09 January 2025
EMA/CHMP/414791/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for written procedure on 19-22 August 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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Table of contents

1. Introduction

1.1. Adoption of agenda

CHMP agenda for 19-22 August 2024

The CHMP adopted the agenda.

1.2. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meetings held on 17 June 2024 and on 15 July 2024.

The CHMP adopted the minutes.

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. Donanemab - EMEA/H/C/006024

to slow disease progression in adult patients with Alzheimer's disease (AD).

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in April 2024.

Action: For information

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 14.12.2023.

The CHMP agreed via written procedure on 31.07.2024 to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in April 2024

3.4.2. 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).

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 14.12.2023.

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 June 2024.

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

3.5.1. LEQEMBI - Lecanemab - EMEA/H/C/005966

Eisai GmbH; a disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer's disease and Mild Alzheimer's disease (Early Alzheimer's disease)

Scope: Re-examination rapporteurs appointment

Action: For adoption

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

Negative opinion adopted on 25.07.2024. List of Outstanding Issues adopted on 27.06.2024, 21.03.2024, 09.11.2023. List of Questions adopted on 25.05.2023.

The CHMP appointed the re-examination rapporteurs.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion

No items

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

No items

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

No items

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

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

No items

8.2. Priority Medicines (PRIME)

No items

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. NYXTHRACIS – Obiltoxaximab – EMEA/H/C/005169

SFL Pharmaceuticals; treatment of inhalational anthrax due to Bacillus anthracis

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Filip Josephson

Scope: Withdrawal of marketing authorisation as of 10 September 2024.

Action: For information

The CHMP noted the 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 2024 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

No items

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

No items

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

No items

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for August 2024: **For adoption**	Adopted

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

Anzupgo - Delgocitinib - EMEA/H/C/006109 LEO Pharma A/S, treatment of moderate to severe chronic hand eczema (CHE), 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.
Axitinib Accord – Erdafitinib - EMEA/H/C/006206 Accord Healthcare S.L.U., treatment of adult patients with advanced renal cell carcinoma	For information only. Comments can be sent to the PL in case necessary.

(RCC), Generic, Generic of Inlyta, Generic application (Article 10(1) of Directive No 2001/83/EC)	
Balversa - Axitinib - EMEA/H/C/006050 Janssen-Cilag International N.V., treatment of adult patients with locally advancedunresectableor metastatic urothelial carcinoma (UC), 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.
EKSUNBI - Ustekinumab - EMEA/H/C/006448 Samsung Bioepis NL B.V., treatment of Crohn's disease and Ulcerative colitisPlaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA), 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.
Fymskina - Ustekinumab - EMEA/H/C/005805 Formycon AG, treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Crohn's Disease and Ulcerative colitis, 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.
IQIRVO - Elafibranor - EMEA/H/C/006231, Orphan Ipsen Pharma, treatment of primary biliary cholangitis (PBC), 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.
Ituxredi - Rituximab - EMEA/H/C/006224 Reddy Holding GmbH, treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis, 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.
Kayfanda - Odevixibat - EMEA/H/C/006462 Ipsen Pharma, treatment of cholestatic pruritus in Alagille syndrome (ALGS), 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.
LEQEMBI - Lecanemab - EMEA/H/C/005966 Eisai GmbH, a disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer's disease and Mild Alzheimer's disease (Early Alzheimer's disease), New active	For information only. Comments can be sent to the PL in case necessary.

substance (Article 8(3) of Directive No 2001/83/EC)	
LOQTORZI - Toripalimab - EMEA/H/C/006120 TMC Pharma (EU) Limited, Combination treatment for metastatic or recurrent locally advanced nasopharyngeal carcinoma and for metastatic or recurrent oesophageal squamous cell carcinoma, 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.
Otulfi - Ustekinumab - EMEA/H/C/006544 Fresenius Kabi Deutschland GmbH, treatment of Crohn's Disease and Ulcerative colitis, treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Duplicate, Duplicate of Fymskina, 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.
Ranibizumab Midas - Ranibizumab - EMEA/H/C/006528 MIDAS Pharma GmbH, treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation (CNV), 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.
Tuznue - Trastuzumab - EMEA/H/C/006252 Prestige Biopharma Belgium, treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and HER2 positive early breast cancer (EBC), 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.
Vevizye - Ciclosporin - EMEA/H/C/006250 Novaliq GmbH, Treatment of dry eye disease in adult patients, 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.
Vyloy - Zolbetuximab - EMEA/H/C/005868, Orphan Astellas Pharma Europe B.V., treatment of locally advanced unresectable or metastatic HER2 negative gastric or gastro-oesophageal	For information only. Comments can be sent to the PL in case necessary.

junction (GEJ) adenocarcinoma, New active substance (Article 8(3) of Directive No 2001/83/EC)	
YUVANCI - Macitentan / Tadalafil - EMEA/H/C/005001 Janssen - Cilag International, treatment of pulmonary arterial hypertension (PAH) in adults patients, Fixed combination application (Article 10b 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

Evrysdi - Risdiplam - EMEA/H/C/005145/II/0026 Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Submission of the PBPK Report 1125037, a physiologically based pharmacokinetic (PBPK) model of RO7034067." Withdrawal request submitted on 26.07.2024.	The MAH withdrew the procedure on 26.07.2024.
Gilenya - Fingolimod - EMEA/H/C/002202/II/0088 Novartis Europharm Limited, Rapporteur: Alexandre Moreau	The MAH withdrew the procedure on 01.08.2024.

Request for Supplementary Information adopted on 25.04.2024. Withdrawal request submitted on 01.08.2024.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0075 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Withdrawal request submitted on 01.08.2024.	The MAH withdrew the procedure on 01.08.2024.
Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0017/G Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia Withdrawal request submitted on 13.08.2024.	The MAH withdrew the procedure on 13.08.2024.

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Aflibercept - EMEA/H/C/006438 treatment of age-related macular degeneration (AMD) and visual impairment
Lifileucel - EMEA/H/C/004741, ATMP treatment of unresectable or metastatic melanoma,
Denosumab - EMEA/H/C/006526 treatment of osteoporosis and bone loss
Sebetralstat - EMEA/H/C/006211, Orphan KALVISTA PHARMACEUTICALS (IRELAND) Limited, treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older
Hydrocortisone - EMEA/H/C/005201, PUMA prevention of bronchopulmonary dysplasia in preterm infants born less than 28 weeks of gestation.
Mirdametinib - EMEA/H/C/006460 treatment of neurofibromatosis type 1
Pridopidine - EMEA/H/C/006261, Orphan Prilenia Therapeutics B.V., treatment of Huntington's disease

Olezarsen - EMEA/H/C/006477
treatment of familial chylomicronemia syndrome

Denosumab - EMEA/H/C/006534
prevention of skeletal related events with advanced malignancies

Zuranolone - EMEA/H/C/006488
the treatment of postpartum depression (PPD) in adults

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

Azacitidine Accord - Azacitidine - EMEA/H/C/005147/X/0021
Accord Healthcare S.L.U., Generic of Vidaza, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Bianca Mulder, "Extension application to introduce a new pharmaceutical form (film-coated tablet) associated with new strengths (200 and 300 mg) and new route of administration (oral use).
The RMP (version 2.0) is updated in accordance."

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/X/0140
Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "Extension application to add a new strength of 25 µg, XBB.1.5, Dispersion for injection."

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

Guanfacine - EMEA/H/C/006312
treatment of ADHD
List of Questions adopted on 22.02.2024.

Acoramidis - EMEA/H/C/006333, Orphan
BridgeBio Europe B.V., for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).
List of Questions adopted on 30.05.2024.

Tiratricol - EMEA/H/C/005220, Orphan
Rare Thyroid Therapeutics International AB, treatment of monocarboxylate transporter 8 (MCT8) deficiency
List of Questions adopted on 22.02.2024.

Ivermectin / Albendazole -
EMEA/H/W/005186, Article 58
prevention and treatment of lymphatic filariasis, and soil-transmitted helminths infections.
List of Questions adopted on 30.05.2024.

Jakavi - Ruxolitinib -
EMEA/H/C/002464/X/0070/G
Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg/ml oral solution) and a new route of administration (gastric use), indicated for the treatment of Graft versus host disease (GvHD) in patients aged 28 days or older.

The above line extension is grouped with a type II variation:
- C.I.6.a - To include treatment of paediatric patients aged 28 days to less than 18 years old in acute and chronic Graft versus Host Disease for JAKAVI, based on final results from studies REACH4 (CINC424F12201) and REACH5 (Study CINC424G12201). REACH4 is a Phase I/II open-label, single-arm, multi-centre study of ruxolitinib added to corticosteroids in paediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation; while REACH5 is a Phase II open-label, single-arm, multi-centre study of ruxolitinib added to corticosteroids in paediatric subjects with moderate and severe chronic graft vs. host disease after allogeneic stem cell transplantation (both for oral solution and already approved tablets presentations). As a consequence, sections 4.1,4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.

The RMP (version 16) is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to implement editorial changes to Annex II."
List of Questions adopted on 25.04.2024.

Seladelpar lysine dihydrate -
EMEA/H/C/004692, Orphan
CymaBay Ireland, Ltd, treatment of primary biliary cholangitis (PBC) including pruritus in

adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA
List of Questions adopted on 27.06.2024.

Linvoseltamab - EMEA/H/C/006370
monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma
List of Questions adopted on 30.05.2024.

Nemolizumab - EMEA/H/C/006149
for the treatment of moderate-to-severe atopic dermatitis and for the treatment of prurigo nodularis
List of Questions adopted on 30.05.2024.

Denosumab - EMEA/H/C/006424
treatment of osteoporosis and bone loss
List of Questions adopted on 25.07.2024.

Pegfilgrastim - EMEA/H/C/006348, PUMA
treatment of neutropenia in paediatric patients
List of Questions adopted on 30.05.2024.

Imetelstat - EMEA/H/C/006105, Orphan
Geron Netherlands B.V., for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS), for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS)
List of Questions adopted on 25.01.2024.

Tisotumab vedotin - EMEA/H/C/005363
treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy
List of Questions adopted on 30.05.2024.

Uzpruvo - Ustekinumab - EMEA/H/C/006101/X/0001
STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Rhea Fitzgerald, "Extension application to introduce a new pharmaceutical form associated with a new strength (130 mg concentrate for solution for infusion) and a new route of administration (intravenous use). The RMP version 1.1 is updated in accordance."

List of Questions adopted on 27.06.2024.

In vitro diagnostic medical device - EMEA/H/D/006545
laboratory use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed paraffin embedded (FFPE) epithelial ovarian, fallopian tube or primary peritoneal cancer tissue specimens by light microscopy
Request for Supplementary Information adopted on 25.07.2024.

Human albumin solution - EMEA/H/D/006410
vitrification of human MII-phase oocytes and embryos for assisted reproductive technology (ART)
reproductive technology (ART).
List of Questions adopted on 30.05.2024.

Beremagene geperpavec - EMEA/H/C/006330, Orphan, ATMP
Krystal Biotech Netherlands B.V., treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene
List of Questions adopted on 15.03.2024.

Clascoterone - EMEA/H/C/006138
indicated for the topical treatment of acne vulgaris in adults and adolescents
List of Questions adopted on 22.02.2024.

Denosumab - EMEA/H/C/006468
prevention of skeletal related events with advanced malignancies and treatment of giant cell tumour of bone
List of Questions adopted on 25.07.2024.

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

Atriance - Nelarabine - EMEA/H/C/000752/S/0068
Sandoz Pharmaceuticals d.d., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Brineura - Cerliponase alfa - EMEA/H/C/004065/S/0047, Orphan
BioMarin International Limited, Rapporteur:

Martina Weise, PRAC Rapporteur: Mari Thorn,

IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/S/0107
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer

Lojuxta - Lomitapide - EMEA/H/C/002578/S/0061
Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Mepsevii - Vestronidase alfa - EMEA/H/C/004438/S/0042, Orphan
Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Maria del Pilar Rayon

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

Atectura Breezhaler - Indacaterol / Mometasone - EMEA/H/C/005067/R/0031
Novartis Europharm Limited, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Bemrist Breezhaler - Indacaterol / Mometasone - EMEA/H/C/005516/R/0026
Novartis Europharm Limited, Duplicate of Atectura Breezhaler, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/R/0006, Orphan, ATMP
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Heli Suila, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder

Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/R/0020, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, Co-Rapporteur: Heli Suila, CHMP Coordinator: Daniela Philadelphy, PRAC Rapporteur: Bianca Mulder

Retsevmo - Selpercatinib -
EMEA/H/C/005375/R/0035
Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

SARCLISA - Isatuximab -
EMEA/H/C/004977/R/0033
Sanofi Winthrop Industrie, Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Monica Martinez Redondo

Zeposia - Ozanimod -
EMEA/H/C/004835/R/0028
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon

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

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel -
EMEA/H/C/004731/II/0043/G, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini, PRAC Rapporteur: Gabriele Maurer

C.I.6 (Type II): Extension of indication for Breyanzi to include treatment of adult patients with 3rd line + follicular lymphoma (FL) based on final results from the pivotal study JCAR017-FOL-001 (FOL-001, TRANSCEND-FL). This is a phase 2, open-label, single-arm, multicohort, multicenter study to evaluate efficacy and safety of JCAR017 in adult subjects with relapsed or refractory (r/r) follicular Lymphoma (FL) or marginal zone lymphoma (MZL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP is being submitted. Furthermore, 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)

Columvi - Glofitamab - EMEA/H/C/005751/II/0005, Orphan

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Jana Lukacisinova, "Extension of indication to include in combination with gemcitabine and oxaliplatin the treatment of adult patients with relapse or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are not candidates for autologous stem cell transplant (ASCT) for COLUMVI, based on results of primary and updated analyses from study GO41944 (STARGLO) listed as a Specific Obligation in the Annex II of the Product Information, as well supportive data from the Phase Ib study GO41943. Study GO41944 (STARGLO) is a Phase III, open-label, multicenter, randomized study of glofitamab in combination with GemOx (Glofit-GemOx) vs. rituximab in combination with GemOx (R-GemOx) in patients with R/R DLBCL. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet. 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)

Enhertu - Trastuzumab - EMEA/H/C/005124/II/0048

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Carla Torre, "Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-low or HER2-ultralow breast cancer (BC) who have received at least one endocrine therapy in the metastatic setting for ENHERTU, based on results from study D9670C00001 (DESTINY-Breast06); this is a phase 3, randomized, multicentre, open-label study of trastuzumab deruxtecan (DS-8201a) compared with investigator's choice chemotherapy in, hormone

receptor-positive, HER2-low and HER2-ultralow BC patients whose disease has progressed on endocrine therapy in the metastatic setting. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI, to update the list of local representatives in the Package Leaflet and to update the PI according to the Excipients Guideline."	
Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0047 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include treatment of adults and children from 6 months of age and older for FLUCELVAX TETRA based on final results from study V130_14. This is a phase 3, randomized, observer-blind, multicenter study to evaluate the efficacy, immunogenicity, and safety of Seqirus' Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (QIVc) compared to a non-influenza vaccine when administrated in healthy subjects aged 6 months through 47 months. 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 3.3 of the RMP has also been submitted."	
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0108 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, "Extension of indication to include treatment of adolescents from 12 to 17 years of age for IMVANEX based on interim results from study DMID 22-0020. This is a Phase 2 randomized open label multisite trial to inform Public Health strategies involving the use of MVA-BN vaccine for mpox. 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. Furthermore, the PI is brought in line with the latest QRD template version 10.4. "	

Invokana - Canagliflozin - EMEA/H/C/002649/II/0069

Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Extension of indication to include treatment of paediatric patients with type 2 diabetes mellitus aged 10 years old and older for INVOKANA, based on final results from study JNJ-28431754DIA3018 as well as study JNJ-28431754DIA1055. Study JNJ-28431754DIA3018 is a double-blind, placebo-controlled, 2-arm, parallel-group, multicenter Phase 3 study in participants with T2DM >10 and <18 years of age who had inadequate glycemic control (ie, HbA1c of >6.5% to <11.0%). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI and update the list of local representatives in the Package Leaflet."

Saxenda - Liraglutide - EMEA/H/C/003780/II/0042

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include the use of SAXENDA for weight management in children from the age of 6 years to less than 12 years based on results from study NN8022-4392; this is a 56-week, double-blind, randomised, placebo-controlled study investigating safety and efficacy of liraglutide on weight management in children with obesity aged 6 to <12 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 34.0 of the RMP has also been submitted."

Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0021/G

Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Nathalie Gault, "Grouped application comprising two type II variations as follows:
C.I.6.a – Extension of indication to include the

treatment of children 9 years of age and older for Supemtek, based on final results from study VAP00027; this is a Phase III, non-randomized, open-label, uncontrolled study to demonstrate the non-inferior HAI immune response of RIV4 for the 4 strains in participants aged 9 to 17 years vs participants aged 18 to 49 years; 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 2.0 of the RMP has also been submitted. C.I.4 - Update of sections 4.8 and 5.1 of the SmPC in order to update paediatric information based on final results from study VAP00026; this is a Phase III, randomized, modified double-blind, active-controlled 2-arm to demonstrate the non-inferior HAI immune response of RIV4 vs licensed IIV4 for the 4 strains based on the egg-derived antigen in all participants. Version 2.0 of the RMP has also been submitted."	
Taltz - Ixekizumab - EMEA/H/C/003943/II/0053 Eli Lilly and Co (Ireland) Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include treatment of juvenile idiopathic arthritis for TALTZ, based on week 16 results from study I1F-MC-RHCG; this is a multicenter, open-label, efficacy, safety, tolerability, and pharmacokinetic study (COSPIRIT-JIA) of subcutaneous ixekizumab with adalimumab reference arm, in children from 2 to less than 18 years of age with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including juvenile-onset ankylosing spondylitis) and juvenile psoriatic arthritis was performed to evaluate the efficacy and safety of ixekizumab for 16 weeks after treatment initiation. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. Furthermore, the PI is in line with the latest QRD template version 10.4."	

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Apidra - Insulin glulisine - EMEA/H/C/000557/II/0095
Sanofi-Aventis Deutschland GmbH, Rapporteur: Thalia Marie Estrup Blicher

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0026/G
Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher

Briumvi - Ublituximab - EMEA/H/C/005914/II/0017/G
Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra

COMIRNATY - COVID-19 mRNA vaccine – EMA/VR/0000224683
BioNTech Manufacturing GmbH., Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine – EMA/VR/0000225514
BioNTech Manufacturing GmbH., Rapporteur: Filip Josephson

Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan - Efavirenz/Emtricitabine/Tenofovir disoproxil – EMA/VR/0000225000
Mylan Pharmaceuticals Limited, Rapporteur: Bruno Sepodes

Emtricitabine/Tenofovir disoproxil Mylan - Emtricitabine/Tenofovir disoproxil – EMA/VR/0000223057
Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite

Eylea - Aflibercept - EMEA/H/C/002392/II/0093
Bayer AG, Rapporteur: Jean-Michel Race

Gardasil - Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0107/G
Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder

HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0101
Baxalta Innovations GmbH, Rapporteur: Jan

Mueller-Berghaus

IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0106
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

Insulin aspart Sanofi - Insulin aspart - EMEA/H/C/005033/II/0018/G
Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt

Insulin lispro Sanofi - Insulin lispro - EMEA/H/C/004303/II/0021
Sanofi Winthrop Industrie, Rapporteur: Outi Mäki-Ikola

Insuman - Insulin human - EMEA/H/C/000201/II/0152/G
Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn

Kauliv - Teriparatide - EMEA/H/C/004932/II/0004
Strides Pharma (Cyprus) Limited, Rapporteur: Martina Weise

KIMMTRAK - Tebentafusp - EMEA/H/C/004929/II/0007, Orphan
Immunocore Ireland Limited, Rapporteur: Aaron Sosa Mejia

Menveo - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0122/G
GSK Vaccines S.r.l, Rapporteur: Patrick Vrijlandt

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0078
Novavax CZ a.s., Rapporteur: Patrick Vrijlandt

Ogivri - Trastuzumab - EMEA/H/C/004916/II/0063
Biosimilar Collaborations Ireland Limited, Rapporteur: Karin Janssen van Doorn

Pergoveris - Follitropin alfa / Lutropin alfa - EMEA/H/C/000714/II/0095/G
Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher

Pombiliti - Cipaglucosidase alfa -

EMEA/H/C/005703/II/0015
Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt

Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0209
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Puregon - Follitropin beta – EMA/VR/0000224916
Organon N.V., Rapporteur: Finbarr Leacy

Remicade – Infliximab – EMA/VR/0000224494
Janssen Biologics B.V., Rapporteur: Kristina Dunder"Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add post-procedural complications (including infectious and non-infections complications) to the list of adverse drug reactions (ADRs) with frequency not known and update treatment recommendations for patients with a planned surgical procedure based on a cumulative review of literature, clinical trial and registry data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Spinraza - Nusinersen - EMEA/H/C/004312/II/0035, Orphan
Biogen Netherlands B.V., Rapporteur: Bruno Sepodes

TALVEY - Talquetamab - EMEA/H/C/005864/II/0012/G, Orphan
Janssen-Cilag International N.V., Rapporteur: Alexandre Moreau

Tecvayli - Teclistamab - EMEA/H/C/005865/II/0015
Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo

Tenofovir disoproxil Viatris - Tenofovir disoproxil - EMA/VR/0000224509
Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite

Tyenne - Tocilizumab - EMEA/H/C/005781/II/0005
Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder

WEZENLA - Ustekinumab -
EMEA/H/C/006132/II/0001
Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola

WS2732
Lantus-EMEA/H/C/000284/WS2732/0135
Suliqua-EMEA/H/C/004243/WS2732/0043
Toujeo-EMEA/H/C/000309/WS2732/0132
Sanofi-Aventis Deutschland GmbH, Lead Rapporteur: Patrick Vrijlandt

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

AQUIPTA - Atogepant -
EMEA/H/C/005871/II/0006
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC based on final results from study ELEVATE (3101-304-002). This is a phase 3, 12 weeks, randomized, double-blind, placebo-controlled, parallel-group study that evaluated the efficacy, safety, and tolerability of atogepant 60 mg once daily (QD) for the prophylaxis of migraine in participants with episodic migraine who had previously failed 2 to 4 classes of oral prophylactic treatments. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

IBRANCE - Palbociclib -
EMEA/H/C/003853/II/0045
Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study A5481092. This is a Phase 1/2 Study to Evaluate palbociclib in Combination with irinotecan and temozolomide or in Combination with topotecan and cyclophosphamide in Paediatric Patients with Recurrent or Refractory Solid Tumours. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4."

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) -
EMEA/H/C/005808/II/0083
Novavax CZ a.s., Rapporteur: Patrick Vrijlandt,

"Submission of the final report from study 2019nCoV-301 (Adult population) listed as a category 3 study in the RMP. This is A Phase 3, Randomized, Observer-Blinded, Placebo Controlled Study To Evaluate The Efficacy, Safety, And Immunogenicity Of A Sars-Cov-2 Recombinant Spike Protein Nanoparticle Vaccine (Sars-Cov-2 Rs) With Matrix-M1 Adjuvant In Adult Participants ≥ 18 Years With A Paediatric Expansion In Adolescents (12 To < 18 Years)."	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0084 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-302 listed as a category 3 study in the RMP. This is a Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1TM Adjuvant in Adult Participants 18 – 84 Years of Age in the United Kingdom."	
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0010, Orphan Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add hypersensitivity, including urticaria and rash, to the list of adverse drug reactions (ADRs) with frequency not known based on post-marketing experience. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce corrections and minor changes to the PI and to update the list of local representatives in the Package Leaflet."	
Torisel - Temsirolimus - EMEA/H/C/000799/II/0092 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, "Update of sections 4.4 and 4.5 of the SmPC in order to update the warnings and drug-drug interaction information with newly marketed drug substances. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Veklury - Remdesivir -	

EMEA/H/C/005622/II/0061
Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update sections 4.9 and 5.1 of the SmPC based on final results from study GS US 540 9053. This is a Phase 1, Partially Blinded, Randomized, Placebo- and Positive-Controlled Study to Evaluate the Effect of Remdesivir on the QT/QTc Interval in Healthy Participants."

Xtandi - Enzalutamide - EMEA/H/C/002639/II/0068/G
Astellas Pharma Europe B.V., Rapporteur: Carolina Prieto Fernandez, "Grouped application comprising two type II variations as follows:
C.I.4 - Update of sections 4.2, 4.4 and 4.8 in order to add a new warning on Dysphagia related to product size and to add dysphagia to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of the MAH safety database and literature search.
C.I.4 – Update of section 4.8 of the SmPC in order to add decreased appetite to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of the MAH safety database and literature search.
The Package Leaftlet is updated accordingly."

B.6.10. CHMP-PRAC assessed procedures

FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan
Vifor France, Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber, "Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicenter, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full

marketing authorisation."

WS2738
Entresto-
EMEA/H/C/004062/WS2738/0065
Neparvis-
EMEA/H/C/004343/WS2738/0062
Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Karin Erneholm, "Update of sections 4.8 and 5.3 of the SmPC in order to update information on long-term data in paediatric patients, based on final results from study CLCZ696B2319E1(PANAROMA-HF OLE) listed as a category 3 study in the RMP (MEA/009); this is a phase 3, multicentre, uncontrolled study to evaluate long-term safety and tolerability of open label sacubitril/valsartan in paediatric patients with heart failure due to systemic left ventricle systolic dysfunction who have completed study CLCZ696B2319 (PANORAMA-HF); the RMP version 8 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led
CRYSVITA - Burosumab -
EMEA/H/C/004275/II/0040, Orphan
Kyowa Kirin Holdings B.V., PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 8.0 in order to remove hyperphosphataemia as an important potential risk and to add a specific adverse drug reaction follow-up form/questionnaire for increased parathyroid hormone levels as a routine pharmacovigilance activity."

PRAC Led
JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) -
EMEA/H/C/005737/II/0078/G
Janssen-Cilag International N.V., PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "A grouped application consisting of three Type II variations, as follows:
C.I.13: Submission of the final report from study COV3003 listed as a category 3 study in

the RMP. This is a randomized, double-blind, phase 3 study to evaluate 6 dose levels of Ad26.COV2.S administered as a two-dose schedule in healthy adults. The RMP version 8.3 has also been submitted. C.I.13: Submission of the final report from study COV3009 listed as a category 3 study in the RMP. This is a randomized, double-blind, placebo controlled phase 3 study to assess the efficacy and safety ofAd26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older. C.I.13: Submission of the final report from study RSV2008 listed as a category 3 study in the RMP. This is a randomized, observer-blind, phase 1 study to evaluate innate and pro-inflammatory responses of an Ad26.RSV.preF-based vaccine, Ad26.COV2.S vaccine and Ad26.ZEBOV vaccine in adults aged 18 to 59 years."	
PRAC Led **Lenvima - Lenvatinib - EMEA/H/C/003727/II/0056** Eisai GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update the safety and efficacy information for the current HCC indication based on final results from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP; this is a multicentre non-interventional, observational Phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. The RMP version 17.0 has also been submitted."	
PRAC Led **Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0082** Novavax CZ a.s., PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission an updated RMP version 5.1 in order to include the safety and effectiveness data available from the non-clinical studies and post-authorization usage regarding the JN.1 variant strain."	

PRAC Led

Rotarix - Rotavirus vaccine (live, oral) - EMEA/H/C/000639/II/0135

GlaxoSmithKline Biologicals S.A., PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of an updated RMP version 24 in order to remove missing information related to long term genetic stability of the vaccine virus strain."

PRAC Led

Ruconest - Conestat alfa - EMEA/H/C/001223/II/0088/G

Pharming Group N.V, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Daniela Philadelphy, "Submission of an updated RMP version 19.3 in order to request the early termination of the EU registry study C1 1412, as well as to update safety information based on cumulative data from clinical trials, the EU registry data, post-marketing data and literature. A request for the extension of the due date for the European survey of educational materials for Ruconest is also included."

PRAC Led

WS2709

Rivaroxaban Viatris- EMEA/H/C/005600/WS2709/0012

Viatris Limited, Generic of Xarelto, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To provide an updated RMP to remove the following safety concerns (classified as Missing information) in order to align with RMP version 13.4 of the reference product Xarelto:
-Patients with severe renal impairment (CrCl < 30 mL/min)
-Patients receiving concomitant systemic inhibitors of CYP 3A4 or P-gp other than azole antimycotics (e.g. ketoconazole) and HIV-protease inhibitors (e.g. ritonavir)
-Pregnant or breast-feeding women
-Long-term therapy with rivaroxaban in treatment of DVT, PE, SPAF and ACS in real-life setting
-Patients with significant liver diseases (severe hepatic impairment/Child Pugh C)
-Patients < 18 years."

PRAC Led

WS2743
Komboglyze-
EMEA/H/C/002059/WS2743/0060
Onglyza-
EMEA/H/C/001039/WS2743/0061
AstraZeneca AB, Lead PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 18.1 in order to remove the previously classified important potential risk serious cutaneous adverse reactions (SCAR)."

B.6.12. CHMP-CAT assessed procedures

Kymriah - Tisagenlecleucel -
EMEA/H/C/004090/II/0086/G, Orphan,
ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, "A grouped application consisting of:
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on cytokine release syndrome based on literature.
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on neurological adverse reaction based on literature. The Package Leaflet is updated accordingly.
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on hypersensitivity reactions based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the PI."

Upstaza - Eladocagene exuparvovec -
EMEA/H/C/005352/II/0023/G, Orphan,
ATMP
PTC Therapeutics International LimitedRapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy

Zolgensma - Onasemnogene abeparvovec -
EMEA/H/C/004750/II/0052, Orphan,
ATMP
Novartis Europharm Limited, Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol, "Update of sections 5.1 and 5.2 of the SmPC in

order to update efficacy and vector shedding data following request in procedure EMA/H/C/004750/P46/022 and based on data from study COAV101A12306. In addition, a reference to section 5.2 is added to section 4.4, as requested in final Assessment report of procedure EMA/H/C/004750/P46/022.”

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

WS2711 **Ambirix-** **EMEA/H/C/000426/WS2711/0134** **Fendrix-** **EMEA/H/C/000550/WS2711/0087** **Infanrix hexa-** **EMEA/H/C/000296/WS2711/0348** **Twinrix Adult-** **EMEA/H/C/000112/WS2711/0169** **Twinrix Paediatric-** **EMEA/H/C/000129/WS2711/0170** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke,
WS2712/G **Bretaris Genuair-** **EMEA/H/C/002706/WS2712/0055/G** **Eklira Genuair-** **EMEA/H/C/002211/WS2712/0055/G** Covis Pharma Europe B.V., Lead Rapporteur: Ewa Balkowiec Iskra, Quality
WS2716/G **Hexacima-** **EMEA/H/C/002702/WS2716/0158/G** **Hexyon-** **EMEA/H/C/002796/WS2716/0162/G** **MenQuadfi-** **EMEA/H/C/005084/WS2716/0036/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus, Quality
WS2720/G **Brimica Genuair-** **EMEA/H/C/003969/WS2720/0043/G**

Duaklir Genuair-
EMEA/H/C/003745/WS2720/0042/G
Covis Pharma Europe B.V., Lead Rapporteur:
Ewa Balkowiec Iskra,Quality ”

WS2723/G
Abseamed-
EMEA/H/C/000727/WS2723/0110/G
Binocrit-
EMEA/H/C/000725/WS2723/0110/G
Epoetin alfa Hexal-
EMEA/H/C/000726/WS2723/0110/G
Sandoz GmbH, Lead Rapporteur: Alexandre
Moreau, Quality

WS2726
Entresto-
EMEA/H/C/004062/WS2726/0064
Neparvis-
EMEA/H/C/004343/WS2726/0061
Novartis Europharm Limited, Lead Rapporteur:
Patrick Vrijlandt, Quality

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)*

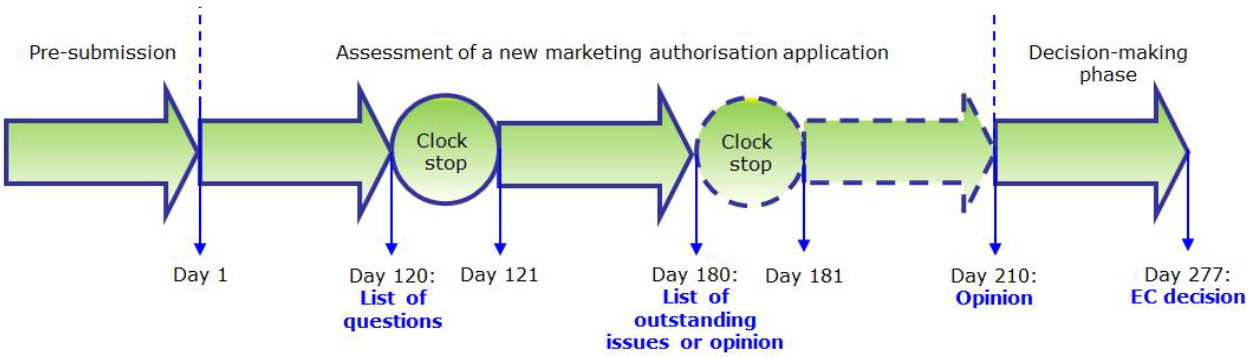
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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