20 June 2016
EMA/CHMP/424610/2016
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 20-23 June 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

20 June 2016, 13:00 – 19:30, room 2A

21 June 2016, 08:30 – 19:30, room 2A

22 June 2016, 08:30 – 19:30, room 2A

23 June 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 20-23 June 2016. See June 2016 CHMP minutes (to be published post July 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 20-23 June 2016

1.3. Adoption of the minutes

CHMP minutes for 23-26 May 2016.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Yargesa - miglustat - EMEA/H/C/004016

JensonR+ Limited; treatment of Gaucher disease

Scope: Oral explanation

Action: Oral explanation to be held on 21 June 2016 at 16:00.

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 23.07.2015.

2.2. Re-examination procedure oral explanations

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

Request for Supplementary Information adopted on 28.04.2016.

Action: Oral explanation to be held on Tuesday 21 June 2016 at 10:00.

Participation of patients' representatives

2.4. Referral procedure oral explanations

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

Rapporteur: Harald Enzmann, Co-Rapporteur: Greg Markey,

Scope: Opinion

Article 31 procedure triggered by BfArM concerning studies performed by Alkem Laboratories, Department of Bioequivalence, C-17/7, MIDC Industrial estate, Taloja, Dist. Raigad – 410 208, India between March 2013 and March 2015, following critical GCP deficiencies reported during an inspection performed by BfArM and IGZ in 2015.

Action: Oral explanation to be held on 21 June 2016 at 14:30.

List of questions adopted on 01.04.2016.

See also 10.6.1.

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - fluticasone propionate / salmeterol - EMEA/H/C/002752

treatment of asthma and COPD

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 22.10.2015.

3.1.2. - fluticasone propionate / salmeterol - EMEA/H/C/004267

treatment of asthma and COPD

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 22.10.2015.

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

treatment of HIV-1.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016, 28.01.2016, 22.10.2015. List of Questions adopted on 21.05.2015.

3.1.4. - reslizumab - EMEA/H/C/003912

treatment of asthma and elevated blood eosinophils who are inadequately controlled on inhaled corticosteroids

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 19.11.2015.

BWP report

3.1.5. - methotrexate - EMEA/H/C/003983

treatment of active rheumatoid arthritis; severe, active juvenile idiopathic arthritis; severe recalcitrant disabling psoriasis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 17.12.2015.

3.1.6. - allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2) - Orphan - ATMP - EMEA/H/C/002801

MolMed SpA; treatment in haploidentical haematopoietic stem cell transplantation

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016, 28.01.2016, 26.03.2015. List of Questions adopted on 24.07.2014.

BWP report

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137

treatment of HIV-1 infection

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.02.2016.

3.2.2. - empagliflozin / linagliptin - EMEA/H/C/003833

treatment of type 2 diabetes mellitus

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.02.2016.

3.2.3. - palbociclib - EMEA/H/C/003853

treatment of breast cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 17.12.2015.

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

3.2.5. - cediranib - Orphan - EMEA/H/C/004003

AstraZeneca AB; treatment of platinum sensitive relapsed (PSR) ovarian cancer relapsed (PSR) ovarian cancer

Scope: 2nd Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 19.11.2015.

3.3. Initial applications; Day 120 list of questions

3.3.1. - paclitaxel - Orphan - EMEA/H/C/004154

Oasmia Pharmaceutical AB; treatment of ovarian cancer

Scope: Day 120 list of questions, request for extension of timeframe

Action: For adoption

3.3.2. - daptomycin - EMEA/H/C/004310

treatment of complicated skin and soft-tissue infections

Scope: Day 120 list of questions

Action: For adoption

3.3.3. - olaratumab - Orphan - EMEA/H/C/004216

Accelerated assessment

Eli Lilly Nederland B.V.; treatment of soft tissue sarcoma

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.4. - baricitinib - EMEA/H/C/004085

treatment of moderate to severe active rheumatoid arthritis (RA)

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - pentosan polysulfate sodium - Orphan - EMEA/H/C/004246

bene-Arzneimittel GmbH; treatment of Interstitial Cystitis

Scope: Day 120 list of questions

Action: For adoption

3.3.6. - tenofovir alafenamide - EMEA/H/C/004169

chronic hepatitis B in adults

Scope: Day 120 list of questions

Action: For adoption

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

3.4.1. - sodium zirconium cyclosilicate - EMEA/H/C/004029

for the treatment of hyperkalaemia

Scope: Letter from the applicant dated 8 June 2016 requesting an extension of clock stop to respond to the List of Questions adopted on 28 April 2016.

Action: For information

List of Questions adopted on 28.04.2016.

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

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

Scope: Letter from the applicant dated 14 June 2016 requesting an extension of clock stop to respond to the List of Outstanding Issues adopted on 19.11.2015.

Action: For discussion

List of Outstanding Issues adopted on 19.11.2015, 22.10.2015, 25.06.2015. List of Questions adopted on 22.01.2015.

3.4.3. - darunavir - EMEA/H/C/004068

treatment of HIV-1

Scope: Letter from the applicant dated 16 June 2016 requesting an extension of clock stop to respond to the List of Outstanding Issues adopted on 26.05.2016.

Action: For adoption

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

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

APEIRON Biologics AG; treatment of neuroblastoma

Scope: Letter from the applicant dated June 2016 requesting an extension of clock stop to respond to the List of Outstanding Issues adopted on 26.05.2016.

Action: For adoption

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

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

3.5.1. Ninlaro - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: Appointment of re-examination rapporteurs, draft timetable, SAG involvement

Action: For discussion

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

Opinion adopted on 26 May 2016.

Letter from the applicant dated 6 June 2016 requesting a re-examination of the Opinion adopted on 26 May 2016 and consultation of Scientific Advisory Group.

3.5.2. 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: Call for nomination of experts to ad-hoc expert group, list of questions to ad-hoc expert group

Request for nomination of experts to ad-hoc expert group with the following expertise:

- Experts in Paediatric Palliative Medicine
- Paediatric neurologists
- General paediatricians who may follow such patients regularly and may have experience with the treatment of this condition.

Action: For adoption

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

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

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

Scope: Letter from the applicant dated 31 May 2016 informing of the decision to withdraw the MAA

Action: For information

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

Insmed Limited; treatment of Mycobacterium avium Complex (MAC) lung disease in adults.

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

the MAA

Action: For information

3.7.3. - alendronic acid / colecalciferol - EMEA/H/C/004172

treatment of postmenopausal osteoporosis

Scope: Letter from the applicant dated 27 May 2016 informing of the decision to withdraw the MAA

Action: For information

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

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

Scope: Letter from the applicant dated 6 June 2016 informing of the decision to withdraw the MAA

Action: For information

List of Questions adopted on 24.09.2015.

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

Merck Sharp & Dohme Limited

Rapporteur: Daniela Melchiorri,

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

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016. 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

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

Otsuka Pharmaceutical Europe Ltd

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

Action: For adoption

Request for Supplementary Information adopted on 25.02.2016, 24.09.2015.

Report from Central Nervous System Working Party

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.

5.1.3. Arzerra - ofatumumab - Orphan - EMEA/H/C/001131/II/0041

Novartis Europharm Ltd

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

Scope: Opinion / Request for Supplementary Information

Scope: "Extension of Indication to include maintenance therapy in Chronic Lymphocytic Leukemia (CLL).
As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In accordance with the new QRD template version 9.1, the MAH is also taking the opportunity of this procedure to update the Annex II and combine the 2 SmPCs for the 100mg a 1,000mg vials."

Action: For adoption

Request for Supplementary Information adopted on 26.05.2016, 28.04.2016, 25.02.2016, 22.10.2015. SAG Oncology meeting was held on 14 April 2016. Oral explanation held on 24 May 2016.

5.1.4. Arzerra - ofatumumab - Orphan - EMEA/H/C/001131/II/0045/G

Novartis Europharm Ltd

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

Scope: "Extension of indication to include the combination of Arzerra with fludarabine and cyclophosphamide or in combination with bendamustine for the treatment of adult patients with relapsed CLL.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet and the RMP (v.13) are updated in accordance."

Action: For adoption

5.1.5. 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 01.04.2016, 19.11.2015.

5.1.6. 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 01.04.2016, 19.11.2015, 25.06.2015.

5.1.7. 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

Request for Supplementary Information adopted on 01.04.2016.

5.1.8. Jardiance - empagliflozin - EMEA/H/C/002677/II/0014

Boehringer Ingelheim International GmbH

Rapporteur: Pieter de Graeff, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Dolores Montero Corominas

Scope: "Extension of indication to include a new indication on prevention of cardiovascular events, based on the final data of the cardiovascular safety phase III clinical trial EMPA-REG OUTCOME. As a consequence, section 4.1 of the SmPC is updated. The Package Leaflet is also updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to make some editorial changes."

Action: For adoption

Request for Supplementary Information adopted on 25.02.2016.

5.1.9. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0007

Merck Sharp & Dohme Limited

Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to include a new indication for Keytruda in second line Non-Small Cell Lung Cancer (NSCLC). 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."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016.

5.1.10. 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

Request for Supplementary Information adopted on 01.04.2016.

5.1.11. Opdivo - nivolumab - EMEA/H/C/003985/II/0012

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 the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL):
- after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin, or
- after at least two prior therapies in patients who are not candidates for ASCT, for OPDIVO as monotherapy.

As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add the proposed new indication, add a warning that patients with active autoimmune disease and symptomatic interstitial lung disease were excluded from clinical trials of cHL, and update the safety and pharmacodynamic information. The Package Leaflet is updated in accordance.
Furthermore, the PI is brought in line with the latest QRD template version 10.0.
Moreover, the updated RMP version 5.0 has been submitted"

Action: For adoption

5.1.12. 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

Request for Supplementary Information adopted on 01.04.2016.

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

Novo Nordisk A/S

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

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

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016, 28.01.2016.

5.1.14. Trisenox - arsenic trioxide - EMEA/H/C/000388/II/0058

Teva B.V.

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

Scope: "Extension of Indication to include induction of remission, and consolidation in adult patients with newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤ 10 x 103/µl) characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene for Trisenox.
As a consequence, sections 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated regarding the posology, efficacy and safety information and warnings. In addition, a Risk Management Plan is introduced. The Package Leaflet is updated in accordance."

Action: For adoption

5.1.15. 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 01.04.2016, 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

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. - andexanet alfa - H0004108

For adult patients treated with a direct or indirect factor Xa (FXa) inhibitor when reversal of anticoagulation is needed in situations such as: in life-threatening or uncontrolled bleeding; for emergency surgery/urgent procedures

Scope: Request for accelerated assessment

Action: For adoption

Letter from the company dated 12 May 2016 requesting an accelerated assessment. Briefing note and Rapporteurs’ recommendation on the request for accelerated assessment.

8.1.2. - masitinib mesylate - H0004398

Treatment of adults with Amyotrophic Lateral Sclerosis

Scope: Request for accelerated assessment

Action: For adoption

Letter from the company dated 24 May 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. InductOs - Dibotermin Alfa - EMEA/H/C/000408

Medtronic BioPharma B.V., Rapporteur: Pieter de Graeff, Co-Rapporteur: Outi Mäki-Ikola,

Action: For adoption

9.1.2. Revatio - sildenafil - EMEA/H/C/000638/II/0073

MAH: Pfizer Limited, Rapporteur: Pieter de Graeff,

Scope: Opinion

"Following the availability of powder for oral suspension formulation and following the request of CHMP, update of sections 4.2, 6.3, 6.4 and 6.6 of Revatio 20mg film-coated tablets SmPC and section 4.2 of Revatio 10mg powder for oral suspension to delete information related to the extemporaneously prepared oral suspension. The film-coated tablet PL is updated accordingly."

Request for Supplementary Information adopted on 26.05.2016.

Action: For adoption

9.1.3. 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

Follow up of previous assessment completed in January 2016

9.1.4. Selincro – Nalmefene - EMEA/H/C/002583

H. Lundbeck A/S, indicated for the reduction of alcohol consumption

Rapporteur: Martina Weise, Co-Rapporteur: Patrick Salmon, PRAC Rapporteur: Martin Huber, PRAC Co-Rapporteur: Almath Spooner

Scope: Update on recent publication in journal 'Addiction' by N. Fitzgerald et al.

Action: For discussion

10. Referral procedures

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

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

10.3. 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

Scope: PKWP response to CHMP question on diclofenac

Disagreements regarding the demonstration of bioequivalence in the fed state

Action: For adoption

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

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

Janssen-Cilag group of companies and associated companies

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

Scope: Opinion or List of outstanding Issues

Action: For adoption

List of outstanding Issues adopted 28.01.2016 and 28.04.2016.

10.5.2. 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: Opinion or 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

List of outstanding issues adopted on 01.04.2016.

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: Harald Enzmann, Co-Rapporteur: Greg Markey,

Scope: Opinion

Article 31 procedure triggered by BfArM concerning studies performed by Alkem Laboratories, Department of Bioequivalence, C-17/7, MIDC Industrial estate, Taloja, Dist. Raigad – 410 208, India between March 2013 and March 2015, following critical GCP deficiencies reported during an inspection performed by BfArM and IGZ in 2015.

Action: For adoption

List of questions adopted on 01.04.2016.

See also 2.4.1.

10.6.2. Dienogest/Ethinylestradiol containing products indicated in acne - Dienogest / EMEA/H/A-31/1435

Rapporteur: Martina Weise, Co-Rapporteur: Nithyanandan Nagercoil,

Scope: Opinion or List of outstanding issues

Action: For adoption

10.6.3. Metformin and metformin containing fixed-dose combinations – metformin containing products – EMEA/H/A-31/1432

Rapporteur: Kristina Dunder, Co-Rapporteur: Pieter de Graeff, Scope: List of outstanding issues

Review of use in patients with renal impairment and precautions regarding lactic acidosis

Action: For adoption

List of Questions adopted 28 January 2016.

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

Rapporteur: tba, Co-Rapporteur: tba,

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

Article 31 triggered by the EC

Letter from the European Commission dated 17 June 2016 notifying of official referral under Article 31 and its grounds.

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

June 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 information

Update on procedure

Request from the European Commission for an EMA scientific Opinion under Article 57

Action: For information

Update on procedure

13.4. Nanomedicines activities

4th TC on the IPRF Nano Working Group on 6 July 2016

Action: For information

Agenda

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. CHMP Seating plan during Slovakian presidency 1 July - 31 December 2016

Action: For information

14.1.2. General update on the procedural handling of GMP inspection issues

Action: For information

14.1.3. Revision of Procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC

Action: For adoption

14.1.4. New procedure for 107q PASS Results - early involvement of CHMP

CHMP sponsor: Johann Hillege,

Action: For information

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

Action: For discussion

Background document

14.1.6. Follow-up actions from the CHMP Strategic Review and Learning meeting in Utrecht

Action: For information

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 06-09 June 2016

Action: For information

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

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 16-17 June 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 30 May- 2 June 2016

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at June 2016 PDCO

Action: For information

Report from the PDCO meeting held on 22-24 June 2016

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 14-16 June 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 20-22 June 2016

Action: For information

Scope: PKWP response to the CMDh letter dated 21 April 2016 regarding administration of crushed/disintegrated tablets

Action: For adoption

Scope: PKWP response to the CMDh letter dated 22 April 2016 regarding low dose acetylsalicylic acid gastro-resistant formulations in fixed dose combinations with substitution indication

Action: For adoption

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

14.3.1. Scientific Advice Working Party (SAWP)

Scope: Report from the SAWP meeting held on 6-9 June 2016. Table of conclusions

Action: For information

Scope: 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. Name Review Group (NRG)

Scope: Endorsement of NRG recommendation

Action: For discussion

14.3.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Christian Schneider / Martina Weise

Scope: Call for nomination of a new Chairperson following end of mandate in September 2016

Action: For information

Nominations should be sent by 31 July 2016.
Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the September 2016 CHMP Plenary meeting.

14.3.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

Scope: Appointment of CHMP representatives (1 member and 1 alternate) to the PCPWP

Action: For adoption

14.3.5. European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope: Appointment of CHMP representatives (1 member and 1 alternate) to the HCPWP

Action: For adoption

14.3.6. Biologics Working Party (BWP)

Draft agenda for BWP face-to-face meeting to be held 11-13 July 2016 (EMA/CHMP/BWP/377241/2016)

Action: For information

Final minutes from face-to-face meeting held 18-20 April 2016 (EMA/CHMP/BWP/281453/2016)

Action: For information

Reflection paper on viral safety of plasma-derived medicinal products with respect to Hepatitis E virus (EMA/CHMP/BWP/723009/2014)

Action: For adoption

Scope: Revised "Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials" (EMA/CHMP/BWP/534898/2008)

Action: For adoption for 6-months public consultation

14.3.7. Vaccines Working Party (VWP)

Scope: Call for nomination for a new chairperson following resignation of Michael Pfleiderer

Action: For information

Nominations should be sent by 31 July 2016

Candidates shall submit a brief résumé in support of their candidature. Election is going to take place at the September 2016 CHMP Plenary meeting.

14.3.8. Blood Products Working Party (VWP)

Scope: Final agenda of WP meeting held face-to-face on 2-3 June 2016 (EMA/CHMP/BPWP/344525/2016)

Action: For information

Scope: Final minutes of WP meeting held by TC on 3 March 2016 (EMA/CHMP/BPWO/170164/2016)

Action: For information

Scope: Election of new vice-chair

Action: For adoption

14.3.9. Cardiovascular Working Party

Chair: Pieter de Graeff/Kristina Dunder

Scope: Concept paper on the need for revision of the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (EMA/317855/2016)

Action: For adoption for 3-months public consultation

Scope: Guideline on clinical investigation of medicinal products in the treatment of lipid disorders (EMA/CHMP/748108/2013 rev 3)

Action: For adoption

Scope: Draft Guideline of medicinal products used in weight management (EMA/CHMP/311805/2014):

Action: For adoption

Overview of comments received (EMA/CHMP/76995/2015)

Action: For information

Scope: Draft Guideline on clinical investigations of Medicinal Products in the treatment of Hypertension (EMA/CHMP/29947/2013)

Action: for adoption

Scope: Overview of comments received (EMA/CHMP/345847/2015)

Action: For information

14.3.10. Central Nervous System Working Party (CNSWP)

Scope: Final minutes of WP meeting held by teleconference on 10 March 2016 (EMA/189345/2016)

Action: For information

14.3.11. Infectious Diseases Working Party (IDWP)

Scope: Call for nomination of a new Chairperson following end of mandate in September 2016

Action: For information

Nominations to be sent by 31 July 2016

Candidates should submit a brief résumé in support of their candidature.

Scope: Guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis (EMEA/CHMP/EWP/30039/2008 Rev 1)

Action: For adoption for release for 6-month consultation

Presentation by Filip Josephson.

Scope: Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antimicrobial medicinal products (Doc ref: EMA/CHMP/594085/2015)

Action: For adoption.

Presentation by Mair Powell

Scope: Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat disease due to Mycobacterium tuberculosis (EMA/CHMP/EWP/14377/2008 Rev 1) –

Action: For adoption for 6-months consultation

14.3.12. Oncology Working Party

Scope: Call for nomination of a new Chairperson following end of mandate in September 2016

Action: For information

Nominations to be sent by 31 July 2016

Candidates should submit a brief résumé in support of their candidature.

14.3.13. Biostatistics Working Party (BSWP)

Scope: Final minutes of BSWP meeting held by teleconference on 19 April 2016 (EMA/279984/2016)

Action: For information

Scope: Draft agenda of BSWP meeting to be held by teleconference on 14 June 2016 (EMA/380152/2016)

Action: For information

Scope: Call for nomination for a new chairperson following resignation of David Jonathan Wright

Action: For information

Expertise sought: Candidates for the position should be professionally qualified senior assessors within the European regulatory network, with relevant expertise in the field of biostatistics. Experience in co-operation with EMA Committees, Working Parties and Working Groups would be of advantage.

Nominations should be sent by 31 July 2016.

Candidates should submit a brief résumé in support of their candidature. Election is going to take place at the September 2016 CHMP Plenary meeting.

14.3.14. Radiopharmaceutical Drafting Group (RadDG)

Scope: Call for nomination of a new Chairperson following end of mandate in September 2016

Action: For information

Nominations to be sent by 31 July 2016

Candidates should submit a brief résumé in support of their candidature.

14.3.15. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Scope: ICH Q3D – implementation strategy

Action: For adoption for 1-month public consultation

Scope: Question-and-answeron product specific active substance information

Action: For adoption

14.3.16. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus,

Scope: Guideline on the clinical investigation of medicinal products for the treatment of Axial Spondyloarthritis (CPMP/EWP/4891/03 Rev.1),

Rapporteur: Arantxa Sancho-Lopez

Action: For adoption for 6-month public consultation

14.3.17. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/ Alfredo Garcia-Arieta,

Scope: Nomination of Ewa Bałkowiec-Iskra as a PKWP observer

Action: For adoption

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

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. Feedback from non-clinical and clinical experts on review of EU guidance on first-in-human clinical trials

Action: For discussion

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)*

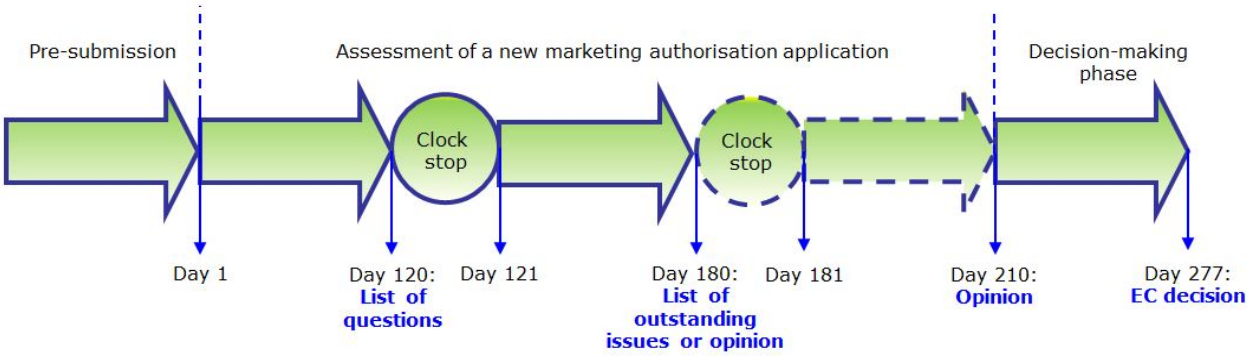
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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