18 July 2016
EMA/CHMP/490374/2016 Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 18-21 July 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

18 July 2016, 13:00 – 19:30, room 2A

19 July 2016, 08:30 – 19:30, room 2A

20 July 2016, 08:30 – 19:30, room 2A

21 July 2016, 08:30 – 15:00, 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).

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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 18-21 July 2016. See July 2016 CHMP minutes (to be published post September 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 18-21 July 2016

1.3. Adoption of the minutes

CHMP minutes for 20-23 June 2016.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.2. Re-examination procedure oral explanations

2.2.1. Sialanar - glycopyrronium bromide - PUMA - EMEA/H/C/003883

Proveca Limited; Symptomatic treatment of sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 to <18 years with neurological disorders.

Scope: Oral explanation and Opinion, report from ad-hoc expert group held on 11 July 2016.

Action: Oral explanation to be held on Tuesday 19 July 2016 at 9.00.

Opinion adopted on 28.04.2016.

See also 3.5.1

2.3. Post-authorisation procedure oral explanations

2.3.1. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0020 & EMEA/H/C/002720/R/0022

MAH: PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus,

Scope: Oral explanation, Type II variation

"Update of sections 4.4, 4.6, 4.7, 4.8, and 5.1 of the SmPC and Annex II in order to reflect the result from the submitted study TC124-GD-020-DMD object of SOB 001. The Package Leaflet and the RMP are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include some minor editorial changes throughout the Product information."
Request for Supplementary Information adopted on 01.04.2016.

Scope: Oral explanation, Renewal of Marketing Authorisation

Action: Possible oral explanation to be held on Tuesday 19 July 2016 at 14.00.

Oral explanation held in June 2016. Request for Supplementary Information adopted on 28.04.2016.

Action: For adoption

See also 9.1.1

2.4. Referral procedure oral explanations

2.4.1. Diclofenac 50 mg Tablets - Diclofenac epolamine - EMEA/H/A-29/1434

Altergon Italia srl

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

RMS: UK, CMS: CZ, FR, SK

Decentralised Procedure number: UK/H/5906/001/DC

Disagreements regarding the demonstration of bioequivalence in the fed state

Scope: Oral explanation

Action: Possible oral explanation to be held on Wednesday 20 July 2016 at 9.00.

See also 10.4.1

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. cabozantinib - EMEA/H/C/004163

Accelerated assessment

treatment of advanced renal cell carcinoma (RCC)

Scope: Opinion

Action: For adoption

List of Questions adopted on 26.05.2016.

3.1.2. chenodeoxycholic acid - Orphan - EMEA/H/C/004061

Sigma-tau Arzneimittel GmbH; treatment of inborn errors of primary bile acid synthesis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 25.02.2016.

3.1.3. enoxaparin sodium - EMEA/H/C/004264

prophylaxis of thromboembolic disorders of venous origin

Rapporteur: Andrea Laslop, Co-Rapporteur: Patrick Salmon, PRAC Rapporteur: Menno van der Elst

PM: Ana Trullas Jimeno, EPL: Anna Baczynska, QM: Ana Cavaleiro Sanches

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 23.07.2015.

3.1.4. enoxaparin sodium - EMEA/H/C/003795

prophylaxis of thromboembolic disorders of venous origin

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 23.07.2015.

3.1.5. lenvatinib - EMEA/H/C/004224

Accelerated assessment

in combination with everolimus for the treatment of unresectable advanced or metastatic renal cell carcinoma (RCC)

Scope: Opinion

Action: For adoption

List of Questions adopted on 26.05.2016.

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

Baxter Innovations GmbH; treatment of pancreatic cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.02.2016. List of Questions adopted on 24.09.2015.

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

treatment of HIV-1 infection and hepatitis B infection

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.05.2016. List of Questions adopted on 28.01.2016.

3.1.8. eluxadoline - EMEA/H/C/004098

for the treatment of irritable bowel syndrome with diarrhoea

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.05.2016. List of Questions adopted on 24.09.2015.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. bezlotoxumab - EMEA/H/C/004136

indicated for the prevention of Clostridium difficile infection (CDI) recurrence

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

3.2.2. pegfilgrastim - EMEA/H/C/004342

treatment of neutropenia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

3.2.3. dasabuvir / ombitasvir / paritaprevir / ritonavir - EMEA/H/C/004235

treatment of hepatitis C

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

3.2.4. pegfilgrastim - EMEA/H/C/004023

treatment of neutropenia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

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

treatment of HIV

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.05.2016. List of Questions adopted on 19.11.2015.

3.2.6. ivabradine - EMEA/H/C/004117

treatment of angina pectoris

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

3.2.7. 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 Outstanding Issues adopted on 28.04.2016, 24.09.2015. List of Questions adopted on 26.03.2015.

3.2.8. obeticholic acid - Orphan - EMEA/H/C/004093

Intercept Italia s.r.l; treatment of primary biliary cirrhosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

3.2.9. follitropin delta - EMEA/H/C/003994

indicated for controlled ovarian stimulation

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.02.2016.

3.2.10. sildenafil - EMEA/H/C/004186

treatment of pulmonary arterial hypertension

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

3.2.11. edotreotide - Orphan - EMEA/H/C/004140

Advanced Accelerator Applications; Diagnosis of gastro-entero-pancreatic neuroendocrine tumours

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.02.2016.

3.2.12. tenofovir disoproxil - EMEA/H/C/004049

treatment of HIV-1 infection and hepatitis B infection

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.05.2016. List of Questions adopted on 17.12.2015.

3.2.13. venetoclax - Orphan - EMEA/H/C/004106

AbbVie Ltd.; treatment of adult patients with chronic lymphocytic leukaemia (CLL)

Scope: Day 180 list of outstanding issues

Action: For adoption

List of Questions adopted on 01.04.2016.

3.3. Initial applications; Day 120 list of questions

3.3.1. rurioctocog alfa pegol - EMEA/H/C/004195

treatment of haemophilia A

Scope: Day 120 list of questions

Action: For adoption

3.3.2. expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue - Orphan - ATMP - EMEA/H/C/004258

TIGENIX, S.A.U.; treatment of complex perianal fistula(s)

Scope: Day 120 list of questions

Action: For adoption

3.3.3. dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171

indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4

Scope: Day 120 list of questions as adopted by CAT

Action: For information

3.3.4. tivozanib hydrochloride monohydrate - Orphan - EMEA/H/C/004131

EUSA PHARMA; treatment of adult patients with advanced renal cell carcinoma (RCC)

Scope: Day 120 list of questions

Action: For adoption

3.3.5. alpha-1-antitrypsin - Orphan - EMEA/H/C/003934

Kamada BioPharma Limited at Fieldfisher LLP; treatment and maintenance therapy of adult patients with congenital deficiency of alpha-1 antitrypsin and lung disease with clinical evidence of emphysema and airway obstruction (FEV1/SVC<70%).

Scope: Day 120 list of questions

Action: For adoption

3.3.6. nitisinone - EMEA/H/C/004281

treatment of hepatorenal tyrosinemia type 1

Scope: Day 120 list of questions

Action: For adoption

3.3.7. pemetrexed - EMEA/H/C/004306

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

Scope: Day 120 list of questions

Action: For adoption

3.3.8. pemetrexed - EMEA/H/C/004488

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

Scope: Day 120 list of questions

Action: For adoption

3.3.9. pregabalin - EMEA/H/C/004277

treatment of neuropathic pain, epilepsy and Generalised Anxiety Disorder (GAD)

Scope: Day 120 list of questions

Action: For adoption

3.3.10. cariprazine - EMEA/H/C/002770

treatment of schizophrenia

Scope: Day 120 list of questions

Action: For adoption

3.3.11. insulin glargine / lixisenatide - EMEA/H/C/004243

for the treatment of adults with type 2 diabetes mellitus

Scope: Day 120 list of questions

Action: For adoption

3.3.12. rolapitant - EMEA/H/C/004196

prevention of nausea and vomiting

Scope: Day 120 list of questions

Action: For adoption

3.3.13. tofacitinib - EMEA/H/C/004214

treatment of active rheumatoid arthritis

Scope: Day 120 list of questions

Action: For adoption

3.3.14. human IgG1 monoclonal antibody specific for human interleukin-1 alpha - EMEA/H/C/004388

Accelerated assessment

treatment of metastatic colorectal cancer

Scope: Day 120 list of questions

Action: For adoption

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

3.4.1. padeliporfin - EMEA/H/C/004182

treatment of prostate cancer

Scope: Letter from the applicant dated 8 July 2016 requesting an extension of clock stop to respond to the List of Questions adopted on 26 May 2016.

Action: For information

List of Questions adopted on 26.05.2016

3.4.2. pegfilgrastim - EMEA/H/C/004211

treatment of neutropenia

Scope: Letter from the applicant dated 8 July 2016 requesting an extension of clock stop to respond to the List of Questions adopted on 26 May 2016.

Action: For information

List of Questions adopted on 26.05.2016

3.4.3. iloperidone - EMEA/H/C/004149

treatment of schizophrenia

Scope: Letter from the applicant dated 6 July 2016 requesting an extension of clock stop to respond to the List of Questions adopted on 28.04.2016

Action: For information

List of Questions adopted on 28.04.2016.

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

3.5.1. Sialanar - glycopyrronium bromide - PUMA - EMEA/H/C/003883

Proveca Limited; Symptomatic treatment of sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 to <18 years with neurological disorders.

Scope: Oral explanation and Opinion, report from ad-hoc expert group held on 11 July 2016.

Action: Oral explanation to be held on Tuesday 19 July 2016 at 9.00.

Opinion adopted on 28.04.2016.

See also 2.2.1.

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

3.7.1. begelomab - Orphan - EMEA/H/C/004144

ADIENNE S.r.l. S.U.; treatment of graft-versus-host disease

Scope: Letter from the applicant dated 4 July 2016 informing of the decision to withdraw the MAA.

Action: For information

List of Questions adopted on 25.02.2016.

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. Fycompa - perampanel - EMEA/H/C/002434/X/0025

Eisai Europe Ltd.

Rapporteur: Robert James Hemmings, PRAC Rapporteur: Julie Williams

Scope: "To add a new pharmaceutical form, oral solution, to the one currently approved (EU/1/12/776/024).
To add a new strength of 0.5 mg/ml for Fycompa finshed product (EU/1/12/776/024)."

Action: For adoption

List of Outstanding Issues adopted on 26.05.2016. List of Questions adopted on 17.12.2015.

4.1.2. Zebinix - eslicarbazepine acetate - EMEA/H/C/000988/X/0050/G

Bial - Portela & Cª, S.A.

Rapporteur: Martina Weise, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Martin Huber

Scope: "Grouping of a line extension application to add a new pharmaceutical form (50 mg/ml oral suspension) and a type II variation (C.I.6.a New indication (paediatric

indication)) to add treatment of children aged 2 years and older. Consequently, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC 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.
The application included a revised RMP version 14.0."

Action: For adoption

List of Questions adopted on 19.11.2015.

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. Stelara - ustekinumab - EMEA/H/C/000958/X/0049/G

Janssen-Cilag International N.V.

Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, PRAC Rapporteur: Julie Williams

Scope: "An extension application covering a new pharmaceutical form (concentrate for solution for infusion), a new strength (130mg) and a new route of administration (intravenous use); a type II variation (C.1.6.a) to add a new indication (Crohn`s Disease)."

Action: For adoption

List of Questions adopted on 28.04.2016.

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

4.3.1. Xtandi - enzalutamide - EMEA/H/C/002639/X/0029

Astellas Pharma Europe B.V.

Rapporteur: Arantxa Sancho-Lopez, PRAC Rapporteur: Dolores Montero Corominas

Scope: "To add new pharmaceutical form and strenghts (film-coated tablets 40 mg and 80 mg) to the currently approved presentations for Xtandi."

Action: For adoption

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

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. Adempas - riociguat - Orphan - EMEA/H/C/002737/II/0011

Bayer Pharma AG

Rapporteur: Pieter de Graeff, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Julie Williams

Scope: "Extension of Indication to include pulmonary arterial hypertension associated with congenital heart disease (PAH-CHD).
As a consequence, sections 4.4 and 5.1 of the SmPC are also updated in order to reflect on the extended indication. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to correct information regarding one of the CYP isoforms involved in the metabolism of riociguat in sections 4.5 and 5.2.
Furthermore, the PI is brought in line with the latest QRD template version 9.1."

Action: For adoption

5.1.2. Ameluz - 5-aminolevulinic acid - EMEA/H/C/002204/II/0020

Biofrontera Bioscience GmbH

Rapporteur: Harald Enzmann,

Scope: "Extension of Indication to include treatment of actinic keratosis of mild to moderate severity on the face and scalp (Olsen grade 1 to 2) and of field cancerization based on the phase III clinical study ALA-AK-CT007. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes in the SmPC and Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 23.06.2016.

5.1.3. Humira - adalimumab - EMEA/H/C/000481/II/0154

AbbVie Ltd.

Rapporteur: Kristina Dunder

Scope: "Extension of Indication to include adolescents from 12 years of age for the Humira hidradenitis suppurativa indication. As a consequence, sections 4.1, 4.2, 5.1 and 5.2, of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

5.1.4. Orencia - abatacept - EMEA/H/C/000701/II/0097

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension of Indication to extend the use of Orencia in combination with methotrexate (MTX) in the treatment of adults with rheumatoid arthritis (RA) who have highly active disease with poor prognostic factors (such as ACPA+ and/or RF+, joint erosion) not previously treated with MTX. As a consequence, sections 4.1 and 5.1 of the SmPC are updated based on results from AVERT study (IM101226). The Package Leaflet is updated accordingly. Moreover, the updated RMP version 20 has been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.02.2016.

5.1.5. Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0126

Gilead Sciences International Ltd

Rapporteur: Greg Markey, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Julie Williams

Scope: "Extension of the indication to add Pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in adults at high risk. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016.

5.1.6. Xalkori - crizotinib - EMEA/H/C/002489/II/0039

Pfizer Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Claire Ferard

Scope: "Extension of Indication to include treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC) based on the results of Study A8081001 (a multinational, multicenter, open-label, single-arm study of the safety, pharmacokinetics, pharmacodynamics, and antitumor activity of crizotinib in patients

with advanced cancer). Consequential changes are proposed to SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Annex II. The application included an updated RMP version 7.0."

Action: For adoption

Request for Supplementary Information adopted on 26.05.2016.

5.1.7. Zebinix - eslicarbazepine acetate - EMEA/H/C/000988/II/0053

Bial - Portela & Cª, S.A.

Rapporteur: Martina Weise, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include the use of Zebinix as monotherapy in adults, in addition to the previously authorised indication as adjunctive therapy. 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. This submission includes an updated RMP (version 15.0). In addition, the MAH is claiming an additional 1-year period of market protection under Article 14(11) of Regulation (EC) No 726/2004.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.8. Zydelig - idelalisib - EMEA/H/C/003843/II/0011

Gilead Sciences International Ltd

Rapporteur: Kristina Dunder, PRAC Rapporteur: Rafe Suvarna

Scope: Revised Opinion

"Extension of Indication to include new indication for Zydelig to include the combination of idelalisib with ofatumumab. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for United Kingdom and Ireland in the Package Leaflet."

Action: For adoption

Opinion adopted on 25.02.2016.

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. Lucentis - ranibizumab - EMEA/H/C/000715/II/0061

Novartis Europharm Ltd

Rapporteur: Kristina Dunder, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Revised assessment timetable

"Extension of Indication to include treatment of visual impairment due to choroidal neovascularization (CNV) based on 6-month data from the pivotal study CRFB002G2301 (MINERVA). Consequential changes are proposed to SmPC sections 4.1, 4.2, 4.8 and 5.1 and the Package Leaflet is proposed to be updated accordingly.
The application included an updated RMP version 16.0."

Request for Supplementary Information adopted on 26.05.2016.

Action: For information

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. PERAMIVIR - H0004299

Treatment of influenza

Scope: Request for accelerated assessment

Action: For adoption

Letter from the company dated 25 May 2016 requesting an accelerated assessment.

Briefing note and Rapporteurs' recommendation on the request for accelerated assessment.

8.1.2. cenegermin - H0004209

Scope: Request for accelerated assessment

Action: For adoption

Letter from the company dated 10.06.2016 requesting an accelerated assessment

Briefing note and Rapporteurs' recommendation on the request for accelerated assessment.

8.2. Priority Medicines (PRIME)

Disclosure of information related to priority medicines cannot be released at present time as these contain commercially confidential information

8.2.1. List of applications received

Action: For information

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0020 & EMEA/H/C/002720/R/0022

MAH: PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus,

Scope: Oral explanation, Type II variation

"Update of sections 4.4, 4.6, 4.7, 4.8, and 5.1 of the SmPC and Annex II in order to reflect the result from the submitted study TC124-GD-020-DMD object of SOB 001. The Package Leaflet and the RMP are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include some minor editorial changes throughout the Product information."
Request for Supplementary Information adopted on 01.04.2016.

Scope: Oral explanation, Renewal of Marketing Authorisation

Action: Possible oral explanation to be held on Tuesday 19 July 2016 at 14.00.

Oral explanation held in June 2016. Request for Supplementary Information adopted on 28.04.2016.

Action: For adoption

See also 2.3.1.

9.1.2. Xarelto - Rivaroxaban - EMEA/H/C/000944 – follow up of LEG 37

Bayer Pharma AG, prevention of venous thromboembolism (VTE), prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation

Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise

Scope: Update on ROCKET AF Trial and International Normalized Ratio (INR) device

Action: For discussion

9.1.3. Ranexa - ranolazine - EMEA/H/C/000805/II/0051

MAH: Menarini International Operations Luxembourg S.A., Rapporteur: Kristina Dunder,

Scope: Request for Supplementary Information / Opinion

"Update of section 5.1 of the SmPC in order to include the data from the final CSR of study RIVER-PCI. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the details of local representative in Bulgaria in the Package Leaflet and to bring the Annex II in line with the latest QRD template version 9.1."

Request for Supplementary Information adopted on 14.04.2016.

Action: For adoption

9.1.4. Helicobacter Test INFAI - 13C-urea - EMEA/H/C/000140/II/0019

MAH: INFAI GmbH, Rapporteur: Andrea Laslop,

Scope: Request for Supplementary Information / Opinion

"Update of the SmPC section 4.2, 4.3, 5.1 and 6.5 in order to add information on use of Refex test meal prior to the Helicobacter Test INFAI administration. The Package leaflet has been updated accordingly. Additionally, the MAH has taken the opportunity to align the PI with the latest QRD template version 9.1."

Request for Supplementary Information adopted on 23.06.2016, 01.04.2016, 28.01.2016.

Action: For discussion

9.1.5. Imbruvica - ibrutinib – Orphan - EMEA/H/C/003791/II/0017/G

MAH: Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams,

Scope: Request for Supplementary Information / Opinion

"Update of sections 4.8 and 5.1 of the SmPC in order update the safety and efficacy information following conclusion of studies MCL 3001 and CLL 3001. Annex II has been updated to remove the obligation to submit final CSR of study MCL 3001. The Package Leaflet and RMP are updated accordingly.
In addition, the Marketing authorisation holder (MAH) introduced minor editorial changes throughout the PI.
Submission of final CSRs for studies MCL 2001 and 1117 in fulfilment of post-authorisation measures.

In addition to the above trials, data from 2 other trials are included in support of the use of ibrutinib in combination with other agents in subjects with relapsed/refractory CLL."
Request for Supplementary Information adopted on 23.06.2016, 25.02.2016.

Action: For discussion

9.1.6. Praluent - alirocumab - EMEA/H/C/003882/II/0009/G

MAH: sanofi-aventis groupe, Rapporteur: Pieter de Graeff,

Scope: Request for Supplementary Information / Opinion

"Update of section 4.2 of the SmPC to include a 300 mg Q4W dosing regimen as a starting dose, based on the results of study CHOICE I (MEA 005).
Section 4.8, 5.1 and 5.2 of the SmPC and the PL have also been updated to reflect the study results.
In addition, the MAH submitted the final study report of study CHOICE II (MEA 009) and additional analysis of the two studies

Action: For discussion

9.1.7. ChondroCelect - Characterised Autologous Cartilage Cells Expressing A Specific Marker Profile - EMEA/H/C/000878

MAH: TiGenix NV, Repair of single symptomatic cartilaginous defects

CHMP Coordinators: Jan Mueller-Berghaus, Outi Mäki-Ikola, Rapporteur: Egbert Flory, Co-Rapporteur: Tiina Palomäki,

Scope: Letter from the MAH dated 5 July 2016 informing of decision to withdraw the marketing authorisation as of 30 November 2016.

Action: For information

9.1.8. Opgenra - Eptotermin Alfa - EMEA/H/C/000819

MAH: Olympus Biotech International Limited, treatment of spondylolisthesis

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Patrick Salmon,

Scope: Letter from the MAH dated 25 May 2016 informing of decision to withdraw the marketing authorisation.

Action: For information

9.1.9. Edistride - dapagliflozin - EMEA/H/C/004161/LEG 001.1, Forxiga - dapagliflozin - EMEA/H/C/002322/LEG 019.1, Ebymect - dapagliflozin, metformin - EMEA/H/C/004162/LEG 001.1, Xigduo - dapagliflozin / metformin EMEA/H/C/002672/LEG 005.1

Applicant: AstraZeneca AB

Scope: Consultation on the assessment of the risk of toe amputation with dapagliflozin-containing medicinal products in the context of the ongoing article 20 of Regulation (EC) No 726/2004 for canagliflozin-containing medicinal products

Action: For information

9.1.10. Jardiance - empagliflozin - EMEA/H/C/002677/LEG 006, Synarjy - empagliflozin, metformin – EMEA/H/C/003770/LEG 004

Applicant: Boehringer Ingelheim GmbH

Scope: Consultation on the assessment of the risk of toe amputation with empagliflozin-containing medicinal products in the context of the ongoing article 20 of Regulation (EC) No 726/2004 for canagliflozin-containing medicinal products

Action: For information

10. Referral procedures

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

10.1.1. Zydelig - idelalisib - EMEA/H/C/003843/A20/0023

Gilead Sciences International Ltd; treatment of chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma
(iNHL).

Referral procedure Rapporteurs: Rapporteur: Rafe Suvarna, Co-Rapporteur: Ulla Waendel Liminga

CHMP Rapporteurs for Zydelig: Rapporteur: Filip Josephson, Co-Rapporteur: Pieter de Graeff

Scope: Opinion, Report from IC SAG Oncology

Action: For adoption

10.1.2. Direct-acting antivirals (DAAV) indicated for the treatment of hepatitis C (interferon free): Daklinza - daclatasvir; Exviera - dasabuvir ; Viekirax - ombitasvir, paritaprevir, ritonavir ; Olysio – simeprevir; Sovaldi - sofosbuvir sofosbuvir, Harvoni - ledipasvir –EMEA/H/A-20/1438

Applicant: Bristol-Myers Squibb Pharma EEIG (Daklinza); AbbVie Ltd (Exviera, Viekirax); Janssen-Cilag International N.V. (Olysio); Gilead Sciences International Ltd (Harvoni, Sovaldi)

CHMP Rapporteurs: Rapporteur: Filip Josephson, Co-Rapporteur: Robert James Hemmings (Daklinza), Rapporteur: Filip Josephson, Co-Rapporteur: Johann Lodewijk Hillege (Exviera, Viekirax), Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Daniela Melchiorri (Olysio); Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs (Sovaldi), Rapporteur: Filip Josephson, Co-Rapporteur: Joseph Emmerich (Harvoni)

PRAC Rapporteur: Margarida Guimarães; PRAC Co-rapporteur: Dolores Montero Corominas

Scope: List of Questions to SAG virology as adopted by PRAC

Review of the benefit-risk balance of DAAV following notification by the European

Commission of a referral under Article 20 of Regulation (EC) No 726/2004 based on pharmacovigilance data

Action: For adoption

10.1.3. INVOKANA canagliflozin , VOKANAMET canagliflozin / metformin, JARDIANCE empagliflozin, SYNJARDY empagliflozin/metformin, FORXIGA dapagliflozin EDISTRIDE dapagliflozin, XIGDUO dapagliflozin/metformin, EBYMECT dapagliflozin/metformin - EMEA/H/A-20/1442

Marketing authorisation holder: Janssen-Cilag International N.V., AstraZeneca AB, Boehringer Ingelheim international GmbH

SGLT2 Inhibitors in lower limb amputations, treatment of type 2 diabetes mellitus

Rapporteur: Martina Weise/ Kristina Dunder, Co-Rapporteur: Kristina Dunder/ Martina Weise (canagliflozin/dapagliflozin); Pieter de Graeff, Bart Van der Schueren (empagliflozin)

Scope: Article 20 procedure to PRAC triggered by European Commission on 15 April 2016 for canagliflozin, Signal of potential increased risk of lower limb amputations, was extended to all SGLT2 inhibitors.

Action: For information

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. Diclofenac 50 mg Tablets - Diclofenac epolamine - EMEA/H/A-29/1434

Altergon Italia srl

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

RMS: UK, CMS: CZ, FR, SK

Decentralised Procedure number: UK/H/5906/001/DC

Disagreements regarding the demonstration of bioequivalence in the fed state

Scope: Oral explanation

Action: Possible oral explanation to be held on Wednesday 20 July 2016 at 9.00.

See also 2.4.1

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

10.5.1. Clenil and associated names - Beclometasone dipropionate - EMEA/H/A-30/1418

Chiesi group of companies and associated companies

Rapporteur: Daniela Melchiorri, Co-Rapporteur: Martina Weise

Scope: Lis of outstanding issues

Harmonisation exercise for Clenil and associated names (beclometasone dipropionate). The review was triggered by Italy due to the need to harmonise the product information across all Member States, including the therapeutic indication, the target populations and the posology recommendations.

Action: For adoption

List of Questions adopted on 25.06.2015. List of outstanding issues adopted 19 November 2015.

10.5.2. 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: Opinion

Action: For adoption

List of outstanding Issues adopted 28.01.2016, 28.04.2016, 23.06.2016.

10.5.3. Etopophos and associated names– etoposide - EMEA/H/A-30/1417

MAH: Bristol-Myers Squibb group of companies and associated companies

Rapporteur: Greg Markey, Co-Rapporteur: Pieter de Graeff,

Scope: List of Outstanding Issues

Harmonisation exercise for Etopophos and associated names

Action: For adoption

List of outstanding issues adopted 25.02.2016 CHMP, List of Questions adopted on 22.10.2015.

10.5.4. Vepesid and associated names - etoposide - EMEA/H/A-30/1425

MAH: Bristol-Myers Squibb group of companies and associated companies

Rapporteur: Greg Markey, Co-Rapporteur: Pieter de Graeff

Scope: List of Outstanding Issues

Harmonisation exercise for Vepesid and associated names

Action: For adoption

List of outstanding issues adopted 25.02.2016 CHMP, List of Questions adopted on 22.10.2015.

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

10.6.1. Pharmaceutics International – EMEA/H/A-31/1444

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: David Lyons,

Scope: List of Outstanding Issues / Opinion

Article 31 triggered by the European Commission

List of Questions 23.06.2016.

10.6.2. Semler Research Centre Private Ltd - EMEA/H/A-31/1443

Rapporteur: Pieter de Graeff, Co-Rapporteur: Concepcion Prieto-Yerro,

Scope: Opinion

Article 31 referral triggered by the UK, Germany, Spain, Denmark and the Netherlands in relation to findings of non-compliance with GCP at the Semler bioanalytical and clinical facilities in Bangalore, India.

Action: For adoption

10.6.3. Vancomycin containing products – (vancomycin) - EMEA/H/A-31/1440

Rapporteur: Concepcion Prieto-Yerro, Co-rapporteur: Alar Irs;

Scope: Opinion

Review of the benefit-risk balance following notification by the Spanish Agency of Medicines and Medical Devices of a referral under Article 31 of Directive 2001/83/EC,

Action: For adoption

List of Questions adopted on 01.04.2016.

10.6.4. Symbioflor 2, Escherichia Coli bacteria (cells and autolysate) - EMEA/H/A-31/1441

Symbiopharm GmbH,

Rapporteur: Harald Enzmann, Co-rapporteur: Milena Stain;

Scope: Letter from the MAH received 23 June 2016 requesting the EMA to suspend the referral.

Reply letter from EMA dated 1 July 2016.

Article 31 triggered by the BfArM in Germany in March 2016 requesting the review of the benefit-risk balance for Symbioflor 2 and associated names following concerns that the effectiveness of the medicine(s) has not been adequately demonstrated.

Action: For information

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

July 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

Request from EDQM for EMA scientific Opinion under Art. 57 (1)J of Regulation (EC) No 726/2004

Action: For adoption

13.4. Nanomedicines activities

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Outcome of the Expert meeting on ATMPs held on 27th May 2016

Scope: Report presentation to CHMP

Action: For information

14.1.2. New timetable proposal for type II variations involving the PRAC

Action: For discussion

Background document

14.1.3. EMA survey on Initial Marketing Authorisation Application (MAA) 2016

Scope: Web-based survey has been announced at the May CHMP and will be performed between September 2016 - February 2017

Action: For discussion

14.1.4. Review of experience with the Early Background Summary

Scope: An Outcome of a review of experience with the Early Background Summaries. A survey amongst CAT/CHMP/PRAC assessors was conducted following the pilot starting at the end of 2014. The data collection and analysis are completed based on a total 121 responses for the 21 products in scope of the exercise.

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 04-07 July 2016

Action: For information

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

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 13-15 July 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 11-14 July 2016

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2016 PDCO

Action: For information

Report from the PDCO meeting held on 20-22 July 2016

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 11-13 July 2016

Action: For information

14.2.6. Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 18-20 July 2016

Action: For information

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 4-7 July 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.

Mandate, objectives and rules of procedure of the Scientific advice working party (SAWP) (Doc ref: EMEA/CHMP/SAWP/69686/04 Rev 10) - revision

Action: For adoption

14.3.2. Respiratory Drafting Group

Concept Paper for the revision of the Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis (EMEA/CHMP/EWP/9147/2008)

Action: For adoption

14.3.3. Antimicrobial Advice ad hoc Expert Group (AMEG)

Scope: "Updated advice on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health (EMA/231573/2016)

Action: For adoption

Overview of comments received (EMA/390632/2016)

Action: For adoption

Background note on the Request from the Commission for update of the advice on the impact on public health and animal health of the use of antibiotics in animals (colistin) (EMA/723718/2014)

Action: For information

14.3.4. Quality Working Party (QWP)

Chair: Jean-Louis Robert,

Scope: Guideline on the Chemistry of Active Substances (EMA/454576/2016)

Action: For adoption

Overview of comments

Action: For information

14.3.5. CHMP ad-hoc drafting group

Scope: Update on the revision of fixed dose combination guideline

Action: For discussion

14.3.6. Safety Working Party (SWP)

Public statement on the use of herbal medicinal products containing pulegone and menthofuran (EMA/HMPC/138386/2005 Rev. 1)

Overview of comments on draft Public statement on the use of herbal medicinal products containing pulegone and menthofuran (EMA/HMPC/258725/2015)

Action: For information

14.4. Cooperation within the EU regulatory network

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 mid-year report

Mid-year report

Action: For information

14.8. Planning and reporting

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. Concept paper on the revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products'

Scope: concept paper developed by a multi-disciplinary expert group, agreement on press-release and timeframe for revision (EMA/CHMP/446302/2016)

Action: For adoption

16. Explanatory notes

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

Oral explanations *(section 2)*

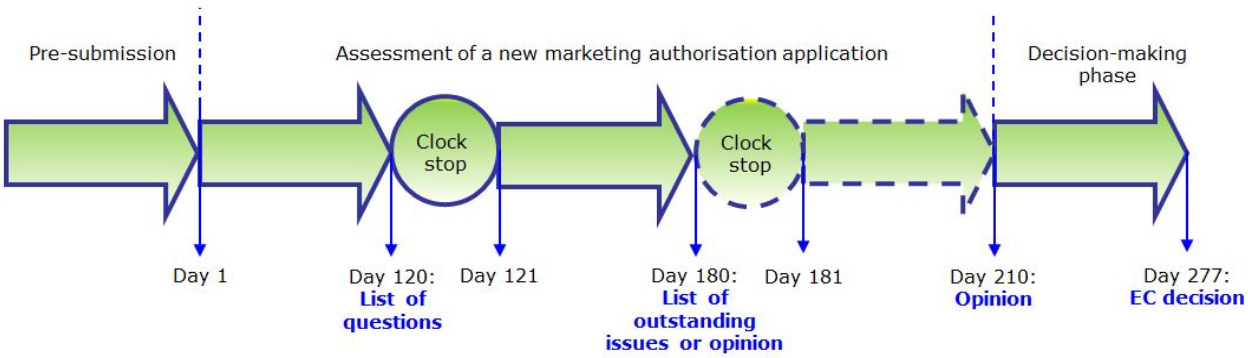
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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