20 July 2015
EMA/CHMP/483193/2015
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 20-23 July 2015

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

20 July 2015, 13:00 – 19:30, room 2A

21 July 2015, 08:30 – 19:30, room 2A

22 July 2015, 08:30 – 19:30, room 2A

23 July 2015, 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 July 2015. See (current) July 2015 CHMP minutes (to be published post September 2015 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 20-23 July 2015

1.3. Adoption of the minutes

CHMP minutes for 22-25 June 2015.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - ferric citrate coordination complex - EMEA/H/C/003776

treatment of hyperphosphataemia

Scope: Oral explanation

Action: Possible oral explanation to be held on 21.07.2015 at 9.00.

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

See 3.1.2

2.1.2. - p. falciparum circumsporozoite protein fused with hepatitis b surface antigen (rts), and combined with hepatitis b surface antigen (s) in the form of non-infectious virus-like particles (vlps) produced in yeast cells (saccharomyces cerevisiae) by recombinant dna technology - EMEA/H/W/002300

indicated for active immunisation against malaria

Scope: Oral explanation and report from the SAG Vaccines

Action: Oral explanation to be held on 20 July 2015 at 15.30.

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 20.11.2014.

See 3.1.5

2.2. Re-examination procedure oral explanations

2.3. Post-authorisation procedure oral explanations

2.4. Referral procedure oral explanations

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - isavuconazole - Orphan - EMEA/H/C/002734

Basilea Medical Ltd; treatment of aspergillosis and mucormycosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 18.12.2014.

3.1.2. - ferric citrate coordination complex - EMEA/H/C/003776

treatment of hyperphosphataemia

Scope: Opinion

Action: For adoption

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

See 2.1.1

3.1.3. - guanfacine - EMEA/H/C/003759

treatment of ADHD

Scope: Opinion

Action: For adoption

Oral explanation was held on 23.06.2015. List of Outstanding Issues adopted on 26.03.2015. List of Questions adopted on 24.07.2014.

3.1.4. - ivabradine - EMEA/H/C/004187

treatment of angina pectoris

Scope: Opinion

Action: For adoption

3.1.5. - p. falciparum circumsporozoite protein fused with hepatitis b surface antigen (rts), and combined with hepatitis b surface antigen (s) in the form of non-infectious virus-like particles (vlps) produced in yeast cells (saccharomyces cerevisiae) by recombinant dna technology - EMEA/H/W/002300

indicated for active immunisation against malaria

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 20.11.2014.

See 2.1.2

3.1.6. - pemetrexed - EMEA/H/C/004114

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

Scope: Opinion

Action: For adoption

List of Questions adopted on 23.04.2015.

3.1.7. - pemetrexed - EMEA/H/C/004011

in combination with cisplatin is indicated for the treatment malignant pleural mesothelioma and non-small cell lung cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2015. List of Questions adopted on 26.02.2015.

3.1.8. - alirocumab - EMEA/H/C/003882

reduction of low-density lipoprotein cholesterol (LDL-C) and increase high-density lipoprotein cholesterol (HDL-C).

Scope: Opinion

Action: For adoption

List of Questions adopted on 23.04.2015.

3.1.9. - ceftolozane / tazobactam - EMEA/H/C/003772

treatment of intra-abdominal urinary tract infections

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 18.12.2014.

3.1.10. - sufentanil - EMEA/H/C/002784

indicated for the management of pain

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.05.2015. List of Questions adopted on 20.11.2014.

3.2. Initial applications; Day 180 list of outstanding issues

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 18.12.2014.

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

BWP Report

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

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 26.02.2015.

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

Biogen Idec Ltd; treatment of Haemophilia A

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

BWP Report

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

treatment of HIV-1

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.04.2015.

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

treatment of acute moderate to severe post-operative pain

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 22.01.2015.

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

treatment of Parkinson's disease

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

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

treatment of asthma

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

BWP Report

3.2.9. - pegaspargase - EMEA/H/C/003789

indicated as combination therapy in acute lymphoblastic leukaemia (ALL)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 20.11.2014.

BWP Report

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.03.2015.

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.02.2015.

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

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 26.02.2015.

3.2.13. - susoctocog alfa - Orphan - EMEA/H/C/002792

Baxter AG; treatment of acquired hemophilia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 23.04.2015. List of Questions adopted on 20.11.2014.

BWP Report

3.3. Initial applications; Day 120 list of questions

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

treatment of multiple myeloma

Scope: Day 120 list of questions

Action: For adoption

3.3.2. - caspofungin - EMEA/H/C/004134

treatment of invasive candidiasis and invasive aspergillosis

Scope: Day 120 list of questions

Action: For adoption

3.3.3. - albutrepenonacog alfa - Orphan - EMEA/H/C/003955

CSL Behring GmbH; prophylaxis and treatment of bleeding in all patients with haemophilia B, treatment of bleeding in all patients with haemophilia B

Scope: Day 120 list of questions

Action: For adoption

3.3.4. BWP Report - trifluridine / tipiracil - EMEA/H/C/003897

treatment of colorectal cancer

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - methotrexate - EMEA/H/C/003756

treatment of rheumatological and dermatological diseases

Scope: Day 120 list of questions

Action: For adoption

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

prophylaxis of influenza

Scope: Day 120 list of questions

Action: For adoption

BWP Report

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

prevention and treatment of dabigatran associated haemorrhage

Scope: Day 120 list of questions

Action: For adoption

BWP Report

3.3.8. - rasagiline - EMEA/H/C/004064

treatment of idiopathic Parkinson’s disease

Scope: Day 120 list of questions

Action: For adoption

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

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

Scope: Day 120 list of questions

Action: For adoption

3.3.10. BWP Report - enoxaparin sodium - EMEA/H/C/004264

prophylaxis of thromboembolic disorders of venous origin

Scope: Day 120 list of questions

Action: For adoption

3.3.11. BWP Report - enoxaparin sodium - EMEA/H/C/003795

prophylaxis of thromboembolic disorders of venous origin

Scope: Day 120 list of questions

Action: For adoption

3.3.12. BWP Report - miglustat - EMEA/H/C/004016

treatment of Gaucher disease

Scope: Day 120 list of questions

Action: For adoption

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

treatment of multiple sclerosis (RMS)

Scope: Day 120 list of questions

Action: For adoption

BWP Report

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

3.4.1. insulin human - EMEA/H/C/003858

treatment of diabetes

Scope: Request for an extension of clock stop

Action: For adoption

Day 180 list of outstanding issues adopted 25.06.2015. List of Questions adopted on 23.10.2014.

Letter from the applicant dated 8 July 2015 requesting extension of clock-stop to respond to Day 180 list of outstanding issues

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

treatment of heart failure (NYHA class II-IV)

Scope: Need for SAG

Action: For discussion

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

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

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

Scope: Request for a re-examination of the Opinion adopted on 25 June 2015 and consultation of SAG

Action: For information and appointment of re-examination (Co)Rapporteur

Letter from the applicant dated 9 July 2015 requesting a re-examination of the Opinion adopted on 25 June 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. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/X/0034/G

Vertex Pharmaceuticals (U.K.) Ltd.

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

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

Action: For adoption

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

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

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

Takeda Pharma A/S

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

Scope: "Annex I_2.(c) To add the new strength of 400 micrograms/dose in a multi-dose nasal spray in pack size of 10's, 20's, 30's & 40 doses.
Type II cat. B.II.e.4.b) To replace the current multi-dose nasal spray by a new improved child resistant multi-dose nasal spray.
3 X Type IB cat. B.II.e.5.d) To add a new pack size of 30 doses for each current strength (50 micrograms/dose, 100 micrograms/dose & 200 micrograms/dose).
Type IA cat. B.II.d.1.a) – To tighten the assay release limit of the multi-dose finished product to 98.0%-102.0%.
Type IA cat. B.II.f.1.a) 1. – To reduce the shelf life of all strengths of the multi-dose finished product to 24 months.

Additionally, the Applicant took the opportunity to include an editorial change, as to change the wording of the specification footnote regarding the droplet size distribution test from ""The test is performed by the vendor on every pumping system batch" to "The test is performed at release of the pumping system"."

Action: For adoption

List of Questions adopted on 26.02.2015.

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

4.3.1. Brilique - ticagrelor - EMEA/H/C/001241/X/0029/G

AstraZeneca AB

Rapporteur: Pieter de Graeff, Co-Rapporteur: Arantxa Sancho-Lopez, PRAC Rapporteur: Menno van der Elst

Scope: "Annex I_2.(c) - extension application for a new strength of 60mg with a new indication: History of Myocardial Infarction.
C.I.4. Type II - To update the product information of the existing Brilique 90mg license with important clinical information from the PEGASUS study."

Action: For adoption

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

Novartis Europharm Ltd

Rapporteur: Pierre Demolis,

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

Action: For adoption

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

Bristol-Myers Squibb Pharma EEIG

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

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

Action: For adoption

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

4.4.1. REVOLADE - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/X/0022/G

Novartis Europharm Ltd

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

Scope: Extension of clock stop

"Extension of indication for paediatric (age 1 year and above) chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who had an insufficient response to other treatments (e.g. corticosteroids, immunoglobulins).

Grouping with the line extension for one new tablet strength (12.5mg) and a new Powder for Oral Suspension formulation (25mg).

The Type II variation and the Extension are grouped within this Application. This grouping is justified, as one of the variations in the group is an extension of the marketing authorisation (Annex III of Commission Regulation (EC) No 1234/2008 of November 2008). Agreed justification. 120 day TT follows Line extension."

Action: For adoption

Letter from the company dated 16.07.2015 requesting an extension to respond to the Request for Supplementary Information adopted in June 2015

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

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

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

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

Novartis Europharm Ltd

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

In addition, the applicant took the opportunity to relocate documents from section 5.3.5.1 to 5.3.5.2."

Action: For adoption

5.1.2. Qutenza - capsaicin - EMEA/H/C/000909/II/0039

Astellas Pharma Europe B.V.

Rapporteur: Bruno Sepodes, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Magda Pedro

Scope: "Extension of indication to include treatment of diabetic patients with peripheral neuropathic pain based on the results of studies E05-CL-3004 (STEP) and E05-CL-3002 (PACE). As a consequence sections 4.1, 4.4 and 4.8 of the SmPC have been updated, and Annex II (additional risk minimisation measures) and the Package Leaflet have been updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC, Annex II, labelling and Package Leaflet. An updated RMP (version 18) was provided as part of the application. The provision of studies STEP and PACE addresses MEA 001.4."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

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

Celgene Europe Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Arnaud Batz

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

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

5.1.4. REVOLADE - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/II/0020

Novartis Europharm Ltd

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

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to add a new indication on the treatment of adult patients with severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy. The package leaflet is updated accordingly. In addition, the MAH has corrected the acronym used for full blood counts (FBC) in the SmPC, Annex II and PL."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015, 26.02.2015.

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

Glaxo Group Ltd

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

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

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

5.1.6. XALKORI - crizotinib - EMEA/H/C/002489/II/0024

Pfizer Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Corinne Fechant

Scope: "Type II variation to apply for extension of XALKORI indication to the first-line treatment ALK-positive advanced NSCLC (section 4.1 of the SmPC) and to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the XALKORI SmPC to
include results of the pivotal Study A8081014, a multinational, multicentre, randomized, open-label, Phase 3 study comparing the efficacy and safety of crizotinib to first-line chemotherapy (pemetrexed / cisplatin or Pemetrexed / carboplatin) in patients with previously untreated ALK-positive advanced non-squamous NSCLC and updated safety results from Studies A8081001, A8081005 and A8081007. In addition, section 5.1 of the SmPC was revised to include updated overall survival data from Studies A8081001 and A8081005."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2015.

5.1.7. Zutectra - human hepatitis b immunoglobulin - EMEA/H/C/001089/II/0024

Biotest Pharma GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to Prevention of hepatitis B virus (HBV) re-infection in HBsAg and HBV-DNA negative patients at least one week – instead of the approved at least 6 months - after liver transplantation for hepatitis B induced liver failure.
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 accordingly.
An updated RMP has been provided."

Action: For adoption

5.1.8. Tafinlar – dabrafenib / Mekinist - trametinib - EMEA/H/C/WS0736

Novartis Europharm Ltd

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

Scope: "Extension of indication to add a new therapeutic indication for the use in combination of trametinib and dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. An updated RMP was also provided."

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

Action: For adoption

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

5.3. 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. - eryaspase - Orphan - H0004055

ERYTECH PHARMA - LYON, Treatment of Acute Lymphoblastic Leukaemia (with Philadelphia chromosome negative) in combination with a polychemotherapy

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 6 July 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note

8.1.2. - Paritaprevir\Ritonavir - H0004183

treatment of chronic hepatitis C (CHC) in adults

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 29 June 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note

8.1.3. – ixazomib- Orphan - H0003844

Takeda Pharma A/S, indicated for the treatment of patients with multiple myeloma who have received at least one prior therapy

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 12 June 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note

8.1.4. – Rociletinib - H0004053

treatment of patients with mutant EGFR NSCLC who have received prior EGFR-directed therapy and have T790M-mediated resistant NSCLC.

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 2 July2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

8.1.5. - Chenodeoxycholic acid - Orphan - H0004061

Sigma-tau Arzneimittel GmbH, treatment of Cerebrotendinous xanthamatosis (CTX), an inborn error of primary bile acid synthesis due to sterol 27-hydroxylase (CYP27A1) deficiency

Scope: Request for an accelerated assessment

Action: For adoption

Letter from the company dated 9 July 2015 requesting for an accelerated assessment.

Rapporteurs' accelerated assessment briefing note.

9. Post-authorisation issues

9.1. Post-authorisation issues

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

Biogen Idec Ltd,

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber,

Scope: Opinion or Request for Supplementary information

Update of sections 4.4 of the SmPC in order to add a recommendation to consider interruption of treatment in patients with low lymphocyte counts (<0.5 x 109/L) persisting for more than six months and to monitor lymphocyte counts until recovery. Update of section 4.8 of the SmPC with information on observed low lymphocyte counts in clinical studies with tecfidera and PML (Progressive multifocal leukoencephalopathy) occurrence in the setting of severe and

prolonged lymphopenia. Furthermore, the due dates of two commitments as part of the RMP have been revised."

Action: For adoption

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

9.1.2. Optaflu - influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/000758/II/0086

Novartis Influenza Vaccines Marburg GmbH,

Rapporteur: Johann Lodewijk Hillege,

Scope: Opinion or Request for Supplementary information

"Seasonal update of the composition of the strains to those officially recommended by WHO and CHMP for the season 2015/2016, and these are the following:

-A/California/7/2009 (H1N1)pdm09- like strain (A/Brisbane/10/2010, wild type)

-A/Switzerland/9715293/2013 (H3N2) - like strain (A/South Australia/55/2014, wild type)

-B/Phuket/3073/2013 – like strain (B/Utah/9/2014, wild type)"

9.1.3. NexoBrid – Bromelain, partially purified - Orphan - EMEA/H/C/002246 - PAM ANX 001.3

MediWound Germany GmbH, removal of eschar

Rapporteur: Harald Enzmann, Co-Rapporteur: Robert James Hemmings,

Scope: The MAH shall conduct a study on enzymatic debridement in burns patients (children and adults): A comparison to standard of care (protocol MW2010-03-02), based on a CHMP approved protocol.

Action: For discussion

9.1.4. Zontivity - vorapaxar - EMEA/H/C/002814/II/0002

MAH: Merck Sharp & Dohme Limited,

Rapporteur: Greg Markey,

Scope: Opinion

"Update of sections 4.2 and 5.1 of the SmPC in order to update the posology and to include the ATC code respectively. The Package Leaflet section 2 is brought in line with the SmPC in regards to renal problem."

Action: For adoption

Request for Supplementary Information adopted on 21.05.2015.

9.1.5. Imbruvica - ibrutinib - Orphan - EMEA/H/C/003791/II/0008/G

Janssen-Cilag International NV,

Rapporteur: Filip Josephson, i,

Scope: Opinion or Request of supplementary information

"Following the review of all clinical trials and post-marketing data, update of section 4.4 of the SmPC to add that some fatal bleeding-related events have been reported. Following the review of the global safety database, update of section 4.4 of the SmPC to inform about reported cases of Progressive Multifocal Leukoencephalopathy (PML). Following the cumulative review of hypersensitivity-related cases, update of section 4.8 of the SmPC to add the adverse reactions urticaria, angioedema and erythema. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity of this procedure to update the contact details of the Danish local representative in the PL."

Action: For adoption

10. Referral procedures

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

10.1.1. CERVARIX -Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – EMEA/H/A20/1421/C/0721/0071 GARDASIL , SILGARD - Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – EMEA/H/A20/1421/C/0703/0060 / EMEA/H/A20/1421/C/0732/0054 GARDASIL 9 (Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/A20/1421/C/3852/0001

MAHs: GlaxoSmithKline Biologicals S.A. (Cervarix), Sanofi Pasteur MSD SNC (Gardasil, Gardasil 9), Merck Sharp & Dohme Limited (Silgard)

PRAC Rapporteur: Julie Williams
PRAC Co-rapporteurs: Qun-Ying Yueand Jean-Michel Dogne
Rapporteur: Daniel Brasseur, Co-Rapporteur: Jan Mueller-Berghaus (Cervarix), Rapporteur: Kristina Dunder, Co-Rapporteur: Pierre Demolis (Gardasil / Silgard), Rapporteur: Kristina Dunder, Co-Rapporteur: Jan Mueller-Berghaus (Gardasil 9),

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.

Procedure started at PRAC in July 2015.

Action: For information

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

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

Scope: CHMP discussion/revision of the interim CHMP AR

Action: For adoption

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

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

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

10.5.1. Cymevene IV and associated names - ganciclovir - EMEA/H/A-30/1406

F. Hoffmann-La Roche
Rapporteur: Rugile Pilviniene, Co-Rapporteur: Alar Irs,

List of Questions adopted on 25.09.2014.

Scope: List of Outstanding Issues

Harmonisation exercise for Cymevene IV and associated names. The review was triggered by the European Commission in September 2014, due to the need of harmonisation of the Summary of Product Characteristics across Member State.

Action: For adoption

List of Outstanding Issues adopted on 26.02.2015.

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

MEDA group of companies and associated companies.

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

Scope: Opinion or List of Outstanding Issues

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

Action: For adoption

List of Outstanding Issues adopted on 26.03.2015.

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

Chiesi group of companies and associated companiesScope: Revised timetable

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

Letter from the MAH dated July 2015 requesting extension of timeframe to submit responses to the List of Questions adopted on 25.06.2015.

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

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

Lead Rapporteur: Rafe Suvarna,

Scope: Optimark - SAWP / PRAC consultation on a post-authorisation measure (joint study ALS-Gd640001) resulting from the 2010 Article 20 referral procedures for gadolinium-containing contrast agents

Action: For information

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

Action: For adoption

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

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

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

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

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

11. Pharmacovigilance issue

11.1. Early Notification System

July 2015 Early Notification System on Envisaged CHMP Recommendations for Regulatory Action (based on Identified Safety Concerns) Accompanied by Communication to the General Summary of recommendations and advice of PRAC meeting held on 06-09 July 2015.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

13.2. Innovation Task Force briefing meetings

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

13.3. 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. Call for nominations of a CHMP co-opted member

The Committee agreed at their June 2015 meeting that a co-opted member should be appointed in the following area of Epidemiology expertise.

Action: For information

14.1.2. Election of CHMP Chair in September 2015

Action: For information

14.1.3. EMA Q&A on procedural and regulatory aspects for PAES

Action: For discussion

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

Action: For adoption for public consultation

14.1.5. Revision of the Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to article 14(9) of regulation (EC) No 726/2004 – Rev 1

Action: For adoption for public consultation

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

Scope: Concept Paper

Action: For discussion

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

Action: For discussion

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

14.1.8. NOAC - New oral anticoagulants – workshop to be held on 23 November 2015

Action: For discussion

14.1.9. Guideline on the role of pathological complete response as an endpoint in neoadjuvant breast cancer studies

Action: For adoption

Overview of comments: 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 July 2015

Action: For information

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

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 16-17 July 2015

Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 06-09 July 2015

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2015 PDCO

Action: For information

Report from the PDCO meeting held on 17-19 July 2015

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 14-16 July 2015

Action: For information

14.2.6. CMDh

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 20-22 July 2015

Action: For information

PKWP/MSWG response to CMDh request on biowaiver justification

Action: For adoption

PKWP-MSWG joint response to CMDh question

Appendix - draft MSWG report

Question to CHMP (BWP) on Biosimilars of Low Molecular Weight Heparins

Action: For discussion

Letter from CMDh dated 7 July 2015 to CHMP (BWP) on Biosimilars of Low Molecular Weight Heparins

RMS Assessment Reports 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 06-09 July 2015. Table of conclusions

Action: For information

Scientific advice letters: Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

14.3.2. Excipients Drafting Group

Questions and answers on aspartame in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1) (EMA/CHMP/134648/2015)

Action: For adoption for 3-month public consultation

Background review for the excipient aspartame (EMA/CHMP/349452/2014)

Questions and answers on boron (boric acid and borates) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1) (EMA/CHMP/619104/2013)

Action: For adoption for 3-month public consultation

Background review for the excipient boron (boric acid and borates) (EMA/CHMP/765436/2012)

Questions and answers on fructose and sorbitol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1) (EMA/CHMP/460886/2014)

Action: For adoption for 3-month public consultation

Background review for the excipients fructose and sorbitol (EMA/CHMP/338441/2014)

Questions and answers on Sodium laurilsulfate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1) (EMA/CHMP/606830/2014)

Action: For adoption for 3-month public consultation

Background review for Sodium laurilsulfate (SLS) used as an excipient (EMA/CHMP/351898/2014)

14.3.3. Quality Working Party (QWP)

QWP comments on FDA's draft Near Infrared (NIR) guideline

Action: For adoption

Joint BWP/QWP/GMDP IWG – Industry European workshop on Lifecycle Management to be held on 28-29 October 2015

Action: For adoption

14.3.4. Respiratory Drafting Group (RDG)

Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Asthma (CHMP/EWP/2922/01 Rev. 1)

Action: For adoption

Overview of comments received

14.3.5. Cardiovascular Working Party

Draft Guideline on clinical evaluation of medicinal products used in weight management

Action: For discussion

14.3.6. Guideline consistency group (GCG)

Scope: Update on the GCG

Action: For discussion

14.3.7. Infectious Diseases Working Party (IDWP)

Scope: Priority list of antibiotics for Article 31 referral for SmPC modernisation

Action: For adoption

14.4. Cooperation within the EU regulatory network

14.4.1. Consultation of Scientific committees on EFSA's draft guidance on uncertainty in scientific assessments

Action: To nominate Committee representatives and to provide comments by 4 September 2015

14.5. Cooperation with International Regulators

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

14.7. CHMP work plan

14.7.1. CHMP 2016 Work Plan

Scope: List of proposed topics

Action: For adoption

14.8. Planning and reporting

14.9. Others

15. Any other business

15.1.1. Making medicines safer – How legislation contributes to patient safety

EMA's 20th anniversary event to be held on 22 July 2015, Promenade level

Action: For information

16. Explanatory notes

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

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

Oral explanations *(section 2)*

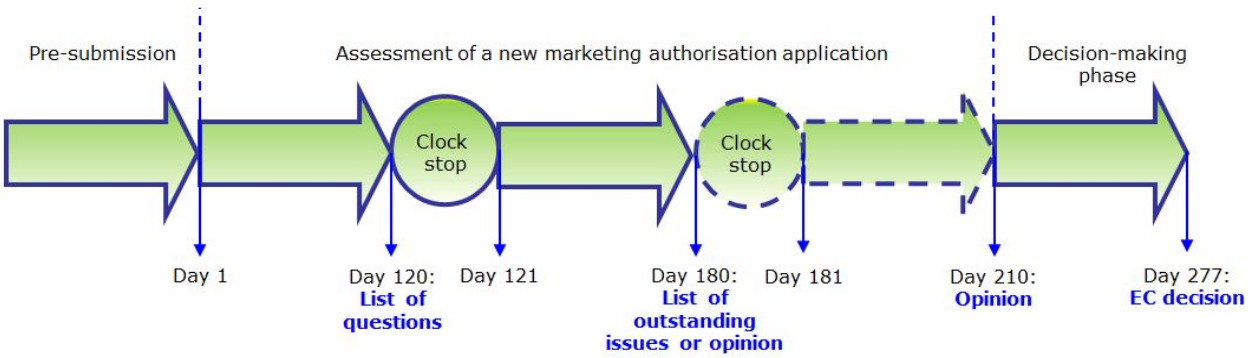
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

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

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 5)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 6)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

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