14 December 2015
EMA/CHMP/838619/2015
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 14-17 December 2015

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

14 December 2015, 13:00 – 19:30, room 3A

15 December 2015, 08:30 – 19:30, room 3A

16 December 2015, 08:30 – 19:30, room 3A

17 December 2015, 08:30 – 13:00, room 3A

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 14-17 December 2015. See December 2015 CHMP minutes (to be published post January 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 14-17 December 2015

1.3. Adoption of the minutes

CHMP minutes for 16-19 November 2015.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday 15 December 2015 at 14.00.

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

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. - caspofungin - EMEA/H/C/004134

treatment of invasive candidiasis and invasive aspergillosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.10.2015. List of Questions adopted on 23.07.2015.

3.1.2. - mercaptamine - Orphan - EMEA/H/C/004038

Lucane Pharma; treatment of corneal cystine deposits

Scope: Opinion

Action: For adoption

An oral explanation was held on 18 November 2015. List of Outstanding Issues adopted on 24.09.2015. List of Questions adopted on 26.03.2015.

3.1.3. - ferric maltol - EMEA/H/C/002733

treatment of iron deficiency anaemia

Scope: Opinion

Action: For adoption

Oral explanation held on 19.11.2015. List of Outstanding Issues adopted on 24.09.2015. List of Questions adopted on 23.04.2015.

3.1.4. - octocog alfa - EMEA/H/C/004147

treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

Scope: Opinion

Action: For adoption

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

3.1.5. - octocog alfa - EMEA/H/C/003825

treatment and prophylaxis of haemophilia A
Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

Scope: Opinion

Action: For adoption

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

3.1.6. - dexamethasone - Orphan - EMEA/H/C/004071

Laboratoires CTRS; treatment of symptomatic multiple myeloma in combination with other medicinal products.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.11.2015, 24.09.2015. List of Questions adopted on 18.12.2014.

3.1.7. - necitumumab - EMEA/H/C/003886

treatment of squamous non-small cell lung cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.11.2015, 24.09.2015. List of Questions adopted on 23.04.2015.

3.1.8. - osimertinib - EMEA/H/C/004124

Non-small-cell lung cancer (NSCLC)

Scope: Opinion

Action: For adoption

List of Questions adopted on 22.10.2015.

3.1.9. - diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982

vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae typeb (Hib)

Scope: Opinion

Action: For adoption

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

3.1.10. - lesinurad - EMEA/H/C/003932

treatment of hyperuricaemia

Scope: Opinion

Action: For adoption

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

3.2. Initial applications; Day 180 list of outstanding issues

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

treatment of HIV

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 24.09.2015.

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

Amicus Therapeutics UK Ltd; Treatment of patients with Fabry desease

Scope: Day 150 list of outstanding issues

Action: For adoption

List of Questions adopted on 22.10.2015.

3.2.3. - trifluridine / tipiracil - EMEA/H/C/003897

treatment of colorectal cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

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

Santen Oy; treatment of chronic non-infectious uveitis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.06.2015.

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

treatment of idiopathic Parkinson's disease (PD)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

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

treatment of sialorrhoea

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.06.2015.

3.2.8. - ixekizumab - EMEA/H/C/003943

treatment of moderate to severe plaque psoriasis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 24.09.2015.

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

treatment of multiple sclerosis (RMS)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

3.3. Initial applications; Day 120 list of questions

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

treatment of HIV-1

Scope: Day 120 list of questions

Action: For adoption

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

treatment of HIV-1

Scope: Day 120 list of questions

Action: For adoption

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

treatment of breast cancer

Scope: Day 120 list of questions

Action: For adoption

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

Takeda Pharma A/S; multiple myeloma

Scope: Day 120 list of questions

Action: For adoption

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

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

Scope: Day 120 list of questions

Action: For adoption

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

treatment of HIV-1 infection and hepatitis B infection

Scope: Day 120 list of questions

Action: For adoption

3.3.7. - rociletinib - EMEA/H/C/004053

treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC)

Scope: Day 120 list of questions

Action: For adoption

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

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

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

Scope: Similarity assessment

Action: For adoption

List of Questions adopted on 19.11.2015.

3.4.2. - 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 5th December 2015 requesting extension of timeframe to respond to Day 120 List of Questions,

Action: For information

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

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

AstraZeneca AB; prevention of atherothrombotic events, treatment of atherothrombotic events in adult patients

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

List of Outstanding Issues adopted on 19.11.2015. List of Questions adopted on 23.07.2015.

4.1.2. 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 packsize of 30 doses for each current strength (50 micrograms/dose, 100 micrograms/dose & 200 micrograms/dose).
Type IA cat. B.II.d.1.a) – To tighten the assay release limit of the multi-dose finished product to 98.0%-102.0%.
Type IA cat. B.II.f.1.a) 1. – To reduce the shelf life of all strengths of the multi-dose finished product to 24 months.

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

Action: For adoption

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

4.1.3. Lojuxta - lomitapide - EMEA/H/C/002578/X/0016

Aegerion Pharmaceuticals Limited

Rapporteur: Pieter de Graeff,

Scope: "The applicant has submitted an application for a line extension to include 30 mg, 40 mg and 60 mg hard capsules."

Action: For adoption

List of Questions adopted on 24.09.2015.

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

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

Eisai Europe Ltd.

Rapporteur: Robert James Hemmings, PRAC Rapporteur: Julie Williams

Scope: "Annex 1_2.(c) - To add a new strength of 0.5 mg/ml for Fycompa finished product (EU/1/12/776/024).
Annex 1_2.(d) - To add a new pharmaceutical form, oral solution, to the one currently approved (EU/1/12/776/024)."

Action: For adoption

4.3.2. 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
In addition, the following changes have been grouped with this extension application:
B.I.a.1.e – To add Boehringer Ingelheim (BIB), Pharma GmbH & Co. KG, Birkendorfer Straße 65, 88397, Biberach an der Riss, Germany as additional site responsible for the manufacturing and quality control of the active substance.

B.I.a.1.j – To add Schering Plough Brinny Co., Ballinacurra Road, Innishannon, County

Cork, Ireland as additional site responsible for the quality control of the active substance.

B.I.a.1.z – To add Biotec House, Central Park , Western Avenue, Bridgend , Industrial Estate, Bridgend, CF31 3RT, UK as a site responsible for storage of the active substance.

B.I.a.1.k – To add Biostorage Technologies, 2910 Fortune Circle W, Suite E, Indianapolis, IN 46241, U.S as additional site responsible for the storage of the WCB and MCB."

Action: For adoption

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

Janssen-Cilag International NV

Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Qun-Ying Yue

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

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

A.2.a - Change of the Name of the Medicinal Product (Section 1 of the SmPC) from "Paliperidone Janssen"

6 x C.I.7.b - deletion of all 6 currently authorised Paliperidone Janssen dosage strengths (i.e. Paliperidone Janssen 25 mg, 50 mg, 75 mg, 100 mg, 150 mg and 150 mg / 100 mg - EU/1/14/971/001-006)."

Action: For adoption

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. Cyramza - ramucirumab - Orphan - EMEA/H/C/002829/II/0003

Eli Lilly Nederland B.V.

Rapporteur: Pieter de Graeff, Co-Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include new indication for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with progression after platinum-based chemotherapy for CYRAMZA.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, one minor typographical error was corrected in section 4.2 of the SmPC."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 24.09.2015, 21.05.2015.

5.1.2. Cyramza - ramucirumab - Orphan - EMEA/H/C/002829/II/0004

Eli Lilly Nederland B.V.

Rapporteur: Pieter de Graeff, Co-Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include a new indication for Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to correct minor editorial mistakes."

Action: For adoption

Request for Supplementary Information adopted on 24.09.2015, 25.06.2015.

5.1.3. Ferriprox - deferiprone - EMEA/H/C/000236/II/0103

Apotex Europe BV

Rapporteur: Pierre Demolis, Co-Rapporteur: Concepcion Prieto Yerro

Scope: "Extension of Indication to include a new indication for Ferriprox in combination with another chelator.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the MAH took the opportunity of this procedure to update the Product Information in compliance with the QRD template version 9.1 and combine the SmPC for the 500mg and 1000mg tablets. The contact details of France and Portugal have been updated in the PL."

Action: For adoption

5.1.4. Gazyvaro - obinutuzumab - Orphan - EMEA/H/C/002799/II/0007

Roche Registration Ltd

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Julie Williams

Scope: "Extension of indication to add the treatment of patients with follicular lymphoma based on the results of the pivotal study GAO4753g. Consequently, updates to sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 of the SmPC, the Package Leaflet and RMP have been proposed. Furthermore, the MAH took the opportunity to make minor editorial changes to sections 4.4, 4.6, 5.3 and 6.6 of the SmPC."

Action: For adoption

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

AbbVie Ltd.

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

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

Action: For adoption

5.1.6. Nplate - romiplostim - Orphan - EMEA/H/C/000942/II/0051

Amgen Europe B.V.

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

Dolores Montero Corominas

Scope: “Extension of Indication to include second line treatment of all non-splenectomised patients (including those without a contraindication to surgery). As a consequence, section 4.1 of the SmPC has been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to update the contact details of the local representatives in Croatia and Italy in the Package Leaflet.”

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015.

5.1.7. Revolade - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/II/0023

Novartis Europharm Ltd

Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Greg Markey, Scope: “Extension of Indication to extend the use of Revolade to non-splenectomized patients.
As a consequence, section 4.1 of the SmPC is updated. The Package Leaflet is updated in accordance.”

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015, 25.06.2015.

5.1.8. Ruconest - conestat alfa - EMEA/H/C/001223/II/0031

Pharming Group N.V

Rapporteur: Greg Markey

Scope: “Extension of Indication to include adolescents in the treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. As a consequence sections 4.1, 4.2, and 5.1 of the SmPC have been updated. The Package Leaflet is updated in accordance.”

Action: For adoption

5.1.9. Tarceva - erlotinib - EMEA/H/C/000618/II/0043

Roche Registration Ltd

Rapporteur: Sinan B. Sarac

Scope: “Modification of the indication to limit maintenance treatment to NSCLC patients with an EGFR-activating mutation based on the data from study BO25460 (IUNO). Consequently, SmPC sections 4.1, 4.8 and 5.1 have been updated. The Package leaflet is updated accordingly.”

Action: For adoption

5.1.10. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0012

PTC Therapeutics International Limited

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Concepcion Prieto Yerro, PRAC

Rapporteur: Sabine Straus

Scope: “Extension of indication for Translarna to include the treatment of cystic fibrosis resulting from a nonsense mutation in at least one allele of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Consequently, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC were updated. The Package leaflet and RMP are being updated accordingly.
The MAH took also the opportunity to implement the QRD template v9.1. and proposed combined SmPC for Translarna 125 mg, 250 mg and 1000 mg granules for oral suspension. Minor editorial changes have been introduced throughout the PI.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

AstraZeneca AB

Rapporteur: Greg Markey

Scope: “Extension of Indication to include new population, children over the age of 2 months and adolescents, for Zinforo. As a consequence, sections 4.1, 4.2, 5.2, 5.3 and 6.6 of the SmPC are updated with new information on dosing, PK and pre-clinical safety. The Package Leaflet is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.”

Action: For adoption

Request for Supplementary Information adopted on 24.09.2015.

5.1.12. 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

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

Gilead Sciences International Ltd

Rapporteur: Kristina Dunder, PRAC Rapporteur: Rafe Suvarna

Scope: “Extension of Indication to include new indication for Zydelig to include the combination of idelalisib with ofatumumab. As a consequence, sections 4.1, 4.8 and 5.1 of

the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for United Kingdom and Ireland in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 22.10.2015.

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

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

Bristol-Myers Squibb Pharma EEIG

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

Scope: Assessment of similarity

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

Action: For adoption

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

MAH: Janssen-Cilag International NV,

Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams,

Scope: Assessment of similarity

"Extension of Indication to broaden the existing indication for chronic lymphocytic leukaemia (CLL) to include all previously untreated patients including those with 17p deletion or TP53 mutation based on the results from the final CSR of study PCYC-1115-CA (MEA 021) for Imbruvica. As a consequence, sections 4.1, 4.6, 4.8, 5.1 and 5.3 of the SmPC are being updated. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes to the SmPC and to bring Annex II in line with the latest QRD template version 9.1. Moreover, the updated RMP version 5.0 has been submitted."

Action: For adoption

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

NPS Pharma Holdings Limited

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

Scope: Letter from the MAH dated November 2015 requesting extension of timeframe to submit responses to the Request for Supplementary Information adopted on 19.11.2015

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

Action: For adoption

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

Biogen Idec Ltd

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

Scope: Letter from the MAH dated 24 November 2015 requesting extension of timeframe to submit responses to the Request for Supplementary Information adopted on 19.11.2015

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

Action: For adoption

Request for Supplementary Information adopted on 25.06.2015.

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

6. Ancillary medicinal substances in medical devices

6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

6.2. 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

9. Post-authorisation issues

9.1. Post-authorisation issues

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

Bayer Pharma AG, prevention of venous thromboembolism (VTE)

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

Scope: Update on ROCKET Trial.

Action: For discussion

Request for Supplementary Information adopted on 19 November 2015.

9.1.2. ChondroCelect- Characterised Autologous Cartilage Cells Expressing A Specific Marker Profile - (EMEA/H/C/000878- MEA 16.5 and 18.5)

TiGenix NV, Repair of single symptomatic cartilaginous defects

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

Scope: Opinion

Scope 16.5.: randomised control trial protocol TIG/ACT/04/2009

Scope 18.5.: non-interventional registry of ChondroCelect, study TGX001-2011 & randomised controlled study in small lesions using microfracture as comparator

Revision of post authorisation measures

Action: For adoption

9.1.3. Aclasta - zoledronic acid - EMEA/H/C/000595/II/0059

Novartis Europharm Ltd,

Rapporteur: Kristina Dunder,

Scope: Opinion

“Update of section 4.4 of the SmPC with information on osteonecrosis of other bones in patients treated with Aclasta. The Package leaflet is proposed to be updated accordingly. Furthermore, the MAH took the opportunity to align the product information with the latest QRD template version 9.1.”

Action: For adoption

9.1.4. Gilenya - fingolimod - EMEA/H/C/002202/II/0037

Novartis Europharm Ltd,

Rapporteur: Pierre Demolis,

Scope: Opinion or Request for Supplementary information

“Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information to include additional warning and guidance on PML. The Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 22.10.2015.

Action: For adoption

9.1.5. Exviera / Viekirax - dasabuvirombitasvir / paritaprevir / ritonavir - EMEA/H/C/003837 EMEA/H/C/003839 / WS0873

AbbVie Ltd.,

Lead Rapporteur: Filip Josephson, Scope: Opinion or Request for Supplementary information

“Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to update the safety information based on post-marketing reports of hepatic decompensation and hepatic failure,

including liver transplantation or fatal outcomes, and to add a warning that Viekirax/Exviera is not recommended in patients with moderate hepatic impairment (Child-Pugh B). The Package Leaflet is updated accordingly."

Action: For adoption

10. Referral procedures

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

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

10.2.1. Desloratadine-containing products

Scope: Appointment of Rapporteurs, List of Questions and timetable

Prescription status of desloratadine-containing products

Action: For adoption

Letter from the BfArM in Germany dated 8 December 2015 requesting under article 5(3) scientific position of CHMP on desloratadine prescription status**.**

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

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

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

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

Chiesi group of companies and associated companiesRapporteur: Daniela Melchiorri, Co-Rapporteur: Martina Weise,Scope: Letter from the MAH dated 27 November 2015 requesting a 1-month extension of timeframe to respond to the List of Outstanding Issues adopted on 19 November 2015.

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

posology recommendations.

Action: For adoption

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

Revised timetable:

Submission of responses: 19 February 2016

Re-start of the procedure: 04 March 2016

Rapporteur and co-rapporteur assessment reports circulated to CHMP: 15 March 2016

CHMP member comments: 21 March 2016

Updated rapporteur and co-rapporteur assessment reports circulated to CHMP: 23 March 2016

Adoption of second list of outstanding issues / CHMP Opinion: March 2016 CHMP

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

Lundbeck group of companies and associated companies

Rapporteur: TBC,

Scope: Appointment of Rapporteurs, List of Questions and timetable

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

Letter from Greece dated 11 December 2015 notifying of the official referral under Article 30.

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

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

December 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 30-03 December 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

Scope: GMP inspections requested by CHMP during 2015

Action: For discussion

Scope: Results of sampling and testing programme 2014

Action: For discussion

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

13.2.1. ITF Briefing Meeting

Action: For adoption

13.2.2. ITF Briefing Meeting

Action: For adoption

13.2.3. ITF Briefing Meeting

Action: For adoption

13.2.4. Completed ITF Briefing Meetings in 2015

Action: For 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

2nd TC of the IPRF Nano Working Group on 12 November 2015

Action: For information

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Election of 5th CHMP co-opted member

The election of co-opted member is to take place at the December 2015 CHMP Plenary.

14.1.2. Update on the pilot on patient involvement at CHMP

Action: For discussion

14.1.3. Workshop on estimands to be held in EMA 25-26 February 2016

Action: For information

14.1.4. Workshop on DOACs held on 23 November 2015

Scope: Debriefing from the workshop and actions

Action: For discussion

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 30 November-03 December 2015

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update

Reports (EURD list) for December 2015

Action: For adoption

Scope: Review of governance for pharmacovigilance implementation

Action: For information

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 10-11 December 2015
Action: For information

Final CAT Summary of Outcomes of the November 2015 meeting

Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 23- 26 November 2015

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at December 2015 PDCO

Action: For information

Report from the PDCO meeting held on 10-12 December 2015

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 8-10 December 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 14-16 December 2015

Action: For information

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

14.3.1. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 30 November 3 December 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. Safety Working Party (SWP)

Work plan for the CHMP Safety Working Party for 2016 (EMA/CHMP/SWP/735015/2015)
Action: For adoption

Final minutes of WP meeting held by teleconference on 27 October 2015 (EMA/CHMP/SWP/713314/2015)

Action: For information

Final agenda of WP meeting held by teleconference on 24 November 2015 (EMA/CHMP/SWP/734639/2015): for information

Action: For information

14.3.3. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

Scope: Final minutes of WP meeting held by teleconference on 1 October 2015 (EMA/CHMP/BPWP/651517/2015)

Final agenda of WP meeting held face-to-face on 26-27 November 2015 (EMA/CHMP/BPWP/731509/2015)

Nomination of Dr. Anders Lindblom as the new Swedish member of BPWP, following the step down of Dr. Bengt Ljungberg (vice-chair)

Action: For information

14.3.4. Cardiovascular Working Party (CVSWP)

Election of the CVS WP Vice-Chair

Scope: Work plan for the CHMP Cardiovascular Working Party for 2016 (EMA/CHMP/728678/2015)

Action: For adoption

Scope: Final minutes of WP meeting held by teleconference on 30 September 2015 (EMA/665335/2015)

Action: for information

Scope: Final agenda of WP meeting held by face-to-face on 24 November 2015 (EMA/727463/2015): for information

Action: For information

Scope: Draft Table of Decisions of WP meeting held face-to-face on 24 November 2015 (EMA/779429/2015)

Action: For information

14.3.5. Central Nervous System Working Party (CNSWP)

Scope: Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy (EMA/CHMP/732154/2013)

Action: For adoption (final release)

Scope: Guideline on the clinical development of medicinal products intended for the treatment of pain (EMA/CHMP/970057/2011) 2nd draft

Action: For adoption for 3-months public consultation

Work plan for the CHMP Central Nervous System Working Party for 2016 (EMA/CHMP/735080/2015)

Action: For adoption

Scope: Final minutes of WP meeting held face-to-face on 7 October 2015 (EMA/665335/2015)

Action: For information

Scope: Final agenda of WP meeting held by teleconference on 8 December 2015 (EMA/737981/2015)

Action: For information

14.3.6. Modelling and Simulation Working Group (MSWG)

Scope: Work plan for the Modelling and Simulation Working Group 2016

Action: For adoption

14.3.7. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink

Scope: Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function (EMA/CHMP/83874/2014

- Overview of comments received (EMA/CHMP/725881/2015)

Action: For adoption

Scope: Work plan for the CHMP Pharmacokinetics Working Party for 2016

(EMA/CHMP/PKWP/671542/2015)

Action: For adoption

Draft agenda of PKWP meeting to be held by adobe on 07 December 2015 (EMA/737635/2015)

Action: For information

Scope: Minutes of the PKWP F2F meeting held on 21-22 October 2015 (EMA/720447/2015)

Action: For information

14.3.8. Biostatistics Working Party (BSWP)

Scope: Work plan for the CHMP Biostatistics Working Party for 2016

Action: For adoption

Scope: Draft Agenda of the BSWP meeting on 08 December 2015

Action: For information

14.3.9. Biosimilar Medicinal Products Working Party (BMWP)

Scope: Work plan for the CHMP Biosimilar Medicinal Products Working Party for 2016

Action: For adoption

Scope Draft Agenda of the BMWP meeting on 02 December 2015

Action: For information

14.3.10. Gastroenterology Drafting Group (Gastroenterology DG)

Scope: Work plan for the Gastroenterology Drafting Group for 2016

Action: For adoption

14.3.11. Infectious Diseases Working Party (IDWP)

Scope: Work plan for the CHMP Infectious Diseases Working Party for 2016

Action: For adoption

14.3.12. Vaccines Working Party (VWP)

Scope: Work plan for the CHMP Vaccines Working Party for 2016

Action: For adoption

Scope: Pentavac/Tetravac (Sanofi Pasteur MSD) - pentavalent combined vaccine (DTaP-IPV-Hib)/tetravalent combined vaccine (DTaP-IPV). Request from CMDh to CHMP. Response letter from CHMP

Action: For adoption

Position paper from VWP and BWP

14.3.13. Extrapolation Working Group

Scope: Status report on the Extrapolation Working Group activities in 2015

Action: For information

14.3.14. Quality Working Party (QWP)

Chair: Jean-Louis Robert,

Scope: QWP response to EDQM request for opinion on revision of tablet monograph (0478)

Action: For adoption

Scope: Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials – Revision

Action: For adoption for public consultation

Scope: QWP comments on EDQM enquiry on specification for sub-visible particles in eye drops and eye lotions

Action: For Adoption

Scope: Question and answer on the use of powders and granules in medicinal products composed of 100% active substance

Action: For adoption

Scope: Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances.

Action: For adoption

Scope: Minutes of the QWP Core Team Adobe meetings held on 11 November 2015

Action: For information

14.3.15. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni,

Scope: Points to consider on Frailty: Evaluation Instruments for Baseline Characterisation of Clinical trial populations (EMA/778709/2015)

Action: For adoption

14.3.16. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl,

Scope: Work plan for the CHMP Pharmacogenomics Working Party for 2016 (EMA/CHMP/PGWP/707191/2015)

Action: For adoption

Scope: Draft agenda of PGWP meeting to be held by adobe on 15 December 2015 (EMA/774558/2015): for information

Action: For information

14.3.17. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus / Nils Feltelius,

Scope: Work plan for the CHMP Rheumatology-Immunology Working Party for 2016 (EMA/CHMP/RIWP/649551/2015):

Action: For adoption

14.3.18. Biologics Working Party (BWP)

Chair: Sol Ruiz,

Scope: Guideline on Epidemiological Data on Blood Transmissible Infections and Overview stakeholder comments (EMA/CHMP/548524/2008. Rev)

Action: For adoption

Scope: BWP work plan for 2016 (EMA/CHMP/BWP/454652/2015)

Action: For adoption

Scope: Draft agenda for BWP face-to-face meeting to be held 18-20 January 2016

(EMA/CHMP/BWP/798829/2015)

Action: For information

Scope: Final minutes from face-to-face meeting held 12-14 October 2015 (EMA/CHMP/BWP/680074/2015)

Action: For information

14.3.19. Respiratory Drafting Group

Election of the Chair of the Respiratory drafting group

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

Expertise required: respiratory disease, cystic fibrosis, orally inhaled medicinal products, asthma, COPD

All CHMP members are invited to submit nominations of experts by 20 January 2015, EOB.

Scope: Work Plan for 2016

Action: For adoption

14.3.20. Radiopharmaceuticals Drafting Group

Work Plan for the Radiopharmaceuticals Drafting Group 2016

Action: For adoption

14.3.21. Excipients Drafting Group (ExcpDG)

Scope: Mandate of the ExcpDG (EMA/CHMP/74184/2015)

Action: For adoption

Scope: Proposed new core members (EMA/CHMP/658081/2015)

Action: For adoption

Call for expression of interest to be Chair or vice-Chair of the ExcpDG

Action: For information

Work plan for the CHMP Excipient Drafting Group for 2016 (EMA/CHMP/833588/2015)

Action: For adoption

Final minutes of DG meeting held by teleconference on 4 November 2015 (EMA/779764/2015)

Action: For information

Final agenda of DG meeting held by teleconference on 3 December 2015 (EMA/797739/2015)

Action: For information

14.4. Cooperation within the EU regulatory network

Scope: Letter from the European Commission, requesting that a definition for 'principal molecular structural features' as referred to in Art 3(3)c of Reg (EC) No 847/2000

Action: For adoption

14.5. Cooperation with International Regulators

14.5.1. Cooperation with WHO Cooperation with WHO on Facilitation of Registration of Centrally Authorised Products in Developing Countries

Scope: Update on Facilitation of Registration of Centrally Authorised Products in Developing Countries – Pilot Scheme

Action: For discussion

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

14.7. CHMP work plan

Scope: CHMP 2016 Work Plan

Action: For discussion

14.8. Planning and reporting

14.9. Others

15. Any other business

15.1. <AOB topic>

16. Explanatory notes

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

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

Oral explanations *(section 2)*

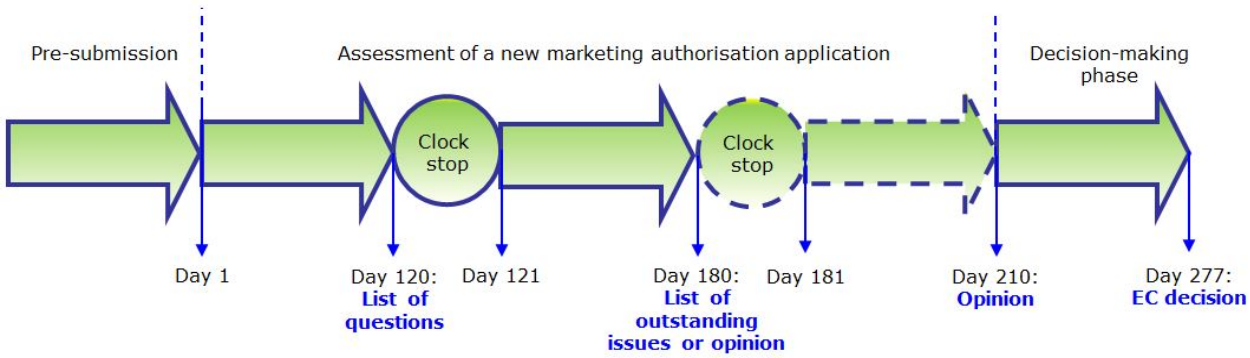
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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