06 October 2023
EMA/CHMP/378018/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for written procedure* on 14-17 August 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

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

Disclaimers

Some of the information contained in this set of minutes 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, these minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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. Adoption of agenda

CHMP agenda for 14-17 August 2023

The CHMP adopted the agenda.

1.2. Adoption of the minutes

The CHMP minutes of the 17-20 July 2023 meeting will be adopted at the CHMP September plenary meeting on 11-14 September 2023.

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. alpelisib - Orphan - EMEA/H/C/005468

Novartis Europharm Limited; treatment of patients with severe manifestations of PIK3CA-related overgrowth spectrum

Scope: Letter by the applicant dated 28 July 2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in March 2023.

Action: For adoption

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 10.11.2022.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in March 2023.

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Lutholaz - pegfilgrastim - EMEA/H/C/005587

YES Pharmaceutical Development Services GmbH; treatment of neutropenia

Scope: Withdrawal Q&A

Action: For information

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 26.04.2023. List of Questions adopted on 24.02.2022.

The CHMP noted the withdrawal question and answer document.

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. Azacitidine Accord - azacitidine - EMEA/H/C/005147/X/0013

Accord Healthcare S.L.U.

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (10 mg/ml powder for solution for infusion) and a new route of administration (intravenous use). The RMP version 2 is updated in accordance."

Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2023.

Action: For adoption

List of questions adopted on 26.04.2023

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2023.

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. Moventig - naloxegol - EMEA/H/C/002810/II/0039

Kyowa Kirin Holdings B.V.

Rapporteur: Christophe Focke, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update information regarding the use of naloxegol in OIC patients with cancer-related pain based on real-world data from non-interventional studies (NACASY, KYONAL, and MOVE studies), post-marketing data, and literature. The Package Leaflet is updated accordingly. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in April 2023.

Action: For adoption

Request for supplementary information adopted on 26.04.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in April 2023.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

6.4. Companion diagnostics – follow-up consultation

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

8.2. Priority Medicines (PRIME)

Information related to priority medicines cannot be released at present time as these contain commercially confidential information

8.2.1. List of applications received

No items

8.2.2. Recommendation for PRIME eligibility

No items

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Jetrea – ocriplasmin – EMEA/H/C/002381

Inceptua AB; treatment of vitreomacular traction (VMT)

Rapporteur: Kristina Dunder, Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.2. Iclusig - ponatinib - Orphan - EMEA/H/C/002695/II/0064

Incyte Biosciences Distribution B.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of newly diagnosed adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), either with Iclusig (ponatinib) in combination with chemotherapy, or with Iclusig (ponatinib) monotherapy after corticosteroid induction in patients not eligible to receive chemotherapy-based regimens, based on final results from studies AP24534-11-001 and INCB 84344-201. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22 of the RMP has also been submitted."Withdrawal of Type II variation application

Action: For information

Request for Supplementary Information adopted on 26.04.2023., 10.11.2022.

The CHMP noted the withdrawal of the Type-II variation application.

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

No items

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

No items

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

August 2023 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

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)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for August 2023

Action: For adoption

The CHMP noted that an updated List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) will be adopted in September 2023.

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

14.3.1. Name Review Group (NRG)

Revised Table of Decisions of the NRG meeting held on 26-27 June 2023.

Action: For adoption

The CHMP adopted the revised table of decisions.

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

No items

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

No items

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

No items

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

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA via written procedure on 1 August 2023:

EMEA/H/C/PSUSA/00002253/202207 (oxybutynin) CAPS: **Kentera** (EMEA/H/C/000532) (oxybutynin), Teva B.V., Rapporteur: Karin Janssen van Doorn NAPS: **NAPs** - EU PRAC Rapporteur: Jo Robays, "17/07/2017 To: 17/07/2022"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended together with the detailed explanation of the scientific grounds for the differences with the PRAC recommendation, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance, concerning the following changes: Update of section 4.8 of the SmPC to add the adverse reaction Palpitation with frequency 'common'. The Package leaflet is updated accordingly. (For oral formulations). Update of section 4.2 of the SmPC to clarify that the patches cannot be cut or divided. The Package leaflet is updated accordingly. (For transdermal formulations).

B.4. EPARs / WPARs

Abrysvo - respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027 Pfizer Europe MA EEIG, prevention of respiratory tract disease, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
APRETUDE - cabotegravir - EMEA/H/C/005756 ViiV Healthcare B.V., pre-exposure prophylaxis of HIV-1 infection, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Degarelix Accord - degarelix acetate - EMEA/H/C/006048 Accord Healthcare S.L.U., treatment of prostate cancer, Generic, Generic of Firmagon, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Enrylaze - crisantaspase - EMEA/H/C/005917 Jazz Pharmaceuticals Ireland Limited, indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of	For information only. Comments can be sent to the PL in case necessary.

acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL), Known active substance (Article 8(3) of Directive No 2001/83/EC)	
Inaqovi - decitabine / cedazuridine - EMEA/H/C/005823 Otsuka Pharmaceutical Netherlands B.V., treatment of myeloid leukaemia, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Krazati - adagrasib - EMEA/H/C/006013 Mirati Therapeutics B.V., treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Litfulo - ritlecitinib - EMEA/H/C/006025 Pfizer Europe MA EEIG, Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Orserdu - elacestrant - EMEA/H/C/005898 Stemline Therapeutics B.V., treatment of postmenopausal woman and men with breast cancer, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Talvey - talquetamab - EMEA/H/C/005864, Orphan Janssen-Cilag International N.V., monotherapy treatment of adult patients with relapsed and refractory multiple myeloma, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tepkinly - epcoritamab - EMEA/H/C/005985, Orphan AbbVie Deutschland GmbH & Co. KG, treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tevimbra - tislelizumab - EMEA/H/C/005919, Orphan Novartis Europharm Limited, treatment of adult patients with unresectable, recurrent, locally advanced or metastatic oesophageal squamous	For information only. Comments can be sent to the PL in case necessary.

cell carcinoma after prior chemotherapy, New active substance (Article 8(3) of Directive No 2001/83/EC)	
Tyenne - tocilizumab - EMEA/H/C/005781 Fresenius Kabi Deutschland GmbH, treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), Giant Cell Arteritis (GCA), treatment of rheumatoid arthritis, chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) and COVID-19, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tyruko - natalizumab - EMEA/H/C/005752 Sandoz GmbH, Therapy for active relapsing remitting multiple sclerosis (RRMS), Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Yesafili - aflibercept - EMEA/H/C/006022 Viatris Limited, treatment of age-related macular degeneration (AMD) and visual impairment, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL 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

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

WS2545/G **Januvia-** **EMEA/H/C/000722/WS2545/0083/G** **Ristaben-** **EMEA/H/C/001234/WS2545/0077/G** **TESAVEL-** **EMEA/H/C/000910/WS2545/0083/G** **Xelevia-** **EMEA/H/C/000762/WS2545/0091/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 10.08.2023.	Request for supplementary information adopted with a specific timetable.

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

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

LUMYKRAS - sotorasib - EMEA/H/C/005522/II/0010/G Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B. Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumours With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC." Request for Supplementary Information adopted on 25.05.2023.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in May 2023. The CHMP agreed to the request for an extension to the clock stop to respond to the RSI adopted in May 2023.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

delgocitinib - EMEA/H/C/006109 treatment of moderate to severe chronic hand eczema (CHE)
givinostat - EMEA/H/C/006079, Orphan Italfarmaco S.p.A., treatment of Duchenne muscular dystrophy (DMD)
enzalutamide - EMEA/H/C/006299 treatment of prostate cancer
vilobelimab - EMEA/H/C/006123

treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).
trastuzumab - EMEA/H/C/006252 is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and HER2 positive early breast cancer (EBC)
avacincaptad pegol - EMEA/H/C/006153 is indicated for the treatment of adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
donanemab - EMEA/H/C/006024 to slow disease progression in adult patients with Alzheimer's disease (AD).
temozolomide - EMEA/H/C/006169, Orphan Orphelia Pharma, treatment of neuroblastoma
zapomeran - EMEA/H/C/006207 active immunisation to prevent COVID-19
odronextamab - EMEA/H/C/006215, Orphan Regeneron Ireland Designated Activity Company, treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)
in vitro diagnostic medical device - EMEA/H/D/006373 detection of PD-L1 protein
lutetium (177Lu) chloride - EMEA/H/C/005882 radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide
ustekinumab - EMEA/H/C/006415 treatment of Crohn's Disease
ciclosporin - EMEA/H/C/006250 Treatment of dry eye disease in adult patients
zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006375 active immunisation against H5 subtype of

Influenza A virus

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

Edurant - rilpivirine - EMEA/H/C/002264/X/0042/G Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Gross-Martirosyan, "Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg dispersible tablets). The new presentation is indicated, in combination with other antiretroviral medicinal products, for the treatment of HIV-1 infection in patients ≥2 to <18 years of age and weighing at least 10 kg to less than 25 kg. The PI and RMP have been updated in accordance. Type II variation (C.I.6.a) to modify the approved therapeutic indication of the already authorised 25 mg film-coated tablets presentation to include, in combination with other antiretroviral medicinal products, treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve and virologically suppressed (HIV-1 RNA less than 50 copies per ml) paediatric patients from 2 to less than 12 years weighing at least 25 kg, based on final results from study studies TMC278-TiDP38-C213 Cohort 2. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. The updated RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to Annex II and to update the list of local representatives in the Package Leaflet."
Eliquis - apixaban - EMEA/H/C/002148/X/0089/G Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Menno van der Elst, "Extension application to: 1) Introduce a new pharmaceutical form (granules in single-dose container) associated with a new strength (0.15 mg). 2) Introduce a new pharmaceutical form (coated granules in sachet) associated with 3 new

strengths (0.5 mg, 1.5 mg and 2 mg) The above two line extensions are grouped with a type II - C.I.6.a variation: Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age for Eliquis (all strengths), based on a pre-specified interim analysis from study CV185325; this is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children who require anticoagulation for a venous thromboembolism; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPCs are updated. The Package Leaflet and Annex II are updated in accordance. Version 21.0 of the RMP has also been submitted.”

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

concizumab - EMEA/H/C/005938 routine prophylaxis to prevent or reduce the frequency of bleeding in patients with: haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors ≥ 12 years of age; haemophilia B (congenital factor IX deficiency) with FIX inhibitors of any age List of Questions adopted on 25.05.2023.
Entyvio - vedolizumab - EMEA/H/C/002782/X/0075 Takeda Pharma A/S, Rapporteur: Armando Genazzani List of Questions adopted on 26.04.2023.
Eylea - aflibercept - EMEA/H/C/002392/X/0084/G Bayer AG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault‟Extension application to add a new strength of Aflibercept 114.3 mg/ml solution for injection (in a vial), to be indicated in adults for the (1) treatment of neovascular (wet) age-related macular degeneration (nAMD) and (2) visual impairment due to diabetic macular oedema (DME), grouped with a type II variation (B.II.g.2)”

List of Questions adopted on 22.06.2023.

germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165
indicated for in vitro labelling of kits for radiopharmaceutical preparation
List of Questions adopted on 16.12.2021.

Kalydeco - ivacaftor - EMEA/H/C/002494/X/0115/G
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Monica Martinez Redondo, "Extension application to introduce a new strength (13.4 mg of ivacaftor granules in sachet), grouped with a type II variation (C.I.6.a) in order to extend the indication of the granule presentations to include children with cystic fibrosis aged 1 to less than 4 months of age and weighing 3 kg or more who have an R117H CFTR mutation or one of the approved 9 gating (class III) mutations based on interim results from study VX15-770-124 (study 124); this is a phase 3, 2-part, open-label study to evaluate the safety, pharmacokinetics, and pharmacodynamics of ivacaftor (IVA) in subjects with CF who are less than 24 months of age at treatment initiation and have a CFTR gating mutation. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3 and 8 of the SmPC of the granules presentations and sections 4.2, 4.8, 5.1 and 5.2 of the SmPC of the tablets presentations are updated. The Labelling for the 13.4 mg granule presentation and the Package Leaflet of the granules and tablets presentations are updated in accordance. Version 15.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.
Type IA A.5.b
Type IA B.II.b.2.a"
List of Questions adopted on 25.05.2023.

epinephrine - EMEA/H/C/006139
Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis
List of Questions adopted on 23.02.2023.

dopamine hydrochloride -

EMEA/H/C/006044, PUMA
Treatment of hypotension in neonates, infants and children
List of Questions adopted on 30.03.2023.

omaveloxolone - EMEA/H/C/006084, Orphan
Reata Ireland Limited, Treatment of Friedreich's ataxia
List of Questions adopted on 26.04.2023.

Skyrizi - risankizumab - EMEA/H/C/004759/X/0033
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Extension application to add a new strength of 90 mg solution for injection in pre-filled syringe, indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy."
List of Questions adopted on 20.07.2023.

pegcetacoplan - EMEA/H/C/005954
Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
List of Questions adopted on 25.05.2023.

Talzenna - talazoparib - EMEA/H/C/004674/X/0015/G
Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, Co-Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension application for Talzenna to introduce a new strength of 0.1 mg hard capsules, grouped with a type II variation (C.I.6.a) in order to extend the indication for Talzenna in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), based on final results from study C3441021 (TALAPRO-2) as well as supplemental data from study C3441006 (TALAPRO-1). Study C3441021 (TALAPRO-2) is a randomized, double-blind, placebo-controlled, phase 3 study of talazoparib in combination with enzalutamide in mCRPC, while study C3441006 (TALAPRO-1) is a phase 2, open-label, response rate study of talazoparib in men with DNA repair defects and mCRPC who

previously received taxane-based chemotherapy and progressed on at least one novel hormonal agent. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.5, 4.7, 4.8, 5.1, 5.2, 6.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."
List of Questions adopted on 22.06.2023.

toripalimab - EMEA/H/C/006120
Combination treatment for metastatic or recurrent locally advanced nasopharyngeal carcinoma and for metastatic or recurrent oesophageal squamous cell carcinoma
List of Questions adopted on 30.03.2023.

etrasimod - EMEA/H/C/006007
treatment of patients with moderately to severely active ulcerative colitis (UC)
List of Questions adopted on 30.03.2023.

Viagra - sildenafil - EMEA/H/C/000202/X/0115
Upjohn EESV, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Maria Concepcion Prieto Yerro, "Extension application to introduce a new pharmaceutical form (orodispersible film)."
List of Questions adopted on 26.01.2023.

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

Atriance - nelarabine - EMEA/H/C/000752/S/0062
Sandoz Pharmaceuticals d.d., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Mepsevii - vestronidase alfa - EMEA/H/C/004438/S/0036, Orphan
Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

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

DECTOVA - zanamivir - EMEA/H/C/004102/R/0017

GlaxoSmithKline Trading Services Limited, Rapporteur: Ingrid Wang, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga

Flucelvax Tetra - influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/R/0040
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Gabriele Maurer

Hemgenix - etranacogene dezaparvovec - EMEA/H/C/004827/R/0007, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP
Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Concetta Quintarelli, CHMP Coordinators: Jan Mueller-Berghaus and Armando Genazzani, PRAC Rapporteur: Rhea Fitzgerald

Palynziq - pegvaliase - EMEA/H/C/004744/R/0038, Orphan
BioMarin International Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rhea Fitzgerald

Pazenir - paclitaxel - EMEA/H/C/004441/R/0015
ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst

Retsevmo - selpercatinib - EMEA/H/C/005375/R/0026
Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst

SIRTURO - bedaquiline - EMEA/H/C/002614/R/0054, Orphan
Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Trecondi - treosulfan -

EMEA/H/C/004751/R/0019, Orphan
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Julia Pallos

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

Metalyse - tenecteplase - EMEA/H/C/000306/II/0070/G
Boehringer Ingelheim International GmbH, Rapporteur: Martina Weise"Grouped application consisting of:
C.I.6.a (Type II): To add the new therapeutic indication Acute Ischemic Stroke (AIS) for the new 25 mg presentation. Consequently, a separate SmPC and Package Leaflet are provided for the 25 mg presentation with the new indication. In addition, the MAH took the opportunity to implement editorial changes and minor updates to the PI of Metalyse 40 mg (8,000 U) and 50 mg (10,000 U).
B.II.e.5.c (Type II): To add the new 25 mg presentation for the sterile parenteral biological medicinal product Metalyse (tenecteplase) powder and solvent for solution for injection.
B.II.b.3.a
B.II.e.1.b.2"

Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0031
Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola, "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk, based on results from study 1002-043 (CLEAR). CLEAR Outcomes Study is a phase 3 multi-centre randomised, double-blind, placebo-controlled study to evaluate whether long-term treatment with bempedoic acid reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease who are statin intolerant. As a consequence, sections 4.1, 4.8 and 5.1 of

the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0035 Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola, "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for NUSTENDI, based on results from study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are statin intolerant; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Vabysmo - faricimab - EMEA/H/C/005642/II/0005 Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients	

with central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). These are global, multicenter, randomized, double-masked, active comparator-controlled, parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.”	
WS2552 **Ongentys-** **EMEA/H/C/002790/WS2552/0060** **Ontilyv-EMEA/H/C/005782/WS2552/0015** Bial Portela & Companhia S.A., Informed Consent of Ongentys, Lead Rapporteur: Martina Weise, Lead PRAC Rapporteur: Maria del Pilar Rayon, “Extension of indication to include treatment of signs and symptoms of Parkinson’s Disease for Ongentys/Ontilyv, based on final results from study BIA-91067-303; this is a pivotal Phase III, multicentre, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of opicapone in patients with early idiopathic Parkinson’s Disease receiving treatment with L-DOPA plus a DDCI, and who are without signs of any motor complication. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.0 of the RMP has also been submitted (only applicable to Ongentys) to reflect the changes made upon approval of the informed consent application, to keep consistency between the eCTD lifecycles of the two marketing authorisations (Ongentys and Ontilyv). Furthermore, the PI is brought in line with the latest QRD template version 10.3. In addition, as part of the application, the MAH is requesting a 1-year extension of the market protection.” Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0050
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

BIMERVAX - sars-cov-2 virus, variants b.1.351-b.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0005/G
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich

BIMERVAX - sars-cov-2 virus, variants b.1.351-b.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0007/G
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich

DaTSCAN - ioflupane (123I) - EMEA/H/C/000266/II/0066/G
GE Healthcare B.V., Rapporteur: Alexandre Moreau

Hemangiol - propranolol - EMEA/H/C/002621/II/0025
Pierre Fabre Medicament, Rapporteur: Jean-Michel Race

Iasibon - ibandronic acid - EMEA/H/C/002025/II/0025
Pharmathen S.A., Generic, Generic of Bondronat, Rapporteur: Thalia Marie Estrup Blicher

IVF Media G5 Series - human albumin solution - EMEA/H/D/000003/II/0008
Vitrolife Sweden AB, Rapporteur: Filip Josephson

Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0042/G, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol

Lacosamide Accord - lacosamide - EMEA/H/C/004443/II/0023/G
Accord Healthcare S.L.U., Generic, Generic of Vimpat, Rapporteur: John Joseph Borg

MINJUVI - tafasitamab -

EMEA/H/C/005436/II/0012/G, Orphan
Incyte Biosciences Distribution B.V.,
Rapporteur: Aaron Sosa Mejia

Orencia - abatacept -
EMEA/H/C/000701/II/0158/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Outi Mäki-Ikola

Orencia - abatacept -
EMEA/H/C/000701/II/0161/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Outi Mäki-Ikola

Ovitrelle - choriogonadotropin alfa -
EMEA/H/C/000320/II/0089
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Pemetrexed Accord - pemetrexed -
EMEA/H/C/004072/II/0025
Accord Healthcare S.L.U., Generic, Generic of
Alimta, Rapporteur: John Joseph Borg

Perjeta - pertuzumab -
EMEA/H/C/002547/II/0068/G
Roche Registration GmbH, Rapporteur: Aaron
Sosa Mejia

PreHevbri - hepatitis b surface antigen
(rdna) - EMEA/H/C/005466/II/0006
VBI Vaccines B.V., Rapporteur: Jan Mueller-
Berghaus

Ryeqo - relugolix / estradiol /
norethisterone acetate -
EMEA/H/C/005267/II/0019/G
Gedeon Richter Plc., Rapporteur: Patrick
Vrijlandt

Ryeqo - relugolix / estradiol /
norethisterone acetate -
EMEA/H/C/005267/II/0020/G
Gedeon Richter Plc., Rapporteur: Patrick
Vrijlandt

Skytrofa - lonapegsomatropin -
EMEA/H/C/005367/II/0019/G, Orphan
Ascendis Pharma Endocrinology Division A/S,
Rapporteur: Patrick Vrijlandt

Spikevax - covid-19 mrna vaccine
(nucleoside-modified) -
EMEA/H/C/005791/II/0111/G
Moderna Biotech Spain, S.L., Rapporteur: Jan

Mueller-Berghaus

TAVNEOS - avacopan - EMEA/H/C/005523/II/0010, Orphan
Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder

TEZSPIRE - tezepelumab - EMEA/H/C/005588/II/0009/G
AstraZeneca AB, Rapporteur: Finbarr Leacy

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0131
MCM Vaccine B.V., Rapporteur: Christophe Focke

Vyepti - eptinezumab - EMEA/H/C/005287/II/0012
H. Lundbeck A/S, Rapporteur: Jan Mueller-Berghaus

WS2526/G
Infanrix hexa-
EMEA/H/C/000296/WS2526/0335/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

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

BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0006
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final report from study HAN-01 listed as a category 3 study in the RMP (MEA/006). This is a phase IIb, randomised, controlled, observer-blinded study to evaluate safety and immunogenicity of a recombinant protein RBD fusion dimer candidate vaccine against SARS-CoV-2 in adult healthy volunteers."

BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0008
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final

report from study HIPRA-HH-10 listed as a category 3 study in the RMP. This is a phase 2b, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion dimer candidate (PHH-1V) against SARS-CoV-2, in adults fully vaccinated with adenovirus vaccine against COVID-19."

Braftovi - encorafenib - EMEA/H/C/004580/II/0031

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information on effect of encorafenib in combination with binimetinib on the single oral dose PK of specific CYP isozymes substrates, and effect of multiple doses of modafinil, a moderate CYP3A4 inducer, on the multiple oral dose PK of encorafenib administered with binimetinib based on final results from arm 1 and 3 of clinical study ARRAY-818-103/C4221003 (REC). ARRAY-818-103/ C4221003 study is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours."

Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0037

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, "Submission of the final clinical study report addendum for study DS8201-A-U303 (DESTINY-Breast04) in order to fulfil the recommendation to submit the final OS analysis. U303 is a phase 3, multicentre, randomised, open-label, active-controlled trial of trastuzumab deruxtecan (T-DXd), an anti-HER2-antibody drug conjugate (ADC), versus treatment of physician's choice for HER2-low, unresectable and/or metastatic breast cancer subjects."

Fetcroja - cefiderocol - EMEA/H/C/004829/II/0016

Shionogi B.V., Rapporteur: Filip Josephson, "Update of section 6.2 of the SmPC in order to update the incompatibility section in line with the PRAC recommendation following the PSUR

for EMEA/H/C/PSUSA/00010849/202211."

Filsuvez - birch bark extract - EMEA/H/C/005035/II/0006, Orphan

Amryt Pharmaceuticals DAC, Rapporteur: Kristina Dunder, "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study EASE (BEB-13); this is a double-blind, randomised, placebo (vehicle) controlled trial to evaluate efficacy and safety of birch bark extract on top of standard of care in children from birth to less than 18 years of age (and adults) with epidermolysis bullosa. In addition, the MAH took the opportunity to introduce minor changes to the PI."

Jakavi - ruxolitinib - EMEA/H/C/002464/II/0068

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.4 and 5.1 of the SmPC in order to add new warnings on 'Major adverse cardiac events (MACE)', 'Thrombosis', and 'Second primary malignancies', following an Art. 20 Class Referral involving JAK inhibitors approved to treat rheumatoid arthritis and to update efficacy information regarding the effects of ruxolitinib in relation to thromboembolic events based on recently published data from MAJIC-PV study (a randomized, controlled open-label study in polycythemia vera (PV))."

JCOVDEN - covid-19 vaccine janssen (ad26.cov2.s) - EMEA/H/C/005737/II/0074/G

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "Grouped application comprising two type II variations (C.I.13) as follows:
- Submission of the final report from study TOX15258 - Ad26.COV2.S (Prophylactic COVID-19 Vaccine): A Transcriptomics Exploratory Study in Cambodian Cynomolgus Monkey.
- Submission of the report from study TV-TEC-236300 - Biophysical studies on interactions between human platelet 4 and Ad26.COV2.S."

Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0028

Bayer AG, Rapporteur: Thalia Marie Estrup

Blicher, "Submission of the final report from study 19764 (PMI) listed as a category 3 study in the RMP as well as pooled data from phase 3 studies 13024 (PROTECT VIII) and 15912 (PROTECT Kids). Study 19764 is a multicenter, single group, uncontrolled, open-label interventional post-marketing investigation (PMI) to assess safety and efficacy of Jivi treatment in patients with hemophilia A."	
Mektovi - binimetinib - EMEA/H/C/004579/II/0027 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of the final report from study ARRAY 818-103 on Arms 1 and 3. This is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours, to assess drug drug interactions between encorafenib + binimetinib combination and midazolam (CYP3A4 substrate), caffeine (CYP1A2 substrate), omeprazole (CYP2C19 substrate), losartan (CYP2C9 substrate), dextromethorphan (CYP2D6 substrate) and modafinil (moderate CYP3A4 inducer)."	
Mozobil - plerixafor - EMEA/H/C/001030/II/0051 Sanofi B.V., Rapporteur: Peter Mol, "Update of section 4.6 of the SmPC in order to update information regarding duration of contraception after cessation of treatment; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor update to the labelling section."	
Ozurdex - dexamethasone - EMEA/H/C/001140/II/0045 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC in order to add "Central serous chorioretinopathy" to the list of adverse drug reactions (ADRs) with frequency "uncommon" based on a safety signal and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and design changes to the Package Leaflet; and to bring the PI in line with the	

latest QRD template version 10.3."

Remsima - infliximab - EMEA/H/C/002576/II/0133/G

Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising three type II variations (C.I.4) as follows:
- Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information based on week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (crohn's disease), listed as a category 3 study in the RMP; study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease.
- Update of sections 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.
- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study).
The RMP version 16.1 has also been submitted. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI."

Scemblix - asciminib - EMEA/H/C/005605/II/0008, Orphan

Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add interaction information between asciminib and OATP1B and BCRP substrates, based on results from three PBPK simulation reports: DMPK-R2001088, DMPK-R2270328 and DMPK-R2300226. The Package Leaflet is updated accordingly."

Scemblix - asciminib -
EMEA/H/C/005605/II/0009, Orphan
Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of section 5.3 of the SmPC in order to update preclinical safety data based on final results from study R1570226: this is a 2-year rat carcinogenicity study. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Veklury - remdesivir -
EMEA/H/C/005622/II/0052
Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update non-clinical information based on results from the non-clinical studies PC-540-2045 and PC-540-2046. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Verzenios - abemaciclib -
EMEA/H/C/004302/II/0028
Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC in order to add a new warning on "arterial thromboembolic events", based on a safety review. The Package Leaflet is updated accordingly."

Zaltrap - aflibercept -
EMEA/H/C/002532/II/0070
Sanofi Winthrop Industrie, Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update information regarding the duration of contraceptive use after cessation of treatment. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

WS2544
Ebymect-
EMEA/H/C/004162/WS2544/0064

Komboglyze-
EMEA/H/C/002059/WS2544/0057
Xigduo-EMEA/H/C/002672/WS2544/0074
AstraZeneca AB, Lead Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Vitamin B12 decrease/deficiency' and to change the frequency of 'Vitamin B12 decrease/deficiency' in the list of adverse drug reactions (ADRs) from frequency 'very rare' to 'common'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

B.6.10. CHMP-PRAC assessed procedures

Amyvid - florbetapir (18F) -
EMEA/H/C/002422/II/0044
Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.4 of the SmPC in order to remove the limitation regarding monitoring response to therapy based on available information in the scientific literature. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to update section 4.8 to the SmPC to align the clinical trial exposures with the RMP."

Kuvan - sapropterin -
EMEA/H/C/000943/II/0078
BioMarin International Limited, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from study KOGNITO, listed as a category 3 study in the RMP. This is a Phase IV Open-Label, Single-Cohort Study of the Long-Term Neurocognitive Outcomes in 4 to 5 Year-Old Children with Phenylketonuria Treated with Sapropterin Dihydrochloride (Kuvan) for 7 Years. The RMP version 16.0 has also been submitted."

Onpattro - patisiran -
EMEA/H/C/004699/II/0034, Orphan
Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from study ALN-TTR02-006 (study 006), listed a category 3 study in the RMP. This is a multicenter, open-label, extension study to evaluate the long-term

safety and efficacy of patisiran in patients with familial amyloidotic polyneuropathy who have completed a prior clinical study with patisiran. The RMP version 2.2 has also been submitted."

Tegsedi - inotersen - EMEA/H/C/004782/II/0038, Orphan

Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.8 of the SmPC in order to modify the warning on liver monitoring and drug-induced liver injury and to add 'drug-induced liver injury' to the list of adverse drug reactions (ADRs) with frequency not known, following the request in the Assessment Report for PAM procedure EMEA/H/C/004782/LEG/008. The Annex II and Package Leaflet are updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI."

Vaborem - meropenem / vaborbactam - EMEA/H/C/004669/II/0020

Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Maria del Pilar Rayon, "Submission of the final reports from Global Microbiology Surveillance Study and Molecular Surveillance Report, listed as a category 3 study in the RMP. The RMP version 2.0 has also been submitted."

Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0043/G

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Valentina Di Giovanni, "Grouped application consisting of: C.I.13: Submission of the final report from study GS-US-320-0108 listed as category 3 studies in the RMP. This is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Negative, Chronic Hepatitis B. The RMP version 10.1 has also been submitted. C.I.13: Submission of the final report from study GS-US-320-0110 listed as category 3 studies in the RMP. This is a is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide

(TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Positive, Chronic Hepatitis B. The RMP version 10.1 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led

Caelyx pegylated liposomal - doxorubicin - EMEA/H/C/000089/II/0107

Baxter Holding B.V., PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "Submission of an updated RMP version 6.1 in order to align to GVP Module V Revision 2 requirements, following a request received within the Assessment Report for procedure EMEA/H/C/PSUSA/00001172/202111."

PRAC Led

Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0036

Daiichi Sankyo Europe GmbH, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the final report from study 'EU survey of relevant healthcare professionals on understanding of key risk minimisations measures pertaining to ILD/pneumonitis' listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS."

PRAC Led

Intuniv - guanfacine - EMEA/H/C/003759/II/0033/G

Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of the final reports from the Drug Utilisation Study of Intuniv (guanfacine extended release) in European countries: a prescriber survey (EUPAS18739) and a retrospective database study (EUPAS18735), listed as category 3 studies in the RMP. The RMP version 4.0 has also been submitted."

PRAC Led

Plenadren - hydrocortisone - EMEA/H/C/002185/II/0043

Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn,

PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study SHP617-400 (EU AIR) listed as a category 3 PASS in the RMP; this is a European multi-centre, multi-country, post-authorization, observation study (registry) of patients with chronic adrenal insufficiency. The RMP version 4.0 has also been submitted."

PRAC Led

Reblozyl - luspatercept - EMEA/H/C/004444/II/0023, Orphan

Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report from study ACE-536-MDS-005 listed as a category 3 study in the RMP. This is a non-interventional post-authorisation safety study (PASS) to evaluate the effectiveness of the additional risk minimisation measure (aRMM) for Reblozyl among Healthcare Providers (HCPs) in the EU/EEA. The RMP version 3.0 has been submitted in order to reflect the completion of the study and to remove the HCP checklist as routine aRMM. The Annex II is updated accordingly."

PRAC Led

REKAMBYS - rilpivirine - EMEA/H/C/005060/II/0019

Janssen-Cilag International N.V., PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 4.1 in order to update the risk characterisation information for the missing information "use in pregnancy" based on interim data of the Antiretroviral Pregnancy Register (APR), listed as a category 3 study in the RMP; and to align the milestones and due dates of this study following the outcome of procedure EMEA/H/C/PSUSA/00010901/202209. In addition, the MAH took the opportunity to update the status and the interim report milestones for the studies DUS and COMBINE-2."

PRAC Led

Stelara - ustekinumab - EMEA/H/C/000958/II/0101/G

Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP

liaison: Jayne Crowe, "Update of section 4.4 of the SmPC in order to remove a warning on cardiovascular events based on final results from non-interventional PASS studies NDI-MACE (CNTO1275PSO4005) and Quantify MACE (PCSIMM004697), listed as category 3 studies in the RMP (MEA/053 and MEA/054). NDI-MACE is a Nordic Database Initiative for Exposure to Ustekinumab: A Review and Analysis of Major Adverse Cardiovascular Events from the Swedish and Danish National Registry Systems; Quantify MACE is an Observational Longitudinal Post-authorization Safety Study of STELARA in the Treatment of Psoriasis and Psoriatic Arthritis: Analysis of Major Adverse Cardiovascular Events (MACE) using Swedish National Health Registers. The Package Leaflet is updated accordingly. The RMP version 27.1 has also been submitted."

PRAC Led
WS2517
Edistride-
EMEA/H/C/004161/WS2517/0063
Forxiga-
EMEA/H/C/002322/WS2517/0084
AstraZeneca AB, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 30 in order to remove the potential important risk for Lower Limb Amputation."

B.6.12. CHMP-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0028/G, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Armando Genazzani

CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0023, Orphan, ATMP
Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Upstaza - eladocagene exuparvovec - EMEA/H/C/005352/II/0014/G, Orphan, ATMP

PTC Therapeutics International Limited, Rapporteur: Maura O'Donovan, CHMP Coordinator: Finbarr Leacy, "Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update information on safety and efficacy, based on final results from studies NTUH-AADC-010 and NTUH-AADC-011. NTUH-AADC-010 is an open-label, single arm, externally controlled trial to evaluate safety, efficacy, pharmacodynamics and immunogenicity of AGIL-AADC in children from 18 months to less than 18 years of age with severe AADC deficiency, while NTUH-AADC-011 is an open-label, single arm, externally controlled trial to evaluate efficacy and safety of AGIL-AADC in children from 18 months to less than 6 years of age with severe AADC deficiency. In addition, sections 4.5, 4.9 and 6.6 of the SmPC are updated in order to provide better clarification and guidance for the medical practice. The Package Leaflet is updated accordingly. The MAH also took the opportunity to update the due date of the final report of study AADC-1602 in the Annex II, considering the 10-year follow up of the last patient in study AADC-011, and to introduce minor editorial changes to the PI."

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0063, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to include new clinical data based on Overall Survival (OS) Primary Analysis from study KTE-C19-107 (ZUMA-7); this is a phase 3, randomized, open-label study evaluating the efficacy of axicabtagene ciloleucel versus standard of care therapy in subjects with relapsed/refractory diffuse large B cell lymphoma (DLBCL) in the 2nd line setting. In addition, the MAH took the opportunity to submit a consolidated Environmental Risk Assessment (ERA) document."

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

WS2408 **Riarify-EMEA/H/C/004836/WS2408/0027** **Trydonis-** **EMEA/H/C/004702/WS2408/0030** Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig	
WS2503/G **Afstyla-** **EMEA/H/C/004075/WS2503/0051/G** **IDELVION-** **EMEA/H/C/003955/WS2503/0067/G** **Respreeza-** **EMEA/H/C/002739/WS2503/0073/G** **Voncento-** **EMEA/H/C/002493/WS2503/0060/G** CSL Behring GmbH, Lead Rapporteur: Jan Mueller-Berghaus	
WS2532/G **Hexacima-** **EMEA/H/C/002702/WS2532/0152/G** **Hexyon-** **EMEA/H/C/002796/WS2532/0156/G** Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus	
WS2540 **Biktarvy-** **EMEA/H/C/004449/WS2540/0057** **Descovy-** **EMEA/H/C/004094/WS2540/0064** **Genvoya-** **EMEA/H/C/004042/WS2540/0088** **Odefsey-** **EMEA/H/C/004156/WS2540/0062** **Vemlidy-** **EMEA/H/C/004169/WS2540/0044** Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes	
WS2545/G **Januvia-** **EMEA/H/C/000722/WS2545/0083/G**	See B.5.8

Ristaben-
EMEA/H/C/001234/WS2545/0077/G
TESAVEL-
EMEA/H/C/000910/WS2545/0083/G
Xelevia-
EMEA/H/C/000762/WS2545/0091/G
Merck Sharp & Dohme B.V., Lead Rapporteur: Patrick Vrijlandt

WS2555/G
Kisplyx-
EMEA/H/C/004224/WS2555/0057/G
Lenvima-
EMEA/H/C/003727/WS2555/0052/G
Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn

WS2561/G
Olanzapine Glenmark-
EMEA/H/C/001085/WS2561/0041/G
Olanzapine Glenmark Europe-
EMEA/H/C/001086/WS2561/0038/G
Olazax-
EMEA/H/C/001087/WS2561/0033/G
Olazax Disperzi-
EMEA/H/C/001088/WS2561/0035/G
Glenmark Arzneimittel GmbH, Generic, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau

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 - EMA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

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

G. ANNEX G

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

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)*

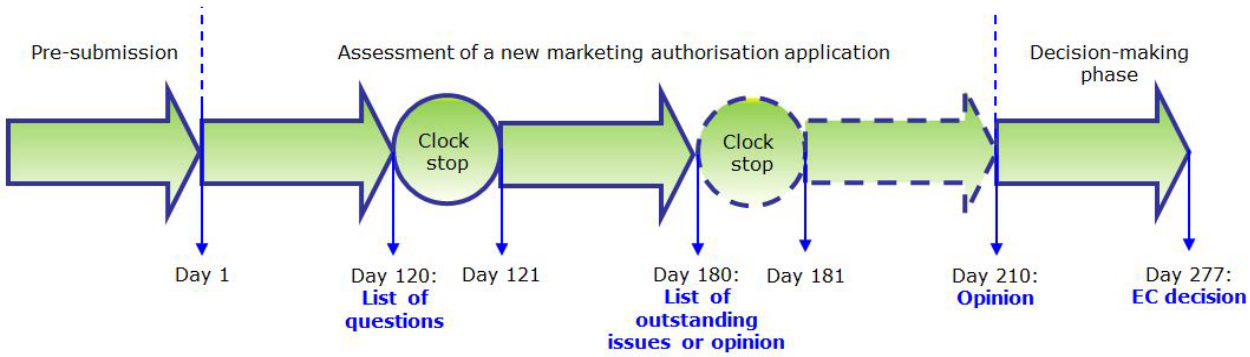
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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