25 January 2016
EMA/CHMP/50700/2015
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 25-28 January 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

25 January 2016, 13:00 – 19:30, room 2A

26 January 2016, 08:30 – 19:30, room 2A

27 January 2016, 08:30 – 19:30, room 2A

28 January 2016, 09:00 – 12:00, room 2A

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 25-28 January 2016. See January 2016 CHMP minutes (to be published post February 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 25-28 January 2016

1.3. Adoption of the minutes

CHMP minutes for 14-17 December 2015.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.2. Re-examination procedure oral explanations

2.3. Post-authorisation procedure oral explanations

2.3.1. Opdivo - nivolumab - EMEA/H/C/003985/II/0002 and EMEA/H/C/003985/II/0003

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Possible oral explanation to be held on Tuesday 26 January 2016 at 11.00

II/ 0002 "Extension of Indication to add treatment as monotherapy of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults, based on Study CA209025; a phase 3 study of nivolumab vs. everolimus in subjects with advanced or metastatic clear-cell RCC who have received prior anti-angiogenic therapy, and the CA209010 addendum study report; phase 2 dose-ranging study of nivolumab in subjects with progressive advanced/metastatic clear-cell RCC who have received prior anti-angiogenic therapy. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are proposed to be updated and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to make editorial changes in the SmPC and

Package Leaflet.
An updated RMP version 4.0 was provided as part of the application. Further, the MAH requested one additional year of market protection for a new indication."

Request for Supplementary Information adopted on 22.10.2015.

II/0003 "Extension of Indication to include treatment in combination with ipilimumab of advanced (unresectable or metastatic) melanoma in adults based on interim data from study CA209067 and the final CSR of study CA209069. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package Leaflet has been revised accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC, Annex II and Package Leaflet. An updated RMP version 3.0 was provided as part of the application as well as a paediatric non-clinical biomarker study provided to fulfil paediatric requirements."

Request for Supplementary Information adopted on 22.10.2015.

Action: For adoption

See also 5.1.4 and 5.1.5 Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

2.4. Referral procedure oral explanations

2.4.1. Novantrone and associated names - mitoxantrone - EMEA/H/A-30/1399

MEDA group of companies and associated companies

Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert Hemmings,

Scope: Possible oral explanation to be held on Tuesday 26 January 2016 at 15.00 and Opinion

Harmonisation exercise for Novantrone and associated names. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

Action: For adoption

Scientific Advisory Group meeting held on 06.11.2015

See also 10.5.2 Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - amlodipine / valsartan - EMEA/H/C/004037

treatment of essential hypertension

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.11.2015. List of Questions adopted on 25.06.2015.

3.1.2. - factor x - Orphan - EMEA/H/C/003855

Accelerated assessment

BIO PRODUCTS LABORATORY; treatment of factor X deficiency

Scope: Opinion

Action: For adoption

List of Questions adopted on 19.11.2015.

3.1.3. - elotuzumab - Orphan - EMEA/H/C/003967

Accelerated assessment

Bristol-Myers Squibb; treatment of myeloma

Scope: Opinion

Action: For adoption

List of Questions adopted on 19.11.2015.

3.1.4. – rasagiline – EMEA/H/C/004064

treatment of idiopathic Parkinson's disease (PD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015.List of Questions adopted on 23.07.2015.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.09.2015. List of Questions adopted on 23.04.2015.

3.1.6. - zonisamide - EMEA/H/C/004127

treatment of epilepsy

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - eftrenonacog alfa - Orphan - EMEA/H/C/004142

Biogen Idec Ltd; treatment and prophylaxis of bleeding in patients with haemophilia B

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

3.2.2. - atazanavir - EMEA/H/C/004048

treatment of HIV-1.

Scope: 2nd List of outstanding Issues

Action: For adoption

List of Outstanding Issues adopted on 22.10.2015. List of Questions adopted on 21.05.2015.

3.2.3. - bortezomib - EMEA/H/C/004076

treatment of multiple myeloma

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

3.2.4. - pandemic influenza vaccine h5n1 (live attenuated, nasal) - EMEA/H/C/003963

prophylaxis of influenza

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

3.2.5. - allogeneic t cells genetically modified to express suicide gene - Orphan - ATMP - EMEA/H/C/002801

MolMed SpA; treatment in haploidentical haematopoietic stem cell transplantation

Scope: 2nd List of Outstanding Issues

Action: For adoption

List of Outstanding Issues adopted on 26.03.2015. List of Questions adopted on 24.07.2014.

3.3. Initial applications; Day 120 list of questions

3.3.1. - aceneuramic acid - Orphan - EMEA/H/C/004176

Ultragenyx UK Limited; treatment of Hereditary Inclusion Body Myopathy (HIBM)

Scope: Day 120 list of questions

Action: For adoption

3.3.2. - alectinib - EMEA/H/C/004164

indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive.

Scope: Day 120 list of questions

Action: For adoption

3.3.3. - bortezomib - EMEA/H/C/004207

treatment of multiple myeloma

Scope: Day 120 list of questions

Action: For adoption

3.3.4. - daratumumab - Orphan - EMEA/H/C/004077

Janssen-Cilag International N.V.; treatment of patients with relapsed and refractory multiple myeloma

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - eryaspase - Orphan - EMEA/H/C/004055

ERYTECH Pharma S.A.; treatment of leukaemia

Scope: Day 120 list of questions

Action: For adoption

3.3.6. - etelcalcetide - EMEA/H/C/003995

treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy

Scope: Day 120 list of questions

Action: For adoption

3.3.7. - tenofovir disoproxil - EMEA/H/C/004120

treatment of HIV-1 infection and hepatitis B infection

Scope: Day 120 list of questions

Action: For adoption

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

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

Santen Oy; treatment of chronic non-infectious uveitis

Scope: List of Questions to Ad-hoc expert group meeting

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 25.06.2015.

3.4.2. - emtricitabine / rilpivirine / tenofovir alafenamide - EMEA/H/C/004156

treatment of HIV-1

Scope: List of Questions and List of experts to SAG.

Action: For adoption

List of Questions adopted on 17.12.2015.

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

treatment of HIV

Scope: List of Questions and List of experts to SAG.

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 24.09.2015.

3.4.1. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050

treatment of HIV

Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Rafe Suvarna

Scope: Letter from the applicant dated 19 January 2016 requesting an extension of clock stop to submit responses to Day 120 List of Questions adopted on 19.11.2015.

Action: For information

List of Questions adopted on 19.11.2015.

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

3.5.1. Dropcys - mercaptamine - Orphan - EMEA/H/C/004038

Lucane Pharma; treatment of corneal cystine deposits

Scope: Letter from the applicant dated 23 December 2015 requesting the re-examination of the CHMP Opinion adopted 17 December 2015, appointment of Re-examination (Co)Rapporteur

Action: For information

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

3.7.1. - aripiprazole - EMEA/H/C/004236

treatment of schizophrenia, treatment and prevention of bipolar disorder (manic episodes)

Scope: Letter from the applicant dated 8 January 2016 informing of the decision to withdraw the MAA

Action: For information

List of Questions adopted on 22.10.2015.

Withdrawal assessment Report

Question and answer document

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. Exjade - deferasirox - Orphan - EMEA/H/C/000670/X/0043

Novartis Europharm Ltd

Rapporteur: Pierre Demolis, PRAC Rapporteur: Corinne Fechant

Scope: "Extension application for a new pharmaceutical form and new strengths (Exjade 90, 180 and 360 mg film-coated tablets)."

Action: For adoption

List of Questions adopted on 23.07.2015.

4.1.2. Revolade - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/X/0022/G

Novartis Europharm Ltd

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Extension of indication for paediatric (age 1 year and above) chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who had an insufficient response to other treatments (e.g. corticosteroids, immunoglobulins).
Grouping with the line extension for one new tablet strength (12.5mg) and a new Powder for Oral Suspension formulation (25mg).

The Type II variation and the Extension are grouped within this Application. This grouping is justified, as one of the variations in the group is an extension of the marketing authorisation (Annex III of Commission Regulation (EC) No 1234/2008 of November 2008).

Action: For adoption

List of Outstanding Issues adopted on 19.11.2015. List of Questions adopted on 25.06.2015.

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

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

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Joseph Emmerich, Co-Rapporteur: Nithyanandan Nagercoil, 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."

Action: For adoption

List of Questions adopted on 23.07.2015.

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

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

4.4.1. Instanyl - fentanyl / fentanyl citrate - EMEA/H/C/000959/X/0030/G

Takeda Pharma A/S

Rapporteur: Pierre Demolis, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Arnaud Batz

Scope: Revised timetable

"Annex I_2.(c) To add the new strength of 400 micrograms/dose in a multi-dose nasal spray in pack size of 10's, 20's, 30's & 40 doses.
Type II cat. B.II.e.4.b) To replace the current multi-dose nasal spray by a new improved child resistant multi-dose nasal spray.
3 X Type IB cat. B.II.e.5.d) To add a new packsize of 30 doses for each current strength (50 micrograms/dose, 100 micrograms/dose & 200 micrograms/dose).
Type IA cat. B.II.d.1.a) – To tighten the assay release limit of the multi-dose finished product to 98.0%-102.0%.
Type IA cat. B.II.f.1.a) 1. – To reduce the shelf life of all strengths of the multi-dose finished product to 24 months.
Additionally, the Applicant took the opportunity to include an editorial change, as to change the wording of the specification footnote regarding the droplet size distribution test from "The test is performed by the vendor on every pumping system batch" to "The test is performed at release of the pumping system"."

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015, 23.07.2015. List of Questions adopted on 26.02.2015.

4.5. 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. Humira - adalimumab - EMEA/H/C/000481/II/0147

AbbVie Ltd.

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri

Scope: "Extension of Indication to include the treatment of patients with moderately paediatric active Crohn's disease.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 of the SmPC are updated.
In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial corrections to the Labelling."

Action: For adoption

5.1.2. HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0021

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop,

Scope: "Extension of Indication to include paediatric population for HyQvia.
As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

5.1.3. Imbruvica - ibrutinib - Orphan - EMEA/H/C/003791/II/0016

Janssen-Cilag International NV

Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams

Scope: "Extension of Indication to broaden the existing indication for chronic lymphocytic leukaemia (CLL) to include all previously untreated patients including those with 17p deletion or TP53 mutation based on the results from the final CSR of study PCYC-1115-CA (MEA 021) for Imbruvica. As a consequence, sections 4.1, 4.6, 4.8, 5.1 and 5.3 of the SmPC are being updated. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial

changes to the SmPC and to bring Annex II in line with the latest QRD template version 9.1. Moreover, the updated RMP version 5.0 has been submitted."

Action: For adoption

5.1.4. Opdivo - nivolumab - EMEA/H/C/003985/II/0002

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Opinion / Request for Supplementary information, Report from SAG Oncology meeting held on 14 January 2016

"Extension of Indication to include treatment as monotherapy of locally advanced or metastatic non-squamous NSCLC after prior chemotherapy in adults based on study CA209057. 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. Further, SmPC section 4.8 has been revised with updated combined clinical trial exposure numbers to reflect inclusion of studies in non-squamous NSCLC and in nivolumab in combination with ipilimumab in advanced melanoma. In addition, the MAH took the opportunity to align the annexes with the latest QRD template version 9.1 and to implement minor editorial changes. A revised RMP version 3.0 was provided as part of the application."

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015.

See also 2.3.1. Post-authorisation procedure oral explanations

5.1.5. Opdivo - nivolumab - EMEA/H/C/003985/II/0003

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Opinion / Request for Supplementary information, Report from SAG Oncology meeting held on 14 January 2016

Scope: "Extension of Indication to include treatment in combination with ipilimumab of advanced (unresectable or metastatic) melanoma in adults based on interim data from study CA209067 and the final CSR of study CA209069. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package Leaflet has been revised accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC, Annex II and Package Leaflet. An updated RMP version 3.0 was provided as part of the application as well as a paediatric non-clinical biomarker study provided to fulfil paediatric requirements."

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015.

See also 2.3.1. Post-authorisation procedure oral explanations

5.1.6. Opdivo - nivolumab - EMEA/H/C/003985/II/0008

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to add treatment as monotherapy of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults, based on Study CA209025; a phase 3 study of nivolumab vs. everolimus in subjects with advanced or metastatic clear-cell RCC who have received prior anti-angiogenic therapy, and the CA209010 addendum study report; phase 2 dose-ranging study of nivolumab in subjects with progressive advanced/metastatic clear-cell RCC who have received prior anti-angiogenic therapy. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are proposed to be updated and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to make editorial changes in the SmPC and Package Leaflet.
An updated RMP version 4.0 was provided as part of the application. Further, the MAH requested one additional year of market protection for a new indication."

Action: For adoption

5.1.7. Revlimid - lenalidomide - Orphan - EMEA/H/C/000717/II/0079

Celgene Europe Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Corinne Fechant

Scope: "Extension of Indication to add treatment of adult patients with relapsed and/ or refractory mantle cell lymphoma (MCL). As a consequence, SmPC sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 have been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the SmPC and Package Leaflet. A revised version of the RMP (version 25.0) was provided as part of this application."

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015, 23.07.2015, 26.03.2015.

5.1.8. Ryzodeg - insulin degludec / insulin aspart - EMEA/H/C/002499/II/0017

Novo Nordisk A/S

Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue

Scope: "Extension of Indication to include paediatric population from 1 to 18 year of age for Ryzodeg. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Furthermore, the PI is brought in line with the latest QRD template version 9.1."

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. Caprelsa - vandetanib - EMEA/H/C/002315/II/0016

AstraZeneca AB

Rapporteur: Pierre Demolis

Scope: Letter from the MAH dated 22 December 2015 requesting an extension of timeframe to respond to Request for Supplementary Information adopted on 19.11.2015,

"Extension of Indication to include paediatric indication population for Caprelsa.
As a consequence, sections 4.1, 4.2, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated in update the safety information. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015.

5.2.2. Humira - adalimumab - EMEA/H/C/000481/II/0146

AbbVie Ltd.

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Ulla Wändel Liminga

Scope: List of Questions to Ad- hoc expert meeting

"Extension of Indication to include treatment of non-infectious intermediate, posterior and panuveitis in adult patients for Humira.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

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

AstraZeneca AB

Rapporteur: Greg Markey

Scope: Letter from the MAH dated 11 January 2016 requesting an extension of timeframe to respond to Request for Supplementary Information adopted on 24.09.2015.

"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

Request for Supplementary Information adopted on 17.12.2015, 24.09.2015.

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

6.1.1. - human serum albumin - EMEA/H/D/004287

Human serum albumin ancillary action prevents adsorption to the container of various amino acids,
vitamins which may be present in trace quantities and acts as a carrier of these substances to support
growth and maintenance of gametes and/or embryos. Scavenges embryotoxic components generated
prevents adsorption to the container of various amino acids and vitamins, acts as a carrier of these substances to support
growth and maintenance of gametes and/or embryos, Scavenges embryotoxic components generated
during embryo's metabolism in vitro

Scope: Day 120 list of questions

Action: For adoption

6.2. Update of Ancillary medicinal substances in medical devices

6.2.1. Floseal Hemostatic Matrix (Floseal VH S/D) - Human Thrombin - EMEA/H/D/000956

TÜV SÜD Product Service GmbH, increase in the haemostatic effect

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Greg Markey,

Scope: CHMP recommendation to the Notified Bodies on the risk of intestinal obstruction in Floseal VH SD, Hemoblast and SurgiFlo

Ancillary medicinal substance/blood derivative substance (Article 1(4)/1(4a) of both Directives No 93/42/EEC and 90/385/EEC)

Background: In December 2015 CHMP requested PRAC to investigate on the potential risk of intestinal obstruction in Floseal VH SD.

On 12 January 2016 a PRAC Advice to CHMP has been adopted on the risk of intestinal obstruction in Floseal VH SD, Hemoblast and SurgiFlo.

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

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. - masitinib mesylate - Orphan - H0004159

AB Science; Treatment of smouldering or indolent systemic mastocytosis with severe handicaps
Claim 1: Treatment of adult patients with smouldering or indolent systemic mastocytosis with severe handicaps unresponsive to optimal symptomatic treatments.
Claim 2: Treatment of adult patients with aggressive forms of mastocytosis not bearing c-Kit mutation Asp-816-Val (D816V) in at least one organ.

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 7 January 2016 requesting an accelerated assessment

Rapporteur's briefing note

8.1.2. tenofovir alafenamide - H0004169

treatment of chronic hepatitis B in adults

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 22 December 2015 requesting an accelerated assessment

Rapporteur's briefing note

8.1.3. - olaratumab - Orphan - H0004216

Eli Lilly Netherlands; indicated in combination with doxorubicin for the treatment of adult patients with advanced or metastatic soft tissue sarcoma (STS) who are not amenable to curative treatment with surgery or radiotherapy.

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 8 December 2015 requesting an accelerated assessment

Rapporteur's briefing note

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Xarelto - Rivaroxaban - EMEA/H/C/000944 - LEG 37

Bayer Pharma AG, prevention of venous thromboembolism (VTE)

Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise,

Scope: Update on ROCKET Trial.

Action: For discussion

Request for Supplementary Information adopted on 17.12.2015 and 19.11. 2015.

9.1.2. DOAC - direct oral anticoagulants

Lead Rapporteur: Jens Heisterberg,

Scope: Review of existing scientific information on PK and PD in DOACs

Action: For information

9.1.3. Deltyba - delamanid - Orphan - EMEA/H/C/002552/R/0010

Otsuka Novel Products GmbH,

Rapporteur: Greg Markey, Co-Rapporteur: Daniel Brasseur, PRAC Rapporteur: Rafe Suvarna,

Scope: Renewal

9.1.4. Review of seed sequencing data - annual influenza vaccines 2015-2016

Action: For adoption

9.1.5. EYLEA - Aflibercept - EMEA/H/C/002392/MEA/015

Bayer Pharma AG

Rapporteur: Pierre Demolis, PRAC Rapporteur: Isabelle Robine,

Scope: PRAC advice to CHMP

PASS protocol for study 18218: assessment of the safety and drug utilisation of intravitral Eylea in real world clinical practice

Action: For discussion

9.1.6. Raxone - idebenone - Orphan - EMEA/H/C/003834/II/0002

Santhera Pharmaceuticals (Deutschland) GmbH,

Rapporteur: John Joseph Borg,

Scope: Opinion or Request for supplementary information

Re-definition of the starting materials

Action: For adoption

10. Referral procedures

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

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

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

Lead Rapporteur: Filip Josephson, Co-Rapporteurs: Pierre Demolis, Jan Mueller-Berghaus, Daniel Brasseur, Johann Lodewijk Hillege, Robert James Hemmings, Sol Ruiz

Scope: CHMP assessment report

Action: For adoption

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

Helm AG

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Greg Markey,

Scope: Procedure withdrawn from the RMS NL and from all CMS

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

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

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

Accord Healthcare Ltd

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Greg Markey,

Scope: Procedure withdrawn from the RMS NL and from 8/14 CMS

Disagreements regarding the suitability of the manufacturing process.

Action: For adoption

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

10.4.3. Tobramycin VVB 300 mg/5 ml nebuliser solution – Tobramycin - EMEA/H/A-29/1428

UAB VVB

Rapporteur: Romaldas Maciulaitis, Co-Rapporteur: Piotr Fiedor

RMS: LT, CMS: BG, EE, HU, LV, PL, RO, Decentralised Procedure Number: LT/H/0112/001/DC

Scope: Opinion

Action: For adoption

The CHMP noted the letter from the State Medicines Control Agency in Lithuania dated 09 October 2015 and updated letter dated 14 October 2015 notifying of an official referral under Article 29(4) and its grounds.

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

Janssen-Cilag group of companies and associated companies

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

Scope: List of outstanding Issues

Action: For adoption

10.5.2. Novantrone and associated names - mitoxantrone - EMEA/H/A-30/1399

MEDA group of companies and associated companies

Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert Hemmings,

Scope: Possible oral explanation to be held on Tuesday 26 January 2016 at 15.00 and Opinion

Harmonisation exercise for Novantrone and associated names. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

Action: For adoption

Scientific Advisory Group meeting held on 06.11.2015

See also 2.4.1 Referral procedure oral explanations

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

10.6.1. Fusafungine (NAP), nasal and oral solution - EMEA/H/A-31/1420

Les Laboratoires Servier, various

PRAC Rapporteur: Julia Pallos; PRAC Co-rapporteur: Jana Mladá

Scope: Final List of questions and final List of experts for SAG anti-infectives

Action: Adopted by written procedure on 20 January 2016

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

January 2016 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

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

13.3. 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. Initial marketing authorisation - revised accelerated assessment procedural timetables

Action: For discussion

14.1.2. Guideline on safety and efficacy follow-up – RMP of ATMPs Appointment of CHMP Rapporteurs for the revision of the guideline

Scope: Appointment of CHMP Rapporteurs for the revision of the guideline

Action: For discussion

14.1.3. GCP Inspections programme for 2016-2017

Action: For adoption

Procedural Advice on the evaluation of advanced medicinal product in accordance with Article 8 of Regulation (EC) No 1394/2007

14.1.4. Procedural Advice on the evaluation of advanced medicinal product in accordance with Article 8 of Regulation (EC) No 1394/2007

Action: For discussion

CHMP members are invited to participate in the update.

14.1.5. Review of experience with the revised RMP review process

Action: For discussion

14.1.6. Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004

Scope: CHMP guideline on conditional marketing authorisation

Action: For adoption for circulation to the European Commission as per Article 11 of Regulation (EC) No 507/2006

14.1.7. Revision of the benefit-risk assessment section of the CHMP assessment reports

CHMP coordinators: Kristina Dunder, Pieter de Graeff

Action: For discussion

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 **11-14 January 2016**

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for January 2016

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 21-22 January 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Not applicable this month

14.2.4. Paediatric Committee (PDCO)

Not applicable this month

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 19-21 January 2016
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 25-27 January 2016

Action: For information

Response from PKWP and RIWP to CMDh request for classification of everolimus in the transplant setting as a narrow therapeutic index drug

CHMP sponsor: Romaldas Maciulaitis

Action: For adoption

Request from CMDh dated 14 January 2016 to CHMP to develop a specific scientific guidance for allergies with lower prevalence to address critical issues in relation to the data generation for corresponding allergen products

Action: For discussion

Response to CMDh request to CHMP/BWP regarding on Biosimilars of Low Molecular Weight Heparins (EMA/CHMP/BWP/764782/2015)

Action: For adoption

Response to CMDh request to CHMP/ PKWP regarding exenatide

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 11-14 January 2016. 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. Radiopharmaceuticals Drafting Group

CHMP coordinator: Patrick Salmon

Scope: Work Plan for the Radiopharmaceuticals Drafting Group 2016

Action: For adoption

Scope: Guideline on core SmPC and Package Leaflet for nanocolloidal technetium (99mTc) albumin (EMA/CHMP/831653/2015)

Action: For adoption

Scope: Guideline on core SmPC and Package Leaflet for gadopentetate dimeglumine (EMA/CHMP/831877/2015)

Action: For adoption

14.3.3. Biologics Working Party (BWP)

Chair: Sol Ruiz

Scope: Draft agenda for BWP face-to-face meeting to be held 15-17 February 2016

(EMA/CHMP/BWP/19300/2015)

Action: For information

Scope: Final minutes from face-to-face meeting held 9-11 November 2015 (EMA/CHMP/BWP/749788/2015)

Action: For information

14.3.4. Central Nervous System Working Party (CNSWP)

Scope: Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias (EMA/CHMP/539931/2014)

Action: For adoption for 6-months consultation

Scope: Overview of comments received on Guideline on clinical investigation of medicinal products for the treatment of Amyotrophic Lateral Sclerosis (ALS) (EMA/CHMP/131550/2015)

Action: For information

14.3.5. International Council on Harmonisation (ICH)

Scope: ICH guideline E18 on genomic sampling and management of genomic data – Step 3

Presentation by Krishna Prasad

Action: For adoption

Scope: ICH guideline E14: The clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs (R3) - Step 4 questions and

answers

Action: For adoption

14.3.6. Vaccines Working Party (VWP)

Scope: Nomination of a core member in replacement of Kari Lankinen.

Action: For adoption

Scope: Call for nomination for core member to replace Michael Pfleiderer

Action: For information

14.3.7. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Scope: Revised mandate, objectives and rules of procedure for the joint CHMP/CVMP Quality Working Party

Action: For adoption

Scope: Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container

Action: For adoption for public consultation

Scope: Q/A on sterilisation of primary packaging

Action: For adoption

14.3.8. Biosimilar Medicinal Products Working Party (BMWP)

Presentation by Christian Schneider

Scope: Workshop on immunogenicity assessment of biotechnology derived therapeutic proteins to be held on 9 March 2016

Action: For information

14.3.9. Oncology Working Party (ONCWP)

Scope: Work plan for the CHMP Oncology Working Party for 2016 (EMA/CHMP/707548/2015)

Action: For adoption

14.3.10. Cardiovascular Working Party (CVSWP)

Scope: Reflection paper on assessment of cardiovascular safety profile of medicinal products for the treatment of cardiovascular and metabolic diseases (EMA/CHMP/50549/2015)

Action: For discussion

Scope: Draft Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure (EMA/CHMP/47656/2015 Rev 2)

Action: For adoption for 6 months consultation

Nomination of Bart van der Schueren as new observer from Belgium

Action: For adoption

14.3.11. Safety Working Party (SWP)

Nomination of Petre Cojocaru as new alternate for Romania

Action: for adoption

14.3.12. Blood Products Working Party (BPWP)

Guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products (EMA/CHMP/BPWP/1619/1999 Rev 2)

Action: For adoption

Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/144533/2009 Rev 1)

Action: For adoption

Draft Guideline on the core SmPC for Human Anti-D Immunoglobulin for Intramuscular Use (EMA/CHMP/BPWP/29205/2005 Rev 2)

Action: For adoption for public consultation

Draft Guideline on the Core SmPC for Human Anti-D Immunoglobulin for Intravenous Use (EMA/CHMP/BPWP/319619/2005 Rev 2)

Action: For adoption for public consultation

14.3.13. Biostatistics Working Party (BSWP)

Nomination of 2 core members

Action: For adoption

14.3.14. Excipients Drafting Group (ExcpDG)

Scope: Election of Chair and Vice-chair of the ExcpDG

Action: For adoption

14.3.15. Respiratory Drafting Group

Scope: Nomination of core members to the Respiratory drafting group

Establishment of the core members of the Respiratory Drafting Group, convened to provide assistance to the CHMP with revision of the guidelines on clinical development of medicinal products for the treatment of cystic fibrosis and orally inhaled medicinal products.

Action: For adoption

Call for further members. Expertise required: respiratory disease, cystic fibrosis, orally inhaled medicinal products, asthma, COPD

All CHMP members are invited to submit nominations of experts

Scope: Work Plan for 2016

Action: For adoption

14.3.16. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus / Nils Feltelius,

Update on the election of the RIWP WP Vice-Chair

14.3.17. Guideline Consistency Group (GCG)

The extension of deadline of the call for nomination. Expressions of interest for one additional member should be sent to

Action: For information

14.4. Cooperation within the EU regulatory network

14.4.1. Antimicrobial Advice ad hoc expert group (AMEG) - Colistin action plan 2016

Action: For discussion

14.4.2. Letter from the European Commission on a definition for 'principal molecular structural features'

Scope: Update the CHMP on progress

Letter from the European Commission, requesting that a definition for 'principal molecular structural features' as referred to in Art 3(3)c of Reg (EC) No 847/2000 on similar active substance is developed by end of February 2016

Action: For discussion

14.5. Cooperation with International Regulators

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

14.7. CHMP work plan

14.7.1. CHMP 2016 Work Plan

Action: For adoption

Letter from the European Commission dated 4 December 2015 regarding 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)*

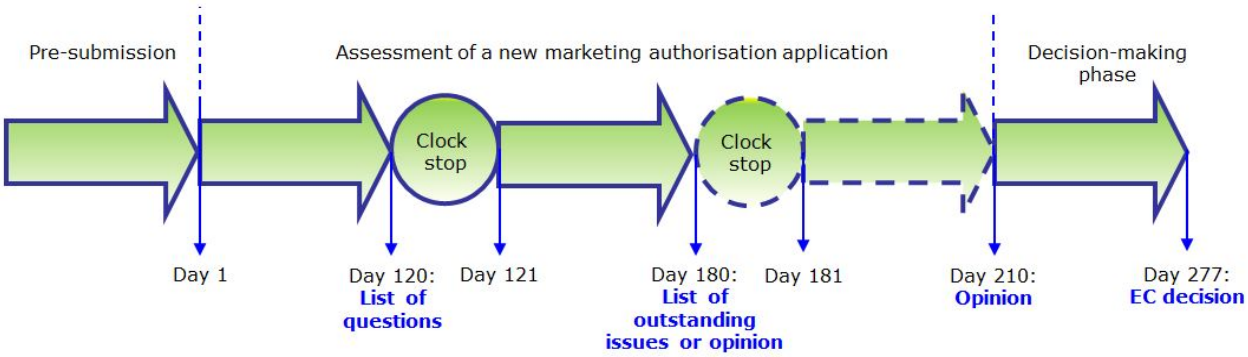
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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/