaceutical Co., Ltd.

Rapporteur: Joseph Emmerich, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Arnaud Batz

Scope: "To amend SmPC section 4.1 (Therapeutic Indications) to remove restrictions on repeated course of treatment in any individual and use only in areas of low transmission with evidence of artesmisinin resistance, based on further clinical experience. Consequent changes in SmPC sections 4.2 (Posology), 4.4 (Special warnings and precautions), 4.8 (Undesirable effects) and the PL are also included.
A recommended change is made to SmPC Section 4.2 (Posology) in relation to dosing in mild to moderate renal impairment.
A minor editorial adjustment is proposed to SmPC section 5.1 (Pharmacodynamic properties)."

Action: For adoption

Request for Supplementary Information adopted on 23.04.2015, 18.12.2014, 26.06.2014.

5.1.9. Rebetol - ribavirin - EMEA/H/C/000246/II/0074

Merck Sharp & Dohme Limited

Rapporteur: Joseph Emmerich

Scope: "Change of the indication of Rebetol to reflect that ribavirine is indicated in the treatment of hepatitis C in combination with other medicinal products and remove reference to the peginterferon used (2a or 2b) in line with the PRAC recommendation in the PSUR assessment (EMEA/H/C/PSUSA/000100007/201307). As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.7, 4.8, 4.9 and 5.1 of the SmPC are updated. The package leaflet is updated accordingly."

Action: For adoption
Request for supplementary information adopted on 25.06.2015, 26.03.2015, 23.10.2014.

5.1.10. Vidaza - azacitidine - Orphan - EMEA/H/C/000978/II/0030

Celgene Europe Limited

Rapporteur: Pieter de Graeff, Co-Rapporteur: Arantxa Sancho-Lopez, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to add treatment of adult patients aged 65 years or older who are not eligible for HSCT with AML with >30% marrow blasts according to the WHO classification, based on the pivotal phase III study AZA- AML-001. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. A revised RMP version 10.0 was provided as part of the application. The application includes a request for an additional year of market protection for a new indication in accordance with Article 10(1) of Directive

2001/83/EC.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 23.04.2015.

5.1.11. Volibris - ambrisentan - Orphan - EMEA/H/C/000839/II/0041

Glaxo Group Ltd

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Radka Montoniová, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to include an expanded therapeutic indication for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1)
In addition, the MAH took the opportunity to update Annex II to reflect a change in the PSUR cycle.
The Package leaflet is proposed to be updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

5.1.12. Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0022

AstraZeneca AB

Rapporteur: Greg Markey,

Scope: "Extension of Indication to include new population, children over the age of 2 months and adolescents, for Zinforo. As a consequence, sections 4.1, 4.2, 5.2, 5.3 and 6.6 of the SmPC are updated with new information on dosing, PK and pre-clinical safety. The Package Leaflet is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

5.2.1. Nplate - romiplostim - Orphan - EMEA/H/C/000942/II/0051

Amgen Europe B.V.

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Dolores Montero Corominas

Scope: Letter from the MAH dated 4 August 2015 requesting extension of timeframe to respond to the Request for supplementary information adopted on 25 June 2015.

"Extension of Indication to include second line treatment of all non-splenectomised patients (including those without a contraindication to surgery). As a consequence, section 4.1 of the SmPC has been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to update the contact details of the local representatives in Croatia and Italy in the Package Leaflet."

Action: For adoption

Request for supplementary information adopted on 25 June 2015.

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

6. Ancillary medicinal substances in medical devices

6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

6.2. Update of Ancillary medicinal substances in medical devices

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

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

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. – daratumumab - Orphan - H0004077

Janssen-Cilag International N.V., treatment of patients with multiple myeloma, who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double-refractory to a PI and IMiD

Scope: Request for an Accelerated Assessment

Action: For adoption

Letter from the company dated 30 July 2015 requesting an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

8.1.2. - Chlorhexidine - (H0003799)

for the prophylaxis of omphalitis (infection of the umbilical cord) in newborn infants

Scope: Request for an Accelerated Assessment

Action: For adoption

Letter from the company dated 30 June 2015 requesting an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Onglyza - Saxagliptin, Saxagliptin Hydrochloride - EMEA/H/C/001039/LEG 038

AstraZeneca AB, treatment of type 2 diabetes mellitus

Rapporteur: Pieter de Graeff, Co-Rapporteur: Karsten Bruins Slot,

Scope: Opinion

In 2014, the CHMP assessed a Type II variation (WS/0529/G) to reflect data outcomes from the SAVOR study in the product information. In April 2015, new FDA analyses relating to the SAVOR study were made available. Based on the new data and the assessment of the MAH's responses to a CHMP list of questions adopted in April 2015, the CHMP requested advice from the PRAC. Based on the review of the available information, the PRAC agreed that further clarification was needed regarding the underlying reasons for the observed imbalance in all-cause mortality before any conclusions on causality can be drawn. The PRAC agreed a list of questions to be addressed to the MAH. The PRAC will provide CHMP with further advice in September 2015 following the assessment of the MAH's responses to the list of questions.

Action: For adoption

See also 9.1.2

9.1.2. Komboglyze - Metformin Hydrochloride, Saxagliptin Hydrochloride - EMEA/H/C/002059/LEG 015

AstraZeneca AB, treatment of type 2 diabetes mellitus

Rapporteur: Pieter de Graeff, Co-Rapporteur: Karsten Bruins Slot,

Scope: Opinion

In 2014, the CHMP assessed a Type II variation (WS/0529/G) to reflect data outcomes from the SAVOR study in the product information. In April 2015, new FDA analyses relating to the SAVOR study were made available. Based on the new data and the assessment of the MAH's

responses to a CHMP list of questions adopted in April 2015, the CHMP requested advice from the PRAC. Based on the review of the available information, the PRAC agreed that further clarification was needed regarding the underlying reasons for the observed imbalance in all-cause mortality before any conclusions on causality can be drawn. The PRAC agreed a list of questions to be addressed to the MAH. The PRAC will provide CHMP with further advice in September 2015 following the assessment of the MAH's responses to the list of questions.

Action: For adoption

See also 9.1.1

9.1.3. Aldurazyme – laronidase - EMEA/H/C/000477/S/0054

Genzyme Europe BV

Rapporteur: Greg Markey, PRAC Rapporteur: Rafe Suvarna

Scope: Annual reassessments for products with proposal for lifting exceptional circumstances

Action: For adoption

9.1.4. Cellcept - mycophenolate mofetil- EMEA/H/C/000082/II/0121

Roche Registration Ltd,

Rapporteur: Rafe Suvarna,

Scope: Request for Supplementary information
Update of sections 4.4 and 4.6 of the SmPC in order to add a warning for pregnant women and update the safety information related to pregnancy. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in line with the latest QRD template version. The requested variation proposed amendments to the Summary of Product Characteristics and Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015, 26.03.2015.

9.1.5. TECFIDERA - Dimethyl Fumarate - EMEA/H/C/002601/WS0689/G; NAPs included in WS: Fumaderm, Fumaderm Intial

Biogen Idec Ltd,

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: Opinion

Update of sections 4.4 of the SmPC in order to add a recommendation to consider interruption of treatment in patients with low lymphocyte counts (<0.5 x 109/L) persisting for more than six months and to monitor lymphocyte counts until recovery. Update of section 4.8 of the SmPC with information on observed low lymphocyte counts in clinical studies with tecfidera and PML (Progressive multifocal leukoencephalopathy) occurrence in the setting of severe and prolonged lymphopenia. Furthermore, the due dates of two commitments as part of the RMP have been revised."

Action: For adoption

Request for Supplementary information adopted on 26.02.2015, 23.04.2015, 23.07.2015. SAG Neurology held on 11 June 2015.

See also 2.3.1.

9.1.6. XALKORI crizotinib (EMEA/H/C/002489) EMEA/H/C/PSUSA/00010042/201502

Pfizer Limited,

Rapporteur: Pierre Demolis, PRAC Rapporteur: Corinne Fechant,

Scope: Opinion

Update of sections 4.4 and 4.8 of the SmPC to add the adverse reaction “cardiac failure” with a frequency “common”. The Package leaflet is updated accordingly.

Action: For adoption

9.1.7. Votubia - everolimus – Orphan- EMEA/H/C/002311/II/0034

Novartis Europharm Ltd, treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

Rapporteur: Harald Enzmann,

Scope: Opinion

“Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update product information after completion of Long Term follow up on duration of responses and time to progression for study M2301 object of this submission. The Package Leaflet is updated accordingly. The data submitted are in fulfilment of SOB024 specific obligation for the conditional MA. With the fulfilment of SOB024 the MAH take the occasion to ask for the switch from conditional MA to full and to remove Votubia from the European list of additional monitored medicines.”

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015.

9.1.8. Zelboraf - vemurafenib - EMEA/H/C/002409/II/0024/G

Roche Registration Ltd,

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga,

Scope: Opinion

“Update of sections 4.4, 4.5 and 4.8 of the SmPC in order to update information on the risk of potentiation of radiation toxicity and updating the risk of progression of cancers with RAS mutations with information on progression of pre-existing pancreatic adenocarcinoma with KRAS mutation. The Package Leaflet is updated accordingly.”

Action: For adoption

Request for Supplementary Information adopted on 23.07.2015.

9.1.9. Gilenya – fingolimod - EMEA/H/C/002202/R/0036

Novartis Europharm Ltd

Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Isabelle Robine,

Scope: Renewals of Marketing Authorisations requiring 2nd Renewal

Action: For adoption

10. Referral procedures

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

10.1.1. Inductos - Dibotermin alfa – EMEA/H/A-20/1422/C/0408/0082

Medtronic BioPharma B.V., treatment of anterior lumbar spine fusion and tibia fracturesRapporteur: Pieter de Graeff, Co-Rapporteur: Outi Mäki-Ikola,

Scope: List of Outstanding Issues

Non-compliance of a manufacturing site

Action: For adoption

10.1.2. Tysabri - natalizumab – EMEA/H/A-20/1416/C/000603/0083

Biogen Idec Ltd, treatment of multiple sclerosis

Rapporteur: Jan Muller-Berghaus, Co-Rapporteur: Daniela Melchiorri,

Scope: List of Questions adopted by PRAC for the SAG neurology

Review of the benefit-risk balance following the notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For adoption

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

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

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

10.4.1. IOGOL and associated names soft capsules, 25 / 50 mg - diclofenac epolamine - EMEA/H/A-29/1414

Regiomedica GmbH

Rapporteur: Martina Weise, Co-Rapporteur: Concepcion Prieto Yerro,

Scope: Oral Explanation and Opinion

Disagreements regarding the demonstration of bioequivalence with the reference product

Possible Oral explanation to be held on 22 September 2015 at 09.00

See also 2.4.1

Action: For adoption

RMS: DE, CMS: AT, BE, CZ, EL, ES, HU, IT, PL, SK, UK, Decentralised procedure number: DE/H/3633/002-003/DC

10.4.2. Linxyd 2 mg/ml, solution for infusion and associated names – linezolid – EMEA/H/A-29/1423

Helm AG

Rapporteur: TBC, Co-Rapporteur: TBC,

Scope: Appointment of Rapporteurs, List of Questions and timetable

Disagreements regarding the suitability of the manufacturing process.

Action: For discussion

RMS: NL, CMS: IE, UK, Mutual Recognition procedure number: NL/H/3416/001/MR

Letter from Medicines Evaluation Board in the Netherlands dated 30 July 2015 notifying of an official referral under article 29 and its grounds.

List of Questions and procedural timetable

10.4.3. Linezolid Accord 2 mg/ml, solution for infusion and associated names – linezolid – EMEA/H/A-29/1424

Accord Healthcare Ltd

Rapporteur: TBC, Co-Rapporteur: TBC,

Scope: Appointment of Rapporteurs, List of Questions and timetable

Disagreements regarding the suitability of the manufacturing process.

Action: For discussion

RMS: NL, CMS: AT, BE, CY, DE, EE, ES, FI, FR, IE, IT, MT, PL, PT, UK, Mutual Recognition procedure number: NL/H/3365/001/MR

Letter from Medicines Evaluation Board in the Netherlands dated 30 July 2015 notifying of an official referral under article 29 and its grounds.

List of Questions and procedural timetable

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

10.5.1. Durogesic transdermal patches – fentanyl - EMEA/H/A-30/1413

MAH: Janssen-Cilag group of companies and associated companies

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Martina Weise,

Scope: List of Questions and timetable

Letter from the European Commission dated 15 September 2015 notifying of an official referral under Article 30.

Action: For adoption

10.5.2. Haldol and associated names (EMEA/H/A-30/1393) (haloperidol), Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Ana Dugonjić,

Scope: revised List of outstanding issues

Action: For adoption

10.5.3. Haldol decanoate and associated names (EMEA/H/A-30/1405) (haloperidol) Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Ana Dugonjić,

Scope: revised List of outstanding issues

Action: For adoption

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

10.6.1. Gadolinium-containing contrast agents (GdCA): gadoversetamide – OPTIMARK (CAP) Gadobenate dimeglumine; gadobutrol; gadodiamide; gadopentetic acid dimeglumine, gadoteric acid (intra articular formulation); gadoteric acid (intrvenous and intravascular formulations); gadoteridol; gadoxetic acid disodium (NAP)

Lead Rapporteur: Rafe Suvarna,

Scope: Annual cumulative reviews on NSF cases submission as a post-authorisation measure resulting from the 2010 Article 20 and Article 31 referral procedures for gadolinium-containing contrast agents

Action: For adoption

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

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

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

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

10.11. 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)

11. Pharmacovigilance issue

11.1. Early Notification System

September 2015 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Summary of recommendations and advice of PRAC meeting held on 07-10 September 2015.

Action: For information

12. Inspections

12.1. GMP inspections

Disclosure of information related to GMP inspections will not be published as it undermines the purpose of such inspections

12.2. GCP inspections

Disclosure of information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Disclosure of information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Disclosure of information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

13.2. Innovation Task Force briefing meetings

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

13.2.1. ITF Briefing Meeting

Action: For adoption

13.2.2. ITF Briefing Meeting

Action: For adoption

13.2.3. ITF Briefing Meeting

Action: For adoption

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

13.4. Nanomedicines activities

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Election of CHMP Chair

Action: For adoption

14.1.2. Discussion of CHMP co-opted member expertise

Action: For discussion

14.1.3. Strategic Review & Learning Meeting under Luxembourg Presidency

Draft list of topics and agenda

Action: For discussion

14.1.4. Enhanced early dialogue to foster development and facilitate accelerated assessment

Scope: Concept Paper

Action: For discussion

14.1.5. Follow-up discussion from Strategic Review & Learning Meeting in Rome on update of template for assessment of claims of additional year of marketing protection

Action: For adoption

Revised CHMP AR Template for assessment of claims of +1 year marketing protection

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 07-10 September 2015

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for September 2015

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 17-18 September 2015
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 6-9 July 2015

Action: For information

Letter from HMPC to CHMP (SWP) dated 15 September 2015 regarding the toxicological assessment of estragole in herbal medicinal products and on the potential impact on other medicinal products containing fennel, anise or other estragole-containing ingredients

Action: For discussion

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2015 PDCO

Action: For information

Report from the PDCO meeting held on 9-11 September 2015

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 1-3 September 2015
Action: For information

14.2.6. CMDh

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 21-23 September 2015

Action: For information

Question from CMDh to CHMP/BWP on Biosimilars of Low Molecular Weight Heparins

Action: For adoption

14.3. Coordination with EMA Working Parties / Working Groups / Drafting Groups

14.3.1. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 1-4 September 2015. Table of conclusions

Action: 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.

14.3.2. Vaccines Working Party (VWP)

Nomination of Isabelle Bekeredjian-Ding (DE) as observer to Vaccines Working Party

Action: For adoption

14.3.3. Cardiovascular Working Party

Guideline on clinical evaluation of medicinal products used in weight management

Overview of comments received

Action: For adoption

Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in non-surgical patients (EMA/CHMP/41252/2015)

Action: For adoption for 6-month public consultation

14.3.4. Pharmacokinetics Working Party

Responses to CMDh question to CHMP (PKWP, SWP) regarding potential risk of longer half-life of acitretin

Action: For adoption

Response to CMDh question to CHMP (PKWP) regarding tacrolimus containing products – evaluation of bioequivalence

Action: For adoption

14.4. Cooperation within the EU regulatory network

14.4.1. Live broadcast of EFSA conference on food safety

The European Food Safety Authority (EFSA) is hosting a scientific conference on 14, 15 and 16 October entitled 'Shaping the future of food safety, together'. The conference will be attended by representatives from the scientific and risk-assessment community, as well as by risk managers from European and other countries. Interested colleagues can watch the conference via live broadcast from the website www.efsaexpo2015.eu and ask questions through a dedicated tool on that site, or via twitter using the hashtag #EFSAexpo2015.

Action: For information

14.5. Cooperation with International Regulators

14.5.1. Presentation on current status of EMA cooperation with FDA

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee

14.6.1. International Society for Stem Cell Research

ISSCR's "Guidelines for Stem Cell Research and Clinical Translation" (EXT/601308/2015)

Action: For discussion

14.7. CHMP work plan

14.8. Planning and reporting

14.9. Others

15. Any other business

15.1. AOB topic

16. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

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 2)*

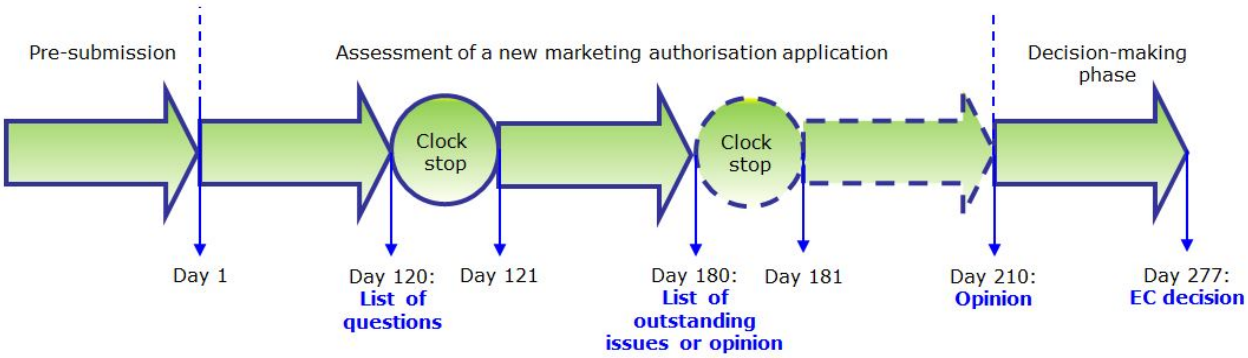
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications *(section 3)*

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

Section 3.1 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 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **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 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 4)*

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 5)*

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 4. 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 6)*

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 3.5)*

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 *(section5.3)*

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 3.7)*

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 7)*

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 8)*

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 9)*

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 10)*

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 11)*

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 12)*

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 13)*

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 14.3.1)*

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 14.2)*

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 14.3)*

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.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/