21 August 2018
EMA/CHMP/565731/2018 Rev.1
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Agenda of CHMP written procedure* 20-23 August 2018

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

*** Written Procedure - comments on the draft documents should be forwarded to the Product Manager (PM) as identified in the CHMP agenda.**

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.

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Table of contents

1. Introduction

1.1. Adoption of agenda

CHMP agenda for 20-23 August 2018

1.2. Adoption of the minutes

The CHMP minutes from the July 2018 meeting will be adopted at the September CHMP Plenary (17 – 20 September 2018).

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

No items

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

No items

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)

No items

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)

No items

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

3.4.1. pegvaliase - Orphan - EMEA/H/C/004744

BioMarin International Limited; treatment of adults with phenylketonuria (PKU) who have inadequate blood phenylalanine control

Scope: Amendment of D120 LoQ which was adopted in July

Action: For adoption

List of questions adopted on 26.07.2018.

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

3.5.1. Exondys - eteplirsen - Orphan - EMEA/H/C/004355

AVI Biopharma International Ltd; treatment of Duchenne muscular dystrophy

Scope: Call for nominations for additional experts to the SAG Neurology

Action: For information

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

Opinion adopted on 31.05.2018. List of Outstanding Issues adopted on 14.12.2017. List of Questions adopted on 21.04.2017.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

No items

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

No items

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

No items

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

4.4.1. Dupixent - dupilumab - EMEA/H/C/004390/X/0004/G

sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to add a new strength of 200 mg solution for injection in pre-filled syringe with safety system (PFS-S) and pre-filled pen (PFP), grouped with a type II variation (C.I.6.a) to add the following indications:
- Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older, who are inadequately controlled with medium-to-high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment, including those with or without an eosinophilic phenotype;
- Maintenance therapy to improve lung function;
- Maintenance therapy to reduce oral steroid use and improve lung function in steroid-dependent asthma patients;
Based on the pivotal studies DRI12544, QUEST and VENTURE.
As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 have been updated and the Package Leaflet has been updated accordingly.
The RMP (version 2.0) is updated accordingly.
In addition, the MAH proposed to merge the SmPCs for the 200 mg and 300 mg strengths."

Request by the applicant dated 02.08.2018 for an extension to the clock stop to respond to the list of questions adopted on 26.07.2018.

Action: For adoption

List of question adopted on 26.07.2018

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

No items

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

No items

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. WS1372

OPDIVO - nivolumab - EMEA/H/C/003985/WS1372/0053
Yervoy - ipilimumab - EMEA/H/C/002213/WS1372/0057

Bristol-Myers Squibb Pharma EEIG

Lead Rapporteur: Jorge Camarero Jiménez, Lead Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include first-line treatment of adult patients with metastatic Non-Small Cell Lung Carcinoma (NSCLC) for OPDIVO and Yervoy; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add information from the pivotal study CA209227 (an open-label, randomised phase 3 trial of nivolumab, or nivolumab plus ipilimumab, or nivolumab plus platinum doublet chemotherapy versus platinum doublet chemotherapy in subjects with chemotherapy-naïve stage IV or recurrent NSCLC). The Package Leaflet and RMP (version 14.0 for Opdivo and version 21.0 for Yervoy) are updated in accordance. In addition, the MAH has taken the opportunity to introduce minor editorial and formatting revisions in the PI."

Request by the applicant dated 03.08.2018 for an extension to the clock stop to respond to the request for supplementary information adopted on 26.07.2018.

Action: For adoption

Request for Supplementary Information adopted on 26.07.2018

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

5.3.1. Blincyto - blinatumomab - Orphan - EMEA/H/C/003731/II/0011

Amgen Europe B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Eva Jirsová

Scope: “Extension of Indication to include the treatment of adults with minimal residual disease (MRD) positive B-cell precursor acute lymphoblastic leukaemia (ALL) for BLINCYTO; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add the new indication and its relevant posology, and to update the safety information. The Labelling is updated in accordance.
RMP version 4.0 is included in this submission.”

Action: Re-examination request, Appointment of Re-examination Rapporteurs

Opinion adopted on 26.07.2018. Oral Explanation held on 24.07.2018. Request for Supplementary Information adopted on 26.04.2018, 14.12.2017, 22.06.2017.

5.3.2. WS1278

OPDIVO - nivolumab - EMEA/H/C/003985/WS1278/0042
Yervoy - ipilimumab - EMEA/H/C/002213/WS1278/0053

Bristol-Myers Squibb Pharma EEIG

Lead Rapporteur: Paula Boudewina van Hennik, Lead Co-Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: “Extension of indication to include the combination treatment with nivolumab and ipilimumab of adult patients with intermediate/poor-risk advanced renal cell carcinoma. As a consequence sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the Opdivo and Yervoy SmPCs are updated. The Package Leaflet and the Risk Management Plan (version 19.0 for Yervoy and version 13.0 for Opdivo) are updated in accordance. In addition, the Worksharing applicant (WSA) took the opportunity to correct some typos throughout the Yervoy and Opdivo product information.”

Action: Re-examination request, Appointment of Re-examination Rapporteurs

Opinion adopted on 26.07.2018. Oral Explanation held on 25.07.2018. Request for Supplementary Information adopted on 31.05.2018, 22.02.2018.

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

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

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)

No items

8. Pre-submission issues

8.1. Pre-submission issue

No items

8.2. Priority Medicines (PRIME)

No items

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. VELCADE - bortezomib - EMEA/H/C/000539/II/0088

Janssen-Cilag International NV

Rapporteur: Daniela Melchiorri

Scope: “Update of sections 4.2 and 5.1 of the SmPC in order to add a new dosing schedule for VELCADE (bortezomib) in combination with melphalan and prednisone (VMP) for the treatment of patients with newly diagnosed multiple myeloma, who are not eligible for high-dose chemotherapy with hematopoetic stem cell transplant.

The proposed new dosing schedule is supported by analyses comparing the current approved VcMP schedule (from 26866138MMY3002 [VISTA] study) with pooled modified less intensive ("once-weekly") VcMP schedules (from 54767414MMY3007 [ALCYONE], GIMENA MM-03-05 [GIMENA]). Additional supportive efficacy and safety data come from GEM2005MAS65 [PETHEMA].

The PL (section 3) is amended accordingly.

In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the PL.”

Final documents including minor updates in assessment report following the adoption at the July 2018 Plenary. Request by the applicant dated 14.08.2018 for an extension to the clock stop to respond to the Request for Supplementary Information adopted on 26.07.2018.

Action: For adoption

Request for Supplementary Information adopted on 26.07.2018, 22.03.2018.

10. Referral procedures

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

No items

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

No items

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

No items

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

10.4.1. Perlinring 0.120mg/0.015mg per 24 hours Vaginal Delivery System - Etonogestrel and Ethinylestradiol - EMEA/H/A-29/1473

MAH: Actavis Group PTC EHF

Scope: Appointment of Rapporteurs, procedure timetable

UK/H/6234/001/DC

Action: For adoption

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

No items

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

10.6.1. Valsartan - EMEA/H/A-31/1471

CHMP Rapporteur: Daniela Melchiorri, CHMP Co-Rapporteur: Martina Weise

CHMP rapporteurs' preliminary joint assessment on risk adopted via written procedure on 02.08.2018

Action: For information

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

No items

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

No items

14.2.2. Committee for Advanced Therapies (CAT)

No items

14.2.3. Committee for Herbal Medicinal Products (HMPC)

No items

14.2.4. Paediatric Committee (PDCO)

No items

14.2.5. Committee for Orphan Medicinal Products (COMP)

No items

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

No items

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

14.3.1. Scientific Advice Working Party (SAWP)

No items

14.3.2. Name Review Group (NRG)

No items

14.3.3. Biologics Working Party (BWP)

No items

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

A. PRE SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Information related to pre-submission of initial applications cannot be released at the present time as these contain commercially confidential information.

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal

B.2.2. Renewals of Marketing Authorisations for unlimited validity

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

B.4. EPARs / WPARs

Braftovi - encorafenib - EMEA/H/C/004580 Pierre Fabre Medicament, treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Deferiprone Lipomed - deferiprone - EMEA/H/C/004710 Lipomed GmbH, treatment of iron overload in	For information only. Comments can be sent to the EPL in case necessary.

thalassemia major, Generic, Generic of Ferriprox, Generic application (Article 10(1) of Directive No 2001/83/EC)	
Dexxience - betrixaban - EMEA/H/C/004309 Portola Pharma UK Limited, treatment of prophylaxis of venous thromboembolism (VTE), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Eladynos - abaloparatide - EMEA/H/C/004157 Radius International Ltd, treatment of osteoporosis, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Gefitinib Mylan - gefitinib - EMEA/H/C/004826 MYLAN S.A.S., treatment of non-small cell lung cancer, Generic, Generic of Iressa, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Hulio - adalimumab - EMEA/H/C/004429 Mylan S.A.S, treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Ilumetri - tildrakizumab - EMEA/H/C/004514 Almirall S.A, treatment of adults with moderate-to-severe plaque psoriasis, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Imfinzi - durvalumab - EMEA/H/C/004771 AstraZeneca AB, treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Kigabeq - vigabatrin - EMEA/H/C/004534, PUMA ORPHELIA Pharma SAS, Treatment in monotherapy of infantile spasms (West's syndrome) and resistant partial epilepsy in infants and children, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Kymriah - tisagenlecleucel - EMEA/H/C/004090, Orphan, ATMP	For information only. Comments can be sent to the EPL in case necessary.

Novartis Europharm Limited, treatment of B cell acute lymphoblastic leukaemia (ALL) and diffuse large B cell lymphoma (DLBCL), New active substance (Article 8(3) of Directive No 2001/83/EC)	
Lenalidomide Accord - lenalidomide - EMEA/H/C/004857 Accord Healthcare Limited, treatment of multiple myeloma, Generic, Generic of Revlimid, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Mektovi - binimetinib - EMEA/H/C/004579 Pierre Fabre Medicament, in combination with encorafenib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Onpattro - patisiran - EMEA/H/C/004699, Orphan Alnylam Netherlands B.V., treatment of hereditary transthyretin-mediated amyloidosis., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Pelgraz - pegfilgrastim - EMEA/H/C/003961 Accord Healthcare Limited, treatment of neutropenia, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Slenyto - melatonin - EMEA/H/C/004425, PUMA RAD Neurim Pharmaceuticals EEC Ltd., treatment of insomnia in children with Autism Spectrum Disorders and neurogenetic diseases, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
UDENYCA - pegfilgrastim - EMEA/H/C/004413 ERA Consulting GmbH, treatment of neutropenia, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
Verzenios - abemaciclib - EMEA/H/C/004302 Eli Lilly Nederland B.V., treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally	For information only. Comments can be sent to the EPL in case necessary.

advanced or metastatic breast cancer, New active substance (Article 8(3) of Directive No 2001/83/EC)	
Xerava - eravacycline - EMEA/H/C/004237 Tetraphase Pharmaceuticals Ireland Limited, treatment of complicated intra-abdominal infections (cIAI) in adults, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.
YESCARTA - axicabtagene ciloleucel - EMEA/H/C/004480, Orphan, ATMP Kite Pharma EU B.V., treatment of diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the EPL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time as these contain commercially confidential information.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0082 AstraZeneca AB, Rapporteur: Bart Van der Schueren Opinion adopted on 03.08.2018. Request for Supplementary Information adopted on 28.06.2018.	Positive Opinion adopted by consensus on 03.08.2018. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

B.5.3. CHMP-PRAC assessed procedures

B.5.4. PRAC assessed procedures

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

B.5.8. Unclassified procedures and worksharing procedures of type I variations

B.5.9. Information on withdrawn type II variation / WS procedure

B.5.10. Information on type II variation / WS procedure with revised timetable

PRAC Led **Humira - adalimumab -** **EMEA/H/C/000481/II/0173** AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, “Submission of the final report from study BSRBR-RA (British Society for Rheumatology Biologics Registers Rheumatoid Arthritis). This is a registry in the UK, evaluating the influence of TNF inhibitor treatment on cancer incidence in RA patients with a history of malignancy. No changes to the PI are proposed.” Request for Supplementary Information adopted on 08.03.2018.	Request for an extension to the clock stop to respond to the request for supplementary information adopted on 08.03.2018.
WS1393/G **Hexacima-** **EMEA/H/C/002702/WS1393/0080/G** **Hexaxim-** **EMEA/H/W/002495/WS1393/0085/G** **Hexyon-** **EMEA/H/C/002796/WS1393/0084/G** Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 19.07.2018.	Request for an extension to the clock stop to respond to the request for supplementary information adopted on 19.07.2018.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

B.6.1. Start of procedure for New Applications: timetables for information

glucagon - EMEA/H/C/003848 treatment of severe hypoglycaemia
erlotinib - EMEA/H/C/005071

treatment of lung and pancreatic cancers
emapalumab - EMEA/H/C/004386, Orphan Novimmune B.V., treatment of paediatric patients with primary haemophagocytic lymphohistiocytosis (HLH).
rituximab - EMEA/H/C/004696 treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis
tigecycline - EMEA/H/C/005114 Treatment of soft tissue and intra-abdominal infections - complicated skin and soft tissue infections, excluding diabetic foot infections - complicated intra-abdominal infections should be used only in situations where it is known or suspected that other alternatives are not suitable
tobramycin - EMEA/H/C/005086 management of chronic pulmonary infection due to Pseudomonas aeruginosa in patients aged 6 years and older with cystic fibrosis (CF).

B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information

Aimovig - erenumab - **EMEA/H/C/004447/X/0001** Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, “Extension application to add a new strength of 140 mg.”

B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information

dapivirine - EMEA/H/W/002168, Article 58 Reducing the risk of HIV-1 infection via vaginal intercourse in sexually active HIV-uninfected women List of Questions adopted on 09.11.2017.
zanamivir - EMEA/H/C/004102 treatment of influenza A or B virus infection List of Questions adopted on 26.04.2018.

Dupixent - dupilumab - EMEA/H/C/004390/X/0004/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Kimmo Jaakkola, “Extension application to add a new strength of 200 mg solution for injection in pre-filled syringe with safety system (PFS-S) and pre-filled pen (PFP), grouped with a type II variation (C.I.6.a) to add the following indications: - Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older, who are inadequately controlled with medium-to-high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment, including those with or without an eosinophilic phenotype; - Maintenance therapy to improve lung function; - Maintenance therapy to reduce oral steroid use and improve lung function in steroid-dependent asthma patients; Based on the pivotal studies DRI12544, QUEST and VENTURE. As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 have been updated and the Package Leaflet has been updated accordingly. The RMP (version 2.0) is updated accordingly. In addition, the MAH proposed to merge the SmPCs for the 200 mg and 300 mg strengths.” List of Questions adopted on 26.07.2018.	See 4.4.1
botulinum toxin type a - EMEA/H/C/004587 temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows List of Questions adopted on 09.11.2017.	
lorlatinib - EMEA/H/C/004646 treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) List of Questions adopted on 31.05.2018.	
lusutrombopag - EMEA/H/C/004720 treatment of thrombocytopenia List of Questions adopted on 31.05.2018.	
lanadelumab - EMEA/H/C/004806, Orphan Shire Pharmaceuticals Ireland Limited,	

prevention of angioedema attacks, treatment of angioedema attacks
List of Questions adopted on 26.06.2018.

treosulfan - EMEA/H/C/004751, Orphan
medac Gesellschaft fur klinische Spezialpraparate mbH, conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT)
List of Questions adopted on 31.05.2018.

B.6.4. Annual Re-assessments: timetables for adoption

Atriance - nelarabine - EMEA/H/C/000752/S/0044
Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Anette Kirstine Stark

Brineura - cerliponase alfa - EMEA/H/C/004065/S/0009, Orphan
BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Ulla Wändel Liminga

IMVANEX - modified vaccinia ankara virus - EMEA/H/C/002596/S/0037
Bavarian Nordic A/S, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams

Lojuxta - lomitapide - EMEA/H/C/002578/S/0032
Aegerion Pharmaceuticals Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst

Naglazyme - galsulfase - EMEA/H/C/000640/S/0073
BioMarin International Limited, Rapporteur: Greg Markey, PRAC Rapporteur: Patrick Batty

B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed

Anoro Ellipta - umeclidinium / vilanterol - EMEA/H/C/002751/R/0022
Glaxo Group Ltd, Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Amelia Cupelli

Caprelsa - vandetanib -

EMEA/H/C/002315/R/0032
Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ghania Chamouni

Hemangiol - propranolol - EMEA/H/C/002621/R/0018
PIERRE FABRE DERMATOLOGIE, Rapporteur: Joseph Emmerich, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Eva A. Segovia

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0021, Orphan, ATMP
Chiesi Farmaceutici S.p.A., Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Julie Williams

Incruse Ellipta - umeclidinium bromide - EMEA/H/C/002809/R/0021
Glaxo Group Ltd, Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Nithyanandan Nagercoil, PRAC Rapporteur: Amelia Cupelli

Laventair Ellipta - umeclidinium / vilanterol - EMEA/H/C/003754/R/0025
Glaxo Group Ltd, Duplicate, Duplicate of Anoro Ellipta, Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Amelia Cupelli

Qutenza - capsaicin - EMEA/H/C/000909/R/0047
Grunenthal GmbH, Rapporteur: Bruno Sepodes, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Ana Sofia Diniz Martins

Renvela - sevelamer carbonate - EMEA/H/C/000993/R/0046
Genzyme Europe BV, Rapporteur: Bart Van der Schueren, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Laurence de Fays

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

Cyramza - ramucirumab - EMEA/H/C/002829/II/0027
Eli Lilly Nederland B.V., Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur:

Kolbeinn Gudmundsson (IS) (MNAT with IS for Coordination, IS for Clinical Safety, IS for Clinical Efficacy, FI for Quality, FI for Non-Clinical, LT for Clinical Pharmacology), PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of Indication to include Cyramza indicated as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have an alpha fetoprotein (AFP) of ≥ 400 ng/mL, after prior sorafenib therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.11 and 5.2 of the SmPC are updated in accordance. The Package Leaflet is updated in accordance. RMP version 8.1 has been submitted." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0060 Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Extension of Indication to include, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous NSCLC in adults for Keytruda. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Additionally, editorial corrections to section 5.1 of the SmPC are introduced (concerning the procedure EMEA/H/C/003820/II/0052). The RMP version 20.1 has also been submitted."	
Revlimid - lenalidomide - EMEA/H/C/000717/II/0102/G, Orphan Celgene Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ghania Chamouni, "Extension of indication to include treatment with Revlimid in combination with bortezomib and dexamethasone of adult patients with previously untreated multiple myeloma. As a consequence, the MAH submitted a request to add 7-capsule pack sizes for the 7.5 mg, 20 mg and 25 mg strengths of Revlimid (lenalidomide) to support the proposed posology and lenalidomide dose modification. Sections 4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the SmPC are	

updated; the Package Leaflet is updated in accordance. Additionally, minor editorial changes have been introduced throughout the PI and annex II key elements of the RMM have been updated to include information on timing of blood and semen donation in line with the SmPC section 4.4.
An updated RMP (version 36.1) has also been submitted."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0014
Roche Registration GmbH, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Extension of Indication to include Tecentriq in combination with bevacizumab, is indicated for the first-line treatment of patients with unresectable locally advanced or metastatic renal cell carcinoma (RCC) whose tumours have a PD-L1 expression ≥ 1%. As a consequence, section 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated in order to add updated safety and efficacy information.
The Package Leaflet is updated in accordance.
RMP version 5.0 has been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Ceprotin - human protein C - EMEA/H/C/000334/II/0106/G
Baxter AG, Rapporteur: Jan Mueller-Berghaus

Ceprotin - human protein C - EMEA/H/C/000334/II/0107/G
Baxter AG, Rapporteur: Jan Mueller-Berghaus

Entecavir Accord - entecavir - EMEA/H/C/004458/II/0001
Accord Healthcare Limited, Generic, Generic of Baraclude, Rapporteur: Ewa Balkowiec Iskra

Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0107
Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege

Flixabi - infliximab - EMEA/H/C/004020/II/0031
Samsung Bioepis UK Limited, Rapporteur: Jan Mueller-Berghaus

HBVAXPRO - hepatitis B vaccine (rDNA) - EMEA/H/C/000373/II/0064
MSD Vaccins, Rapporteur: Jan Mueller-Berghaus, “Update of section 6.5 of the SmPC in order to update the storage information for HBVAXPRO. The MAH took the opportunity to reflect sodium warnings into the product information and to add in the labelling a special warning related to latex and allergic reactions. The package leaflet is updated accordingly.”

Levemir - insulin detemir - EMEA/H/C/000528/II/0089
Novo Nordisk A/S, Rapporteur: Sinan B. Sarac

Orencia - abatacept - EMEA/H/C/000701/II/0120/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola

Orphacol - cholic acid - EMEA/H/C/001250/II/0025, Orphan
Laboratoires CTRS, Rapporteur: Robert James Hemmings

Respreeza – human alpha-1-proteinase inhibitor - EMEA/H/C/002739/II/0024
CSL Behring GmbH, Rapporteur: Kristina Dunder

Thyrogen - thyrotropin alfa - EMEA/H/C/000220/II/0099/G
Genzyme Europe BV, Rapporteur: Peter Kiely

Vimpat - lacosamide - EMEA/H/C/000863/II/0074/G
UCB Pharma S.A., Rapporteur: Filip Josephson

Xofigo - radium-223 - EMEA/H/C/002653/II/0034
Bayer AG, Rapporteur: Harald Enzmann

Yargesa - miglustat - EMEA/H/C/004016/II/0004
JensonR+ Limited, Generic, Generic of Zavesca, Rapporteur: Milena Stain

WS1438/G
Hexacima- EMEA/H/C/002702/WS1438/0083/G
Hexaxim- EMEA/H/W/002495/WS1438/0088/G
Hexyon- EMEA/H/C/002796/WS1438/0087/G

Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS1462
Rixathon-
EMEA/H/C/003903/WS1462/0014
Riximyo-
EMEA/H/C/004729/WS1462/0014
Sandoz GmbH, Lead Rapporteur: Jan Mueller-Berghaus

B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Adenuric - febuxostat -
EMEA/H/C/000777/II/0051
Menarini International Operations Luxembourg S.A., Rapporteur: Andrea Laslop, "Update of section 5.1 of the SmPC in order to include the results of the clinical safety study CARES (TMX-67_301), to compare the cardiovascular outcomes of febuxostat and allopurinol in subjects with gout and cardiovascular comorbidities; this is a Multicenter, Randomized, Active-Control, Phase 3B Study. In addition, the Marketing authorisation holder (MAH) took the opportunity to provide a consolidated Module 2.7.6 in order to list all the synopsis of individual studies in a unique tabular format."

Brineura - cerliponase alfa -
EMEA/H/C/004065/II/0007, Orphan
BioMarin International Limited, Rapporteur: Martina Weise, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the safety information of Brineura in relation to device-related complications and meningitis, and to include meningitis as a possible adverse reaction, based on data collected from clinical trials and post-marketing experience. The package leaflet is updated accordingly."

Brineura - cerliponase alfa -
EMEA/H/C/004065/II/0011, Orphan
BioMarin International Limited, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC to include a warning in relation to the access device use life following a review of the global safety database for all device-related events. The PL is updated accordingly."

Cetrotide - cetrorelix -
EMEA/H/C/000233/II/0068
Merck Europe B.V., Rapporteur: Martina Weise, "Update of section 4.2 of the SmPC based on literature review to add an alternative option for the treatment initiation to start once the leading follicle(s) reach a size that could lead to premature LH (Luteinizing Hormone) surge and ovulation.
The Package Leaflet (PL) is updated in accordance. Correction in section 3 of the PL to regarding the timing of ovulation induction.
In addition, the Marketing authorisation holder (MAH) took the opportunity to delete the list of local representatives in the Package Leaflet.
Furthermore, the PI is brought in line with the latest QRD template version 10.0."

Darzalex - daratumumab -
EMEA/H/C/004077/II/0019, Orphan
Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "Update of sections 4.2, 4.8 and 5.2 of the SmPC in order to include the possibility for a split first dose for the treatment of patients with multiple myeloma, based on the Phase 1b open-label, nonrandomized, multicenter Study 54767414MMY1001. The package leaflet is updated accordingly."

Ivemend - fosaprepitant -
EMEA/H/C/000743/II/0040
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, "Update of sections 4.4 of the SmPC in order to update the safety information related to Infusion Site Reactions (ISR) based on reports of post-marketing experience resulting the cumulative search of the company global safety data base for serious adverse events (interventional, spontaneous, literature and non-interventional study reports) which led to a safety labelling change notification issued by the FDA on the 23rd January2018; the Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include edits in the SmPC previously and in the Package Leaflet."

Kuvan - sapropterin -
EMEA/H/C/000943/II/0060, Orphan
BioMarin International Limited, Rapporteur:

Peter Kiely, “Update of the section 4.8 of the Summary of Product Characteristics (SmPC) to add oesophagitis as a new adverse drug reaction with a frequency unknown. The Package Leaflet (PL) is updated accordingly and editorial changes are made in section 4 of the PL.”	
Kuvan - sapropterin - EMEA/H/C/000943/II/0061, Orphan BioMarin International Limited, Rapporteur: Peter Kiely, “Update of section 5.2 of the Summary of Product Characteristics (SmPC) for Kuvan in order to update the information related to the interaction with digoxin (P-gp) when administered concomitantly based on pharmacokinetic study in healthy volunteers.”	
Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0035 GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus, “Submission of the final report from study MALARIA-071. This is a phase IIA, open-label, controlled, single-centre, single-country study, to evaluate efficacy, safety, reactogenicity and immunogenicity of GSK Biologicals’ candidate malaria vaccine in healthy malaria-naïve adults.”	
Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0083 Pfizer Europe MA EEIG, Rapporteur: Greg Markey, “Update of section 4.4 of the SmPC in order to include a safety warning of the risk for invasive disease caused by Meningococcal polysaccharide serogroups A, C, W-135 and Y because of the use of Nimenrix with concomitant treatment of eculizumab.”	
Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0084 Pfizer Europe MA EEIG, Rapporteur: Greg Markey, “Update of section 4.2 of the SmPC in order to update the posology information in infants, following the final results from study MenACWY-TT-087 (Study 087); this is a phase IIIb, controlled, randomised, open study aimed	

to demonstrate the immunogenicity and safety of Nimenrix in healthy infants, given on a 3+1 primary and booster (2, 4, 6 and 15-18 months of age), a 1+1 primary and booster (6 and 15-18 months of age) or as a single dose at 15-18 months of age. The Package Leaflet is updated accordingly. The MAH took the opportunity to include editorial changes in sections 4.4 and 4.8 of the SmPC."	
RAVICTI - glycerol phenylbutyrate - EMEA/H/C/003822/II/0023, Orphan Horizon Pharma Ireland Limited, Rapporteur: Greg Markey, "Update of section 5.1 of the Summary of Product Characteristics (SmPC) in order to update the efficacy and safety information based on study HPN-100-011, a non randomised, open-label safety extension study on the long term use of HPN-100 in Urea Cycle Disorders. In addition, QRD changes are made in Annex IIIA related to the addition of section 17 and 18 and in line with the QRD template version 10.0"	
Rubraca - rucaparib - EMEA/H/C/004272/II/0002, Orphan Clovis Oncology UK Limited, Rapporteur: Jorge Camarero Jiménez, "Submission of the final study report (QS-CLV-010) on the exploratory population pharmacokinetic analysis of rucaparib undertaken to test additional semi-mechanistic absorption and distribution models."	
Stelara - ustekinumab - EMEA/H/C/000958/II/0066 Janssen-Cilag International NV, Rapporteur: Greg Markey, "Update of section 4.8 of the SmPC to add allergic alveolitis and eosinophilic pneumonia as rare adverse reaction. The PL is updated accordingly."	
Stribild - elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil - EMEA/H/C/002574/II/0097 Gilead Sciences Ireland UC, Rapporteur: Robert James Hemmings, "Submission of the final report from study GS-US-236-0112, a phase 2/3, open-label study of the pharmacokinetics, safety and antiviral activity of the	

elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate single tablet regimen (STR) in HIV-1 infected antiretroviral treatment-naive adolescents. This submission fulfils the post-authorisation measures MEA 019 and P46 020."

Sutent - sunitinib - EMEA/H/C/000687/II/0070

Pfizer Limited, Rapporteur: Daniela Melchiorri, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to include paediatric study results (from studies A6181196 and ACNS1021) performed in compliance with a paediatric investigation plan (PIP)."

TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0054/G

Biogen Idec Ltd, Rapporteur: Martina Weise, "Type II grouped variation (3xC.I.13) for the submission of results of the below listed studies in order to fulfil LEG 004:
1. RSCH-2018-30: In vitro transcriptional profiling feasibility pilot study to determine the mechanism of action for lymphopenia in dimethyl fumarate-treated patients.
2. DMF-109MS301: Ex vivo transcriptional profiling study to assess the transcriptional changes induced by DMF in whole blood in 109MS301 and 109MS302 cohorts.
3. NLD-BGT-15-10945 (kinetic study): Characterisation of the immune-modulatory effects of Tecfidera in multiple sclerosis patients: exploration of drug mechanism and methodological feasibility."

Viekirax - ombitasvir / paritaprevir / ritonavir - EMEA/H/C/003839/II/0048

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Submission of the final report from study M13-101 listed as a category 3 study in the RMP. This is an open-label study to examine the safety, antiviral activity and pharmacokinetics of 12 weeks of paritaprevir/ritonavir/ombitasvir in combination with Peginterferon α-2a and Ribavirin (PegIFN/RBV) in Chronic Hepatitis C Virus (HCV) infected patients who had experienced virologic failure while participating in a previous MAH combination study."

WS1454

Zypadhera-
EMEA/H/C/000890/WS1454/0035
Zyprexa-
EMEA/H/C/000115/WS1454/0127
Zyprexa Velotab-
EMEA/H/C/000287/WS1454/0095
Eli Lilly Nederland B.V., Duplicate, Duplicate of Olansek (SRD), Lead Rapporteur: Outi Mäki-Ikola, “Update section 4.8 of the SmPC to add stuttering as adverse drug reaction based on data from clinical trials and spontaneous reporting. PL is updated accordingly. In addition, the MAH took this opportunity to revised wording of section 5.2 for smokers to improve clarity.”

WS1472
Exviera-EMEA/H/C/003837/WS1472/0040
Viekirax-
EMEA/H/C/003839/WS1472/0049
AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Filip Josephson, “Submission of the final report from study M12-999 listed as a category 3 study in the RMP. This is an open-label, phase 2 study to evaluate the safety and efficacy of the combination of of ombitasvir/paritaprevir/ritonavir with or without dasabuvir and with or without ribavirin (RBV) in adult liver or renal transplant recipients with Hepatitis C Virus (HCV) GT1 or GT4 infection (CORAL I).”

WS1473
Exviera-EMEA/H/C/003837/WS1473/0041
Viekirax-
EMEA/H/C/003839/WS1473/0050
AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Filip Josephson, “Submission of the final report from study M14-004 listed as a category 3 study in the RMP. This is a multipart, open-label study to evaluate the safety and efficacy of ombitasvir/paritaprevir/ritonavir with or without dasabuvir coadministered with and without ribavirin in adults with Genotype 1 or 4 Chronic Hepatitis C Virus infection and Human Immunodeficiency Virus, Type 1 co-infection (TURQUOISE-I).”

WS1474/G
Prezista-
EMEA/H/C/000707/WS1474/0098/G

Rezolsta-
EMEA/H/C/002819/WS1474/0027/G
Symtuza-
EMEA/H/C/004391/WS1474/0011/G
Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, "C.I.4 Update sections 4.3 and 4.5 of the SmPC of Prezista, Rezolsta and Symtuza to implement a new contraindication for the concomitant use with dabigatran and to add information regarding potential interaction with the edoxaban and dabigatran. The Package Leaflets are updated accordingly.
C.I.4 Update section 4.5 of the SmPC of Prezista, Rezolsta and Symtuza to add information regarding potential interaction with Hepatitis C virus direct-acting antivirals: glecaprevir/pibrentasvir (concomitant administration not recommended). The Package Leaflets are updated accordingly."

B.6.10. CHMP-PRAC assessed procedures

Avastin - bevacizumab -
EMEA/H/C/000582/II/0106/G
Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Doris Stenver, "1) Type II Variation (C.I.4): Update of section 5.1 of the SmPC to reflect final overall survival data from the long-term follow-up study JO25567 in order to fulfil ANX 085 for study JO29424.
2) Type IB Variation (C.I.11.z): Change in the deadline for the fulfilment of ANX 086 from Q4 2018 to Q2 2019.
Annex II.D and the RMP (ver 29.0) have been updated accordingly. The RMP is submitted according to template Rev 2 and consolidates the approved versions (27.1 & 28.1)."

ELOCTA - efmoroctocog alfa -
EMEA/H/C/003964/II/0026
Swedish Orphan Biovitrum AB (publ), Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Julie Williams, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add a statement for a once-weekly prophylaxis dose and to update the safety information based on the final results from study 8HA01EXT listed as a category 3 study in the RMP; this is a interventional study that evaluated the long-

term safety (particularly immunogenicity) and efficacy of ELOCTA in the prevention and treatment of bleeding episodes and for perioperative management. This variation is a follow-up of P46/005 submitted on 16.04.18 RMP version 2.1 was submitted and followed revision 2 of the template."

Entyvio - vedolizumab - EMEA/H/C/002782/II/0034

Takeda Pharma A/S, Rapporteur: Greg Markey, PRAC Rapporteur: Adam Przybylkowski, "Update of section 5.1 of the SmPC in order to provide the final efficacy results up to week 348 regarding clinical study c13008, listed as a category 3 study in the RMP. This is a Phase 3, Open-label Study to Determine the Long-term Safety and Efficacy of Vedolizumab in subjects with Ulcerative Colitis and Crohn's Disease. The RMP version 4 has also been submitted."

Erbitux - cetuximab - EMEA/H/C/000558/II/0082

Merck KGaA, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "C.I.4) To update sections 4.4 and 4.8. of the SmPC regarding the existing warning on Interstitial lung disease (ILD), by specifying potentially fatal ILD outcome, patients with contributory factors at risk of fatal events and need for close monitoring of these patients.
RMP version 19.0 has been submitted in relation to the above changes and also to include changes recommended in latest PSUSA.
MAH also took the opportunity to update Annex II-D to delete an obsolete sentence which refers to an RMP to be submitted in 2014."

IMVANEX - modified vaccinia ankara virus - EMEA/H/C/002596/II/0035

Bavarian Nordic A/S, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, "Update of sections 4.4., 4.8 and 5.1 of the SmPC in order to update the safety information and to add urticaria as an adverse reaction following the final results from study POX-MVA-037 (phase II, randomized, open-label, multicenter trial designed to evaluate the safety and immunogenicity of IMVANEX (MVA-BN smallpox vaccine) when increasing the dose or the number of injections compared with the

standard 2-dose regimen in a population of adult, vaccinia naive, immunocompromised subjects with human immunodeficiency virus (HIV) infection) listed as a category 3 study in the RMP (described as post authorisation MEA 007); The RMP version 7.1 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10."	
IMVANEX - modified vaccinia ankara virus - EMEA/H/C/002596/II/0036 Bavarian Nordic A/S, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update the safety information and to provide confirmation in terms of immunogenicity based on the results from study (POX-MVA-006) (a randomized, open-label phase III non-inferiority trial to compare indicators of efficacy for smallpox vaccine to the US licensed replicating smallpox vaccine in 18-42 year old healthy vaccinia-naïve subjects) listed as an obligation in the Annex II (ANX 004); the Package Leaflet is updated accordingly. The RMP version 7.2 has also been submitted."	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0058 Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Menno van der Elst, "Update of section 4.4 of the SmPC, to include in the existing warning regarding immune-related adverse reactions the fact that these reactions may be fatal in patients treated with pembrolizumab. The Package Leaflet is being updated accordingly, and for consistency with the already existing statement in the SmPC section 4.4, the Package Leaflet will also include that immune-related adverse reactions can occur after discontinuation of pembrolizumab treatment. An updated RMP version 19.1 was submitted as part of the application."	
Mircera - methoxy polyethylene glycol-epoetin beta - EMEA/H/C/000739/II/0068 Roche Registration GmbH, Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, "Submission of the final report from study BH21260 listed as a category 3 study in	

the RMP (MEA008.5). This is a randomized, controlled, open-label, multicenter, parallel-group study to assess all-cause mortality and cardiovascular morbidity in patients with chronic kidney disease on dialysis and those not on renal replacement therapy under treatment with Mircera® or reference ESAs. The RMP (version 12.0) is updated accordingly and transitioned to the new EU RMP template in line with the revised Good Pharmacovigilance Practice (GVP) Module V (Revision 2) guideline."

Reyataz - atazanavir / atazanavir sulfate - EMEA/H/C/000494/II/0117

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Adrien Inoubli, "Submission of the final reports from studies AI424397 (PRINCE I) and AI424451 (PRINCE II) listed as a category 3 studies in the RMP. These studies were phase IIIb, prospective, single arm, open-label, international, multicentre studies to evaluate the safety, efficacy and pharmacokinetics of atazanavir powder boosted with ritonavir and administered with an optimised NRTI background therapy, in HIV infected paediatric patients.
The RMP version 15.0 has also been submitted to reflect on the final data from these two paediatric studies. In addition, the MAH took the opportunity to introduce the new RMP template Rev. 2."

Vimpat - lacosamide - EMEA/H/C/000863/II/0073/G

UCB Pharma S.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.4, 4.5 and 4.8 of the SmPC in order to include new safety information on cardiac arrhythmias based on safety signal assessment report (SSAR). Update of section 4.8 of the SmPC to update the frequency of some adverse events (AEs) based on data obtained from the updated safety pool analysis (Pool DBC-1). The Package Leaflet is updated accordingly. The RMP version 13 has also been submitted."

Xolair - omalizumab - EMEA/H/C/000606/II/0092

Novartis Europharm Limited, Rapporteur:

Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.2, 4.4, 4.6 and 6.6 of the Xolair solution for injection in pre-filled syringe SmPC to allow for home use in severe allergic asthma and chronic spontaenous urticaria. Consequential updates are applied to the SmPC for powder and solvent for solution for injection.
Artwork for the outer box, the blister and the syringe label for Xolair solution for injection in pre-filled syringe have been updated to ensure that patients/lay caregiver can more easily distinguish the 2 strengths of Xolair PFS.
The Package Leaflet and Labelling are updated accordingly.
The RMP version 13 has also been submitted.”

B.6.11. PRAC assessed procedures

PRAC Led
Aranesp - darbepoetin alfa - EMEA/H/C/000332/II/0148
Amgen Europe B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, “Update of annex IID to implement information on education material proposal to address the incorrect self-administration of Aranesp via the SureClick pre-filled pen and associated dosing errors. The RMP (version 9.1) is updated accordingly and aligned to the latest revision 2.”

PRAC Led
Betmiga - mirabegron - EMEA/H/C/002388/II/0030
Astellas Pharma Europe B.V., Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Concepcion Prieto Yerro, “Submission of the final report of the Drug Utilization Study of mirabegron using real-word healthcare databases from the NL, UK and FI (study 178-PV-002), as agreed via MEA 009.2.”

PRAC Led
Evicel - human fibrinogen / human thrombin - EMEA/H/C/000898/II/0063
Omrix Biopharmaceuticals N. V., PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, “C.I.11:

Submission of an updated RMP version 14.2 in order to transition to RMP version 2, updated exposure data, updates following PRAC request in accordance to PSUSA/00010297 (removal of lack of efficacy as identified risk), reclassification and/or removal of risk from the safety specification."	
PRAC Led **Farydak - panobinostat -** **EMEA/H/C/003725/II/0013, Orphan** Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Patrick Batty, PRAC-CHMP liaison: Greg Markey, "Submission of an updated RMP version 5.0 in order to remove the commitment to conduct a non-interventional PASS study (LBH589D2408) of panobinostat use in relapsed or relapsed/refractory multiple myeloma patients who have received at least two prior regimens including bortezomib and an immunomodulatory agent in a real-world setting according to the current EU prescribing information and document adherence to dosing regimen (including the dosing card, blister pack) by describing clinical characteristics, frequency and severity of the medication error events; listed as a category 3 study in the RMP."	
PRAC Led **ReFacto AF - moroctocog alfa -** **EMEA/H/C/000232/II/0147** Pfizer Europe MA EEIG, Rapporteur: Mark Ainsworth, PRAC Rapporteur: Doris Stenver, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of the final report from study B1831007 (previously referred to as Study 3082B2-4435-WW) listed as a category 3 study in the RMP. This is a post authorization safety surveillance registry in previously untreated patients with severe hemophilia A in usual care settings, in order to fulfil the post-approval commitment MEA 115."	
PRAC Led **Repatha - evolocumab -** **EMEA/H/C/003766/II/0028** Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Tuomo Lapveteläinen, "Submission of an updated RMP	

version 5.0 in order to provide the final results of study 20120332 (GAUSS-3, part C), listed as a category 3 study in the RMP. This is a 3-part, phase 3, multicenter, randomized, double-blind, ezetimibe-controlled, parallel-group study. Part C was a 2-year, open-label extension that evaluated the long-term safety and efficacy of evolocumab in hypercholesterolemic subjects unable to tolerate an effective dose of a statin. The MAH has consequentially proposed to remove missing information of use in patients with severe hepatic impairment (Child-Pugh class C) and use in patients with hepatitis C."

PRAC Led

Thalidomide Celgene - thalidomide - EMEA/H/C/000823/II/0056, Orphan

Celgene Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ghania Chamouni, PRAC-CHMP liaison: Alexandre Moreau, "Update of the RMP version 19 in line with the updated Guideline on Good Pharmacovigilance Practices (GVP) Module V to propose the reclassification and/or renaming of known safety concerns associated with the use of thalidomide. Consequently, Annex IID, SmPC section 4.4 and 4.6 and PL have been updated accordingly."

PRAC Led

Votrient - pazopanib - EMEA/H/C/001141/II/0049

Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Doris Stenver, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of the final report from the non-interventional post-authorisation safety study PZP034AKR02 to monitor the safety and effectiveness of Votrient in Korea. This study is listed as a category 3 study in the RMP."

PRAC Led

Votrient - pazopanib - EMEA/H/C/001141/II/0050

Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Doris Stenver, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of the final report from the observational study PZP034A2401 'A prospective observational study of real world treatment patterns and treatment outcomes in patients with advanced or metastatic renal cell

carcinoma receiving pazopanib. This study is listed as a category 3 study in the RMP."	
PRAC Led **WS1441** **Descovy-** **EMEA/H/C/004094/WS1441/0034** **Genvoya-** **EMEA/H/C/004042/WS1441/0051** **Odefsey-** **EMEA/H/C/004156/WS1441/0035** **Vemlidy-** **EMEA/H/C/004169/WS1441/0016** Gilead Sciences Ireland UC, Lead Rapporteur: Robert James Hemmings, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Daniela Melchiorri, "Submission of an updated RMP version 3.1 for Vemlidy, Descovy and Odefsey, as well as version 3.3 for Genvoya according to GVP Module V (revision 2) in order to revise the safety concerns in alignment with the approved RMP for Biktarvy. In addition, the MAH took the opportunity to update category 3 studies and the address of the MAH."	

B.6.12. CHMP-CAT assessed procedures

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS1394 **Hexacima-** **EMEA/H/C/002702/WS1394/0082** **Hexaxim-** **EMEA/H/W/002495/WS1394/0087** **Hexyon-** **EMEA/H/C/002796/WS1394/0086** Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus	
WS1421 **Infanrix hexa-**	

EMEA/H/C/000296/WS1421/0244
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren

WS1430
Descovy-
EMEA/H/C/004094/WS1430/0033
Genvoya-
EMEA/H/C/004042/WS1430/0049
Odefsey-
EMEA/H/C/004156/WS1430/0034
Vemlidy-
EMEA/H/C/004169/WS1430/0014
Gilead Sciences Ireland UC, Lead Rapporteur: Robert James Hemmings

WS1431
Ceprotin-
EMEA/H/C/000334/WS1431/0105
Baxter AG, Lead Rapporteur: Jan Mueller-Berghaus

WS1435/G
Infanrix hexa-
EMEA/H/C/000296/WS1435/0245/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren

WS1442
Infanrix hexa-
EMEA/H/C/000296/WS1442/0246
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren

WS1445
Kisplyx-EMEA/H/C/004224/WS1445/0017
Lenvima-
EMEA/H/C/003727/WS1445/0020
Eisai Europe Ltd., Lead Rapporteur: Bart Van der Schueren

WS1446
Kisplyx-EMEA/H/C/004224/WS1446/0016
Lenvima-
EMEA/H/C/003727/WS1446/0019
Eisai Europe Ltd., Lead Rapporteur: Bart Van der Schueren

WS1447
Atripla-EMEA/H/C/000797/WS1447/0132
Eviplera-
EMEA/H/C/002312/WS1447/0093
Stribild-EMEA/H/C/002574/WS1447/0096

Truvada-
EMEA/H/C/000594/WS1447/0150
Viread-EMEA/H/C/000419/WS1447/0192
Gilead Sciences Ireland UC, Lead Rapporteur: Greg Markey

WS1457/G
Fertavid-
EMEA/H/C/001042/WS1457/0040/G
Puregon-
EMEA/H/C/000086/WS1457/0098/G
Merck Sharp & Dohme B.V., Informed Consent of Puregon, Lead Rapporteur: Nithyanandan Nagercoil

WS1458
Cervarix-
EMEA/H/C/000721/WS1458/0097
Fendrix-
EMEA/H/C/000550/WS1458/0065
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren

WS1465/G
Abseamed-
EMEA/H/C/000727/WS1465/0075/G
Binocrit-
EMEA/H/C/000725/WS1465/0075/G
Epoetin alfa Hexal-
EMEA/H/C/000726/WS1465/0074/G
Sandoz GmbH, Lead Rapporteur: Alexandre Moreau

WS1470
Abseamed-
EMEA/H/C/000727/WS1470/0076
Binocrit-
EMEA/H/C/000725/WS1470/0076
Epoetin alfa Hexal-
EMEA/H/C/000726/WS1470/0075
Medice Arzneimittel Pütter GmbH & Co. KG, Duplicate, Duplicate of Epoetin alfa Hexal, Lead Rapporteur: Alexandre Moreau

Mosquirix-
EMEA/H/W/002300/WS1434/0034
Shingrix-
EMEA/H/C/004336/WS1434/0008
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Jan Mueller-Berghaus

Mosquirix-

EMEA/H/W/002300/WS1450/0037
Shingrix-
EMEA/H/C/004336/WS1450/0010
GlaxoSmithkline Biologicals SA, Lead
Rapporteur: Jan Mueller-Berghaus

B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY

B.7.1. Yearly Line listing for Type I and II variations

B.7.2. Monthly Line listing for Type I variations

B.7.3. Opinion on Marketing Authorisation transfer (MMD only)

B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)

B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)

B.7.6. Notifications of Type I Variations (MMD only)

C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMEA CERTIFICATION OF PLASMA MASTER FILES

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

F.1. Parallel Distribution - Pursuant to Article 9 of Council Regulation (EC) No. 2743/98 of 14 December 1998, as amended

F.2. Request for scientific opinion on justification of exceptional circumstance and for imperative grounds of public health

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Qualification of Biomarkers:

HTA:

G.2. Ongoing procedures

G.3. PRIME

G.3.1. List of procedures concluding at 20-23 August 2018 CHMP plenary:

G.3.2. List of procedures starting in August 2018 for September 2018 CHMP adoption of outcomes

H. ANNEX H - Product Shared Mailboxes – e-mail address

16. Explanatory notes

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

Oral explanations *(section 2)*

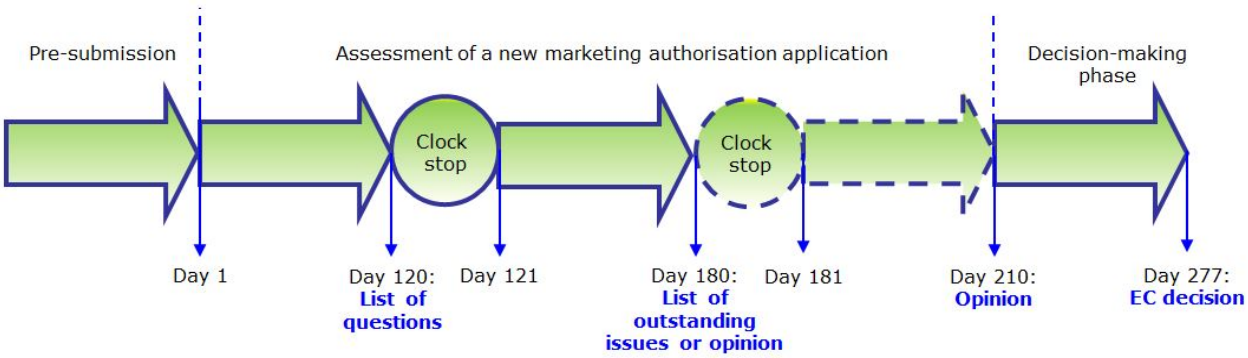
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

Extensions of marketing authorisations are applications for the change or addition of new strengths,

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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