12 August 2022
EMA/691785/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for written procedure* on 16-19 August 2022

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 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).

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Table of contents

1. Introduction

1.1. Adoption of agenda

CHMP agenda for 16-19 August 2022 written procedure

1.2. Adoption of the minutes

The CHMP minutes for the 18-21 July 2022 meeting will be adopted at the September CHMP plenary on 12-15 September 2022.

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. dabigatran etexilate - EMEA/H/C/005922

prevention of venous thromboembolic events

Scope: Letter by the applicant dated 22.07.2022 requesting an extension to the clock stop to respond to the list of questions adopted in June 2022.

Action: For adoption

List of Questions adopted on 23.06.2022.

3.4.2. trastuzumab - EMEA/H/C/005769

treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)

Scope: Letter by the applicant dated 27.07.2022 requesting an extension to the clock stop to respond to the list of questions adopted in May 2022. The extension of the clock-stop was adopted via written procedure on 02 August 2022.

Action: For information

List of Questions adopted on 19.05.2022.

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

3.5.1. Tuznue - trastuzumab - EMEA/H/C/005066 / Hervelous - trastuzumab - EMEA/H/C/005880

Prestige Biopharma Belgium, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)

Scope: re-examination timetable adopted via written procedure on 2nd August 2022

Action: For information

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

Opinion: 19.05.2022. List of Outstanding Issues adopted on 27.01.2022, 25.03.2021, 10.12.2020. List of Questions adopted on 19.09.2019.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. surufatinib - EMEA/H/C/005728

treatment of progressive neuroendocrine tumours

Scope: Withdrawal of initial marketing authorisation.

Action: For information

List of Questions adopted on 11.11.2021.

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

No items

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

No items

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)

No items

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Glidipion – pioglitazone – EMEA/H/C/002558

Actavis Group PTC ehf; treatment of type 2 diabetes mellitus

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: Withdrawal of marketing authorisation

Action: For information

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 2022 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

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 2022

Action: For adoption

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

14.3.1. Name Review Group (NRG)

Table of Decisions for an ad-hoc name review

Action: For adoption

14.3.2. NASEM workshop on the current role and future needs for nonhuman primate models in biomedical research

Proposal to have Sonja Beken, current member of the NcWP and 3RsWP, representing CHMP/EMA at the NASEM workshop to discuss in a dedicated session the EU view on translatability and validation of emerging technologies to refine, reduce, and replace nonhuman primates in biomedical research. The workshop organised by the National Academies of Sciences, Engineering, and Medicine's Committee on the State of the Science and Future Needs for Nonhuman Primate Model Systems will take place on the 25 August 2022 in Washington DC (US). Sonja Beken will be participating remotely. This topic is in line with the 3-year workplan of the non-clinical domain which has been endorsed by the domain governance and CHMP.

Action: For endorsement

14.3.3. CMDh question to NcWP on potentially mutagenic impurity chloromethyl isopropyl carbonate (CMIC) in tenofovir disoproxyl-containing medicinal products

In the July 2022 CMDh meeting, the CMDh discussed the potentially mutagenic impurity chloromethyl isopropyl carbonate (CMIC) in tenofovir disoproxyl-containing medicinal products. The CMDh agreed to request an assessment by the Non-clinical Working Party to determine the mutagenic risk of CMIC, based on the existing data.

Action: For endorsement

14.3.4. EC Request for a scientific opinion on the classification as medicinal products of certain substances used in blood bags CDP (citrate, dextrose and phosphate) and CPDA (citrate, dextrose, phosphate and adenine)

Appointment of CHMP sponsor and timetable to prepare a response letter to the EC as a follow-up on discussions at the July PROM and CHMP plenary regarding the European Commission request.

Following call for interest ending 7th **August 2022**, appointment of sponsor.

Action: For adoption

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

B.4. EPARs / WPARs

Amvuttra - vutrisiran - EMEA/H/C/005852, 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 PL in case necessary.
Celdoxome pegylated liposomal - doxorubicin hydrochloride -	For information only. Comments can be sent to

EMEA/H/C/005330 YES Pharmaceutical Development Services GmbH, treatment of breast cancer, treatment of ovarian cancer, treatment of multiple myeloma, treatment of AIDS related Kaposi's sarcoma, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	the PL in case necessary.
EXKIVITY - mobocertinib - EMEA/H/C/005621 Takeda Pharma A/S, Treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic 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 PL in case necessary.
iLuzyce - lutetium (177lu) chloride - EMEA/H/C/005859 Billev Pharma ApS, used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride, Well-established use application (Article 10a of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Lupkynis - voclosporin - EMEA/H/C/005256 Otsuka Pharmaceutical Netherlands B.V., treatment of class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN). 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.
Mounjaro - tirzepatide - EMEA/H/C/005620 Eli Lilly Nederland B.V., treatment of adults with type 2 diabetes mellitus, 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.
NULIBRY - fosdenopterin - EMEA/H/C/005378, Orphan Comharsa Life Sciences Ltd, treatment of molybdenum cofactor deficiency type A, 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.
Opdualag - nivolumab / relatlimab - EMEA/H/C/005481 Bristol-Myers Squibb Pharma EEIG, treatment of advanced (unresectable or metastatic) melanoma, New active substance (Article 8(3)	For information only. Comments can be sent to the PL in case necessary.

of Directive No 2001/83/EC)	
Tecvayli - teclistamab - EMEA/H/C/005865 Janssen-Cilag International N.V., treatment of relapsed or 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.
TEZSPIRE - tezepelumab - EMEA/H/C/005588 AstraZeneca AB, add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma, 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.
Thalidomide Lipomed - thalidomide - EMEA/H/C/005715 Lipomed GmbH, treatment of multiple myeloma, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Vabysmo - faricimab - EMEA/H/C/005642 Roche Registration GmbH, treatment of neovascular (wet) age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DME), 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.

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

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

Voraxaze - glucarpidase - EMEA/H/C/005467/II/0005, Orphan SERB S.A.S., Rapporteur: Ondřej Slanař Withdrawal request submitted on 25.07.2022.	The MAH withdrew the procedure on 25.07.2022.

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

VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0054, Orphan Takeda Pharmaceuticals International AG, Rapporteur: Martina Weise, "Submission of the final report from study SHP-GCB-402: a multicentre, open-label, single-arm, phase 4 study designed to prospectively evaluate the effects of VPRIV on bone-related pathology in treatment-naïve subjects with type 1 Gaucher disease." Request for Supplementary Information adopted on 28.04.2022.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in April 2022.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

sparsentan - EMEA/H/C/005783, Orphan Vifor France, for the treatment of primary immunoglobulin A nephropathy (IgAN).

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

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

Adcirca - tadalafil - EMEA/H/C/001021/X/0035/G
Eli Lilly Nederland B.V., Informed Consent of Cialis, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Extension application to introduce a new pharmaceutical form associated with a new strength (2 mg/ml oral suspension) grouped with a type II variation (C.I.6.a) to include paediatric use (from 6 months to 17 years) based on study 4 (H6D-MC-LVHV [LVHV]) - A 24-week placebo-controlled efficacy and safety study with an open-label long-term extension phase. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The paediatric indication is applicable to the new and all existing presentations. The Package Leaflet and Labelling are updated accordingly. Furthermore, the PI is brought in line with the latest QRD template and editorial changes have been implemented. The RMP (version 9.1) is updated in accordance."
List of Questions adopted on 19.05.2022.

etranacogene dezaparvovec - EMEA/H/C/004827, Orphan, ATMP
CSL Behring GmbH, treatment of adults with Haemophilia B
List of Questions adopted on 15.07.2022.

tremelimumab - EMEA/H/C/004650
treatment of adults with metastatic NSCLC with no sensitising epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumour aberrations
List of Questions adopted on 22.04.2022.

paclitaxel - EMEA/H/C/005997
treatment of metastatic breast cancer, Generic, Generic of Abraxane
List of Questions adopted on 19.05.2022.

ruxolitinib - EMEA/H/C/005843
treatment of non-segmental vitiligo
List of Questions adopted on 24.02.2022.

Triumeq - dolutegravir / abacavir / lamivudine -

EMEA/H/C/002754/X/0101/G
ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Extension application to introduce a new pharmaceutical form associated with new strength (5 mg/60 mg/30 mg dispersible tablet). The new presentation is indicated for the treatment of Human Immunodeficiency Virus (HIV) infected children weighing at least 14 kg to less than 25 kg.
This extension application is grouped with a type II variation (C.I.6.a) to include treatment of children weighing at least 25kg for the already approved film-coated tablets for Triumeq (EU/1/14/940/001-002); as a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance.
The RMP (version 19) is updated in accordance."
List of Questions adopted on 19.05.2022.

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

nelarabine - EMEA/H/C/000752/S/0058

smallpox vaccine (live modified vaccinia virus ankara) - EMEA/H/C/002596/S/0077

lomitapide - EMEA/H/C/002578/S/0052

vestronidase alfa - EMEA/H/C/004438/S/0032, Orphan
Ultragenyx Germany GmbH

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

Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/R/0052
Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Gross-Martirosyan

CRYSVITA - burosumab - EMEA/H/C/004275/R/0031, Orphan
Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Brigitte Keller-Stanislawski

Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/R/0049
ViiV Healthcare B.V., Rapporteur: Janet Koenig, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Nathalie Gault

KANJINTI - trastuzumab - EMEA/H/C/004361/R/0022
Amgen Europe B.V., BREDA, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski

Paxlovid - (1R,2S,5S)-N-((1S)-1-Cyano-2-((3s)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido) butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir - EMEA/H/C/005973/R/0023
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber

Prasugrel Mylan - prasugrel - EMEA/H/C/004644/R/0014
Mylan Pharmaceuticals Limited, Generic, Generic of Efient, Rapporteur: Alar Irs, PRAC Rapporteur: Anette Kirstine Stark

Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/R/0079
AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné

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

Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0025
Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include the paediatric population from 1 year to less than 18 years of age based on final results from study V920-016 (PREVAC); this is a phase 2, randomized, double-blind, placebo-controlled study of 2 leading Ebola vaccine candidates (Ad26.ZEBOV/MVA-BN-Filo and V920) and 3

vaccine strategies (Ad26.ZEBOV/MVABN-Filo, 1-dose V920, and 2 dose V920) to evaluate immunogenicity and safety in healthy children and adolescents from 1 to 17 years of age and adults 18 years of age and older. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the Annex II and the list of local representatives in the Package Leaflet."

Iclusig - ponatinib -
EMEA/H/C/002695/II/0064, Orphan
Incyte Biosciences Distribution B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Ulla Wändel Liminga, "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."

WS2299
Edistride-
EMEA/H/C/004161/WS2299/0055
Forxiga-
EMEA/H/C/002322/WS2299/0076
AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Mari Thorn, "Extension of indication to include population with Heart Failure and LVEF > 40% for Forxiga and its duplicate Edistride, based on final results from study D169CC00001 (DELIVER); The DELIVER study is a category 3, Post-Authorisation Safety Study (PASS) listed in the dapagliflozin RMP to evaluate the potential risk of lower limb amputation; This was an international, multi-centre, parallel-group, event-driven, randomised, double-blind,

placebo-controlled Phase III study in patients with HF and LVEF > 40%, evaluating the effect of dapagliflozin 10 mg compared with placebo, given once daily in addition to background therapy, including treatments to control co-morbidities, in reducing the composite of CV death or an HF event (hospitalisation for HF or urgent HF visit). As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet are updated in accordance. Version 27 of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Armisarte - pemetrexed - EMEA/H/C/004109/II/0030/G
Actavis Group PTC ehf, Rapporteur: Alar Irs

Nexviadyme - avalglucosidase alfa - EMEA/H/C/005501/II/0001, Orphan
Genzyme Europe BV, Rapporteur: Andrea Laslop

Nexviadyme - avalglucosidase alfa - EMEA/H/C/005501/II/0002, Orphan
Genzyme Europe BV, Rapporteur: Andrea Laslop

Nexviadyme - avalglucosidase alfa - EMEA/H/C/005501/II/0003/G, Orphan
Genzyme Europe BV, Rapporteur: Andrea Laslop

OPDIVO - nivolumab - EMEA/H/C/003985/II/0124/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa

Qarziba - dinutuximab beta - EMEA/H/C/003918/II/0047, Orphan
EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik

Remsima - infliximab - EMEA/H/C/002576/II/0117/G
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola

Spikevax - elasomeran - EMEA/H/C/005791/II/0076/G
Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus

Terrosa - teriparatide - EMEA/H/C/003916/II/0026/G

Gedeon Richter Plc., Rapporteur: Daniela Philadelphy

Tremfya - guselkumab - EMEA/H/C/004271/II/0034/G
Janssen-Cilag International N.V., Rapporteur: Agnes Gyurasics

Ultomiris - ravulizumab - EMEA/H/C/004954/II/0030
Alexion Europe SAS, Rapporteur: Blanca Garcia-Ochoa

Voraxaze - glucarpidase - EMEA/H/C/005467/II/0004, Orphan
SERB S.A.S., Rapporteur: Ondřej Slanař

ZYNRELEF - bupivacaine / meloxicam - EMEA/H/C/005205/II/0009/G
Heron Therapeutics, B.V., Rapporteur: Alexandre Moreau

WS2309/G
Hexacima- EMEA/H/C/002702/WS2309/0135/G
Hexyon- EMEA/H/C/002796/WS2309/0139/G
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS2332/G
Ongentys- EMEA/H/C/002790/WS2332/0051/G
Ontilyv- EMEA/H/C/005782/WS2332/0005/G
Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise

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

ADCETRIS - brentuximab vedotin - EMEA/H/C/002455/II/0103, Orphan
Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.8 and 5.1 of the SmPC to reflect new safety and efficacy information based on long-term data from the second interim analysis of OS (103 events) from study ECHELON-1, undertaken in previously untreated CD30+ Stage IV HL. In addition, following the completion of all specific obligations and considering the recent switch from a conditional to a full MA (variation II-99),

the MAH takes the opportunity to propose the removal of the black triangle (regarding additional monitoring) from the SmPC and the Package Leaflet. Further, minor editorial changes are proposed in the SmPC and Package Leaflet and the contact details of the local representatives are being updated in the Package Leaflet.”	
Benlysta - belimumab - EMEA/H/C/002015/II/0107 GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, “Update of section 4.4 of the SmPC based on final results from study 205646; this is an interventional Phase III Study to Evaluate the Efficacy and Safety of Belimumab Administered in Combination with Rituximab to Adult Subjects with Systemic Lupus Erythematosus (SLE). In addition, the MAH took the opportunity to implement editorial changes.”	
Betaferon - interferon beta-1b - EMEA/H/C/000081/II/0143/G Bayer AG, Rapporteur: Martina Weise, “Update of sections 4.4 and 4.8 of the SmPC based on pooled clinical trial data from six phase II-IV studies: NASPMS (Study No. 3112), Pivotal RRMS (Study No. 13103), EUSPMS (Study No.93079), BENEFIT (Study No. 304747), BEYOND (Study No. 306440) and BEYOND pilot (Study No. 307000), post-marketing experience, scientific literature and FAERS database; the Package Leaflet is updated accordingly. Update of section 4.8 of the SmPC in order to merge the existing two tables for ADRs, requested by the PRAC following the assessment of PSUSA procedure EMEA/H/C/PSUSA/00001759/202107), based on pooled data from four placebo controlled trials: NASPMS (Study No. 3112), Pivotal RRMS (Study No. 13103), EUSPMS (Study No. 93079), and BENEFIT (Study No. 304747); the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes and to update the list of local representatives in the Package Leaflet.”	
COMIRNATY - tozinameran - EMEA/H/C/005735/II/0139	

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Update of sections 4.8 and 5.1 of the SmPC of COMIRNATY 30 µg concentrate for dispersion for injection and COMIRNATY 30 µg dispersion for injection as well as section 4.8 of the SmPC of COMIRNATY 10 µg concentrate for dispersion for injection in order to update information based on six month post (booster) dose three interim report data in patients aged 16 years of age and above from studies C4591001 and C4591031. Study C4591001 is a phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against COVID-19 in healthy individuals, while study C4591031 is a phase 3 master protocol to evaluate additional dose(s) of BNT162b2 in healthy individuals previously vaccinated with BNT162b2."

Imfinzi - durvalumab - EMEA/H/C/004771/II/0050

AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, "Update of section 5.1 of the SmPC in order to include the most recent overall survival (OS) data based on final results from the CASPIAN Study (D419QC00001). This is a phase III, randomized, multicenter, open-label, comparative study to determine the efficacy of durvalumab or durvalumab and tremelimumab in combination with platinum-based chemotherapy for the first-line treatment in patients with extensive disease small-cell lung cancer (SCLC)."

Jardiance - empagliflozin - EMEA/H/C/002677/II/0071

Boehringer Ingelheim International GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.1 of the SmPC based on a meta-analysis report for the non-interventional study EMPRISE–Europe and Asia (1245.195), undertaken to assess the effectiveness and safety of empagliflozin compared with DPP-4 inhibitors in adult patients with type 2 diabetes. The MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet and to update the list of local representatives in the Package Leaflet."

LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0031

Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Aaron Sosa Mejia, "Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions (ADRs) and efficacy information based on final results from study R2810-ONC-1540 in order to fulfil REC/005; this is a nonrandomized, multicenter, phase 2 study of cemiplimab in patients with advanced cutaneous squamous cell carcinoma; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0032

Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Aaron Sosa Mejia, "Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions (ADRs) and efficacy results for the BCC indication based on the primary analysis data from study R2810-ONC-1620 listed in the Annex II; this is a phase 2 study of cemiplimab in patients with advanced basal cell carcinoma who experienced progression of disease on hedgehog pathway inhibitor therapy or were intolerant of prior hedgehog pathway inhibitor therapy. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Norvir - ritonavir - EMEA/H/C/000127/II/0163

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.2 of the SmPC in order to modify administration based on final results from three bioavailability and bioequivalence studies: M11-472, M12-279, and M11-475; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Padcev - enfortumab vedotin - EMEA/H/C/005392/II/0002

Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia, "Submission of the final report from study "An Open-label, Randomized Phase 3

Study to Evaluate Enfortumab Vedotin vs Chemotherapy in Subjects with Previously Treated Locally Advanced or Metastatic Urothelial Cancer" (EV-301) listed as a category 3 study. EV-301 is a global, open-label, randomized phase 3 study in adult subjects with locally advanced or metastatic UC who had received a platinum-containing chemotherapy and had experienced disease progression or relapse during or following treatment with PD-1 or PD-L1 inhibitors."	
Plenadren - hydrocortisone - EMEA/H/C/002185/II/0038 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, "Update of section 4.4 of the SmPC in order to add a warning on pheochromocytoma crisis following a safety signal. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet and other minor corrections considered as editorial changes."	
Retsevmo - selpercatinib - EMEA/H/C/005375/II/0016 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to add chylothorax and chylous ascites to the list of adverse drug reactions (ADRs) based on a review of adverse events. The Package Leaflet is updated accordingly."	
Retsevmo - selpercatinib - EMEA/H/C/005375/II/0017 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of section 4.5 of the SmPC in order to update drug-drug interaction information based on the final results from study J2G-MC-JZJV; this is a phase 1, single-center, open-label, drug-drug interaction (DDI) study to investigate the effect of selpercatinib on the pharmacokinetic profiles of dabigatran, a P-glycoprotein (P-gp) substrate, in healthy volunteers. The Package Leaflet is updated accordingly."	
Taxotere - docetaxel - EMEA/H/C/000073/II/0141	

Sanofi Mature IP, Rapporteur: Alexandre Moreau, "Update of sections 4.4, 4.6 and 5.3 of the SmPC to include further information regarding genotoxicity, pregnancy/lactation exposure with associated adverse outcomes and recommendations regarding use of contraception, and update of section 5.2 of the SmPC regarding the pharmacokinetic terminal elimination half-life (t1/2). The Package Leaflet is updated accordingly."	
Translarna - ataluren - EMEA/H/C/002720/II/0068, Orphan PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.1 of the SmPC in order to update efficacy information upon the request by the CHMP following the outcome of P46/026 based on final results from study PTC124-GD-045-DMD (Study 045); this is an open-label, single-arm, phase 2 study designed to evaluate the ability of ataluren treatment to increase dystrophin protein levels in muscle cells of subjects with nonsense mutation duchenne muscular dystrophy (nmDMD)."	
WS2321 **CONTROLOC Control- EMEA/H/C/001097/WS2321/0040** **PANTOZOL Control- EMEA/H/C/001013/WS2321/0042** **SOMAC Control- EMEA/H/C/001098/WS2321/0041** Takeda GmbH, Lead Rapporteur: Romaldas Mačiulaitis, "Update of sections 4.4 and 4.8 of the SmPC in order to add "Severe Cutaneous Adverse Reactions (SCARs)" information and to add "Acute Generalized Exanthematous Pustulosis (AGEP)" to the list of adverse drug reactions (ADRs) with frequency "not know" based on post-marketing experience, adverse reaction databases and literature; the Package Leaflet is updated accordingly. In addition, the MAH proposes to update section 4.5 of the SmPC to introduce information regarding Drug-Laboratory Interactions. Furthermore, the MAH took the opportunity to implement editorial changes and to update the list of local representatives in the Package Leaflet."	

WS2334 **Dovato-EMEA/H/C/004909/WS2334/0034** **Juluca-EMEA/H/C/004427/WS2334/0046** **Tivicay-EMEA/H/C/002753/WS2334/0082** **Triumeq-EMEA/H/C/002754/WS2334/0108** ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update information on pregnancy and breast-feeding based on supporting published medical literature data on DolPHIN-1 (Dolutegravir in pregnant HIV mothers and their neonates, NCT02245022)."	
WS2336 **Gardasil-EMEA/H/C/000703/WS2336/0100** **Gardasil 9-EMEA/H/C/003852/WS2336/0058** Merck Sharp & Dohme B.V., Lead Rapporteur: Kristina Dunder, "To update section 5.1 of the SmPC to add the effect of vaccination campaigns on the reduction in the incidence of Juvenile-onset Recurrent Respiratory Papillomatosis (JoRRP) based upon published observational studies."	
WS2342/G **Prezista-EMEA/H/C/000707/WS2342/0119/G** **Rezolsta-EMEA/H/C/002819/WS2342/0049/G** **Symtuza-EMEA/H/C/004391/WS2342/0046/G** Janssen-Cilag International N.V., Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add 'crystal nephropathy' to the list of adverse drug reactions (ADRs) with frequency rare based on recent post-marketing data; the Package Leaflets are updated accordingly. In addition, the MAH proposes to update sections 4.4 and 4.6 of the SmPC in order to implement the recommendation of the CHMP to remove the disease information relating to sexual transmission of HIV and to amend the sections related to breast-feeding; the Package Leaflets are updated accordingly."	

B.6.10. CHMP-PRAC assessed procedures

COMIRNATY - tozinameran - EMEA/H/C/005735/II/0140 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst
COMIRNATY - tozinameran - EMEA/H/C/005735/II/0141 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.4 and 4.8 of the SmPC in order to update the occurrence of myocarditis because more information is available in the age group 5-11 years; and to update the statement in the SmPC section 4.4 regarding the risk of myocarditis after a third dose of Comirnaty based on real-world evidence requested by PRAC following the assessment of MEA/002.13 procedure. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in section 4.4 of the SmPC."
EVUSHELD - tixagevimab / cilgavimab - EMEA/H/C/005788/II/0003 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 4.2, 4.8, 4.9, 5.1 and 5.2 of the SmPC in order to change the posology recommendations in the pre-exposure prophylaxis indication based on study TACKLE (D8851C00001). The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted."
Fintepla - fenfluramine - EMEA/H/C/003933/II/0015, Orphan Zogenix ROI Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "To update sections 4.2 and 5.2 of the SmPC to update the safety information based on final results from study ZX008-1903 listed as a category 3 study in the RMP; this is a Phase 1, Open-Label, Single-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ZX008 (Fenfluramine Hydrochloride) in Subjects with Varying Degrees of Hepatic Impairment. The primary objective of this study was to

compare the PK of a single dose of ZX008 (fenfluramine HCl) in subjects with varying degrees of hepatic impairment with that of healthy matched control subjects.
The updated RMP version 2.7 has also been submitted."

GIVLAARI - givosiran - EMEA/H/C/004775/II/0011/G, Orphan
Alnylam Netherlands B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Martin Huber, "Update of section 5.3 of the SmPC based on final results from study AS1-GLP18-007 listed as a category 3 study in the RMP; This is a 104-week Subcutaneous Injection Carcinogenicity Study in Sprague Dawley Rats.
Update of section 5.3 of the SmPC based on final results from study AS1-GLP18-004; This is a 26-week Subcutaneous Injection Carcinogenicity Study in TgRasH2 Mice.
The RMP version 2.1 has also been submitted.
In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

GIVLAARI - givosiran - EMEA/H/C/004775/II/0013/G, Orphan
Alnylam Netherlands B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Martin Huber, "Submission of the final reports from studies ALN-AS1-003 (Study 003) and ALN-AS1-002 (Study 002) listed as a category 3 studies in the RMP. Study 003 is a phase 3 randomized, double-blind, placebo-controlled multicenter study with an open-label extension to evaluate the efficacy and safety of givosiran in patients with acute hepatic porphyrias, while Study 002 is a multicenter, open-label extension study to evaluate the long-term safety and clinical activity of subcutaneously administered ALN AS1 in patients with acute intermittent porphyria who have completed a previous clinical study with ALN-AS1. The RMP version 2.2 has also been submitted."

Invokana - canagliflozin - EMEA/H/C/002649/II/0060
Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Submission of the final report from non-clinical

studies 1 and 2, listed as category 3 studies in the RMP, in order to fulfil MEA/007.2. Nonclinical study 1 was designed to evaluate the effects of canagliflozin on ketone clearance and production; nonclinical study 2 objective is to evaluate the effects of canagliflozin on ketone clearance and production during prolonged fast. The RMP version 9.1 has also been submitted."

Kisplyx - lenvatinib - EMEA/H/C/004224/II/0052

Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: David Olsen, "Update of section 4.8 of the SmPC based on pooled safety data including results of Study 307, an ongoing, multicenter, randomised, open-label study that is being conducted to compare the efficacy and safety of lenvatinib in combination with everolimus or pembrolizumab versus sunitinib as first-line (1L) treatment in adults with advanced renal cell carcinoma (RCC). The provision of the CSR addresses the post-authorisation measure MEA/FSR 009.3. The Package Leaflet is updated accordingly. An updated RMP version 15.0 has been submitted."

NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0057, Orphan

MediWound Germany GmbH, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the 24-months' CSR addendum of the MW2010-03-02 (DETECT) category 1 study; a multicentre, multinational, randomized, controlled, assessor blinded study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to gel vehicle and compared to standard of care. The provision of the CSR addresses the post-authorisation measure ANX 001.7. An updated RMP version 8.0 was provided as part of the application."

Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0033

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Update of section 5.1 of the SmPC based on interim results from study PK/PD study listed as a specific obligation in the Annex II in order to fulfil SOB 1 and SOB 3; this is a PK and

PK/PD Analysis of Intravenously Administered Andexanet after dosing to steady state with a factor Xa inhibitor, rivaroxaban or Apixaban, in healthy subjects and patients who have acute major bleeding. In addition, the MAH took the opportunity implement editorial changes in Annex II of the SmPC. The RMP version 3.0 has also been submitted."

Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0018, Orphan

Roche Registration GmbH, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final report from study GO29365 listed as a category 3 study in the RMP in order to address MEA/002. This is a phase Ib/II, multicenter, open-label study evaluating the safety, tolerability, and anti-tumor activity of polatuzumab vedotin in combination with rituximab or obinutuzumab plus bendamustine in patients with R/R follicular lymphoma or R/R diffuse large B-cell lymphoma. The RMP version 3.0 has also been submitted."

Spikevax - elasomeran - EMEA/H/C/005791/II/0075/G

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0064

Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Menno van der Elst, "Submission of the final report from non-clinical studies 1 and 2, listed as category 3 studies in the RMP in order to fulfil MEA/006.2. Nonclinical study 1 was designed to evaluate the effects of canagliflozin on ketone clearance and production; nonclinical study 2 objective is to evaluate the effects of canagliflozin on ketone clearance and production during prolonged fast. The RMP version 9.1 has also been submitted."

WS2318/G
Ebymect-
EMEA/H/C/004162/WS2318/0058/G
Edistride-
EMEA/H/C/004161/WS2318/0056/G
Forxiga-
EMEA/H/C/002322/WS2318/0077/G

Qtern-
EMEA/H/C/004057/WS2318/0036/G
Xigduo-
EMEA/H/C/002672/WS2318/0068/G
AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Mari Thorn, "C.I.4
Update of section 4.4 of the SmPC in order to remove the potential risk of Lower Limb Amputation (LLA) based on studies D1690C00018, D1690C00019, DECLARE, DAPA-HF, DAPA-CKD, and DELIVER.
The Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to align it with the latest QRD template.
In addition, the MAH took the opportunity to update the list of local representatives in the Qtern Package Leaflet.

C.I.11.z
Submission of an updated RMP in order to align the EU RMPs for the FDCs Xigduo, Ebymect and Qtern, to recently approved updates to the Forxiga EU RMP.

C.I.z
Update of section 4.5 of the SmPC to include a further PI harmonization to address the consideration raised by PRAC and CHMP during the ongoing dapagliflozin procedure PSUSA/00010029/202110.

The Forxiga RMP and Edistride RMP version 28 has been submitted.
The Qtern RMP version 7 has been submitted.
The Xigduo RMP and Ebymect RMP version 13 has been submitted."

B.6.11. PRAC assessed procedures

PRAC Led
Entyvio - vedolizumab -
EMEA/H/C/002782/II/0073
Takeda Pharma A/S, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from study MLN0002_401 listed as a category 3 study in the RMP in order to fulfil MEA/001.2;

this is an international observational prospective cohort study comparing vedolizumab to other biologic agents in patients with ulcerative colitis or Crohn's disease. The RMP version 8.0 has also been submitted."

PRAC Led

Idacio - adalimumab -

EMEA/H/C/004475/II/0017

Fresenius Kabi Deutschland GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 6 in order to propose a continuation of the observational registry (RABBIT) Study #1 (Study Identifier: FKS0-000-RAB) and the cancelation of the observational registry (IBD UK) (Study Identifier: FKS0-000-IBD). In addition, the MAH took the opportunity to align the RMP with the current approved RMP of the reference product."

PRAC Led

NINLARO - ixazomib -

EMEA/H/C/003844/II/0041, Orphan

Takeda Pharma A/S, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study NSMM-5001 (INSIGHT) listed as a Specific Obligation in the Annex II of the Product Information. This is a global, prospective, non-interventional, observational study of presentation, treatment patterns, and outcomes in multiple myeloma patients. The Annex II and the RMP (submitted version 9.0) are updated accordingly.
In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

PRAC Led

Obizur - susoctocog alfa -

EMEA/H/C/002792/II/0049

Baxalta Innovations GmbH, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report for study 241501 listed as a category 2 study in the RMP in order to fulfil SOB/001.4. This is a prospective and retrospective, non-interventional post-authorisation safety study (PASS) to evaluate the safety and effectiveness of Obizur in real-life practice. The RMP version

6.0 has also been submitted."

PRAC Led
Praluent - alirocumab -
EMEA/H/C/003882/II/0072
sanofi-aventis groupe, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from study ALIROC07997 listed as a category 3 study in the RMP. This is a post-authorization safety study (PASS) using healthcare databases to monitor the safety of alirocumab in HIV patients. The RMP version 7.0 has also been submitted."

PRAC Led
WS2306
Aripiprazole Mylan Pharma-
EMEA/H/C/003803/WS2306/0020
Mylan Pharmaceuticals Limited, Generic, Generic of Abilify, Lead Rapporteur: Eva Skovlund, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "To align the safety concerns in the RMP with the reference product. In addition, nationally authorised product has been included in the RMP for the company."

PRAC Led
WS2320
Stribild-EMEA/H/C/002574/WS2320/0120
Truvada-
EMEA/H/C/000594/WS2320/0177
Gilead Sciences Ireland UC, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "To update Annex II and the RMP for Truvada and Stribild to version 18.1 and 14.1 to remove of the paediatric additional Risk Minimisation Measures (aRMMs) for HIV indication.
In addition, the MAH took the opportunity to introduce changes to the PI."

B.6.12. CHMP-CAT assessed procedures

talimogene laherparepvec -
EMEA/H/C/002771/II/0057, ATMP
Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lahteenvuo, "Update to sections 4.4 and 4.8 of the SmPC to revise the safety instructions

regarding the risk of disseminated herpetic infection adverse drug reactions following an MAH review of aggregate safety data of herpetic and disseminated herpetic infections that were reported in patients who were not immunocompromised and those who were immunocompromised. The Package Leaflet is updated accordingly.”

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

WS2311/G **Advagraf-** **EMEA/H/C/000712/WS2311/0068/G** **Modigraf-** **EMEA/H/C/000954/WS2311/0043/G** Astellas Pharma Europe B.V., Lead Rapporteur: Jayne Crowe
WS2314 **Aerius-EMEA/H/C/000313/WS2314/0103** **Azomyr-** **EMEA/H/C/000310/WS2314/0107** **Neoclarityn-** **EMEA/H/C/000314/WS2314/0101** Organon N.V., Duplicate, Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke
WS2315/G **Biktarvy-** **EMEA/H/C/004449/WS2315/0051/G** **Descovy-** **EMEA/H/C/004094/WS2315/0058/G** **Genvoya-** **EMEA/H/C/004042/WS2315/0084/G** **Odefsey-** **EMEA/H/C/004156/WS2315/0055/G** **Vemlidy-** **EMEA/H/C/004169/WS2315/0041/G** Gilead Sciences Ireland UC, Lead Rapporteur:

Bruno Sepodes

WS2328
HyQvia-EMEA/H/C/002491/WS2328/0082
Kiovig-EMEA/H/C/000628/WS2328/0119
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

WS2341
Aflunov-EMEA/H/C/002094/WS2341/0081
Foclivia-EMEA/H/C/001208/WS2341/0078
Seqirus S.r.l, Lead Rapporteur: Armando Genazzani

WS2350/G
Neupro-EMEA/H/C/000626/WS2350/0094/G
UCB Pharma S.A., Lead Rapporteur: Bruno Sepodes

WS2352
Mirapexin-EMEA/H/C/000134/WS2352/0103
Sifrol-EMEA/H/C/000133/WS2352/0094
Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher

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.

E.1. Timetables – 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

G. ANNEX G

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