27 January 2025
EMA/CHMP/585836/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 27-30 January 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

27 January 2025, 09:30 – 19:30, virtual meeting/room 1C

28 January 2025, 08:30 – 19:30, virtual meeting/room 1C

29 January 2025, 08:30 – 19:30, virtual meeting/room 1C

30 January 2025, 08:30 – 15:00, virtual meeting/room 1C

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 27-30 January 2025. See January 2025 CHMP minutes (to be published post February 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 27-30 January 2025

1.3. Adoption of the minutes

CHMP minutes for 09-12 December 2024.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 7 of October and 20 January 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Vorasidenib - Orphan - EMEA/H/C/006284

Les Laboratoires Servier; treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a IDH1 R132 mutation or IDH2 R172 mutation
Scope: Oral explanation

Action: Oral explanation to be held on 28 January 2025 at 11:00

List of Outstanding Issues adopted on 19.09.2024, 25.07.2024. List of Questions adopted on 23.04.2024.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028

Infai GmbH

Rapporteur: Christian Gartner

Scope: Oral explanation

Action: Oral explanation to be held on 29 January 2025 at 14:00

Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.

See 2.3

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Pneumococcal polysaccharide conjugate vaccine (21-valent) - EMEA/H/C/006267

for active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

3.1.2. Datopotamab - EMEA/H/C/006547

Treatment of adult patients with inoperable or metastatic HR-positive / HER2-negative breast cancer with disease progression following chemotherapy in the metastatic setting

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

3.1.3. Pegfilgrastim - EMEA/H/C/006407

treatment of neutropenia

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

3.1.4. Eltrombopag - EMEA/H/C/006459

treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

3.1.5. Ivermectin / Albendazole - Article 58 - EMEA/H/W/005186

prevention and treatment of lymphatic filariasis, and soil-transmitted helminths infections.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

3.1.6. Aflibercept - EMEA/H/C/006339

treatment of age-related macular degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

3.1.7. Aflibercept - EMEA/H/C/006551

treatment of age-related macular degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

3.1.8. Tisotumab vedotin - EMEA/H/C/005363

treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

3.1.9. Chikungunya virus virus-like particle - PRIME - Article 28 - EMEA/H/C/005470

prevention of disease caused by chikungunya (CHIKV) virus

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2024. List of Questions adopted on 15.10.2024.

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

3.2.1. Troriluzole - Orphan - EMEA/H/C/006068

Biohaven Bioscience Ireland Limited; is indicated for the treatment of adult patients with spinocerebellar ataxia genotype 3 (SCA3)

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues.

Action: For adoption

List of Questions adopted on 22.02.2024.

3.2.2. Trastuzumab - EMEA/H/C/006219

treatment of metastatic and early breast cancer

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues that are to be adopted at the January meeting.

Action: For adoption

List of Questions adopted on 30.05.2024.

3.2.3. Diflunisal - Orphan - EMEA/H/C/006248

AO Pharma AB; Treatment of ATTR amyloidosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

3.2.4. AMINO ACIDS - Orphan - EMEA/H/C/005557

Recordati Rare Diseases; treatment of decompensation episodes in MSUD patients

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

3.2.5. Ferric citrate coordination complex - EMEA/H/C/006402

treatment of iron deficiency anaemia in adult chronic kidney disease (CKD) patients with elevated serum phosphorus levels

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

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

3.3.1. Denosumab - EMEA/H/C/006490

Treatment of osteoporosis in postmenopausal women and in men, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients.

Scope: List of questions

Action: For adoption

3.3.2. Denosumab - EMEA/H/C/006722

prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

3.3.3. Nipocalimab - EMEA/H/C/006379

treatment of generalised Myasthenia Gravis

Scope: List of questions

Action: For adoption

3.3.4. Denosumab - EMEA/H/C/006238

treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.5. Belumosudil - Orphan - EMEA/H/C/006421

Sanofi Winthrop Industrie; Treatment of chronic graft-versus host disease (cGVHD) disease (cGVHD) after failure of at least two prior lines of systemic therapy

Scope: List of questions

Action: For adoption

3.3.6. Rilonacept - Orphan - EMEA/H/C/006537

FGK Representative Service GmbH; treatment of idiopathic pericarditis
Scope: List of questions

Action: For adoption

3.3.7. Denosumab - EMEA/H/C/006552

Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults and treatment of adults and skeletally mature adolescents with giant cell tumour of bone.

Scope: List of questions

Action: For adoption

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

3.4.1. Hydrocortisone - PUMA - EMEA/H/C/005201

prevention of bronchopulmonary dysplasia in preterm infants born less than 28 weeks of gestation.

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in December 2024.

Action: For adoption

List of Questions adopted on 12.12.2024.

3.4.2. Nirogacestat - Orphan - EMEA/H/C/006071

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in December 2024.

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 27.06.2024.

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

3.5.1. Kizfizo - Temozolomide - Orphan - EMEA/H/C/006169

Orphelia Pharma; treatment of neuroblastoma

Scope: Re-examination; Questions to the SAG

Action: For adoption

Hybrid application (Article 10(3) of Directive No 2001/83/EC)

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 14.12.2023.

3.5.2. CINAINU - Liquid ethanolic extract 30 per cent (W/W) of *Allium cepa* fresh bulb and *Citrus limon* fresh fruit / Dry aqueous extract of *paullinia cupana* seed / Dry hydroethanolic extract of *theobroma cacao* seed - EMEA/H/C/004155

Legacy Healthcare (France) S.A.S.; treatment of alopecia areata in children and adolescents

Scope: Re-examination; Questions to the AHEG

Action: For adoption

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

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 12.10.2023.

3.6. Initial applications in the decision-making phase

3.6.1. Wainzua - Eplontersen - Orphan - EMEA/H/C/006295

AstraZeneca AB; treatment of hereditary transthyretin-mediated amyloidosis (ATTRv) in adult patients with stage 1 or stage 2 polyneuropathy.

Scope: Revised similarity assessment report

Action: For adoption

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

Opinion adopted on 17.10.2024. List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 22.02.2024.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Datopotamab - EMEA/H/C/006081

treatment of adult patients with locally advanced or metastatic non squamous non-small cell lung cancer (NSCLC)

Scope: Withdrawal of marketing authorization application

Action: For information

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

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

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

4.1.1. OPDIVO - Nivolumab - EMEA/H/C/003985/X/0144

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use). Version 40.0 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 17.10.2024.

4.1.2. Rybrevant - Amivantamab - EMEA/H/C/005454/X/0014

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection), two new strengths of 1600 mg and 2240 mg (160 mg/ml concentration) and a new route of administration (subcutaneous use)."

Action: For adoption

List of Questions adopted on 17.10.2024.

4.1.3. Taltz - Ixekizumab - EMEA/H/C/003943/X/0051

Eli Lilly and Co (Ireland) Limited;

Rapporteur: Kristina Dunder

Scope: "Extension application to add a new strength of 40 mg for Taltz, Solution for injection"

Action: For adoption

List of Questions adopted on 17.10.2024.

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

4.2.1. Evrysdi - Risdiplam - EMEA/H/C/005145/X/0024/G

Roche Registration GmbH;

Rapporteur: Fátima Ventura

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg film-coated tablets) grouped with a Type II variation (C.I.4) to update sections 4.2 and 5.2 of the SmPC in order to update the recommended method of administration based on the food effect results from study BP42066; this is a phase 1, open-label, multiperiod crossover study to investigate the safety, food effect, bioavailability, and bioequivalence of oral doses of two different formulations of risdiplam in healthy subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the Product Information and to align the Package Leaflets of both formulations."

Action: For adoption

List of Questions adopted on 19.09.2024.

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

4.3.1. Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/X/0033/G

Bayer AG;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to add a new strength of Jivi 4000 UI powder and solvent for solution for injection for treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency).Version 3.1 of the RMP has also been submitted.
In addition, the MAH has taken the opportunity to align the product information with the pre-specified language from the updated EC Excipient Guideline.

Action: For adoption

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

5.1.1. Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0007

Pfizer Europe Ma EEIG;

Rapporteur: Jayne Crowe, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include active immunization of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Substudy A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥18 to <60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. 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 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. 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)

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 19.09.2024.

5.1.2. Amvuttra - Vutrisiran - Orphan - EMEA/H/C/005852/II/0015

Alnylam Netherlands B.V.;

Rapporteur: Janet Koenig, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include treatment of wild-type or hereditary transthyretin-mediated amyloidosis in adult patients with cardiomyopathy (ATTR-CM), based on primary analysis results from study HELIOS-B (ALN-TTRSC02-003); a Phase 3, Randomized, Double-blind, Placebo-controlled, Multicentre Study to Evaluate the Efficacy and Safety of vutrisiran in Patients With Transthyretin Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. An updated version 1.3 of the RMP has also been submitted. As part of the application the MAH applied for +1 year of additional market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.3. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - ATMP - EMEA/H/C/004731/II/0043/G

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Gabriele Maurer, CHMP Coordinator: Paolo Gasparini

Scope: "A grouped application consisting of:

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, multicentre 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)

Action: For adoption

Request for Supplementary Information adopted on 08.11.2024.

5.1.4. Calquence - Acalabrutinib - EMEA/H/C/005299/II/0028

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include CALQUENCE in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL), based on interim results from study AMPLIFY (D8221C00001). This is a Randomized, Multicentre, Open-Label, Phase 3 Study to Compare the Efficacy and Safety of Acalabrutinib in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukaemia Without del(17p) or TP53 Mutation (AMPLIFY). 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 of the RMP has also been submitted."

Action: For adoption

5.1.5. Columvi - Glofitamab - Orphan - EMEA/H/C/005751/II/0005

Roche Registration GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova

Scope: "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, multicentre, 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)

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

5.1.6. Cystadrops - Mercaptamine - Orphan - EMEA/H/C/003769/II/0032

Recordati Rare Diseases;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of children from 6 months of age for CYSTADROPS, based on final results from study CYT-C2-001. This is an Open-label, Single-arm, Multicentre Study to Assess the Safety of Cystadrops in Paediatric Cystinosis Patients from 6 Months to Less Than 2 Years Old. 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 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI and the list of local representatives in the Package Leaflet."

Action: For adoption

5.1.7. Dapivirine Vaginal Ring 25 mg - Dapivirine - EMEA/H/W/002168/II/0027

International Partnership for Microbicides Belgium AISBL;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include reducing the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women 16 years and older for Dapivirine Vaginal Ring 25 mg, based on final results from study MTN-034 (REACH) listed as a category 3 study in the RMP; this is a Phase 2a crossover trial evaluating the safety of and adherence to a vaginal matrix ring containing dapivirine and oral emtricitabine/tenofovir disoproxil fumarate in an adolescent and young adult female population. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.5 of the RMP has also been submitted."

Action: For adoption

5.1.8. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0076

Janssen-Cilag International N.V.;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication for Darzalex in combination with bortezomib, lenalidomide and dexamethasone for the treatment of newly diagnosed multiple myeloma, to include also adult patients who are not eligible for stem cell transplant (SCT), based on the results of the final PFS analysis from Study CEPHEUS (54767414MMY3019), a randomised, open-label, active-controlled, multicentre phase 3 study in adult participants, comparing the clinical outcome of D-VRd with VRd in participants with untreated multiple myeloma for whom stem cell transplant is not planned as initial therapy, in terms of the primary endpoint of MRD negativity rate in participants with CR or better rate and major secondary endpoints of CR or better rate, PFS and sustained MRD negativity.
As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated and the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the contact details of the local representatives in the Package Leaflet.
An updated RMP version 11.1 has also been submitted."

Action: For adoption

5.1.9. Dupixent - Dupilumab - EMEA/H/C/004390/II/0083

Sanofi Winthrop Industrie;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents 12 years and older, who are symptomatic despite treatment with H1 antihistamines and who are intolerant to or inadequately controlled by anti-IgE therapy for Dupixent, based on the results from studies EFC16461 (CUPID) study B (pivotal) and study A (supportive); EFC16461 Study B was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in adult and adolescent participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were intolerant or incomplete responders to omalizumab and EFC16461 Study A was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were naïve to omalizumab. 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 11.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 30.05.2024.

5.1.10. FABHALTA - Iptacopan - Orphan - EMEA/H/C/005764/II/0001

Novartis Europharm Limited;

Rapporteur: Janet Koenig, PRAC Rapporteur: Lina Seibokiene

Scope: "Extension of indication to include, in combination with a renin-angiotensin system (RAS) inhibitor, the treatment of adult patients with complement 3 glomerulopathy (C3G) for FABHALTA, based on interim analysis results from study CLNP023B12301 (APPEAR-C3G) and supported by additional evidence of efficacy and safety data from Phase II study CLNP023X2202 (X2202) and Phase IIIb study CLNP023B12001B (C3G-REP). APPEAR-C3G is

a Phase 3, multicentre, randomized, double-blind, parallel arm, placebo-controlled study to evaluate the efficacy and safety of iptacopan in patients with C3G. The study included a 6-month blinded, placebo-controlled period, followed by a 6-month period in which all patients receive open-label iptacopan (total study duration of 12 months). As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8 and 5.1 of the SmPC are being 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."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.11. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. 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)

Action: For adoption

5.1.12. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0069

AstraZeneca AB;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy for IMFINZI, based on final results from study D933QC00001 (ADRIATIC); this is a phase III, randomized, double-blind, placebo-controlled, multi-centre, global study to assess the efficacy and safety of durvalumab monotherapy and durvalumab in combination with tremelimumab compared to placebo as consolidation treatment in patients with LS-SCLC whose disease had not progressed following definitive platinum-based chemoradiation therapy (ADRIATIC). 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. Version 12, 1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to Annex II. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.13. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0073

AstraZeneca AB;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include IMFINZI in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with muscle invasive bladder cancer (MIBC), based on an ongoing pivotal study D933RC00001 (NIAGARA); this is a phase 3, randomized, open-label, multi-centre, global study to determine the efficacy and safety of durvalumab in combination with gemcitabine+cisplatin for neoadjuvant treatment followed by durvalumab alone for adjuvant treatment in patients with muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 13 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and update the PI according to the Excipients Guideline."

Action: For adoption

5.1.14. Jaypirca - Pirtobrutinib - EMEA/H/C/005863/II/0002

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection."

Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024.

5.1.15. Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/II/0034

Bayer AG;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment and prophylaxis of bleeding in previously treated patients ≥7 years of age with haemophilia A for JIVI, based on integrated analysis results from Part A of the Alfa-PROTECT study (21824) and PROTECT Kids main study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe haemophilia A. PROTECT Kids is a multi-centre, Phase 3, non-controlled, open-label trial to evaluate the pharmacokinetics, safety, and efficacy of BAY 94-9027 for prophylaxis and treatment of bleeding in previously treated children (age <12 years) with severe haemophilia A. 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. Version 3.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

5.1.16. NUBEQA - Darolutamide - EMEA/H/C/004790/II/0024

Bayer AG;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include in combination with androgen deprivation therapy (ADT) the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for NUBEQA, based on final results from study 21140 (ARANOTE); this is a randomized, double-blind, placebo-controlled Phase 3 study of darolutamide to demonstrate the superiority of darolutamide in addition to ADT over placebo plus ADT in patients with mHSPC. 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 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and update the Package Leaflet to more patient friendly wording based on patient council feedback."

Action: For adoption

5.1.17. RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0056

AbbVie Deutschland GmbH & Co. KG;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: "Extension of indication to include treatment of giant cell arteritis (GCA) in adult patients for RINVOQ based on final results from study M16-852. This is a phase 3, global, multicentre, randomized, double-blind, PBO-controlled study evaluating the efficacy and safety of upadacitinib in subjects with GCA. 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 15.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.18. Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0017

Roche Registration GmbH;

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include treatment of paediatric patients from 2 to less than 12 years old, weighing at least 10kg, who do not require supplemental oxygen and who are at increased risk of progression to severe COVID-19 for Ronapreve, based on final results from study COV-2067; this was a seamless, adaptive, Phase 3, randomized, double-blinded, placebo-controlled, multi-centre study to evaluate the efficacy, safety, and tolerability of casirivimab+imdevimab combination therapy in paediatric and adult outpatients with mild to moderate COVID-19. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024, 30.05.2024.

5.1.19. RXULTI - Brexpiprazole - EMEA/H/C/003841/II/0015

Otsuka Pharmaceutical Netherlands B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Miroslava Gocova

Scope: "Extension of indication to include treatment of schizophrenia in adolescent patients aged from 13 years to 17 years for RXULTI, based on results from the following clinical studies: one phase 1 dose-escalation trial (Trial 331-10-233) and two phase 3 clinical trials (Trial 331-10-234 and Trial 331-10-236). In addition, a paediatric extrapolation study was completed (Study 331-201-00185). These studies investigated the efficacy and safety of brexpiprazole in paediatric patients (13-17 years old) with schizophrenia. 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 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (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."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.20. Sivextro - Tedizolid phosphate - EMEA/H/C/002846/II/0054

Merck Sharp & Dohme B.V.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of paediatric patients aged from birth to less than 12 years for SIVEXTRO, based on final results from studies MK-1986-013, MK-1986-014 and MK-1986-018. MK-1986-013 is a single-dose trial to evaluate pharmacokinetics (PK) and safety of oral and intravenous (IV) administration of tedizolid

phosphate in patients from 2 years to <12 years of age; MK-1986-014 is an open-label, multicentre, 2-part, single and multiple dose study to assess the PK of tedizolid phosphate and its active metabolite, tedizolid, and the safety of tedizolid phosphate following single and multiple dose IV and single oral dose. MK-1986-018 is a randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients from birth to less than 12 years of age; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement minor editorial corrections."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.21. Slenyto - Melatonin - EMEA/H/C/004425/II/0028

RAD Neurim Pharmaceuticals EEC SARL;

Rapporteur: Kristina Dunder, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include treatment of insomnia in children and adolescents aged 2-18 with Attention-Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have been insufficient, based on results from phase III study NEU_CH_7911 and literature. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

5.1.22. Stelara - Ustekinumab - EMEA/H/C/000958/II/0108

Janssen-Cilag International N.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies for STELARA, based on final results from study CNTO1275CRD3004. This is a Phase 3 Study of the Efficacy, Safety, and Pharmacokinetics of Ustekinumab as Open label Intravenous Induction Treatment Followed by Randomized Double blind Subcutaneous Ustekinumab Maintenance in Paediatric Participants with Moderately to Severely Active Crohn's Disease. 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 29.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.23. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0016

Beigene Ireland Limited;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include first-line treatment of adult patients with extensive-stage Small Cell Lung Cancer (SCLC) for Tevimbra in combination with etoposide and platinum chemotherapy based on final results from study BGB-A317-312; a phase 3, randomized, double-blind, placebo-controlled study of platinum plus etoposide with or without tislelizumab in patients with untreated extensive-stage small cell lung cancer. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The MAH also took the opportunity to make editorial changes to the SmPC, Annex II and Package Leaflet.
The supportive studies BGB-A317-309 and BGB-A317-315 are provided for the purpose of updating the safety data package as well as updated data (latest CSR versions with new data cut-off) from the monotherapy pool (tislelizumab used at 200mg Q3W) consisting of the studies 001, 102, 203, 204, 208, 209, 301, 302, and 303 and from the combination with chemotherapy pool consisting of the studies 205, 206, 304, 305, 306, 307 and 312.
Version 2.4 of the RMP has also been submitted."

Action: For adoption

5.1.24. Vyvgart - Efgartigimod alfa - Orphan - EMEA/H/C/005849/II/0020

Argenx;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension of indication to include the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) with active disease despite treatment with corticosteroids or immunoglobulins for VYVGART, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP); and based on interim results from study ARGX-113-1902; this is an open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with (CIDP).
As a consequence, sections 4.1, 4.2. 4.4, 4.8, 5.1 and 5.2 of the SmPC has been updated. The Package Leaflet has been updated in accordance with the SmPC. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

5.1.25. WS2717
OPDIVO - Nivolumab - EMEA/H/C/003985/WS2717/0146
Yervoy - Ipilimumab - EMEA/H/C/002213/WS2717/0115

Bristol-Myers Squibb Pharma EEIG;

Lead Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder

Scope: "A Worksharing application for OPDIVO and YERVOY, as follows:

Extension of indication to include a new indication for OPDIVO in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. 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 41.0 of the RMP has also been submitted. Extension of indication to include a new indication for YERVOY in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. 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 44.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

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

6.1.1. Human serum albumin - EMEA/H/D/006611

use in Assisted Reproductive Technologies (ART)

Scope: Day 120 list of questions

Action: For adoption

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006648

use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) tissue, using EnVision FLEX visualization system on Dako Omnis

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006668

to detect EGFR mutations in FFPE tissue from adult patients diagnosed with non-small cell lung cancer (NSCLC)

Scope: Opinion

Action: For adoption

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

8.1.1. Linerixibat – H0006241

indicated for the treatment of cholestatic pruritus in adult patients with primary biliary cholangitis (PBC)

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.1.2. Tovorafenib - H0006140

indicated as monotherapy for the treatment of patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have received one or more prior systemic therapies

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.1.3. Lenacapavir – H0006659

Use for pre-exposure prophylaxis to prevent sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg.

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.1.4. Lenacapavir – H0006658

Use for pre-exposure prophylaxis to prevent sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg.

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.1.5. Plozasiran – Orphan - H0006579

Arrowhead Pharmaceuticals Ireland Limited; is indicated as an adjunct to diet to reduce triglyceride levels in patients with familial chylomicronemia syndrome (FCS).

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Ngenla - Somatrogon - Orphan - EMEA/H/C/005633/II/0016

Pfizer Europe MA EEIG;

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: Withdrawal of extension of indication application

Action: For information

Request for Supplementary Information adopted on 19.09.2024.

9.1.2. Zeposia - Ozanimod - EMEA/H/C/004835/R/0028

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Fátima Ventura, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Renewal of Marketing Authorisation for unlimited validity

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

See 2.3

9.1.3. Grastofil – Filgrastim – EMEA/H/C/002150

Accord Healthcare S.L.U.

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Sol Ruiz

Scope: Withdrawal of Marketing Authorisation due to commercial reasons

Action: For information

9.1.4. FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan

Vifor France

Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber

Scope: "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, multicentre, 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."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

9.1.5. Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028

Infai GmbH

Rapporteur: Christian Gartner

Scope: "Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.

See 2.3

9.1.6. Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0007

Chiesi Farmaceutici S.p.A.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

Scope: "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. 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."

Action: For adoption

9.1.7. Comirnaty - COVID-19 mRNA vaccine - EMA/VR/0000237985

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope: "A grouped application consisting of:

C.I.4: Update of sections 4.5 and 4.8 of the SmPC in order to update co-administration of Comirnaty and RSV related information based on final results from C5481001 sub-study A. This is a Phase 1/2 sub-study to evaluate the safety, tolerability and Immunogenicity of Combined Vaccine Candidate(s) against Infectious Respiratory Illnesses, Including COVID-

19 and RSV, in Healthy Individuals. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.5 and 4.8 of the SmPC in order to update co-administration of Comirnaty and PCV related information based on final results from interventional study B7471026. This is a Phase 3, Randomized, Double-Blind Trial to Describe the Safety and Immunogenicity of 20-valent Pneumococcal Conjugate Vaccine when co-administered with a Booster Dose of BNT162b2 in Adults 65 Years of Age and Older. The Package Leaflet is updated accordingly.

In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

January 2025 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

Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information

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

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

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 January 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at January 2025 PDCO

Action: For information

Agenda of the PDCO meeting to be held on 28-31 January 2025

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 13-16 January 2025. Table of conclusions

Action: For information

Scientific advice letters: Information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

14.3.3. Election of Vice-Chair – Vaccines Working Party (VWP)

Following the call for nominations launched in December 2024, CHMP to elect the Vice-Chair from the candidates who submitted nominations.

Nomination(s) received

Action: For election

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

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Clock-stop extensions and feedback from GIREX

Action: For discussion

15.1.2. Health Threats and ETF update

Health Threats and ETF update

Action: For information

15.1.3. EMA feedback to the European Commission on the use of titanium dioxide as excipient in medicinal products – safety aspects

Feedback document to the European Commission adopted in December 2024 has been slightly amended and is re-tabled for information'.

Action: For information

15.1.4. SAG mandate renewal and (re)nominations

Update of the renewal of SAG mandate/call for nomination of experts for the 5 therapeutic SAGs (Neurology, Oncology, Vaccines, Infectious Diseases and Cardiovascular Issues).

Action: For discussion

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)*

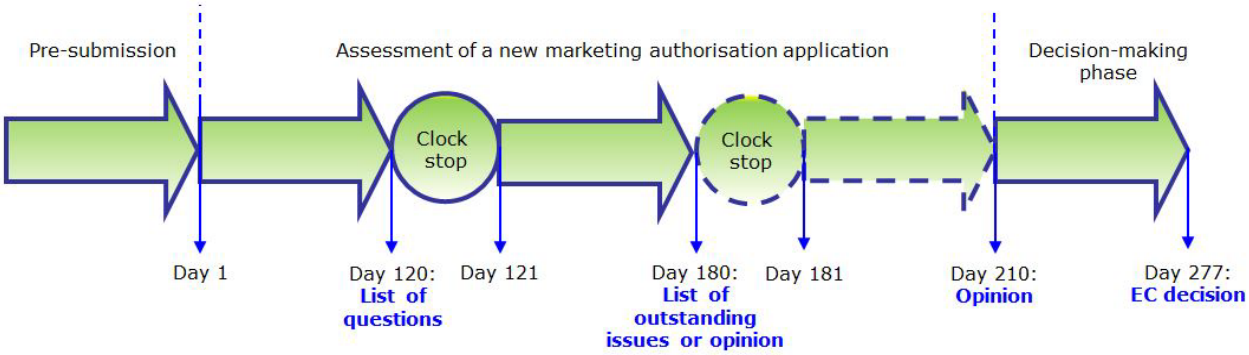
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2025
EMA/CHMP/585933/2024

Annex to 27-30 January 2025 CHMP Agenda

Pre-submission and post-authorisations issues

Note: Starting with January 2025, EMA is publishing in Excel format the CHMP agenda annex with the regulatory procedures handled in IRIS. This is a secure online platform for managing product-related scientific and regulatory procedures with EMA. This change follows the transition of the post-authorisation regulatory procedures to IRIS. It is also in the context of the digitalisation of EMA's activities, and will help facilitate data analysis.

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for January 2025: **For adoption**

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

Final Outcome of Rapporteurship allocation for January 2025: **For adoption**

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Bylvay - Odevixibat -
EMEA/H/C/004691/S/0023, Orphan
Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

Myalepta - Metreleptin -
EMEA/H/C/004218/S/0039, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Adam Przybylkowski

Zokinvy - Lonafarnib -
EMEA/H/C/005271/S/0012, Orphan
TMC Pharma (EU) Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

BYANNLI - Paliperidone -
EMEA/H/C/005486/R/0008
Janssen-Cilag International N.V., Informed Consent of Xeplion, Rapporteur: Kristina Dunder, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Karin Bolin

Xenleta - Lefamulin -
EMEA/H/C/005048/R/0010
Nabriva Therapeutics Ireland DAC, Rapporteur: Jayne Crowe, Co-Rapporteur: Ingrid Wang,

PRAC Rapporteur: Eva Jirsová

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Bavencio - Avelumab - EMEA/H/C/004338/R/0050
Merck Europe B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Karin Erneholm

Daurismo - Glasdegib - EMEA/H/C/004878/R/0015, Orphan
Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, Co-Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 12.12.2024.

Fingolimod Accord - Fingolimod - EMEA/H/C/005191/R/0011
Accord Healthcare S.L.U., Generic of Gilenya, Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Tiphaine Vaillant

Gencebok - Caffeine citrate - EMEA/H/C/005435/R/0012
Gennisium Pharma, Rapporteur: Alar Irs, PRAC Rapporteur: Sonja Hrabcik

Insulin aspart Sanofi - Insulin aspart - EMEA/H/C/005033/R/0020
Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Mari Thorn

Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/R/0059, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Martin Huber

LIVOGIVA - Teriparatide - EMEA/H/C/005087/R/0015
Theramex Ireland Limited, Rapporteur: Christian Gartner, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Tiphaine Vaillant

MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/R/0023
Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jean-Michel

Race, PRAC Rapporteur: Jean-Michel Dogné	
Zabdeno - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/R/0022 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Jean-Michel Dogné	
Zeposia - Ozanimod - EMEA/H/C/004835/R/0028 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Fátima Ventura, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Maria del Pilar Rayon Request for Supplementary Information adopted on 14.11.2024.	See 9.1
Zercepac - Trastuzumab - EMEA/H/C/005209/R/0039 Accord Healthcare S.L.U., Rapporteur: Sol Ruiz, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Gabriele Maurer	

B.2.3. Renewals of Conditional Marketing Authorisations

Deltyba - Delamanid - EMEA/H/C/002552/R/0076, Orphan Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Jo Robays Request for Supplementary Information adopted on 14.11.2024.	
Incellipan - Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006051/R/0002 Seqirus Netherlands B.V., Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Mari Thorn	
Lorviqua - Lorlatinib - EMEA/H/C/004646/R/0040 Pfizer Europe MA EEIG, Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Barbara Kovacic Bytyqi	
Ondexxya - Andexanet alfa - EMEA/H/C/004108/R/0049 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder	
Pandemic influenza vaccine H5N1 AstraZeneca - Pandemic influenza vaccine	

(H5N1) (live attenuated, nasal) - EMEA/H/C/003963/R/0074
AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sonja Hrabcik

WAYLIVRA - Volanesorsen - EMEA/H/C/004538/R/0029, Orphan
Akcea Therapeutics Ireland Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Post-authorisation safety studies

PRAC recommendations on PASS results adopted at the PRAC meeting held on 13-16 January 2025 PRAC:

Revlimid (CAP) - EMEA/H/C/PSR/S/0049 (lenalidomide)

PRAC Rapporteur: Tiphaine Vaillant

Scope: Annex II of the product information is updated to remove PASS study CC-5013-MDS-012, as the study has been concluded. A revised RMP version 41.1 has been adopted.

PRAC recommendation to CHMP

Action: For adoption

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 13-16 January 2025 PRAC:

Signal of tumour lysis syndrome

lenvatinib – LENVIMA, KISPLYX (CAP)

Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Kristina Dunder; Janet Koenig, PRAC Rapporteur: Mari Thorn; David Olsen
PRAC recommendation on a variation
Action: For adoption

Signal of growth of eyelashes

afatinib – GIOTRIF (CAP)

Rapporteur: Filip Josephson, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Mari Thorn
PRAC recommendation on a variation
Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its January 2025 meeting:

EMEA/H/C/PSUSA/00000045/202406
(ublituximab)
CAPS:
Briumvi (EMEA/H/C/005914) (Ublituximab), Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Liana Martirosyan, "27/12/2023 To: 27/06/2024"

EMEA/H/C/PSUSA/00000136/202406
(tislelizumab)
CAPS:
Tevimbra (EMEA/H/C/005919) (Tislelizumab), Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "25/12/2023 To: 25/06/2024"

EMEA/H/C/PSUSA/00000226/202405
(apixaban)
CAPS:
Eliquis (EMEA/H/C/002148) (Apixaban), Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder, "18/05/2021 To: 17/05/2024"

EMEA/H/C/PSUSA/00000531/202404
(capecitabine)
CAPS:
Capecitabine Accord (EMEA/H/C/002386) (Capecitabine), Accord Healthcare S.L.U., Rapporteur: Filip Josephson
Capecitabine medac (EMEA/H/C/002568) (Capecitabine), medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Filip Josephson
Ecansya (EMEA/H/C/002605) (Capecitabine), KRKA, d.d., Novo mesto, Rapporteur: Kristina Dunder
Xeloda (EMEA/H/C/000316) (Capecitabine), CHEPLAPHARM Arzneimittel GmbH, Rapporteur: Janet Koenig
NAPS:
NAPs - EU, PRAC Rapporteur: Martin Huber, "30/04/2021 To: 29/04/2024"

EMEA/H/C/PSUSA/00001692/202406
(hydroxycarbamide (for centrally authorised product only))
CAPS:
Siklos (EMEA/H/C/000689) (Hydroxycarbamide), Theravia, Rapporteur: Karin Janssen van Doorn
Xromi (EMEA/H/C/004837) (Hydroxycarbamide), Nova Laboratories Ireland Limited, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Jo Robays, "28/06/2023 To: 28/06/2024"

EMEA/H/C/PSUSA/00010084/202405
(dabrafenib)
CAPS:
Finlee (EMEA/H/C/005885) (Dabrafenib), Novartis Europharm Limited, Rapporteur: Filip Josephson
Tafinlar (EMEA/H/C/002604) (Dabrafenib), Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn, "27/08/2022 To: 29/05/2024"

EMEA/H/C/PSUSA/00010186/202405
(vedolizumab)
CAPS:
Entyvio (EMEA/H/C/002782) (Vedolizumab), Takeda Pharma A/S, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Adam Przybylkowski, "19/05/2021 To: 19/05/2024"

EMEA/H/C/PSUSA/00010395/202405
(tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)))
CAPS:
Jinarc (EMEA/H/C/002788) (Tolvaptan), Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Amelia Cupelli, "17/05/2021 To: 17/05/2024"

EMEA/H/C/PSUSA/00010644/202405
(atezolizumab)
CAPS:
Tecentriq (EMEA/H/C/004143) (Atezolizumab), Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre, "18/05/2023 To: 17/05/2024"

EMEA/H/C/PSUSA/00010848/202405
(onasemnogene abeparvovec)
CAPS:
Zolgensma (EMEA/H/C/004750) (Onasemnogene abeparvovec), Novartis Europharm Limited, Rapporteur: Emmely de Vries, PRAC Rapporteur: Karin Bolin, "24/05/2023 To: 23/05/2024"

EMEA/H/C/PSUSA/00010852/202405
(ozanimod)
CAPS:
Zeposia (EMEA/H/C/004835) (Ozanimod), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Fátima Ventura, PRAC Rapporteur: Maria del Pilar Rayon, "20/05/2023 To: 19/05/2024"

EMEA/H/C/PSUSA/00010874/202406
(entrectinib)
CAPS:
Rozlytrek (EMEA/H/C/004936) (Entrectinib), Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "18/12/2023 To: 17/06/2024"

EMEA/H/C/PSUSA/00010894/202406
(trastuzumab deruxtecan)
CAPS:
Enhertu (EMEA/H/C/005124) (Trastuzumab), Daiichi Sankyo Europe GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre, "20/12/2023 To: 19/06/2024"

EMEA/H/C/PSUSA/00010905/202406
(latanoprost / netarsudil)
CAPS:
Roclanda (EMEA/H/C/005107) (Latanoprost / Netarsudil), Santen Oy, Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski, "17/06/2023 To: 17/06/2024"

EMEA/H/C/PSUSA/00010907/202406
(fenfluramine)
CAPS:
Fintepla (EMEA/H/C/003933) (Fenfluramine), UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "Update of sections 4.4 and 4.8 of the SmPC to amend the warning regarding VHD and to add VHD with a frequency 'not known' to the adverse reactions table. The Package leaflet is updated accordingly.
Update of Annex IID - Additional risk minimisation measures and Annex IID – Obligation to conduct post-authorisation measures to reclassify the important potential risk of VHD to important identified risk."

EMEA/H/C/PSUSA/00010955/202406
(roxadustat)
CAPS:
Evrenzo (EMEA/H/C/004871) (Roxadustat), Astellas Pharma Europe B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Anna Mareková, "17/12/2023 To: 16/06/2024"

EMEA/H/C/PSUSA/00011014/202406
(efgartigimod alfa)
CAPS:
Vyvgart (EMEA/H/C/005849) (Efgartigimod alfa), Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "16/12/2023 To: 16/06/2024"

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

Abiraterone Accord - Abiraterone acetate - EMEA/H/C/005408/II/0007
Accord Healthcare S.L.U., Generic of Zytiga, Rapporteur: Alar Irs

AJOVY - Fremanezumab - EMEA/H/C/004833/II/0052
TEVA GmbH, Rapporteur: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 19.12.2024.

Request for supplementary information adopted with a specific timetable.

Alprolix - Eftrenonacog alfa -

EMEA/H/C/004142/II/0048, Orphan Swedish Orphan Biovitrum AB (publ), Rapporteur: Daniela Philadelphy	
Amsparity - Adalimumab - EMEA/H/C/004879/II/0011 Pfizer Europe MA EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 23.01.2025.	Positive Opinion adopted by consensus on 23.01.2025.
Aptivus - Tipranavir - EMEA/H/C/000631/II/0096/G Boehringer Ingelheim International GmbH, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 19.12.2024.	Request for supplementary information adopted with a specific timetable.
Besremi - Ropeginterferon alfa-2b - EMEA/H/C/004128/II/0037 AOP Orphan Pharmaceuticals GmbH, Rapporteur: Janet Koenig Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 14.11.2024.	Positive Opinion adopted by consensus on 19.12.2024.
BIMERVAX - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/006058/II/0018/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich	
Brukinsa - Zanubrutinib - EMEA/H/C/004978/II/0026/G BeiGene Ireland Ltd, Rapporteur: Boje Kvorning Pires Ehmsen Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Champix - Varenicline - EMEA/H/C/000699/II/0085/G Pfizer Europe MA EEIG, Rapporteur: Thalia Marie Estrup Blicher	
Entyvio - Vedolizumab - EMEA/H/C/002782/II/0084/G Takeda Pharma A/S, Rapporteur: Paolo Gasparini Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 12.09.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Flixabi - Infliximab - EMEA/H/C/004020/II/0090/G Samsung Bioepis NL B.V., Rapporteur: Jan	Request for supplementary information adopted with a specific timetable.

Mueller-Berghaus Request for Supplementary Information adopted on 16.01.2025.	
Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0056/G Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 05.12.2024.	Positive Opinion adopted by consensus on 16.01.2025.
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 Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 10.10.2024.	Positive Opinion adopted by consensus on 16.01.2025.
Gardasil 9 - Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0077/G Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder	
Herzuma - Trastuzumab - EMEA/H/C/002575/II/0067/G Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 19.12.2024.	Request for supplementary information adopted with a specific timetable.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0161 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
Ituxredi - Rituximab - EMEA/H/C/006224/II/0001 Reddy Holding GmbH, Rapporteur: Jan Mueller-Berghaus	
KIMMTRAK - Tebentafusp - EMEA/H/C/004929/II/0009/G, Orphan Immunocore Ireland Limited, Rapporteur: Boje Kvorning Pires Ehmsen	
Menveo - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0122/G	Positive Opinion adopted by consensus on 16.01.2025.

GSK Vaccines S.r.l, Rapporteur: Patrick Vrijlandt Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 28.11.2024, 03.10.2024.	
Odomzo - Sonidegib - EMEA/H/C/002839/II/0053/G Sun Pharmaceutical Industries Europe B.V., Rapporteur: Peter Mol Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 14.11.2024.	Positive Opinion adopted by consensus on 16.01.2025.
Omlyclo - Omalizumab - EMEA/H/C/005958/II/0004/G Celltrion Healthcare Hungary Kft., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Mari Thorn	
Omvoh - Mirikizumab - EMEA/H/C/005122/II/0010/G Eli Lilly Nederland B.V., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 23.01.2025.	Request for supplementary information adopted with a specific timetable.
Opdualag - Nivolumab / Relatlimab - EMEA/H/C/005481/II/0011/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol	
Otulfi - Ustekinumab - EMEA/H/C/006544/II/0001/G Fresenius Kabi Deutschland GmbH, Duplicate of Fymskina, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0015 Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 10.10.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0031/G Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 16.01.2025.	
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0211/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Qarziba - Dinutuximab beta - EMEA/H/C/003918/II/0062/G, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 21.11.2024, 12.09.2024.	Positive Opinion adopted by consensus on 16.01.2025.
Ranibizumab Midas - Ranibizumab - EMEA/H/C/006528/II/0001/G MIDAS Pharma GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0034 Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 23.01.2025, 19.09.2024.	Request for supplementary information adopted with a specific timetable.
Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0035/G Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 23.01.2025, 19.09.2024.	Request for supplementary information adopted with a specific timetable.
Remsima - Infliximab - EMEA/H/C/002576/II/0143/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 14.11.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Respreeza - Human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0078/G CSL Behring GmbH, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
RoActemra - Tocilizumab - EMEA/H/C/000955/II/0124/G	Positive Opinion adopted by consensus on 19.12.2024.

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 19.12.2024.	
SIMBRINZA - Brinzolamide / Brimonidine - EMEA/H/C/003698/II/0027/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Simulect - Basiliximab - EMEA/H/C/000207/II/0122 Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0052/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy	
Sogroya - Somapacitan - EMEA/H/C/005030/II/0016, Orphan Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Spectrila - Asparaginase - EMEA/H/C/002661/II/0042/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 31.10.2024.	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0146 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 19.12.2024.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0148/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 23.01.2025.	Request for supplementary information adopted with a specific timetable.
Steglujan - Ertugliflozin / Sitagliptin - EMEA/H/C/004313/II/0030/G Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.

STEQEYMA - Ustekinumab - EMEA/H/C/005918/II/0004/G Celltrion Healthcare Hungary Kft., Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0015/G Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 07.11.2024, 03.10.2024, 06.06.2024, 08.02.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Trodelvy - Sacituzumab govitecan - EMEA/H/C/005182/II/0035/G Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 14.11.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Trulicity - Dulaglutide - EMEA/H/C/002825/II/0073/G Eli Lilly Nederland B.V., Rapporteur: Janet Koenig Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Uzpruvo - Ustekinumab - EMEA/H/C/006101/II/0002/G STADA Arzneimittel AG, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 19.12.2024, 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Uzpruvo - Ustekinumab - EMEA/H/C/006101/II/0005 STADA Arzneimittel AG, Rapporteur: Christian Gartner Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Vazkepa - Icosapent ethyl - EMEA/H/C/005398/II/0028/G Amarin Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig	
VEYVONDI - Vonicog alfa - EMEA/H/C/004454/II/0037 Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.

WS2549/G **Hexacima-EMEA/H/C/002702/WS2549/0159/G** **Hexyon-EMEA/H/C/002796/WS2549/0163/G** Sanofi Winthrop Industrie, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 07.11.2024.	Positive Opinion adopted by consensus on 16.01.2025.
WS2563 **Axura-EMEA/H/C/000378/WS2563/0090** **Memantine Merz-EMEA/H/C/002711/WS2563/0025** Merz Pharmaceuticals GmbH, Lead Rapporteur: Antonio Gomez-Outes Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2727 **Esperoct-EMEA/H/C/004883/WS2727/0025** **NovoEight-EMEA/H/C/002719/WS2727/0044** **NovoSeven-EMEA/H/C/000074/WS2727/0125** **NovoThirteen-EMEA/H/C/002284/WS2727/0032** **Refixia-EMEA/H/C/004178/WS2727/0038** Novo Nordisk A/S, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 19.12.2024, 05.09.2024.	Request for supplementary information adopted with a specific timetable.
WS2741 **Flebogamma DIF-EMEA/H/C/000781/WS2741/0086** Instituto Grifols, S.A., Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2747/G **Nuwiq-EMEA/H/C/002813/WS2747/0063/G** **Vihuma-EMEA/H/C/004459/WS2747/0045/G** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 31.10.2024.	
WS2748	Request for supplementary information adopted

Silodosin Recordati-EMEA/H/C/004964/WS2748/0015 Silodyx-EMEA/H/C/001209/WS2748/0056 Urorec-EMEA/H/C/001092/WS2748/0059 Recordati Ireland Ltd, Lead Rapporteur: Margareta Bego Request for Supplementary Information adopted on 19.12.2024, 14.11.2024.	with a specific timetable.
WS2770/G **Filgrastim Hexal-EMEA/H/C/000918/WS2770/0079/G Zarzio-EMEA/H/C/000917/WS2770/0080/G** Sandoz GmbH, Lead Rapporteur: Peter Mol Request for Supplementary Information adopted on 19.12.2024.	Request for supplementary information adopted with a specific timetable.
WS2773/G **ProQuad-EMEA/H/C/000622/WS2773/0169/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2777/G **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2777/0020/G Qdenga-EMEA/H/C/005155/WS2777/0021/G** Takeda GmbH, Lead Rapporteur: Sol Ruiz Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2780 **Riltrava Aerosphere-EMEA/H/C/005311/WS2780/0017 Trixeo Aerosphere-EMEA/H/C/004983/WS2780/0024** AstraZeneca AB, Lead Rapporteur: Finbarr Leacy, Lead PRAC Rapporteur: Jan Neuhauser	
WS2781/G **Efficib-EMEA/H/C/000896/WS2781/0117/G Janumet-EMEA/H/C/000861/WS2781/0115/G Ristfor-EMEA/H/C/001235/WS2781/0104/G Velmetia-EMEA/H/C/000862/WS2781/0123/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Patrick Vrijlandt	Positive Opinion adopted by consensus on 16.01.2025.

Opinion adopted on 16.01.2025.	
WS2782/G **Januvia-** **EMEA/H/C/000722/WS2782/0088/G** **Ristaben-** **EMEA/H/C/001234/WS2782/0082/G** **TESAVEL-** **EMEA/H/C/000910/WS2782/0088/G** **Xelevia-** **EMEA/H/C/000762/WS2782/0097/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2796 **Fluenz-EMEA/H/C/006514/WS2796/0005** **Pandemic influenza vaccine H5N1** **AstraZeneca-** **EMEA/H/C/003963/WS2796/0075** AstraZeneca AB, Lead Rapporteur: Christophe Focke	

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

ADCETRIS - Brentuximab vedotin - EMEA/H/C/002455/II/0113, Orphan Takeda Pharma A/S, Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC in order to update clinical information based on final results from ECHELON-1 final OS analysis data (C25003 CSR addendum 3). This is a randomized, open-label, phase 3 trial of A+AVD versus ABVD as frontline therapy in patients with advanced classical Hodgkin lymphoma. In addition, the MAH took the opportunity to update the PI according to the Excipients Guideline and to introduce minor formatting changes to the PI." Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
AGAMREE - Vamorolone - EMEA/H/C/005679/II/0009, Orphan Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: Janet Koenig, "Type II - C.I.4 - To update sections 4.2 and 6.6 of the SmPC to add information concerning the administration of the product via enteral feeding tubes. The package leaflet is also updated with the information. This variation is submitted to address a recommendation for further quality development that was made at the time of the assessment of the initial application for the	Positive Opinion adopted by consensus on 16.01.2025.

marketing authorisation."
Opinion adopted on 16.01.2025.

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0028

Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.8 and 5.1 based on primary analysis and first-year analysis results from study VAS00006 (HARMONIE). This is an ongoing phase IIIb randomized open-label study of nirsevimab (versus no intervention) in preventing hospitalizations due to respiratory syncytial virus in infants (under 12 months) in order to determine the efficacy and safety of a single intramuscular (IM) dose of nirsevimab. In addition, the MAH took the opportunity to introduce minor formatting changes."

Cimzia - Certolizumab pegol - EMEA/H/C/001037/II/0110

UCB Pharma S.A., Rapporteur: Kristina Dunder, "Update of sections 4.2 and 4.6 of the SmPC in order to update information on pregnancy based on final results from study UP0085, OTIS Phase I report and post marketing data. UP0085 is a Phase 1b, prospective, longitudinal, interventional, open-label study evaluating the impact of pregnancy on the PK of CZP. OTIS Phase I report presents the formal analysis of pregnancy outcome and infant and child follow-up data from the OTIS CZP Pregnancy Registry (RA0023). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4."
Request for Supplementary Information adopted on 14.11.2024, 13.06.2024.

Drovelis - Drospirenone / Estetrol - EMEA/H/C/005336/II/0026

Gedeon Richter Plc., Rapporteur: Kristina Dunder, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on results from study MIT-Es001-C303. This is a Phase III, Open-label, Single-Arm Study to Evaluate the Safety, Compliance and Pharmacokinetics associated with the use of a Combined Oral Contraceptive Containing 15 mg Estetrol monohydrate and 3 mg Drospirenone in Post-menarchal Female Adolescents for 6 cycles. The

Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 14.11.2024, 25.07.2024.	
Emblaveo - Aztreonam / Avibactam - EMEA/H/C/006113/II/0002 Pfizer Europe Ma EEIG, Rapporteur: Filip Josephson, "Submission of the corrected report from study C3601002 (REVISIT). This is a Phase 3 Prospective, Randomized, Multicentre, Open-Label, Central Assessor Blinded, Parallel Group, Comparative Study to Determine the Efficacy, Safety and Tolerability of Aztreonam Avibactam (ATM-AVI) ± Metronidazole (MTZ) Versus Meropenem ± Colistin (MER ± COL) for the Treatment of Serious Infections due to Gram Negative Bacteria, Including Metallo β-Lactamase (MBL) Producing Multidrug Resistant Pathogens, for Which There are Limited or no Treatment Options."	
EVOTAZ - Atazanavir / Cobicistat - EMEA/H/C/003904/II/0050 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Fátima Ventura, "Update of sections 4.3 and 4.5 of the SmPC in order to add a new contraindication and to include Drug-Drug Interactions (DDIs) information for the coadministration of Atazanavir/cobicistat (ATV/COBI) with the kinase inhibitor, fostamatinib, and the gonadotropin-releasing hormone receptor antagonist, elagolix based on post-marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI."	
Eylea - Aflibercept - EMEA/H/C/002392/II/0095 Bayer AG, Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add warnings for polysorbate into the SmPC and the Package Leaflet in line with the instructions in the most recent updates to the Appendix of the EC Excipient Guideline." Opinion adopted on 19.12.2024. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 19.12.2024.

on 24.10.2024.	
Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028 Infai GmbH, Rapporteur: Christian Gartner, "Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC." Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.	See 9.1
HEPLISAV B - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005063/II/0037 Dynavax GmbH, Rapporteur: Filip Josephson, "Update of section 4.9 of the SmPC in order to revise information regarding overdose to indicate "Not Applicable" following review of overall safety data. In addition, the MAH took the opportunity to make some editorial updates to the PI and bring it in line with the latest QRD template." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0088/G Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC based on results from Study CLL3011 (GLOW study). This is a Randomized, Open-label, Phase 3 Study of the Combination of Ibrutinib plus Venetoclax versus Chlorambucil plus Obinutuzumab for the First-line Treatment of Subjects with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). C.I.4: Update of section 5.1 of the SmPC based on results from Study PCYC-1116-CA. This is an Open-label Extension Study in Patients 65 Years or Older with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) Who Participated in Study PCYC-1115-CA	Request for supplementary information adopted with a specific timetable.

(Ibrutinib versus Chlorambucil)." Request for Supplementary Information adopted on 16.01.2025.	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0026, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Uveitis' to the list of adverse drug reactions (ADRs) with frequency 'common' based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI."	
Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0026 Estetra SRL, Duplicate of Drovelis, Rapporteur: Kristina Dunder, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on results from study MIT-Es001-C303. This is a Phase III, Open-label, Single-Arm Study to Evaluate the Safety, Compliance and Pharmacokinetics associated with the use of a Combined Oral Contraceptive Containing 15 mg Estetrol monohydrate and 3 mg Drospirenone in Post-menarchal Female Adolescents for 6 cycles. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 14.11.2024, 25.07.2024.	
LysaKare - L-lysine hydrochloride / L-arginine hydrochloride - EMEA/H/C/004541/II/0019 Advanced Accelerator Applications, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to align it with Lutathera SmPC based on post-marketing data and literature. In addition, the MAH took the opportunity to implement editorial changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0037 Sanofi Winthrop Industrie, Rapporteur: Daniela Philadelphy, "Update of section 4.8 of the SmPC in order to add "Febrile convulsions" and	Positive Opinion adopted by consensus on 23.01.2025.

"seizures" to the list of adverse drug reactions (ADRs) with frequency not known, based on a safety review. The Package Leaflet is updated accordingly. The MAH took the opportunity to include editorial changes in the product information." Opinion adopted on 23.01.2025. Request for Supplementary Information adopted on 24.10.2024.	
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." Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 17.10.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0090 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-301 (Adolescent part) listed as a category 3 study in the RMP. This is a phase 3 study of efficacy, effectiveness, safety, and immunogenicity in adolescents." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0093 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from study 2019nCoV-314 listed as a category 3 study in the RMP. This is a phase 3, randomized, double-blinded study to evaluate the safety and immunogenicity of omicron subvariant and bivalent SARS-CoV-2 rS vaccines in adolescents (12 – 18 years) previously vaccinated with mRNA COVID-19 vaccines."	
Omjjara - Momelotinib -	Request for supplementary information adopted

EMEA/H/C/005768/II/0004/G, Orphan Glaxosmithkline Trading Services Limited, Rapporteur: Christophe Focke, "A grouped application comprised of one Type II, one Type IB and one Type IA Variation, as follows: Type II (C.I.4): Update of section 4.8 of the SmPC in order to add 'rash' to the list of adverse drug reactions (ADRs) with frequency 'common' based on a safety review of clinical studies and post- marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add editorial changes to the PI and update the list of local representatives in the Package Leaflet. Type IB (C.I.z): Update of section 5.2 of SmPC in order to include minor updates to the absorption and biotransformation subsections of the PI based on data from the already submitted study GS-US-352-0102. Type IA (A.6): Include the ATC Code L01EJ04 in Section 5.1 of the Summary of Product Characteristics (SmPC)." Request for Supplementary Information adopted on 19.12.2024.	with a specific timetable.
Orserdu - Elacestrant - EMEA/H/C/005898/II/0009 Stemline Therapeutics B.V., Rapporteur: Peter Mol, "Update of section 5.2 of the SmPC in order to provide additional pharmacokinetic information following the PAM procedure for study MRPO-2023-PDE004 and based on the report SLP 43753974; this is an assessment of the potential role of P-gp in the supra-proportional exposure of elacestrant and the potential impact of P-gp inhibitors on elacestrant exposure at the dose of 100 mg. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4." Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0059/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application consisting of: C.I.4: Update of section 4.5 of the SmPC in	Request for supplementary information adopted with a specific timetable.

order to add drug-drug interaction information with albendazole based on the post-marketing data and literature and to update information on drug-drug interactions with methadone and ethinyl estradiol based on the literature; the Package Leaflet is updated accordingly. C.I.4: Update of section 4.5 of the SmPC in order to update information on drug-drug interactions with calcium channel antagonists based on the cumulative safety data and literature." Request for Supplementary Information adopted on 23.01.2025.	
Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0027 Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Update of sections 4.2 and 4.4 of the SmPC in order to update administration instructions based on final results from studies AL42478 and WP42873. AL42478 is an Expanded Access, Single-Arm, Multicentre Study to Provide At Home Subcutaneous Administration of Pertuzumab and Trastuzumab Fixed-Dose Combination (PH FDC SC) for Patients with HER2-positive Breast Cancer During the COVID-19 Pandemic. WP42873 is a randomized, open-label, 2-arm, parallel group, single dose, multi-centre study in healthy male subjects to investigate the comparability of pharmacokinetics of the fixed-dose combination of pertuzumab and trastuzumab administered subcutaneously using a handheld syringe or using the on-body delivery system. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0210 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.4 of the SmPC in order to update the existing warning on 'Aseptic Meningitis Syndrome (AMS)' to add a class monitoring precaution for recurrent AMS, associated with IVIg treatment, potentially progressing to brain oedema (cerebral oedema). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the	Request for supplementary information adopted with a specific timetable.

Package Leaflet." Request for Supplementary Information adopted on 16.01.2025.	
Rystiggo - Rozanolixizumab - EMEA/H/C/005824/II/0009/G, Orphan UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of two type II variations, as follows: C.I.4: Update of section 4.2 of the SmPC in order to modify administration instructions to include the option of self-administration (by the patient or a caregiver) based on the results from study MG0020. This is a phase 3, open-label, crossover study to evaluate Rozanolixizumab self-administration by study participants with generalized myasthenia gravis. C.I.4: Update of sections 4.2 and 6.6 of the SmPC in order to modify administration instructions to include additional supportive data for the manual push (MP) method based on the results from the following clinical studies MG0007 phase 3 open label extension (OLE) and UP0106 phase 1 exploratory study. UP0106A is a randomized, participant-blind, investigator-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of Rozanolixizumab administered subcutaneously via manual push versus syringe driver to healthy participants. While MG007 is an open-label extension study to evaluate Rozanolixizumab in study participants with generalized myasthenia gravis. The Package Leaflet and Labelling are updated accordingly." Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0050 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Update of sections 4.8 and 5.1 of the SmPC in order to add information based on data of the final study report M15-997 (LIMMITLESS) listed as a category 3 study in the RMP. This is a multicentre, open label study to assess the safety and efficacy of risankizumab for maintenance in moderate to severe plaque type psoriasis. In addition, the MAH took the	

opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 14.11.2024.	
Soliris - Eculizumab - EMEA/H/C/000791/II/0131, Orphan Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study ECU-MG-303; this is a Phase 3, open-label, multicentre study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in paediatric patients with refractory generalized myasthenia gravis (gMG). In addition, the MAH took the opportunity to introduce a sentence regarding polysorbate in line with QRD template and minor changes to the PI." Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 17.10.2024, 18.07.2024.	Positive Opinion adopted by consensus on 19.12.2024.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0147 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from study mRNA-1273-P205 listed as a category 3 study in the RMP. This is a Phase 2/3 Study to Evaluate the Immunogenicity and Safety of mRNA Vaccine Boosters for SARS-CoV-2 Variants." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Stelara - Ustekinumab - EMEA/H/C/000958/II/0107 Janssen-Cilag International N.V., Rapporteur: Jayne Crowe, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information based on results from study CNTO1275CRD1003. This is a phase 1, open-label, drug interaction study to evaluate the effect of ustekinumab on cytochrome P450 enzyme activities following induction and maintenance dosing in participants with active Crohn's disease or ulcerative colitis. In addition, the MAH took the opportunity to update sections 4.8 and 5.1 to include patient exposure numbers based on results from study CNTO1275UCO3001. This is a phase 3,	Positive Opinion adopted by consensus on 19.12.2024.

randomised, double-blind, placebo-controlled, parallel-group, multicentre protocol to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis. During the procedure the MAH has also taken the opportunity to update the PI based on the QRD template, which includes a warning on the polysorbate threshold. The requested variation proposed amendments to the Summary of Product Characteristics & Patient Information Leaflet" Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 19.09.2024.	
Strensiq - Asfotase alfa - EMEA/H/C/003794/II/0070, Orphan Alexion Europe SAS, Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to reflect data on effectiveness of asfotase alfa in treating adults with paediatric-onset with hypophosphatasia (HPP) based on real world evidence [RWE], and publications from the Global HPP Registry (ALXN-HPP-501), an observational study [EmPATHY] and UK managed access agreement study another observational prospective study. 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 and add editorial changes to the Labelling." Request for Supplementary Information adopted on 19.12.2024.	Request for supplementary information adopted with a specific timetable.
Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0025 Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, "Update of sections 4.2 and 4.4 of the SmPC in order to reinforce the importance of injecting Sunlenca subcutaneously and not intradermally, and to add a new warning on 'Injection Site Reactions with Improper Administration' to describe that intradermal administration has been associated with serious injection site reactions including necrosis and ulcer, based on a cumulative safety review. The Package Leaflet is updated accordingly. The Instructions for Use (IFU) of Sunlenca solution for injection have also been updated to improve readability for healthcare	

professionals. In addition, the MAH took the opportunity to introduce editorial and formatting changes to the PI.”	
Trodelvy - Sacituzumab govitecan - EMEA/H/C/005182/II/0037 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus, “Update of sections 4.2, 4.4 and 6.6 of the SmPC in order to add information on the timing of fatal infections as well as recommendations on the use of primary prophylaxis with G-CSF in patients who are at high risk for neutropenia, based on clinical trials data, post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”	
Truqap - Capivasertib - EMEA/H/C/006017/II/0002 AstraZeneca AB, Rapporteur: Janet Koenig, “Update of section 5.1 of the SmPC in order to update the clinical efficacy information to reflect a new overall survival (OS) interim analysis pertaining to study D3615C00001 (CAPItello-291) in order to fulfil REC 004; this is a phase III double-blind randomised study assessing the efficacy and safety of capivasertib + fulvestrant versus placebo + fulvestrant as treatment for locally advanced (inoperable) or metastatic Hormone Receptor positive, Human Epidermal Growth Factor Receptor 2 negative (HR+/HER2−) breast cancer following recurrence or progression on or after treatment with an aromatase inhibitor. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI and to update the list of local representatives in the Package Leaflet.” Opinion adopted on 23.01.2025.	Positive Opinion adopted by consensus on 23.01.2025.
Uptravi - Selexipag - EMEA/H/C/003774/II/0042/G Janssen-Cilag International N.V., Rapporteur: Janet Koenig, “A grouped application comprised of 3 Type II Variations as follows: C.I.4: Update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on results from the paediatric PK study AC-065A203; this is a phase 2 multicentre, open-label, single-arm study to evaluate the safety, tolerability and	Positive Opinion adopted by consensus on 19.12.2024.

pharmacokinetics of selexipag in children from 2 years to less than 18 years of age with pulmonary arterial hypertension (PAH).

C.I.4: Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy and safety information based on results from study AC-065A310 (SALTO); this is a phase 3 multicentre, double-blind, randomized, placebo-controlled, parallel group study with open-label extension period to assess the efficacy and safety of selexipag as add-on to standard of care in children from 2 years to less than 18 years of age with pulmonary arterial hypertension (PAH).

C.I.4: Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy information based on results from the pharmacodynamic (PD) similarity/comparison study to compare the PD and clinical responses for efficacy based on study AC-065A203, study AC-065A310 and study AC-065A302 in paediatric participants from 2 years to less than 18 years of age and adult participants with PAH.

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."
Opinion adopted on 19.12.2024.
Request for Supplementary Information adopted on 12.09.2024, 16.05.2024.

Voydeya - Danicopan - EMEA/H/C/005517/II/0004/G, Orphan
Alexion Europe, Rapporteur: Antonio Gomez-Outes, "A grouped application comprised of two Type II variations, as follows:

C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions and update clinical efficacy and safety information, based on final results from study ALXN2040-PNH-301; this is a Phase 3 Study of Danicopan (ALXN2040) as Add-on Therapy to a C5 Inhibitor (Eculizumab or Ravulizumab) in patients with Paroxysmal Nocturnal Haemoglobinuria who have clinically evident Extravascular Haemolysis (EVH). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of

local representatives in the Package Leaflet to bring it in line with the latest QRD template version. C.I.13: Submission of the final report from study ACH471-101; this is a multicentre, open-label, multiple dose Phase 2 study to assess efficacy, safety, and tolerability of add-on danicopan to background eculizumab therapy in adult participants with PNH.”	
Vyloy - Zolbetuximab - EMEA/H/C/005868/II/0003/G, Orphan Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus, “Submission of results from studies GLOW (8951-CL-0302) and SPOTLIGHT (8951-CL-0301). GLOW is a Phase 3, Global, Multi-Centre, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus CAPOX Compared with Placebo Plus CAPOX as First-line Treatment of Subjects with Claudin (CLDN) 18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma. SPOTLIGHT is a Phase 3, Global, Multicentre, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus mFOLFOX6 Compared with Placebo Plus mFOLFOX6 as First-line Treatment of Subjects with Claudin (CLDN) 18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma.”	
Xtandi - Enzalutamide - EMEA/H/C/002639/II/0068/G Astellas Pharma Europe B.V., Rapporteur: Antonio Gomez-Outes, “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 Leaflet is updated accordingly.”	Positive Opinion adopted by consensus on 16.01.2025.

Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 26.09.2024.	
WS2758 **Vfend-EMEA/H/C/000387/WS2758/0155** Pfizer Europe MA EEIG, Lead Rapporteur: Patrick Vrijlandt, "Update of section 4.3 of the SmPC in order to add a contraindication for concomitant use with finerenone based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement administrative changes to section 4.5 of the SmPC and other editorial changes to the PI, as well as to update the list of local representatives in the Package Leaflet."	

B.5.3. CHMP-PRAC assessed procedures

ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0028, Orphan Swedish Orphan Biovitrum AB (publ), Rapporteur: Alexandre Moreau, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 4.8 of the SmPC in order to add urticaria/hives to the list of adverse drug reactions (ADRs) with frequency "common" and to add anaphylactic reaction and anaphylactic shock to the list of ADRs with frequency "uncommon", based on post-marketing data and literature; the Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Bylvay - Odevixibat - EMEA/H/C/004691/II/0022/G, Orphan Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "A grouped application including two type II variations: - Update of sections 4.2, 4.4, 4.8, and 5.1 of the SmPC based on the clinical study report for the completed 72 weeks of Study A4250-008; an open-label, phase III study to evaluate the long-term efficacy and safety of odevixibat in children with PFIC (category 3 study in the RMP; MEA 002). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to	Request for supplementary information adopted with a specific timetable.

implement minor editorial changes in the SmPC and the Package Leaflet. An updated RMP version 6.1 is included in this submission. - Submission of the clinical study report for Study A4250-J001; a Phase I PK study in healthy Japanese adult male patients." Request for Supplementary Information adopted on 16.01.2025.	
Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0007 Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. 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."	See 9.1
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, multicentre, 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	See 9.1

from conditional marketing authorisation to full marketing authorisation." Request for Supplementary Information adopted on 17.10.2024.	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0020, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information regarding thiamine levels based on a review of the primary results of the study FEDR-MF-002. This is a Phase 3, multicentre, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared with BAT in subjects with DIPSS intermediate-2 or high-risk primary MF, post-PV MF, or post-ET MF and previously treated with ruxolitinib. The RMP version 3 has also been submitted." Request for Supplementary Information adopted on 17.10.2024, 25.04.2024.	
Kadcyla - Trastuzumab emtansine - EMEA/H/C/002389/II/0071/G Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Karin Erneholm, "A grouped application consisting of: C.I.4 (Type II): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study BO27938 (KATHERINE) listed as a PAES in the Annex II and as a category 3 study in the RMP. This is a Randomized, Multicentre, Open Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer who have Residual Tumour Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy. The Package Leaflet is updated in accordance. The RMP version 16.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI. Furthermore, the MAH took the opportunity to update Annex II-D and to implement editorial changes to the Labelling section.	Request for supplementary information adopted with a specific timetable.

” Request for Supplementary Information adopted on 16.01.2025, 31.10.2024.	
Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0041 Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, “Update of sections 4.6 and 5.3 of the SmPC in order to amend the recommendations for breast-feeding during ocrelizumab therapy, based on newly available clinical data. The Package Leaflet is updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.” Request for Supplementary Information adopted on 16.01.2025, 31.10.2024, 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Pluvicto - Lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483/II/0022 Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: John Joseph Borg, “Update of section 4.8 of the SmPC in order to update safety information based on final results from study PSMA-617-01 (CAAA617A12301 – VISION) listed as a category 3 study in the RMP; this is an international, prospective, open-label, multicentre, randomized Phase 3 study of 177Lu-PSMA-617 in the treatment of patients with progressive PSMA-positive metastatic castration-resistant prostate cancer. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.” Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Pyramax - Pyronaridine / Artesunate - EMEA/H/W/002319/II/0036 Shin Poong Pharmaceutical Co., Ltd., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Zoubida Amimour, “Update of sections 4.4 and 4.6 of the SmPC with revised recommendations for treatment during pregnancy. The Package Leaflet has been updated accordingly. An updated RMP version 18 was provided as part of the application.” Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.

Pyzchiva - Ustekinumab - EMEA/H/C/006183/II/0005/G Samsung Bioepis NL B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 14.11.2024.	
Ranibizumab Midas - Ranibizumab - EMEA/H/C/006528/II/0002/G MIDAS Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Ranivisio - Ranibizumab - EMEA/H/C/005019/II/0017/G Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0076 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.8 and 5.1 of the SmPC to include the final results of study ZOSTER-049, listed as a category 3 study in the RMP. This is a Phase 3b, open label, multi-country, long-term follow-up study that assessed the prophylactic efficacy, safety, and immunogenicity persistence of Shingrix in adults ≥50 years of age at the time of primary vaccination in studies ZOSTER 006 and ZOSTER-022. The study also assessed 1 or 2 additional doses of Shingrix on a 0 or 0, 2-month schedule in two subgroups of older adults. The updated RMP version 8.0 is also included. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Package Leaflet; and to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 16.01.2025, 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Spinraza - Nusinersen - EMEA/H/C/004312/II/0034/G, Orphan Biogen Netherlands B.V., Rapporteur: Fátima Ventura, PRAC Rapporteur: Karin Bolin, "A grouped application consisting of: C.I.4: Update of sections 5.1 and 5.2 of the	Positive Opinion adopted by consensus on 16.01.2025.

SmPC based on final results from study CS11 (SHINE) listed as a PAES in the Annex II. The Annex II and the RMP v12.1 are updated accordingly. SHINE is a phase III, open-label extension study for patients with Spinal Muscular Atrophy (SMA) who previously participated in investigational studies of ISIS 396443. C.I.4: Update of section 5.1 of the SmPC based on interim results from study CS5 (NURTURE, 232SM201). NURTURE is a Phase II, open-label study to assess the efficacy, safety, tolerability, and pharmacokinetics of multiple doses of nusinersen delivered intrathecally to patients with genetically diagnosed and presymptomatic SMA. C.I.4: Update of section 5.1 of the SmPC in order to relocate the updated information regarding immunogenicity from SmPC section 4.8 to section 5.1 as per applicable CHMP guidance. The data has been revised based on an updated integrated analysis across several studies. C.I.4: Update of section 5.1 of the SmPC based on the outcome of a systematic literature review (SLR) and Natural History data from an International SMA registry (ISMAR)." Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 05.09.2024.	
Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0022/G Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins, "Grouping of two type II variations: - Update of section 5.1 of the SmPC to include efficacy and resistance data based on week 156 interim data from Study GS-US-200-4625; a phase 2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimized background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug resistance (category 3 study in the RMP). Additionally, upon request by the CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-	Request for supplementary information adopted with a specific timetable.

resolved at the end of follow-up. - Provision of the final study report of Study GS-US-200-4334: a phase 2 randomized, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP). An updated RMP version 2.1 was included as part of the application." Request for Supplementary Information adopted on 16.01.2025.	
Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0053 Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.4 and 5.1 of the SmPC in order to amend an existing warning on immunocompromised individuals and to add immunogenicity data in individuals 10 years of age and above with complement deficiencies or splenic dysfunction based on final results from study B1971060; listed as a category 3 study in the RMP. This was an open-label, single-arm, multicentre trial in which up to 50 immunocompromised participants ≥10 years of age with asplenia (anatomic or functional) or complement deficiency have been enrolled and received Trumenba on a 2-dose, 0- and 6-month schedule. The RMP version 8.0 has been approved. In addition, the MAH took the opportunity to introduce minor editorial changes to the SmPC." Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 16.01.2025.
Truqap - Capivasertib - EMEA/H/C/006017/II/0001 AstraZeneca AB, Rapporteur: Janet Koenig, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the posology recommendation and the warning regarding Diabetic Ketoacidosis (DKA) and add it to the list of adverse drug reactions (ADRs) with frequency uncommon based on a safety review. The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted. In addition, the MAH took the opportunity to remove post authorisation	

measures which were added to Annex II in error, 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." Request for Supplementary Information adopted on 14.11.2024.	
Vabysmo - Faricimab - EMEA/H/C/005642/II/0016 Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre, "Update of section 5.1 of the SmPC to reflect the long-term safety profile of faricimab in patients with diabetic macular oedema (DME) based on the final results from study GR41987 (Rhone-X) listed as a category 3 study of the RMP. Rhone-X was a phase III interventional, multicentre, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with diabetic macular oedema. The RMP version 7.0 has also been submitted." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
WEZENLA - Ustekinumab - EMEA/H/C/006132/II/0003/G Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Rhea Fitzgerald Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 31.10.2024.	Positive Opinion adopted by consensus on 16.01.2025.
XALKORI - Crizotinib - EMEA/H/C/002489/II/0084 Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Submission of the final report from study CRZ-NBALCL listed as a category 3 study in the RMP. This is a phase I/II study to evaluate the adverse effects of ocular toxicity and bone toxicity and impaired bone growth associated with crizotinib in paediatric and young adult patients with recurrent/refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma or neuroblastoma. The RMP version 9.2 is updated accordingly." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0012/G, Orphan	Request for supplementary information adopted with a specific timetable.

Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "A grouped application consisting of: C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study DFI12712 ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicentre, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy, safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC. C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted." Request for Supplementary Information adopted on 16.01.2025, 31.10.2024.	

B.5.4. 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." Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 03.10.2024.	Positive Opinion adopted by consensus on 16.01.2025.
PRAC Led **Enbrel - Etanercept - EMEA/H/C/000262/II/0255**	Request for supplementary information adopted with a specific timetable.

Pfizer Europe MA EEIG, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Update of sections 4.2 and 4.4 of the SmPC in order to remove information regarding the Patient Card, based on final results from study B1801309 (BSR Register of Anti-TNF Treated Patients and Prospective Surveillance Study for Adverse Events: Enbrel). This is a non-interventional PASS study listed as a category 3 study in the RMP. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.7 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4." Request for Supplementary Information adopted on 16.01.2025.	
PRAC Led **Erbitux - Cetuximab - EMEA/H/C/000558/II/0103** Merck Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 19.2 in order to re-classify important identified risks and important potential risks and to remove them from the summary of safety concerns, following the PRAC assessment for PSUSA/00000635/202309." Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
PRAC Led **Fintepla - Fenfluramine - EMEA/H/C/003933/II/0028, Orphan** UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of a revised protocol for study EP0218 listed as an obligation in the Annex II of the Product Information. This is a Long-term Registry in approved indications for fenfluramine, with a specific focus on cardiovascular events and growth retardation. The RMP version 4.0 is updated accordingly. In addition, the MAH introduced minor amendments in the targeted follow-up questionnaire for cardiovascular adverse events."	
PRAC Led	

Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/II/0052/G, Orphan Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Grouped application comprising two type II variations as follows: Type II (C.I.3.b) – Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on rash and to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency "not known" following the outcome of procedure PSUSA/00010868/202310. The Package Leaflet is updated accordingly. Type II (C.I.z) – Submission of post-marketing breast-feeding case reports." Request for Supplementary Information adopted on 05.09.2024.	
PRAC Led **Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/II/0055, Orphan** Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.6 of the SmPC in order to amend the existing wording on exposure during pregnancy following PSUR procedure (EMEA/H/C/PSUSA/00010868/202310)." Request for Supplementary Information adopted on 31.10.2024.	
PRAC Led **POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0026, Orphan** Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Update of section 4.8 of the SmPC in order to add 'granuloma' to the list of adverse drug reactions (ADRs) with frequency 'unknown', based on post marketing data; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Ruconest - Conestat alfa - EMEA/H/C/001223/II/0088/G** Pharming Group N.V, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Daniela	Positive Opinion adopted by consensus on 16.01.2025.

Philadelphy, "Submission of an updated RMP version 20.0 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." Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 03.10.2024.	
PRAC Led **Uptravi - Selexipag - EMEA/H/C/003774/II/0045** Janssen-Cilag International N.V., PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from study 67896049PAH0002 (EXTRACT) and interim report for study AC-065A401 (EXPOSURE), listed as a category 3 study in the RMP. EXTRACT is a Retrospective Medical Chart Review of Patients with PAH newly treated with either Uptravi (selexipag) or any other PAH-specific therapy. EXPOSURE is an observational cohort study of PAH patients newly treated with either Uptravi (selexipag) or any other PAH-specific therapy, in clinical practice." Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 03.10.2024, 13.06.2024.	Positive Opinion adopted by consensus on 16.01.2025.
PRAC Led **Veklury - Remdesivir - EMEA/H/C/005622/II/0062** Gilead Sciences Ireland UC, PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "Submission of the final report from study COVID-PR (CO-US-540-6127 listed as a category 3 study in the RMP. This is a non-interventional, patient-reporting, post marketing cohort study designed to collect safety data from pregnant and recently pregnant women treated with monoclonal antibodies or antiviral drugs for mild, moderate, or severe COVID-19 at any time from the first day of the last menstrual period to the end of pregnancy. The RMP version 8.2 is updated accordingly." Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.

PRAC Led **WS2794** **Segluromet-** **EMEA/H/C/004314/WS2794/0026** **Steglatro-** **EMEA/H/C/004315/WS2794/0025** **Steglujan-** **EMEA/H/C/004313/WS2794/0029** Merck Sharp & Dohme B.V., Lead PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of the final report from study 8835-062 listed as a category 3 study in the RMP for Steglatro, Steglujan and Segluromet. This is a non-interventional post-authorization safety study (PASS) to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents. The RMP version 2.3 have also been submitted." Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.

B.5.5. CHMP-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0035, Orphan, ATMP Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	
Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0068, ATMP Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo Opinion adopted on 24.01.2025.	
Zolgensma - Onasemnogene abeparvovec - EMEA/H/C/004750/II/0055, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol	
WS2813/G **Tecartus-** **EMEA/H/C/005102/WS2813/0055/G** **Yescarta-** **EMEA/H/C/004480/WS2813/0086/G** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan	Positive Opinion adopted by consensus on 16.01.2025.

Mueller-Berghaus
Opinion adopted on 16.01.2025.

B.5.6. CHMP-PRAC-CAT assessed procedures

Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0092, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Gabriele Maurer, "Update of section 4.2 of the SmPC in order to update the 'monitoring after infusion' recommendations, based on existing clinical trial data as well as literature references reporting real word experience. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce a minor change to the HCP educational programme in the Annex II in order to enhance readability."

B.5.7. PRAC assessed ATMP procedures

PRAC Led
CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0034, Orphan, ATMP
Janssen-Cilag International NV, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of an updated RMP version 5.2 in order to add a new important identified risk of "Secondary malignancy of T-cell origin", to change the important potential risk of "Second primary malignancies" to "Second primary malignancy except secondary malignancy of T-cell origin", and to include an additional pharmacovigilance activity for testing of secondary malignancies of T-cell origin, following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040)."

PRAC Led
Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - EMEA/H/C/003854/II/0040, Orphan, ATMP
Fondazione Telethon ETS, PRAC Rapporteur:

Liana Martirosyan, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 7.0 in order to to propose amendments to the STRIM-005 and STRIM-003 study protocols, as well as revised timelines for completion of both studies. In addition, the Annex II is updated accordingly." Request for Supplementary Information adopted on 13.09.2024.	
PRAC Led **WS2771** **Tecartus-** **EMEA/H/C/005102/WS2771/0054** **Yescarta-** **EMEA/H/C/004480/WS2771/0084** Kite Pharma EU B.V., Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin."	

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

WS2737 **Olanzapine Glenmark-** **EMEA/H/C/001085/WS2737/0044** **Olanzapine Glenmark Europe-** **EMEA/H/C/001086/WS2737/0041** **Olazax-EMEA/H/C/001087/WS2737/0036** **Olazax Disperzi-** **EMEA/H/C/001088/WS2737/0038** Glenmark Arzneimittel GmbH, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 12.12.2024.	
WS2765/G **Aflunov-** **EMEA/H/C/002094/WS2765/0087/G** **Foclivia-** **EMEA/H/C/001208/WS2765/0090/G** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2765/0006/G** Seqirus S.r.l., Informed Consent of Aflunov,	Positive Opinion adopted by consensus on 19.12.2024.

Lead Rapporteur: Maria Grazia Evandri Opinion adopted on 19.12.2024. Request for Supplementary Information adopted on 31.10.2024.	
WS2774/G **Dapagliflozin Viatris-EMEA/H/C/006006/WS2774/0005/G** Viatris Limited, Generic of Forxiga, Lead Rapporteur: Tomas Radimersky Request for Supplementary Information adopted on 16.01.2025.	Request for supplementary information adopted with a specific timetable.
WS2786 **BiResp Spiromax-EMEA/H/C/003890/WS2786/0045** **DuoResp Spiromax-EMEA/H/C/002348/WS2786/0045** Teva Pharma B.V., Lead Rapporteur: John Joseph Borg Opinion adopted on 16.01.2025. Request for Supplementary Information adopted on 05.12.2024.	Positive Opinion adopted by consensus on 16.01.2025.
WS2788 **Biopoin-EMEA/H/C/001036/WS2788/0057** **Eporatio-EMEA/H/C/001033/WS2788/0056** ratiopharm GmbH, Lead Rapporteur: Alexandre Moreau Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2790 **M-M-RvaxPro-EMEA/H/C/000604/WS2790/0129** **ProQuad-EMEA/H/C/000622/WS2790/0170** Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 19.12.2024.	Positive Opinion adopted by consensus on 19.12.2024.
WS2791/G **Aflunov-EMEA/H/C/002094/WS2791/0091/G** **Foclivia-EMEA/H/C/001208/WS2791/0095/G** **Zoonotic Influenza Vaccine Seqirus-EMEA/H/C/006375/WS2791/0009/G** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 19.12.2024.	
WS2795 **Glyxambi-** **EMEA/H/C/003833/WS2795/0063** **Jentadueto-** **EMEA/H/C/002279/WS2795/0076** **Trajenta-** **EMEA/H/C/002110/WS2795/0057** Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2797 **Vfend-EMEA/H/C/000387/WS2797/0157** Pfizer Europe MA EEIG, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 23.01.2025.	Positive Opinion adopted by consensus on 23.01.2025.
WS2811/G **Abseamed-** **EMEA/H/C/000727/WS2811/0112/G** **Binocrit-** **EMEA/H/C/000725/WS2811/0112/G** **Epoetin alfa Hexal-** **EMEA/H/C/000726/WS2811/0112/G** Sandoz GmbH, Lead Rapporteur: Alexandre Moreau Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.
WS2812/G **Filgrastim Hexal-** **EMEA/H/C/000918/WS2812/0080/G** **Zarzio-** **EMEA/H/C/000917/WS2812/0081/G** Sandoz GmbH, Lead Rapporteur: Peter Mol Opinion adopted on 16.01.2025.	Positive Opinion adopted by consensus on 16.01.2025.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Nadofaragene firadenovec - **EMEA/H/C/005856, ATMP** treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC)., **Nogapendekin alfa / Inbakicept -** **EMEA/H/C/006622** treatment of adult patients with BCG-

unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours

Blarcamesine - EMEA/H/C/006475
treatment of Alzheimer's disease and dementia

Influenza and COVID-19 vaccine - EMEA/H/C/006472
immunisation for the prevention of diseases associated with seasonal influenza viruses and SARS-CoV-2

Donidalorsen - EMEA/H/C/006554
for routine prevention of recurrent attacks of hereditary angioedema (HAE)

Trofinetide - EMEA/H/C/006482, Orphan
Comharsa Life Sciences Limited, Treatment of Rett syndrome in adults and paediatric patients 2 years of age and older

Denosumab - EMEA/H/C/006722
prevention of skeletal related events with advanced malignancies

Iloperidone - EMEA/H/C/006561
Treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA/H/C/006639
indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

Golimumab - EMEA/H/C/006621
treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis

Eflornithine - EMEA/H/C/006067, Orphan
Norgine B.V., treatment of high-risk neuroblastoma responsive to prior multiagent, multimodality therapy

Lutetium (177Lu) chloride - EMEA/H/C/006596
used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride

Imlunestrant - EMEA/H/C/006184
treatment of adult patients with oestrogen

receptor (ER)-positive
In vitro diagnostic medical device - EMEA/H/D/006656 assay to assess the mismatch repair (MMR) proteins (MLH1, PMS2, MSH2, and MSH6) in formalin-fixed, paraffin-embedded (FFPE) colorectal cancer (CRC) tissue using EnVision FLEX visualization system on Dako Omnis automated staining instrument
mRNA-1283 - EMEA/H/C/006428 Active immunisation to prevent COVID 19 caused by SARS-CoV-2 in individuals 12 years of age and older.
Aficamten - EMEA/H/C/006228 treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adult patients
Denosumab - EMEA/H/C/006492 Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients.
Ranibizumab - EMEA/H/C/006502 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), visual impairment due to choroidal neovascularisation (CNV), retinopathy of prematurity (ROP) with zone.
Teplizumab - EMEA/H/C/005496 To delay both the onset of Stage 3 type 1 diabetes (T1D) and the progression of Stage 3 T1D
Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - EMEA/H/C/006525, Orphan, ATMP Fondazione Telethon Ets, treatment of patients with Wiskott-Aldrich Syndrome (WAS),

Mavorixafor - EMEA/H/C/006496, Orphan
X4 Pharmaceuticals (Austria) GmbH, Treatment of WHIM syndrome

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

Koselugo - Selumetinib - EMEA/H/C/005244/X/0018/G, Orphan
AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn, "Extension application to introduce a new pharmaceutical form (Granules in capsules for opening) associated with new strengths (5 mg and 7.5 mg capsule) grouped with a Type II variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to align the SmPC and labelling of Koselugo capsules and Koselugo granules in capsules for opening. The Package Leaflet and Labelling are updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Lunsumio - Mosunetuzumab - EMEA/H/C/005680/X/0015, Orphan
Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn, "Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (5 mg and 45 mg) and new route of administration (subcutaneous use).
The RMP (version 3.0) is updated in accordance."

Remsima - Infliximab - EMEA/H/C/002576/X/0149
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion) associated with a new strength (40 mg/ml)."

Spinraza - Nusinersen - EMEA/H/C/004312/X/0038, Orphan
Biogen Netherlands B.V., Rapporteur: Fátima Ventura, PRAC Rapporteur: Karin Bolin, "Extension application to add a new strength of 28 mg and 50 mg.

The RMP (version 12.x) is updated in accordance (version 12.2 is under assessment in procedure EMEA/H/C/004312/II/0034/G)."

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

Adempas - Riociguat - EMEA/H/C/002737/X/0041
Bayer AG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola, "Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension (PAH) paediatric indication. As a consequence, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated."
List of Questions adopted on 17.10.2024.

L-Acetylleucine - EMEA/H/C/006327, Orphan
Intrabio Ireland Limited, is indicated in adults and children from birth for chronic treatment of Niemann-Pick Type C (NPC).
List of Questions adopted on 17.10.2024.

Atropine - EMEA/H/C/006385, PUMA
treatment of myopia in children aged 3 years and older
List of Questions adopted on 19.09.2024.

Obecabtagene autoleucel - EMEA/H/C/005907, Orphan, ATMP
Autolus GmbH, treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)
List of Questions adopted on 19.07.2024.

Deutetrabenazine - EMEA/H/C/006371
treatment of tardive dyskinesia
List of Questions adopted on 25.07.2024.

Denosumab - EMEA/H/C/006434
treatment of osteoporosis and bone loss
List of Questions adopted on 19.09.2024.

Denosumab - EMEA/H/C/006435
prevention of skeletal related events with advanced malignancies

List of Questions adopted on 19.09.2024.

Denosumab - EMEA/H/C/006269
prevention of skeletal related events with advanced malignancies
List of Questions adopted on 17.10.2024.

Denosumab - EMEA/H/C/006268
treatment of osteoporosis and bone loss
List of Questions adopted on 17.10.2024.

Denosumab - EMEA/H/C/006199
prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone
List of Questions adopted on 19.09.2024.

Denosumab - EMEA/H/C/006376
prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone
List of Questions adopted on 19.09.2024.

Inavolisib - EMEA/H/C/006353
treatment of adult patients with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer
List of Questions adopted on 19.09.2024.

Denosumab - EMEA/H/C/006152
for the treatment of osteoporosis and bone loss.
List of Questions adopted on 19.09.2024.

Autologous cartilage-derived articular chondrocytes, in-vitro expanded - EMEA/H/C/004594, ATMP
repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV
List of Questions adopted on 19.04.2024.

Octreotide - EMEA/H/C/006322, Orphan
Camurus AB, treatment of acromegaly
List of Questions adopted on 19.09.2024.

Sepiapterin - EMEA/H/C/006331, Orphan
PTC Therapeutics International Limited, treatment of hyperphenylalaninemia (HPA) in adult and paediatric patients with phenylketonuria (PKU)

List of Questions adopted on 19.09.2024.

Teprotumumab - EMEA/H/C/006396
treatment of moderate to severe Thyroid Eye Disease (TED).
List of Questions adopted on 19.09.2024.

Teriparatide - EMEA/H/C/005687
treatment of osteoporosis
List of Questions adopted on 09.11.2023.

Aflibercept - EMEA/H/C/006192
treatment of age-related macular degeneration (AMD) and visual impairment, treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)
List of Questions adopted on 25.07.2024.

Human albumin solution - EMEA/H/D/006540
Ex vivo heart perfusion
List of Questions adopted on 14.11.2024.

Denosumab - EMEA/H/C/006377
for the treatment of osteoporosis and bone loss
List of Questions adopted on 19.09.2024.

Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded - EMEA/H/C/005772, Orphan, ATMP
Cordex Biologics International Limited,
treatment of adult patients with haematological malignancies
List of Questions adopted on 11.10.2024.

Zanidatamab - EMEA/H/C/006380, Orphan
Jazz Pharmaceuticals Ireland Limited, Treatment of biliary tract cancer
List of Questions adopted on 17.10.2024.

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

Ceplene - Histamine dihydrochloride - EMEA/H/C/000796/S/0049
Laboratoires Delbert, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu

Defitelio - Defibrotide - EMEA/H/C/002393/S/0069, Orphan
Gentium S.r.l., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

Livmarli - Maralixibat - EMEA/H/C/005857/S/0019, Orphan

Mirum Pharmaceuticals International B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

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

ARIKAYCE liposomal - Amikacin - EMEA/H/C/005264/R/0014, Orphan
Insmed Netherlands B.V., Rapporteur: Jayne Crowe, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jean-Michel Dogné

Arsenic trioxide medac - Arsenic trioxide - EMEA/H/C/005218/R/0006
medac Gesellschaft fur klinische Spezialpraparate mbH, Generic of TRISENOX, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant

Cabazitaxel Accord - Cabazitaxel - EMEA/H/C/005178/R/0012
Accord Healthcare S.L.U., Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Tiphaine Vaillant

Jyseleca - Filgotinib - EMEA/H/C/005113/R/0038
Alfasigma S.p.A., Rapporteur: Kristina Dunder, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Petar Mas

Koselugo - Selumetinib - EMEA/H/C/005244/R/0019, Orphan
AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Lumeblue - Methylthioninium chloride - EMEA/H/C/002776/R/0007
Cosmo Technologies Limited, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Lunsumio - Mosunetuzumab - EMEA/H/C/005680/R/0014, Orphan
Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Lytgobi - Futibatinib - EMEA/H/C/005627/R/0008
Taiho Pharma Netherlands B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Mari Thorn

PHELINUN - Melphalan - EMEA/H/C/005173/R/0005
ADIENNE S.r.l., Rapporteur: Peter Mol, PRAC Rapporteur: Mari Thorn

Rozlytrek - Entrectinib - EMEA/H/C/004936/R/0026
Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Clopidogrel Zentiva - Clopidogrel - EMEA/H/C/000975/II/0092
Zentiva k.s., Duplicate of Clopidogrel BMS (SRD), Informed Consent of Iscover, Rapporteur: Fátima Ventura, PRAC Rapporteur: Carla Torre, "Extension of indication to include, in combination with acetylsalicylic acid (ASA), patients with ST segment elevation acute myocardial infarction (STEMI) who are undergoing percutaneous coronary intervention (PCI) for CLOPIDOGREL ZENTIVA. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. Version 0.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, introduce minor editorial changes to the PI and bring it in line with the latest QRD template version 10.4."

Flucelvax - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/006532/II/0001
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include treatment of children from 6 months of age and older for FLUCELVAX, based on results from study V130_14. This is a Phase III, Randomized, Observer-blind, Multicentre 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 4.0 of the RMP is also being submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the MAH took the opportunity to implement changes to sections 4.4 and 4.5 of the SmPC."

Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0092

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Extension of indication to include IMBRUVICA in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for autologous stem cell transplantation (ASCT), based on results from study MCL3003. This is a randomized, 3-arm, parallel-group, open-label, international, multicentre Phase 3 study. The purpose of Study MCL3003 is to compare 3 alternating courses of R CHOP/R-DHAP followed by ASCT (control Arm A), versus the combination with ibrutinib in induction and maintenance (experimental Arm A+I), or the experimental arm without ASCT (experimental Arm I) in participants with previously untreated MCL who are eligible for ASCT. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Version 23.1 of the RMP has also been submitted."

LUTATHERA - Lutetium (177Lu) oxodotreotide - EMEA/H/C/004123/II/0058, Orphan

Advanced Accelerator Applications, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Extension of indication to include the treatment of unresectable or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescents aged 12 years and older for LUTATHERA based on primary analysis

results from study CAAA601A32201 (also referred to as NETTER-P) as well as results from modelling and simulation analysis of PK and dosimetry data of Lutathera in adolescents. NETTER-P study is a Phase II, multicentre open-label study which evaluated the safety and dosimetry of Lutathera in adolescent patients with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and pheochromocytoma and paragangliomas (PPGLs). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 11 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."	
SARCLISA - Isatuximab - EMEA/H/C/004977/II/0035 Sanofi Winthrop Industrie, Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, "Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the induction treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are eligible for autologous stem cell transplant (ASCT) for SARCLISA, based on the results from study IIT15403 (GMMG-HD7); this is a randomized phase III study designed to assess the efficacy and safety of Sarclisa for the induction and maintenance treatment of NDMM. 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 accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI."	
Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0018 Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Extension of indication for Tevimbra in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, for the treatment of adult patients with resectable NSCLC based on interim results from study BGB-A317-315. Study BGB-A317-315 is a phase 3 randomized, placebo-controlled, double-blind study to compare the efficacy and safety of neoadjuvant treatment with tislelizumab plus platinum-based doublet	

chemotherapy followed by adjuvant tislelizumab versus neoadjuvant treatment with placebo plus platinum-based doublet chemotherapy followed by adjuvant placebo in patients with resectable Stage II or IIIA NSCLC. 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 2.7 of the RMP has also been submitted.”

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0023 LEO Pharma A/S, Rapporteur: Jayne Crowe
Advate - Octocog alfa - EMEA/H/C/000520/II/0124 Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus
Briumvi - Ublituximab - EMEA/H/C/005914/II/0023/G Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra
Ceprotin - Human protein C - EMEA/H/C/000334/II/0143/G Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus
Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – EMA/VR/0000232276 GlaxoSmithKline Biologicals, Rapporteur: Christophe Focke, PL: Elisa Pedone,
CooperSurgical Inc ART Media - Human albumin solution - EMEA/H/D/002307/II/0012 Coopersurgical Inc., Rapporteur: Kristina Dunder
Cosentyx - Secukinumab - EMEA/H/C/003729/II/0124 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola
ELAHERE - Mirvetuximab soravtansine - EMEA/H/C/005036/II/0001/G, Orphan AbbVie Deutschland GmbH & Co. KG, Rapporteur: Johanna Lähteenvuo

Entyvio - Vedolizumab - EMEA/H/C/002782/II/0088/G
Takeda Pharma A/S, Rapporteur: Paolo Gasparini

EVRA - Ethinylestradiol / Norelgestromin - EMEA/H/C/000410/II/0054
Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt

Fluad - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006538/II/0001/G
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

GIVLAARI - Givosiran - EMEA/H/C/004775/II/0022, Orphan
Alnylam Netherlands B.V., Rapporteur: Patrick Vrijlandt

GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0177/G
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0163
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0164
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Idacio - Adalimumab - EMEA/H/C/004475/II/0024/G
Fresenius Kabi Deutschland GmbH, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Bolin

Lamzede - Velmanase alfa - EMEA/H/C/003922/II/0040/G, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt

LifeGlobal Media - Human albumin solution - EMEA/H/D/004287/II/0009
Coopersurgical Inc., Rapporteur: Maria Grazia Evandri

Origio - Human albumin solution - EMEA/H/D/000830/II/0021
Coopersurgical Inc., Rapporteur: Jayne Crowe

Ozempic - Semaglutide - EMEA/H/C/004174/II/0051

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0060
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race

POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0028/G, Orphan
Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol

Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0213
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0214
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Roclanda - Latanoprost / Netarsudil - EMEA/H/C/005107/II/0031/G
Santen Oy, Rapporteur: Jayne Crowe

Semglee - Insulin glargine - EMEA/H/C/004280/II/0053
Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig

Simulect - Basiliximab - EMEA/H/C/000207/II/0123/G
Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus

Skyrizi - Risankizumab - EMEA/H/C/004759/II/0054/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy

Sondelbay - Teriparatide - EMEA/H/C/005827/II/0008
Accord Healthcare S.L.U., Rapporteur: Finbarr Leacy

TAKHZYRO - Lanadelumab - EMEA/H/C/004806/II/0043/G, Orphan
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder

Trulicity - Dulaglutide - EMEA/H/C/002825/II/0073/G
Eli Lilly Nederland B.V., Rapporteur: Janet Koenig

Opinion adopted on 16.01.2025.

Ultomiris - Ravulizumab -
EMEA/H/C/004954/II/0048
Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes

Vyloy - Zolbetuximab -
EMEA/H/C/005868/II/0006/G, Orphan
Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus

Wegovy - Semaglutide -
EMEA/H/C/005422/II/0027
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

WS2622
HyQvia-EMEA/H/C/002491/WS2622/0103
Kiovig-EMEA/H/C/000628/WS2622/0130
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

WS2804/G
Aerius-
EMEA/H/C/000313/WS2804/0108/G
Azomyr-
EMEA/H/C/000310/WS2804/0112/G
Neoclarityn-
EMEA/H/C/000314/WS2804/0106/G
Organon N.V., Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke

WS2805/G
Celldemic-
EMEA/H/C/006052/WS2805/0003/G
Incellipan-
EMEA/H/C/006051/WS2805/0003/G
Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphy

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

AQUIPTA - Atogepant -
EMEA/H/C/005871/II/0008
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of section 4.6 of the SmPC in order to amend information on pregnancy and lactation based on data from study M22-394; this is a phase 1 lactation study to evaluate the pharmacokinetics and safety of ubrogepant and atogepant in healthy adult lactating female subjects one to six months

post-partum. The Package Leaflet is updated accordingly."

Cerezyme - Imiglucerase - EMEA/H/C/000157/II/0136

Sanofi B.V., Rapporteur: Patrick Vrijlandt, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Transient hypertension' to the list of adverse drug reactions (ADRs) with frequency not known as well as to reflect the warning on Infusion-associated reactions (IARs), based on a safety review. The Package Leaflet is updated accordingly."

Efmody - Hydrocortisone - EMEA/H/C/005105/II/0013

Neurocrine Netherlands B.V., Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 4.4, 4.5, and 4.8 of the SmPC based on the pooled safety analysis of DIUR-006; this is a phase 3 extension study of efficacy, safety and tolerability of Chronocort in the treatment of congenital adrenal hyperplasia. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

Enhertu - Trastuzumab - EMEA/H/C/005124/II/0054

Daiichi Sankyo Europe GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Submission of the final report from study DS8201-A-U201 listed as a Recommendation (REC). This is a phase 2 multicentre, open-label efficacy and safety study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for HER2- positive, unresectable and/or metastatic breast cancer subjects previously treated with T-DM1."

Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0021

Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Submission of the final report from study DNDi-FEX-09-HAT. This is a phase 3b, open-label study assessing effectiveness, safety and compliance with fexinidazole in patients with human African trypanosomiasis due to T.b. gambiense at any stage."

Fintepla - Fenfluramine - EMEA/H/C/003933/II/0030, Orphan

UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the

SmPC in order to include new efficacy data for Lennox-Gastaut syndrome (LGS) based on final results from EP0214 'ZX008-1601' study. This phase 3 Open-Label Extension (OLE) international multicentre study was conducted in two parts and two cohorts. Part 1 was a randomized, double-blind, placebo-controlled trial of two fixed doses of ZX008 (fenfluramine hydrochloride) oral solution as adjunctive therapy for seizures in children and adults with LGS. Part 2 was an open-label extension to assess the long-term safety and tolerability of ZX008 in children and adults."	
Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0091 Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "Submission of the final report from study PCYC-1142-CA (CAPTIVATE). This is a Phase 2, international, multicentre study of the combination of ibrutinib plus venetoclax in subjects with treatment-naïve chronic lymphocytic leukaemia (CLL) /small lymphocytic lymphoma(SLL) in order to assess both minimal residual disease (MRD)-guided discontinuation and fixed duration therapy."	
IMCIVREE - Setmelanotide - EMEA/H/C/005089/II/0034, Orphan Rhythm Pharmaceuticals Netherlands B.V., Rapporteur: Karin Janssen van Doorn, "Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs) based on the availability of new safety data. The Package Leaflet is updated accordingly."	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0027, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.2 and 5.2 of the SmPC in order to add administration option based on results from clinical trial FEDR-CP-005. This is a phase 1, open-label, single-centre, 2-part crossover study to evaluate the relative bioavailability of fedratinib when administered as contents of capsules dispersed in a nutritional supplement orally or via nasogastric tube or administered orally as divided doses of intact capsules with a nutritional supplement in healthy adult subjects. The Package Leaflet is being updated accordingly. In addition, the MAH took the opportunity to add editorial changes to	

the PI.”	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0165 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, “C.I.13: Submission of the final safety analysis report of participants with hematologic malignancies enrolled in MSD Sponsored studies who received an allogenic hematopoietic stem cell transplantation (HSCT) following therapy with pembrolizumab.”	
Metalyse - Tenecteplase - EMEA/H/C/000306/II/0075/G Boehringer Ingelheim International GmbH, Rapporteur: Janet Koenig, “A grouped application comprised of 4 Type II Variations, as follows: C.I.4: Update of sections 4.3 and 4.4 of the SmPC in order to update the safety information pertaining to the prevention of bleeding risk related to thrombolytic treatment based on a dataset consisting of literature review including published clinical study outcomes. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to update the safety information for patients with body weight < 50 kg based on the dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.3 and 4.4 of the SmPC related to the medical recommendations for prior stroke patients based on a dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to revise the medical recommendation in line with the most current medical knowledge in treatment guidelines. 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 introduce minor editorial changes to the PI, as well as to update the excipient information according to the latest EU	

Excipients Guideline. Furthermore, the PI is being brought in line with the latest QRD template (version 10.4).”
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0097/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, “Submission of the final clinical study reports from clinical study 2019nCoV-313 Part 1 and Part 2 listed as a category 3 study in the RMP. This is A 2-Part Phase 2/3 Open-Label Study to Evaluate the Safety and Immunogenicity of an XBB.1.5 (Omicron Subvariant) SARS -CoV-2 rS Vaccine Booster Dose in Previously mRNA COVID-19 Vaccinated and Baseline SARS-CoV-2 Seropositive COVID-19 Vaccine Naïve Participants.”
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0012 Bioprojet Pharma, Rapporteur: Peter Mol, “Submission of the study note PH24048. This is an update of the final PopPK model (PH20043) submitted at initial Marketing Authorization Approval integrating the results of study 15-03 (HAROSA III). In addition, the results of re-estimated model parameters and covariates are provided.”
Rezzayo - Rezafungin - EMEA/H/C/005900/II/0007, Orphan Mundipharma GmbH, Rapporteur: Fátima Ventura, “ Update of sections 4.8, and 5.1 of the SmPC based on final results of China extension part from study ReSTORE; this is a pivotal Phase 3, multicentre, randomised, double-blind study of the efficacy and safety of rezafungin versus the active control caspofungin IV, followed by optional oral fluconazole step-down, in the treatment of subjects with IC; updated population PK modelling was also presented; the Package Leaflet is updated accordingly.”
Samsca - Tolvaptan - EMEA/H/C/000980/II/0051 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Paolo Gasparini, “Update of section 4.5 of the SmPC in order to add drug-drug interaction information with St John’s wort based on literature and to implement the recommendation from EMA on the risk of drug

interactions with Hypericum perforatum (St John's Wort) and antiretroviral medicinal products. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0036, Orphan

Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC in order to update efficacy and safety information following the request by CHMP in the outcome for procedure EMEA/H/C/005367/P46/003.1 based on final results from the paediatric study CT-301EXT (enliGHten). In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4."

Tabrecta - Capmatinib - EMEA/H/C/004845/II/0016

Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, "Update of sections 4.8 and 5.1 of the SmPC in order to update information on based on the results of the clinical study CINC280A2201 'GEOMETRY mono-1' and add 'body temperature increased' to the list of adverse drug reactions (ADRs) with frequency 'very common'. CINC280A2201 is a global, multi-cohort, non-randomized, open-label Phase II study designed to evaluate the efficacy and safety of single-agent capmatinib in adult patients with epidermal growth factor receptor (EGFR) wild type (wt), advanced non-small cell lung cancer (NSCLC). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

Taltz - Ixekizumab - EMEA/H/C/003943/II/0054

Eli Lilly and Co (Ireland) Limited, Rapporteur: Kristina Dunder, "Update section 4.8 of the SmPC to add eczematous eruptions (dyshidrotic eczema and exfoliative dermatitis) to the list of adverse drug reactions (ADRs) with frequency uncommon and rare, respectively, following a review of all associated data. The package leaflet is updated in accordance."

Vectibix - Panitumumab - EMEA/H/C/000741/II/0105

Amgen Europe B.V., Rapporteur: Eva Skovlund, "Update of section 4.8 of the SmPC in order to update the information regarding the incidence of infusion-related reactions to reflect the total number of subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and administrative changes to the PI and to bring it in line with the latest QRD template version 10.4, and to update the list of local representatives in the Package Leaflet."	
Vyloy - Zolbetuximab - EMEA/H/C/005868/II/0005, Orphan Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to update immunogenicity data based on the validation report for the new method (8951-ME-0016) to replace the method originally used to test ADA samples from the pivotal studies SPOTLIGHT and GLOW. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI."	
Xarelto - Rivaroxaban - EMEA/H/C/000944/II/0113 Bayer AG, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add ´splenic rupture´ to the list of adverse drug reactions (ADRs) with frequency 'very rare' based on the data from the clinical trials, post-marketing data sources and literature; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity introduce editorial updates as agreed with QRD group."	
Xeljanz - Tofacitinib - EMEA/H/C/004214/II/0068 Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, "Update of section 4.6 of the SmPC in order to update information on breast-feeding section based on literature and post-marketing data. In addition, the MAH took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet."	
Zejula - Niraparib - EMEA/H/C/004249/II/0057/G, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, "C.I.4: Update of section 4.5 of the SmPC in order to update information on	

pharmacokinetic drug-drug interactions based on Physiologically based on results from pharmacokinetic (PBPK) modelling; this is Evaluation of GSK3985771 (Niraparib) Drug-Drug Interaction (DDI) Risk Assessment as a Perpetrator using PBPK Modelling; 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 introduce editorial changes to the PI. C.I.4: Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on results from Refined PRIMA Model; this is an amendment to addendum to population pharmacokinetic and exposure-response modelling of niraparib in PRIMA study; the Package Leaflet is updated accordingly.”	
WS2793 **Braftovi-** **EMEA/H/C/004580/WS2793/0042** **Mektovi-** **EMEA/H/C/004579/WS2793/0036** Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, “Submission of the final report from study C4221004, aiming at investigating the potential associations between baseline tumour biomarkers and treatment outcome in the 2-part Phase III Randomized, Open Label, Multicentre Study of LGX818 Plus MEK162 Versus Vemurafenib and LGX818 Monotherapy in Patients with Unresectable or Metastatic BRAF V600 Mutant Melanoma (COLUMBUS study).”	
WS2818 **PecFent-** **EMEA/H/C/001164/WS2818/0062** Gruenenthal GmbH, Lead Rapporteur: Janet Koenig, “Update of section 4.5 of the SmPC in order to add drug-drug interaction information between opioids and anticholinergics; the Package Leaflet is updated accordingly.”	
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda- **EMEA/H/W/005362/WS2809/0021** **Qdenga-** **EMEA/H/C/005155/WS2809/0022** Takeda GmbH, Lead Rapporteur: Sol Ruiz, “Update of section 4.8 of the SmPC in order to add eye pain to the list of adverse drug reactions (ADRs) with frequency uncommon	

based on post-marketing data; 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 introduce editorial changes to the PI."

B.6.10. CHMP-PRAC assessed procedures

Bavencio - Avelumab - EMEA/H/C/004338/II/0051

Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Erneholm, "Update of sections 4.4 and 4.8 of the SmPC in order to add "neutropenia" to the list of adverse drug reactions (ADRs) with frequency "not known" based on post marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 8.2 has also been submitted. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline."

Columvi - Glofitamab - EMEA/H/C/005751/II/0010, Orphan

Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova, "Submission of the updated 2-year follow-up report from study NP30179 listed as a Specific Obligation in the Annex II of the Product Information. This is a multicentre, open-label Phase I/II study to evaluate the safety, efficacy, tolerability, and pharmacokinetics of escalating doses of glofitamab in patients with relapsed/refractory B-cell Non-Hodgkin's Lymphoma (NHL). The Annex II and the RMP version 4.0 are updated accordingly. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation."

Kayfanda - Odevixibat - EMEA/H/C/006462/II/0001/G

Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of:
C.I.4: Update of sections 4.4, 4.8, and 5.1 of the SmPC based on results from Study A4250-015 listed as a category 3 study in the RMP; this is a Phase 3, multicentre, open-label extension study to evaluate the long-term safety and efficacy of odevixibat in patients with ALGS. The

Package Leaflet is updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. C.I.13: Submission of the 72 week report from study A4250-008. This is a Phase 3, multicentre, open-label extension study to investigate the long-term efficacy and safety of odevixibat in patients with Progressive Familial Intrahepatic Cholestasis Types 1 and 2 (PEDFIC 2)."	
Kisplyx - Lenvatinib - EMEA/H/C/004224/II/0061 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: David Olsen, "Submission of the final report from study E7080-G000-307 listed as a category 3 study in the RMP. This is a multicentre, open-label, randomized, phase 3 trial to compare the efficacy and safety of lenvatinib in combination with everolimus or pembrolizumab versus sunitinib alone in first-line treatment of subjects with advanced renal cell carcinoma. The RMP version 18.0 has also been submitted."	
Litfulo - Ritlecitinib - EMEA/H/C/006025/II/0007 Pfizer Europe MA EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.8 of the SmPC in order to update of the long-term efficacy and safety information based on interim results from study B7981032 listed as a category 3 study in the RMP; this is a Phase 3 Open-Label, Multi-Centre, Long-Term Study Investigating the Safety and Efficacy of PF-06651600 in Adult and Adolescent Participants With Alopecia Areata. The RMP version 2 has also been submitted."	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0096/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Gabriele Maurer	
PONVORY - Ponesimod - EMEA/H/C/005163/II/0018/G Laboratoires Juvise Pharmaceuticals, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Erneholm, "Grouped application comprised of two Type II Variations, as follows:	

C.I.13: Submission of the final report from study AC-058B202; this is a Multicentre, Randomized, Double-blind, Parallel-group Extension to Study AC-058B201 to Investigate the Long-term Safety, Tolerability, and Efficacy of 10, 20, and 40 mg/day Ponesimod, an Oral S1P1 Receptor Agonist, in Patients with Relapsing-remitting Multiple Sclerosis.

C.I.13: Submission of the final report from study AC-058B303 (OPTIMUM-LT); this is a Multicentre, Non-Comparative Extension to Study AC-058B301, to Investigate the Long-Term Safety, Tolerability, and Control of Disease of Ponesimod 20 mg in Subjects with Relapsing Multiple Sclerosis.
The RMP version 4.1 has also been submitted."

Rozlytrek - Entrectinib - EMEA/H/C/004936/II/0025
Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "Submission of the final integrated analysis report for bone biomarkers based on GO40782 [STARTRK-2], CO40778 [STARTRK-NG], and BO41932 [TAPISTRY] studies (PAESs). The RMP version 6 has also been submitted."

Tibsovo - Ivosidenib - EMEA/H/C/005936/II/0012, Orphan
Les Laboratoires Servier, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Submission of an updated RMP version 2.1 for TIBSOVO and a replacement study protocol for study S095031-218. This is a phase 1, multicentre, open-label, safety and pharmacokinetic study of orally administered ivosidenib in participants with IDH1-mutated malignancies and hepatic or renal impairment. Study milestones in RMP were updated accordingly."

Tysabri - Natalizumab - EMEA/H/C/000603/II/0150
Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 4.4 of the SmPC in order to modify administration instructions to add the option for self-administration or administration by a caregiver and to update educational guidance, based on

supportive data including final results from study 101MS330; this is a Single-Arm, Open-Label, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of Natalizumab Administered to Japanese Participants With Relapsing-Remitting Multiple Sclerosis via a Subcutaneous Route of Administration. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 32.1 has also been submitted."

Yondelis - Trabectedin - EMEA/H/C/000773/II/0070

Pharma Mar, S.A., Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.4 and 4.6 of the SmPC in order to update the contraceptive precautions when receiving Yondelis, in line with EMA recommendations. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4."

ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0015/G, Orphan

Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of five Type II variations, as follows:

C.I.13: Submission of the final report from non-clinical study 1022-9241 listed as a category 3 study in the RMP. This is a 26-Week Toxicity Study of Ganaxolone Metabolite, M2, by Oral Gavage in the Sprague-Dawley rat with a 2-Week Recovery Period. The RMP version 3 has also been submitted.

C.I.13: Submission of the final report from non-clinical study 20447815 listed as a category 3 study in the RMP. This is a An Oral (Gavage) Study of the Effects of M2 (Ganaxolone Metabolite) Administration on Embryo/Fetal Development in CD (Sprague Dawley) IGS Rat. The RMP version 3 has also been submitted.

C.I.13: Submission of the final report from Weight of Evidence (WoE) assessment to evaluate the need for a 2-year carcinogenicity

study in rats with GNX, listed as a category 3 study in the RMP.

C.I.13: Submission of the final report from WoE assessment to evaluate the need for a 2-year carcinogenicity study in rats with M2, listed as a category 3 study in the RMP.

C.I.13: Submission of the final report from WoE assessment to evaluate the need for a juvenile toxicity study with M2, listed as a category 3 study in the RMP."

WS2798
Nilemdo-
EMEA/H/C/004958/WS2798/0045
Nustendi-
EMEA/H/C/004959/WS2798/0050
Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Kimmo Jaakkola, "Update of sections 4.2, 4.4, and 5.2 of the SmPC in order to amend information concerning renal impairment based on the final results from Study 1002-071 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to evaluate the pharmacokinetics of bempedoic acid in healthy subjects with normal renal function and subjects with end-stage renal disease receiving HD; the Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led
Alunbrig - Brigatinib / Brigatinib -
EMEA/H/C/004248/II/0056
Takeda Pharma A/S, PRAC Rapporteur: Carla Torre, PRAC-CHMP liaison: Fátima Ventura, "Submission of the final report from Brigatinib-5007 study listed as a category 3 study in the RMP. This is a non-interventional cohort study to provide real-world evidence of the occurrence of early-onset pulmonary events in patients with anaplastic lymphoma kinase-positive advanced non-small cell lung cancer treated with brigatinib: a post-authorisation safety study. The RMP version 7 has also been submitted. The MAH proposes the removal of the additional risk minimization measure, the Alunbrig Patient Alert Card (PAC), for the risk of early-onset

pulmonary events (EOPEs). In addition, the MAH took the opportunity to introduce editorial changes to the PI."

PRAC Led

Cinryze - C1 ESTERASE INHIBITOR (HUMAN) - EMEA/H/C/001207/II/0104

Takeda Manufacturing Austria AG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of sections 4.6, 5.1 and 5.3 of the SmPC based on final results from the Icatibant Outcome Survey (IOS), listed as an imposed PASS in the Annex II. This is a prospective, observational disease registry. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the product information in line with the latest QRD template version 10.4 and to update Annex II of the PI."

PRAC Led

Cosentyx - Secukinumab - EMEA/H/C/003729/II/0127

Novartis Europharm Limited, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Update section 4.4 of the SmPC to update the safety information following the PSUSA PSUSA/00010341/202312 procedure in order to assess the safety topics of tuberculosis and hepatitis C virus with secukinumab. The Package Leaflet is updated accordingly."

PRAC Led

Fasenra - Benralizumab - EMEA/H/C/004433/II/0054

AstraZeneca AB, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Submission of the final report from study D3250R00042 listed as a category 3 study in the RMP. This is a noninterventional, descriptive post authorisation safety study of the incidence of malignancy in severe asthma patients receiving benralizumab and other therapies. The RMP version 7.1 has also been submitted."

PRAC Led

Firazyr - Icatibant - EMEA/H/C/000899/II/0061

Takeda Pharmaceuticals International AG

Ireland Branch, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a prospective, observational disease registry. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4."

PRAC Led

Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0093

Janssen-Cilag International N.V., PRAC Rapporteur: Barbara Kovacic Bytyqi, PRAC-CHMP liaison: Selma Arapovic Dzakula, "Submission of the study report for additional pharmacovigilance analysis to further evaluate the risk of haemorrhage in participants receiving ibrutinib and concomitant vitamin K antagonists with or without antiplatelet drugs, listed as a category 3 study in the RMP."

PRAC Led

Lonsurf - Trifluridine / Tipiracil - EMEA/H/C/003897/II/0031

Les Laboratoires Servier, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study DIM-95005-001 (PROMETCO), listed as a category 3 PASS in the RMP. This is a non-interventional, observational, real world evidence prospective cohort study in the management of metastatic colorectal cancer. The RMP version 11.1 has also been submitted as the missing information "Use in patients in worse condition than ECOG 0-1" has been removed based on the results from PROMETCO. The PART II - section SVII 1 & SVII 2 has been updated to comply with GVP module V revision 2."

PRAC Led

Mimpara - Cinacalcet - EMEA/H/C/000570/II/0076

Amgen Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study 20180204 listed as a category 3 study in the RMP. This is a non-interventional observational registry study to evaluate the use and safety of

cinacalcet among paediatric patients with secondary hyperparathyroidism (HPT)."

PRAC Led

OPDIVO - Nivolumab - EMEA/H/C/003985/II/0149

Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final clinical study report (CSR) for the PASS study CA209234 listed as a category 3 study in the RMP. This is an observational, multicentre, prospective study in patients treated with nivolumab for melanoma and lung cancer in order assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab (monotherapy or with ipilimumab) in routine oncology care facilities. The RMP version 42.0 has also been submitted."

PRAC Led

Revlimid - Lenalidomide - EMEA/H/C/000717/II/0130

Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from study CC-5013-MCL-005 listed as a category 3 study in the RMP. This is a non-interventional, post-authorization safety study of patients with relapsed or refractory mantle cell lymphoma to further investigate and characterize the association of lenalidomide with tumour flare reaction and high tumour burden. The RMP version 42.0 has also been submitted."

PRAC Led

Spravato - Esketamine - EMEA/H/C/004535/II/0026

Janssen-Cilag International N.V., PRAC Rapporteur: Terhi Lehtinen, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final study report for the non-interventional study PCSNSP002812 listed as a category 3 study in the RMP. This is a survey in order to assess the effectiveness of SPRAVATO educational materials for additional risk minimization measures in the European Union. The RMP version 8.1 has also been submitted."

PRAC Led

Zejula - Niraparib - EMEA/H/C/004249/II/0058, Orphan

GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, "Submission of the final report from study 3000-04-001/ GSK213705 listed as a category 3 study in the RMP; this is a non-interventional PASS to evaluate the risks of myelodysplastic syndrome/acute myeloid leukaemia and second primary malignancies in adult patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer receiving maintenance treatment with Zejula. The RMP version 10.0 has also been submitted."

PRAC Led
WS2802
Entresto-
EMEA/H/C/004062/WS2802/0070
Neparvis-
EMEA/H/C/004343/WS2802/0067
Novartis Europharm Limited, Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report for study CLCZ696B2014 listed as a category 3 study in the RMP; this is a non-interventional post-authorization multi-database safety study to characterize the risk of angioedema and other specific safety events of interest in association with use of Entresto (sacubitril/valsartan) in adult patients with heart failure. The RMP version 9.0 for Entresto and Neparvis has also been submitted."

PRAC Led
WS2803
Entresto-
EMEA/H/C/004062/WS2803/0071
Neparvis-
EMEA/H/C/004343/WS2803/0068
Novartis Europharm Limited, Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report for study CLCZ696B2015 listed as a category 3 study in the RMP for Entresto and Neparvis; this is a non-interventional post-authorization multi-database safety study to assess the risk of myotoxicity, hepatotoxicity and acute pancreatitis in statin-exposed heart failure patients with or without concomitant use of sacubitril/valsartan. The RMP version 9.0 for Entresto and Neparvis has

also been submitted.”
PRAC Led **WS2815** **Anoro Ellipta-** **EMEA/H/C/002751/WS2815/0049** **Laventair Ellipta-** **EMEA/H/C/003754/WS2815/0052** GlaxoSmithKline (Ireland) Limited, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, “Submission of an updated RMP version 10.0 for Anoro Ellipta and Laventair Ellipta Inhalation powder, pre-dispensed [55µg/ 22µg] following completion of Category 1 PASS 201038 in order to remove the safety concerns accordingly.”
PRAC Led **WS2816** **Incruse Ellipta-** **EMEA/H/C/002809/WS2816/0043** **Rolufta Ellipta-** **EMEA/H/C/004654/WS2816/0027** GlaxoSmithKline (Ireland) Limited, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, “Submission of an updated RMP version 8.0 for Incruse Ellipta and Rolufta Ellipta in order to reflect the completion of the category 1 PASS study 201038 and remove the safety concerns accordingly.”
PRAC Led **WS2819** **Ozempic-** **EMEA/H/C/004174/WS2819/0053** **Wegovy-** **EMEA/H/C/005422/WS2819/0029** Novo Nordisk A/S, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “To align the RMPs to the version approved for Rybelsys on 3 October 2024.”

B.6.12. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel - **EMEA/H/C/004662/II/0058/G, Orphan, ATMP** Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang
Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel -

EMEA/H/C/004731/II/0055/G, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0037, Orphan, ATMP
Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0012/G, Orphan, ATMP
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0085, Orphan, ATMP
Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Submission of the final report from study KT-US-482-0147 (ZUMA-26). This is a Prospective, Noninterventional, Clinical Efficacy Study Investigating and Analyzing the Impact of Tumour Cd19 Antigen Expression and Density on Response to Axicabtagene Ciloleucel Treatment Using a Quantitative Flow Cytometry Method."

WS2813/G
Tecartus- EMEA/H/C/005102/WS2813/0055/G
Yescarta- EMEA/H/C/004480/WS2813/0086/G
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, Quality

B.6.13. CHMP-PRAC-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0036, Orphan, ATMP
Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays, , "Update of sections 4.8, and 5.1 of the SmPC in order to update the list of adverse

drug reactions (ADRs), and update clinical efficacy and safety information based on second interim analysis from study 68284528MMY3002 (CARTITUDE-4); this is a phase 3 randomized study comparing ciltacabtagene autoleucel, a chimeric antigen receptor T cell (CAR-T) therapy directed against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in subjects with relapsed and lenalidomide-refractory multiple myeloma; The RMP version 5.3 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

B.6.14. PRAC assessed ATMP procedures

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

WS2774/G
Dapagliflozin Viatris-
EMEA/H/C/006006/WS2774/0005/G
Viatris Limited, Generic of Forxiga, Lead Rapporteur: Tomas Radimersky

WS2788
Biopoin-
EMEA/H/C/001036/WS2788/0057
Eporatio-
EMEA/H/C/001033/WS2788/0056
ratiopharm GmbH, Lead Rapporteur: Alexandre Moreau
Opinion adopted on 16.01.2025.

WS2795
Glyxambi-
EMEA/H/C/003833/WS2795/0063
Jentadueto-
EMEA/H/C/002279/WS2795/0076
Trajenta-
EMEA/H/C/002110/WS2795/0057
Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt
Opinion adopted on 16.01.2025.

WS2797
Vfend-EMEA/H/C/000387/WS2797/0157
Pfizer Europe MA EEIG, Lead Rapporteur: Patrick Vrijlandt

WS2807
Ebymect-
EMEA/H/C/004162/WS2807/0068
Xigduo-EMEA/H/C/002672/WS2807/0078
AstraZeneca AB, Lead Rapporteur: Kristina Dunder

WS2810/G
Copalia-
EMEA/H/C/000774/WS2810/0138/G
Copalia HCT-
EMEA/H/C/001159/WS2810/0116/G
Dafiro-
EMEA/H/C/000776/WS2810/0142/G
Dafiro HCT-
EMEA/H/C/001160/WS2810/0118/G
Exforge-
EMEA/H/C/000716/WS2810/0137/G
Exforge HCT-
EMEA/H/C/001068/WS2810/0115/G
Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher

WS2811/G
Abseamed-
EMEA/H/C/000727/WS2811/0112/G
Binocrit-
EMEA/H/C/000725/WS2811/0112/G
Epoetin alfa Hexal-
EMEA/H/C/000726/WS2811/0112/G
Sandoz GmbH, Lead Rapporteur: Alexandre Moreau
Opinion adopted on 16.01.2025.

WS2812/G
Filgrastim Hexal-
EMEA/H/C/000918/WS2812/0080/G
Zarzio-
EMEA/H/C/000917/WS2812/0081/G
Sandoz GmbH, Lead Rapporteur: Peter MolOpinion adopted on 16.01.2025.

WS2820
Blitzima-
EMEA/H/C/004723/WS2820/0081
Truxima-
EMEA/H/C/004112/WS2820/0084
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

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. PMF Certification Dossiers

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

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

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

G. ANNEX G

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

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

G.2. PRIME

Some information related to PRIME cannot be released at the present time as these contain commercially confidential information.