29 March 2016
EMA/CHMP/221503/2016
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 29 March - 01 April 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

29 March 2016, 14:30 – 19:30, room 2A

30 March 2016, 08:30 – 19:30, room 2A

31 March 2016, 08:30– 19:30, room 2A

01 April 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 29-01 April 2016. See March 2016 CHMP minutes (to be published post April 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 29 March - 01 April 2016.

1.3. Adoption of the minutes

CHMP minutes for 22-25 February 2016.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

Takeda Pharma A/S; multiple myeloma

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 30 March 2016 at 14.00.

List of Outstanding Issues adopted on 25.02.2016. List of Questions adopted on 17.12.2015.

2.1.2. - glycopyrronium bromide - PUMA - EMEA/H/C/003883

treatment of sialorrhoea

Scope: Oral explanation

Action: Oral explanation to be held on Thursday 31 March 2016 at 9.00.

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

2.1.3. - daclizumab - EMEA/H/C/003862

treatment of multiple sclerosis (RMS)

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 30 March 2016 at 9.00.

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

BWP report

2.2. Re-examination procedure oral explanations

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

Lucane Pharma; treatment of corneal cystine deposits

Scope: Oral explanation and re-examination Opinion

Action: Oral explanation to be held on Wednesday 30 March 2016 at 11.00.

Well-established use application (Article 10a of Directive No 2001/83/EC).

Opinion adopted on 17 December 2015.

2.3. Post-authorisation procedure oral explanations

2.4. Referral procedure oral explanations

3. Initial applications

3.1. Initial applications; Opinions

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

Accelerated assessment

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

Scope: Opinion

Action: For adoption

List of Questions adopted on 28.01.2016.

BWP report

3.1.2. - infliximab - EMEA/H/C/004020

treatment of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, psoriasis and ulcerative colitis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.02.2016. Oral explanation was held February CHMP. List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 23.07.2015.

3.1.3. - migalastat - Orphan - EMEA/H/C/004059

Amicus Therapeutics UK Ltd; treatment of patients with Fabry disease

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.02.2016, 17.12.2015. List of Questions adopted on 22.10.2015.

3.1.4. - sacubitril / valsartan - EMEA/H/C/004343

treatment of heart failure (NYHA class II-IV)

Scope: Opinion

Action: For adoption

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

prophylaxis of influenza

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.01.2016. List of Questions adopted on 23.07.2015.

BWP report

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

prevention of nausea and vomiting associated with cancer chemotherapy

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

GlaxoSmithKline Trading Services; severe combined immunodeficiency

Scope: Opinion

Action: For adoption

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

BWP report

3.1.8. Uptravi - selexipag - EMEA/H/C/003774

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

Scope: Revised Opinion

Action: For adoption

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

Opinion adopted on 28 January 2016.

Letter from the European Commission received 24 February 2016.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - fluticasone propionate / salmeterol xinafoate - EMEA/H/C/002752

treatment of asthma and COPD

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

3.2.2. - fluticasone propionate / salmeterol xinafoate - EMEA/H/C/004267

treatment of asthma and COPD

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

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

treatment of multiple myeloma

Scope: 2nd Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 28.01.2016. List of Questions adopted on 23.07.2015.

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

treatment of HIV-1

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 17.12.2015.

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

3.2.6. - pemetrexed - EMEA/H/C/003895

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.10.2015.

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

treatment of Gaucher disease

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

3.2.8. - grazoprevir / elbasvir - EMEA/H/C/004126

treatment of chronic hepatitis C (CHC) in adults

Scope: 2nd Day 180 list of outstanding issue

Action: For adoption

Day 180 list of outstanding issue adopted 25.02.2016. List of Questions adopted on 19.11.2015.

3.3. Initial applications; Day 120 list of questions

3.3.1. - abaloparatide - EMEA/H/C/004157

treatment of osteoporosis

Scope: Day 120 list of questions

Action: For adoption

3.3.2. - bezlotoxumab - EMEA/H/C/004136

Accelerated assessment

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

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.3. - brodalumab - EMEA/H/C/003959

moderate to severe plaque psoriasis

Scope: Day 120 list of questions

Action: For adoption

BWP report

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

treatment of hepatitis C

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - pegfilgrastim - EMEA/H/C/004023

treatment of neutropenia

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.6. - etanercept - EMEA/H/C/004192

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.7. - ivabradine - EMEA/H/C/004241

treatment of angina pectoris

Scope: Day 120 list of questions

Action: For adoption

3.3.8. - ivabradine - EMEA/H/C/004217

treatment of angina pectoris

Scope: Day 120 list of questions

Action: For adoption

3.3.9. - ivabradine - EMEA/H/C/004117

treatment of angina pectoris

Scope: Day 120 list of questions

Action: For adoption

3.3.10. - pegfilgrastim - EMEA/H/C/004342

treatment of neutropenia

Scope: Day 120 list of questions

Action: For adoption

3.3.11. - sildenafil - EMEA/H/C/004289

treatment of patients with pulmonary arterial hypertension

Scope: Day 120 list of questions

Action: For adoption

3.3.12. - sildenafil - EMEA/H/C/004186

treatment of pulmonary arterial hypertesion

Scope: Day 120 list of questions

Action: For adoption

3.3.13. - sofosbuvir / velpatasvir - EMEA/H/C/004210

Accelerated assessment

treatment of chronic hepatitis C virus

Scope: Day 120 list of questions

Action: For adoption

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

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

Scope: Day 120 list of questions

Action: For adoption

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

3.4.1. - 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: Update on outcome from CAT March meeting

Action: For discussion

List of Outstanding Issues adopted on 28.01.2016, 26.03.2015. List of Questions adopted on 24.07.2014.

BWP report

3.4.2. - rituximab - EMEA/H/C/004112

treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL), Rheumatoid arthritis and Granulomatosis with polyangiitis and microscopic polyangiitis

Scope: Letter from the applicant dated 9 March 2016 requesting extension of clock stop to respond to the Day 120 List of Questions,

Action: For adoption

List of Questions adopted on 25.02.2016.

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

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

Scope: Letter from the applicant dated 7 March 2016 requesting extension of clock stop to respond to the Day 120 List of Questions.

Action: For adoption

List of Questions adopted on 28.01.2016.

3.4.4. - cabozantinib - EMEA/H/C/004163

treatment of advanced renal cell carcinoma (RCC)

Scope: Assessment Report on similarity

Action: For adoption

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

Baxter Innovations GmbH; treatment of pancreatic cancer

Scope: Letter from the applicant dated 18 March 2016 requesting extension of clock stop to respond to List of Outstanding Issues.

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

3.4.6. lenvatinib - EMEA/H/C/004224

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

Scope: Assessment Report on similarity

Action: For adoption

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: Oral explanation and re-examination Opinion

Action: For adoption

Well-established use application (Article 10a of Directive No 2001/83/EC)

Opinion adopted on 17 December 2015

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

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

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

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

Takeda Pharma A/S; management of breakthrough pain

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

Scope: Opinion

Type II cat. B.II.e.4.b) To add a new improved child resistant multi-dose nasal spray.

3 X Type IB cat. B.II.e.5.d To introduce a new pack size.

Type IA cat. B.II.d.1.a) To tighten the specification limits of the finished product

Additionally, the Applicant took the opportunity to include an editorial change.

Action: For adoption

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

4.1.2. Keytruda - pembrolizumab - EMEA/H/C/003820/X/0001/G

Merck Sharp & Dohme Limited

Rapporteur: Daniela Melchiorri,

Scope: Opinion

"To introduce concentrate for solution for infusion (25 mg/mL) as additional pharmaceutical form for Keytruda

Action: For adoption

List of Questions adopted on 17.12.2015.

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. Mabthera - rituximab - EMEA/H/C/000165/X/0101/G

Roche Registration Limited

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Pieter de Graeff, PRAC Rapporteur: Doris Stenver

Scope: Day 180 list of outstanding issue

"Grouping of:
- Line extension to add a new strength 1600 mg solution for subcutaneous injection, a new indication is proposed for this strength (different from 1400mg strength).
- Type II variation to update the product information of the existing strengths as a consequence to the line extension application
- Type II variation to update the RMP"

Action: For adoption

List of Questions adopted on 26.03.2015.

4.2.2. Trevicta / Paliperidone Janssen - paliperidone - EMEA/H/C/004066/X/0007/G

Janssen-Cilag International NV

Rapporteur: Filip Josephson, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Qun-Ying Yue

Scope: Day 180 list of outstanding issue

"This variation is part of a grouped application consisting of an extension application to introduce four new strengths of a once-every-3-month paliperidone injection formulation (175 mg, 263 mg, 350 mg and 525 mg) together with the variations identified below:

C.I.6.a - extension of indication for to revise the injection frequency to ' once-every-3-months' following prior adequate treatment with XEPLION for at least four months. Consequently, changes to Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are proposed. The PL and RMP are proposed to be revised accordingly.

A.2.a - Change of the Name of the Medicinal Product (Section 1 of the SmPC) from "Paliperidone Janssen" to "TREVICTA".
6 x C.I.7.b - deletion of all 6 currently authorised Paliperidone Janssen dosage strengths (i.e. Paliperidone Janssen 25 mg, 50 mg, 75 mg, 100 mg, 150 mg and 150 mg / 100 mg - EU/1/14/971/001-006)."

Action: For adoption

List of Questions adopted on 17.12.2015.

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

4.5. 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. Adcetris - brentuximab vedotin - Orphan - EMEA/H/C/002455/II/0025

Takeda Pharma A/S

Rapporteur: Pieter de Graeff, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to include new indication for Adcetris (ADCETRIS is indicated for the treatment of adult patients at increased risk of relapse or progression following ASCT"). 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

Request for Supplementary Information adopted on 22.10.2015, 25.06.2015.

List of questions to SAG Oncology

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

5.1.3. Avastin - bevacizumab - EMEA/H/C/000582/II/0086

Roche Registration Limited

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Doris Stenver

Scope: "Extension of indication to extend the use of Avastin in combination with erlotinib for the first line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous NSCLC with EGFR activating mutations. As a consequence sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are proposed to be updated. The Package Leaflet and RMP are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015.

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

AstraZeneca AB

Rapporteur: Pierre Demolis

Scope: "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.

5.1.5. Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0067

GlaxoSmithKline Biologicals

Rapporteur: Daniel Brasseur, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of Indication to include prevention against premalignant anal lesions and anal cancer as of 9 years of age for Cervarix.
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 RMP (v.11.0) including the new indication."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015, 25.06.2015.

5.1.6. Halaven - eribulin - EMEA/H/C/002084/II/0028

Eisai Europe Ltd.

Rapporteur: Filip Josephson, Co-Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include a new indication for Halaven 0.44 mg/ml solution for injection to expand its use to the treatment of soft tissue sarcoma, following the outcome of a Phase 3 study, Study 309.
As a consequence, sections 4.1, 4.4, 4.8, and 5.1 of the SmPC are updated in order to update the safety information. The Package Leaflet and RMP are updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in line with the latest QRD template version 9.1."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015.

5.1.7. 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

Request for Supplementary Information adopted on 28.01.2016.

5.1.8. Ilaris - canakinumab - EMEA/H/C/001109/II/0043

Novartis Europharm Ltd

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to amend the Systemic Juvenile Idiopathic Arthritis (SJIA) indication to include treatment of active Still's disease including Adult-Onset Still's Disease (AOSD) in patients aged 2 years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids.
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 updated accordingly. In addition, the MAH took the opportunity to bring the annexes in line with the latest QRD template. An updated RMP version 10 was provided as part of the application."

Action: For adoption

5.1.9. 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

Request for Supplementary Information adopted on 28.01.2016.

5.1.10. Kyprolis - carfilzomib - Orphan - EMEA/H/C/003790/II/0001/G

Amgen Europe B.V.

Rapporteur: Arantxa Sancho-Lopez

Scope: "Extension of Indication to include new indication for Kyprolis to be used with either lenalidomide and dexamethasone or dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) updated section 6.6 of the SmPC to include the option to administer Kyprolis in a 100 mL intravenous bag containing 5% glucose solution for injection in line with the extension of indication part of this variation. Furthermore the MAH took the opportunity to include some editorial changes and harmonisations in the PI."

Action: For adoption

5.1.11. Nevanac - nepafenac - EMEA/H/C/000818/II/0032

Alcon Laboratories (UK) Ltd

Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Extension of indication to include the indication 'reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients' also for the 3 mg/ml strength based on data from the phase III studies C-12-067 and C-12-071. 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 updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in SmPC and to update the annexes in line with the latest QRD template. An updated RMP version 7 was provided as part of the application."

Action: For adoption

5.1.12. 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: "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 28.01.2016, 22.10.2015.

5.1.13. Revestive - teduglutide - Orphan - EMEA/H/C/002345/II/0020

NPS Pharma Holdings Limited

Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Torbjorn Callreus

Scope: "Extension of Indication to include paediatric population for Revestive.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated in order to update the safety information. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015.

5.1.14. RoActemra - tocilizumab - EMEA/H/C/000955/II/0057

Roche Registration Limited

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with methotrexate (MTX) in the RoActemra SmPC for the subcutaneous formulation.
As a consequence, section 4.1 of the SmPC is updated. The 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. Moreover, the updated RMP version 18 has been submitted."

Action: For adoption

5.1.15. Simponi - golimumab - EMEA/H/C/000992/II/0063

Janssen Biologics B.V.,

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga,

Scope: "Update of the SmPC sections 4.2 and 5.1 in order to reflect the data from a multicentre, placebo-controlled, double-blind, randomised-withdrawal, parallel group study (GO KIDS) in children (2 to 17 years of age) with active polyarticular juvenile idiopathic arthritis (pJIA). The Package leaflet is proposed to be updated accordingly. This procedure includes also an update to the RMP."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015, 26.03.2015.

5.1.16. Tysabri - natalizumab - EMEA/H/C/000603/II/0077

Biogen Idec Ltd

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include new indication for Tysabri.
As a consequence, sections 4.1 AND 4.4 of the SmPC are updated in order to provide physicians with more options for treating RRMS patients with high disease activity who fail an initial disease modifying therapy (DMT). Consequential changes to sections 4.2, 4.3, 5.1 and Package Leaflet in Sections 2 and 3 are also proposed."

Action: For adoption

Request for Supplementary Information adopted on 19.11.2015, 25.06.2015.

5.1.17. Victoza - liraglutide - EMEA/H/C/001026/II/0038

Novo Nordisk A/S

Rapporteur: Pieter de Graeff, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of Indication to include second-line monotherapy in type II diabetes for Victoza. Additionally, the MAH updated information related to hepatic and renal impairment. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated with new efficacy and safety information. The Package Leaflet is updated in accordance.
Furthermore, the Marketing authorisation holder (MAH) took the opportunity to align the PI with the latest QRD template version 9.1."

Action: For adoption

5.1.18. Zontivity - vorapaxar - EMEA/H/C/002814/II/0005

Merck Sharp & Dohme Limited

Rapporteur: Greg Markey, PRAC Rapporteur: Carmela Macchiarulo

Scope: "Extension of Indication to include treatment of patients with Peripheral Arterial Disease (PAD) and as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the contact details of local representative in Luxembourg in the Package Leaflet.
Furthermore, the PI is brought in line with the latest QRD template version 9.1. Moreover, revised RMP version 2.0 was provided as part of the application."

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

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

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

6.2.1. - 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: Letter from the applicant dated 8 March 2016 requesting a extension of timeframe to respond to Day 120 LoQ.

Action: For adoption

List of Questions adopted on 28.01.2016.

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. Monoclonal Antibody Sgn-30 - EMEA/H/C/004388

treatment of metastatic colorectal cancer

Scope: Letter from the company dated 21 January 2016 requesting an accelerated assessment

Rapporteur's briefing note

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

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

PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus

Scope: Request for Supplementary information

"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."

Action: For discussion

9.1.2. Onglyza - saxagliptin, saxagliptin / metformin hydrochloride EMEA/H/C/001039/WS0902/0037, Komboglyze- saxagliptin, saxagliptin / metformin hydrochloride - EMEA/H/C/002059/WS0902/0028

AstraZeneca AB,

Lead Rapporteur: Pieter de Graeff,

Scope:

"Update of section 5.1 of the SmPC, upon request by the CHMP following the assessment of the post-authorisation measures LEG 038.1 (Onglyza) and LEG 015.1 (Komboglyze), with information regarding effect on all-cause mortality. In addition, the MAH took the

opportunity to implement minor editorial changes in the Package Leaflet and to update the contact information for the local representative in Poland in the Package Leaflet."

Action: For discussion

9.1.3. Voncento - human coagulation factor VIII / human von willebrand factor EMEA/H/C/002493/II/0017/G

CSL Behring GmbH, Rapporteur: Pieter de Graeff, PRAC Rapporteur: Sabine Straus,

Scope: Request for Supplementary information or Opinion, proposal to remove the commitment to conduct a post-marketing study for haemophilia patients

"C.I.4 (type II): Update of section 4.8 of the SmPC in order to update the frequencies of undesirable effects to reflect the final clinical study data from study CSLCT-BIO-08-53 in haemophilia A paediatric patients. The Package Leaflet is updated accordingly. The submission of the final CSR CSLCT-BIO-08-53 also leads to changes to the RMP (ver. 6.1) in order update the Company Core Safety Information (CCSI).
C.I.11.z (type IB): Submission of a revised RMP in order to remove the commitment to conduct a post-marketing study for haemophilia A patients (CSLCT-BIO-12-78) for Voncento as consequence of new data from study CSLCT-BIO-08-53.
In addition, the Marketing authorisation holder (MAH) took the opportunity to combine different strengths in the SmPC and Package Leaflet."
Request for Supplementary Information adopted on 19.11.2015.

Action: For discussion

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).

PRAC Rapporteur: Rafe Suvarna, PRAC Co-Rapporteur: Ulla Wändel Liminga

CHMP Rapporteur: Kristina Dunder, CHMP Co-Rapporteur: Pieter de Graeff,

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

Action: For information

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

Letter from European Commission dated 11 March 2016 informing of an official referral under Article 20 to PRAC and its grounds.

Recommendation to European Commission on interim measure.

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

10.2.1. Desloratadine-containing products

Rapporteur: Daniel Brasseur, Co-Rapporteur: Andrea Laslop,

Scope: Letter from Merck Sharp & Dohme (Europe), Inc. dated 16 March requesting two weeks extension of timeframe to submit responses to the List of Questions adopted 17 December 2015.

Prescription status of desloratadine-containing products

Action: For adoption

Revised timetable:

Submission of responses: 14 April 2016

Re-start of the procedure: 28 April 2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 11 May 2016

Comments: 16 May 2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 19 May 2016

CHMP list of outstanding issues or CHMP Opinion: June 2016 CHMP

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

10.5. 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 companiesRapporteur: Daniela Melchiorri, Co-Rapporteur: Martina Weise,Scope: List 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. Haldol and associated names (EMEA/H/A-30/1393) (haloperidol), Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić,

Scope: Opinion or List of Outstanding Issues

Action: For adoption

List of Outstanding Issues adopted 26 March 2015.

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

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić,

Scope: Opinion or List of Outstanding Issues

Action: For adoption

List of Outstanding Issues adopted 26 March 2015.

10.5.4. Saroten and associated names - amitriptyline - EMEA/H/A-30/1430

Lundbeck group of companies and associated companies

Rapporteur: George Aislaitner, Co-Rapporteur: Alar Irs,

Scope: List of Outstanding Issues

Harmonisation exercise for Saroten and associated names (amitriptyline). Review triggered by Greece due to the need to harmonise the product information across all Member States, including the therapeutic indication, the posology, the contra-indications, the adverse effects and the recommendations for use.

Action: For adoption

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

10.6.1. Alkem Laboratories Limited, India - EMEA/H/A-31/1436

Rapporteur: TBA, Co-Rapporteur: TBA

Scope: reliability of the data of bioequivalence studies, Appointment of (Co)Rapporteur

Action: For adoption

Letter from BfArM in Germany dated 8 March 2016 notifying of an official referral under Article 31 and its grounds.

10.6.2. Gadolinium-containing contrast agents (GdCA): gadobenic acid (NAP); gadobutrol (NAP); gadodiamide (NAP); gadopentetic acid (NAP); gadoteric acid (NAP); gadoteridol (NAP); gadoxetic acid (NAP); gadoversetamide – OPTIMARK (CAP)

Applicant: Mallinckrodt Deutschland GmbH (Optimark); various

Rapporteur: TBA, Co-Rapporteur: TBA, PRAC Rapporteur: Rafe Suvarna; PRAC Co-rapporteur: Doris Stenver

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data, Appointment of (Co)Rapporteur

Action: For information

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

Rapporteur: TBA, Co-rapporteur: TBA;

Scope: 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,

Appointment of (Co)Rapporteur, List of Questions and timetable

Action: For adoption

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

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

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

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

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

11. Pharmacovigilance issue

11.1. Early Notification System

March 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

Scope: ITF Briefing Meeting

Meeting date: 12 April 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: 15 April 2016

Action: For adoption

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

13.4. Nanomedicines activities

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Joint CHMP-COMP Strategic Review & Learning Meeting to be held in Utrecht, 30 May-1 June 2016 under the Netherland's Presidency of the Council of the European Union

Scope: Agenda topics of the upcoming Strategic Review and Learning meeting

Action: For discussion

Strategic Review and Learning meeting will be held, in part, jointly with the COMP.

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 **14-17 March 2016**

Action: For information

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

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 22-23 March 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Not applicable this month

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at March 2016 PDCO

Action: For information

Report from the PDCO meeting held on 30 March – 1 April 2016

Action: For information

Scope: Reflection paper on extrapolation of efficacy and safety in paediatric medicine development

Action: For adoption

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 21-23 March 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 29-31 March 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 14-17 March 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. Ad-hoc Influenza Working Group

Scope: EU Strain selection for the Influenza Vaccines for the Season 2016/2017

Action: For adoption

Scope: EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2016/2017

Action: For adoption

Report from the Ad Hoc Influenza working group to the BWP

Presentation by Alan Fauconnier

14.3.3. Quality Working Party (QWP)

CHMP: Jean-Louis Robert,

Scope: Questions and Answers on API mixtures

Action: For adoption

Scope: Reflection paper on the Dissolution specification for generic oral immediate release products

Action: For adoption for 3-month public consultation

14.3.4. Biologics Working Party (BWP)

CHMP: Sol Ruiz

Scope: Guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission (EMA/CHMP/BWP/187338/2014)

Action: For adoption

14.3.5. Cardiovascular Working Party (CVSWP)

CHMP: Pieter de Graeff

Scope: Draft guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome (EMA/CHMP/207892/2015)

Action: For adoption for 6 months public consultation

14.3.6. Infectious Diseases Working Party (IDWP)

PDCO: Maria Fernandez Cortizo

Scope: Concept paper on an addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements (CPMP/EWP/558/95 rev 2)

Action: For adoption for public consultation

14.4. Cooperation within the EU regulatory network

14.4.1. 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 March 2016

Action: For adoption

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

14.8. Planning and reporting

14.8.1. New marketing authorisation applications for 2016 with appointed rapporteurs

Action: For information

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. Zika virus: Viral safety of plasma-derived and urine-derived medicinal products with respect to Zika virus

CHMP: Sol Ruiz

Scope: BWP report

Action: For adoption

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)*

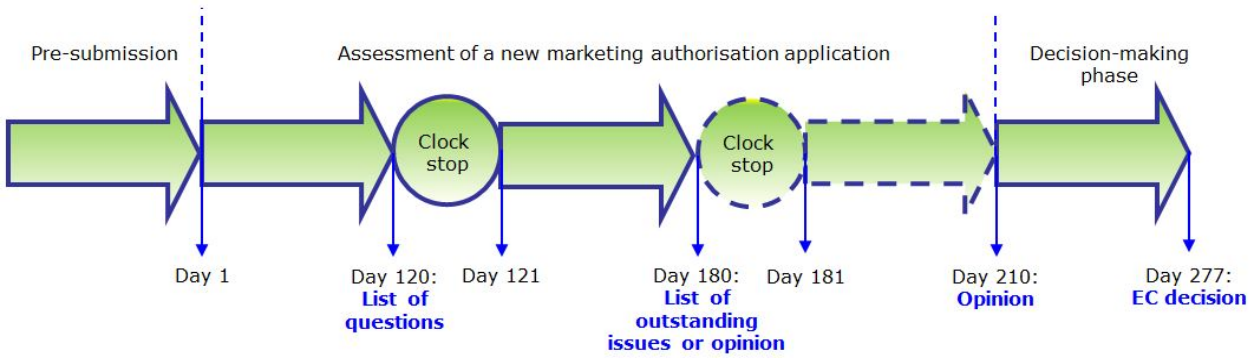
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

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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/