18 March 2024
EMA/CHMP/82603/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 18-21 March 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 March 2024, 13:00 – 19:30, virtual meeting/room 1C

19 March 2024, 08:30 – 19:30, virtual meeting/room 1C

20 March 2024, 08:30 – 19:30, virtual meeting/room 1C

21 March 2024, 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 18-21 March 2024. See March 2024 CHMP minutes (to be published post April 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 18-21 March 2024.

1.3. Adoption of the minutes

CHMP minutes for 19-22 February 2024 plenary meeting.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 11 March 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Aprocitentan - EMEA/H/C/006080

treatment of resistant hypertension

Scope: Oral explanation

Action: Oral explanation to be held on 20 March 2024 at 11:00

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 22.06.2023.

2.1.2. Omecamtiv mecarbil - EMEA/H/C/006112

treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%

Scope: Oral explanation

Action: Oral explanation to be held on 19 March 2024 at 11:00

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 26.04.2023.

2.1.3. Lecanemab - EMEA/H/C/005966

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

Scope: Oral explanation

Action: Oral explanation to be held on 19 March 2024 at 14:00

Participation of patient representatives

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 25.05.2023.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Rinvoq - upadacitinib - EMEA/H/C/PSUSA/00010823/202302

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Petar Mas

Scope: Oral explanation

Action: Oral explanation to be held on 20 March 2024 at 16:00

See 9.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Dantrolene sodium, hemiheptahydrate - Orphan - EMEA/H/C/006009

Norgine B.V.; treatment of malignant hyperthermia (including suspected cases)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.06.2023. List of Questions adopted on 10.11.2022.

3.1.2. Insulin icodec - EMEA/H/C/005978

treatment of diabetes mellitus in adults

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

3.1.3. Dimethyl fumarate - EMEA/H/C/006471

treatment of multiple sclerosis

Scope: Opinion

Action: For adoption

3.1.4. Dimethyl fumarate - EMEA/H/C/006397

for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).

Scope: Opinion

Action: For adoption

3.1.5. Dimethyl fumarate - EMEA/H/C/006500

treatment of multiple sclerosis

Scope: Opinion

Action: For adoption

3.1.6. Aztreonam / Avibactam - EMEA/H/C/006113

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Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.02.2024. List of Questions adopted on 12.12.2023.

3.1.7. Iptacopan - PRIME - Orphan - EMEA/H/C/005764

Novartis Europharm Limited; treatment of paroxysmal nocturnal haemoglobinuria

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

3.1.8. Denosumab - EMEA/H/C/005964

treatment of osteoporosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024. List of Questions adopted on 14.09.2023.

3.1.9. Bevacizumab - EMEA/H/C/005723

Treatment of neovascular (wet) age-related macular degeneration (nAMD).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 26.04.2023.

3.1.10. Dopamine hydrochloride - PUMA - EMEA/H/C/006044

Treatment of hypotension in neonates, infants and children

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024, 12.10.2023. List of Questions adopted on 30.03.2023.

3.1.11. Omalizumab - EMEA/H/C/005958

treatment of asthma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

3.1.12. Denosumab - EMEA/H/C/006378

prevention of skeletal related events with advanced malignancies

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024. List of Questions adopted on 14.09.2023.

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

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Takeda Manufacturing Austria AG; treatment of congenital thrombotic thrombocytopenic purpura (cTTP) due to ADAMTS13 deficiency

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.2. Efanesoctocog alfa - Orphan - EMEA/H/C/005968

Swedish Orphan Biovitrum AB (publ); Treatment and prophylaxis of bleeding in patients with haemophilia A

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024. List of Questions adopted on 14.09.2023.

3.2.3. Fidanacogene elaparvovec - PRIME - ATMP - EMEA/H/C/004774

indicated for the treatment of severe and moderately severe haemophilia B

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 08.09.2023.

3.2.4. Buprenorphine - EMEA/H/C/006188

treatment of opioid drug dependence

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 22.06.2023.

3.2.5. Dabigatran etexilate - EMEA/H/C/006023

Prevention of venous thromboembolic events

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 21.07.2022.

3.2.6. Dasatinib - EMEA/H/C/006251

Indicated for the treatment of chronic myelogenous leukaemia (CML)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.7. Dasiglucagon - EMEA/H/C/006214

treatment of severe hypoglycemia in patients with diabetes

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

3.2.8. Rituximab - EMEA/H/C/006224

treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.9. rdESAT-6 / rCFP-10 - EMEA/H/C/006177

Diagnosis of infection with Mycobacterium tuberculosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.06.2023.

3.2.10. Ustekinumab - EMEA/H/C/005918

treatment of adult patients with moderately to severely active Crohn’s disease and active ulcerative colitis.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.10.2023.

3.2.11. Zolbetuximab - Orphan - EMEA/H/C/005868

Astellas Pharma Europe B.V.; treatment of locally advanced unresectable or metastatic HER2 negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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

3.3.1. Garadacimab - Orphan - EMEA/H/C/006116

CSL Behring GmbH; routine prevention of attacks of hereditary angioedema (HAE)

Scope: List of questions

Action: For adoption

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

Scope: List of questions

Action: For adoption

3.3.3. Beremagene geperpavec - PRIME - Orphan - ATMP - EMEA/H/C/006330

Krystal Biotech Netherlands B.V.; treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

Scope: List of questions

Action: For information

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3.4.1. Tiratricol - Orphan - EMEA/H/C/005220

Rare Thyroid Therapeutics International AB; treatment of monocarboxylate transporter 8 (MCT8) deficiency

Scope: Letter by the applicant dated 28.02.2024 requesting an extension to the clock stop to respond to the list of questions adopted in February 2024.

Action: For adoption

List of Questions adopted on 22.02.2024.

3.4.2. Leniolisib - Orphan - EMEA/H/C/005927

Pharming Technologies B.V.; Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Scope: Letter by the applicant dated 12.03.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in January 2024.

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024, 09.11.2023, 20.07.2023. List of Questions adopted on 24.01.2023.

3.4.3. Masitinib - Orphan - EMEA/H/C/005897

AB Science; in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS)

Scope: Letter by the applicant dated 29.02.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in January 2024.

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024, 25.05.2023. List of Questions adopted on 15.12.2022.

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. AMGEVITA - Adalimumab - EMEA/H/C/004212/X/0036/G

Amgen Europe B.V.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new strength, 80 mg [0.8 ml (100 mg/ml)] solution for injection, grouped with quality variations.
The RMP (version 6.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 12.10.2023.

4.1.2. COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/X/0199

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope: "Extension application to add a new presentation of Comirnaty Omicron XBB.1.5, 3 micrograms/dose concentrate for dispersion for injection for infants and children aged 6 months to 4 years."

Action: For adoption

4.1.3. LUMYKRAS - Sotorasib - EMEA/H/C/005522/X/0009

Amgen Europe B.V.

Rapporteur: Alexandre Moreau

Scope: "Extension application to add a new strength of 240 mg film-coated tablet."

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 22.06.2023.

4.1.4. Spevigo - Spesolimab - EMEA/H/C/005874/X/0006/G

Boehringer Ingelheim International GmbH

Rapporteur: Kristina Dunder, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Nathalie Gault

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.
This line extension is grouped with a type II variation (C.I.6.a) to extend the indication for Spevigo 450 mg concentrate for solution for infusion to include treatment of generalised pustular psoriasis (GPP) flares in adolescents (from 12 years of age), based on final results from study 1368-0027 (Effisayil 2) and extrapolation; this is a multi-center, randomized, parallel group, double blind, placebo controlled, phase IIb dose-finding study to evaluate efficacy and safety of BI 655130 (spesolimab) compared to placebo in preventing GPP flares in patients with history of GPP. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 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 marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI and

update the list of local representatives in the Package Leaflet."

Action: For adoption

List of Questions adopted on 09.11.2023.

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. Reagila - Cariprazine - EMEA/H/C/002770/X/0033

Gedeon Richter Plc.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible tablets). The RMP (version 3.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 09.11.2023.

4.2.2. XALKORI - Crizotinib - EMEA/H/C/002489/X/0080/G

Pfizer Europe MA EEIG

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form (granules in capsules for opening) associated with new strengths (20, 50 and 150 mg), grouped with a type II variation (C.I.6.a) to include the treatment of paediatric patients with relapsed or refractory, systemic ALK-positive ALCL or unresectable, recurrent, or refractory ALK-positive IMT to change the lower end of the age range from >=6 years to ≥1 year for Xalkori following the assessment of II/0072 based on final results from study ADVL0912. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 12.10.2023.

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

No items

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

4.4.1. Eurartesim - Piperaquine tetraphosphate / Artenimol - EMEA/H/C/001199/X/0041

Alfasigma S.p.A.

Rapporteur: Janet Koenig

Scope: Letter by the applicant dated 23.02.2024 requesting an extension to the clock stop to respond to the list of questions adopted in January 2024.

Action: For adoption

List of Questions adopted on 25.01.2024.

4.4.2. Opsumit - Macitentan - EMEA/H/C/002697/X/0051/G

Janssen-Cilag International N.V.

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Change of timetable to respond to the list of questions adopted in February 2024

Action: For information

List of Questions adopted on 22.02.2024.

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. Alecensa - Alectinib - EMEA/H/C/004164/II/0047

Roche Registration GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Jana Lukacisinova

Scope: "Extension of indication to include the use of Alecensa as monotherapy in adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as adjuvant treatment following tumour resection, based on final results from

study BO40336 (ALINA), a randomized, active controlled, multicenter, open-label, Phase III study designed to evaluate the efficacy and safety of alectinib compared with platinum-based chemotherapy in the adjuvant setting in patients with completely resected Stage IB (tumors 4 cm) to Stage IIIA ALKpositive NSCLC. 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 4.0 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 introduce editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.2. Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0020

UCB Pharma S.A.

Rapporteur: Finbarr Leacy, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include treatment of moderate to severe hidradenitis suppurativa (HS) in adults, based on final results from study HS0003 (BE HEARD I) and study HS0004 (BE HEARD II). These are phase 3, randomized, double blind, placebo controlled, multicenter, pivotal studies evaluating the efficacy and safety of bimekizumab in study participants with moderate to severe HS. Further supportive data are based on the results of phase 2 study HS0001 and phase 3 currently ongoing open-label extension study HS0005. 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 1.10 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024, 12.10.2023.

5.1.3. CellCept - Mycophenolate mofetil - EMEA/H/C/000082/II/0170/G

Roche Registration GmbHRapporteur: Thalia Marie Estrup Blicher

Scope: "C.I.6.a: Extension of indication to include paediatric patients (3 months to 18 years of age) for hepatic and cardiac transplants and to extend the indication for renal transplants for paediatric patients starting from 3 months, based on pharmacokinetic data, published literature and the Roche Global Safety Database. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.
Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets formulation in order to be in line with the other three CellCept formulations; and for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.
In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring the PI in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

5.1.4. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus

Scope: "Extension of indication to include treatment of children aged 1 year and older to the already approved eosinophilic esophagitis (EoE) indication for Dupixent based on final results from study R668-EE-1877 (Part A, Part B, and Part A Addendum) - A Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Dupilumab in Pediatric Patients with Active Eosinophilic Esophagitis. 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."

Action: For adoption

5.1.5. Fasenra - Benralizumab - EMEA/H/C/004433/II/0052

AstraZeneca AB

Rapporteur: Fátima Ventura (PT) (MNAT with EL for Clinical Pharmacology, EL for Clinical Efficacy, EL for Clinical Safety), PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include treatment of eosinophilic granulomatosis with polyangiitis for Fasenra, based on results from study D3253C00001 (Mandara); this was a randomised, double-blind, multicentre, parallel group, active-controlled, non-inferiority study that evaluated the efficacy and safety of benralizumab compared with mepolizumab in treatment of patients with EGPA on corticosteroid therapy with or without stable immunosuppressive therapy. 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 6.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes. 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

5.1.6. IMCIVREE - Setmelanotide - Orphan - EMEA/H/C/005089/II/0018

Rhythm Pharmaceuticals Netherlands B.V.

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Anna Mareková

Scope: "Extension of indication to include the population of children aged 2 years and above for the treatment of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin Type 1 (PCSK1) deficiency or biallelic leptin receptor (LEPR) deficiency and Bardet-Biedl Syndrome (BBS) for IMCIVREE, based on the final results from study RM-493-033 "A Phase 3 Multicenter, One-Year, Open-Label Study of Setmelanotide in Pediatric Patients Aged 2 To <6 Years of Age with Rare Genetic Causes of Obesity"; this is an open label study to evaluate the weight-related parameters along with the safety and tolerability of setmelanotide in patients aged 2 to <6 years. 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 2.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Action: For adoption

5.1.7. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0064

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include IMFINZI in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, for the treatment of adults with resectable (tumours ≥ 4 cm and/or node positive) NSCLC and no known EGFR mutations or ALK rearrangements for IMFINZI, based on the interim results from study D9106C00001 (AEGEAN); this is a Phase III, double-blind, placebo-controlled, multi-center international study of neoadjuvant/adjuvant durvalumab for the treatment of patients with resectable stages II and III non-small cell lung cancer. 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 11 of the RMP has also been submitted."

Action: For adoption

5.1.8. Kevzara - Sarilumab - EMEA/H/C/004254/II/0044

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension of indication to include treatment of Polymyalgia Rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper for Kevzara, based on results from study EFC15160; this is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of sarilumab in patients with polymyalgia rheumatica; 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 4.0 of the RMP is also submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.9. Kisqali - Ribociclib - EMEA/H/C/004213/II/0045

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Stage II or Stage III early breast cancer, irrespective of nodal status, in combination with an AI for Kisqali based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance.

Version 8.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023.

5.1.10. Nilemdo - Bempedoic acid - EMEA/H/C/004958/II/0031

Daiichi Sankyo Europe GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk, based on results from study 1002-043 (CLEAR). CLEAR Outcomes Study is a phase 3 multi-centre randomised, double-blind, placebo-controlled study to evaluate whether long-term treatment with bempedoic acid reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease who are statin intolerant. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024, 09.11.2023.

5.1.11. Nustendi - Bempedoic acid / Ezetimibe - EMEA/H/C/004959/II/0035

Daiichi Sankyo Europe GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for NUSTENDI, based on results from study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are statin intolerant; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024, 09.11.2023.

5.1.12. Onivyde pegylated liposomal - Irinotecan hydrochloride trihydrate - Orphan - EMEA/H/C/004125/II/0034

Les Laboratoires Servier

Rapporteur: Filip Josephson, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas for Onivyde in combination with oxaliplatin, 5 fluorouracil (5 FU) and leucovorin (LV) based on final results from phase 3 study NAPOLI 3 (D-US-60010-001); this is an interventional study with a primary objective to evaluate the efficacy of the regimen of irinotecan liposome injection + oxaliplatin + 5-fluorouracil (5-FU)/leucovorin (LV) versus nab-paclitaxel + gemcitabine in improving overall survival (OS) in subjects who have not previously received chemotherapy for metastatic adenocarcinoma of the pancreas; As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. The updated RMP version 4.1 is also submitted.", 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 12.10.2023.

5.1.13. Otezla - Apremilast - EMEA/H/C/003746/II/0044/G

Amgen Europe B.V.

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Monica Martinez Redondo

Scope: "A grouped application of a Type II variation with two Type IA variations, as follows:
Type II (C.I.6.a): Extension of indication to include the treatment of moderate to severe chronic plaque psoriasis in children and adolescents from the age of 6 years who have a contraindication, have an inadequate response, or are intolerant to at least one other systemic therapy or phototherapy for OTEZLA, based on final results from study CC-10004-PPSO-003 as well as results from studies CC-10004-PPSO-001 and CC-10004-PPSO-004. CC-10004-PPSO-003 is a phase 3, multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of apremilast (CC-10004) in paediatric subjects from 6 through 17 years of age with moderate to severe plaque psoriasis. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial and formatting changes to the PI and to update the list of local representatives in the Package Leaflet.
2 Type IA (B.II.e.5.a.1): Update of sections 6.5 and 8 of the SmPC to introduce two new pack sizes within approved range as a result of the indication update."

Action: For adoption

5.1.14. Pravafenix - Fenofibrate / Pravastatin sodium - EMEA/H/C/001243/II/0037

Laboratoires SMB s.a.

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault

Scope: "Extension of indication to include treatment of mixed hyperlipidaemia in adult patients while on a treatment with pravastatin 40 mg monotherapy or on another moderate-intensity statin regimen for PRAVAFENIX, based on final results from the non-interventional PASS: POSE (Pravafenix Observational Study in Europe); this is a European, observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice. As a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

5.1.15. Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0022

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication for RETSEVMO to include the treatment of adults with advanced or metastatic RET fusion-positive solid tumours with disease progression on or after prior systemic therapies or who have no satisfactory therapeutic options, based on interim data from study LIBRETTO-001 (LOXO-RET-17001); LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in adult and adolescent patients with advanced RET-altered tumours. As a consequence, sections 4.1, 4.2 and 5.1 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 MAH took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024, 09.11.2023, 20.07.2023, 30.03.2023.

5.1.16. RYBREVANT - Amivantamab - EMEA/H/C/005454/II/0011

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: " Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including a third-generation EGFR tyrosine kinase inhibitor (TKI) for RYBREVANT, based on the final results from study 61186372NSC3002 (MARIPOSA 2); this is a randomized, open label, multicenter Phase 3 study that compares efficacy and safety of amivantamab in combination with carboplatin and pemetrexed (ACP) with carboplatin and pemetrexed (CP). The primary objective of the MARIPOSA 2 study is to compare efficacy, as demonstrated by PFS, in participants treated with ACP versus CP alone. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the EU RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) is requesting an additional year of market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.17. Slenyto - Melatonin - EMEA/H/C/004425/II/0025

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 neurogenetic disorders (e.g., Angelman syndrome, Rett syndrome, Tuberous sclerosis complex and Williams syndrome) for SLENYTO, based on Phase III study NEU_CH_7911, post-marketing data and literature; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. 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

5.1.18. Triumeq - Dolutegravir / Abacavir / Lamivudine - EMEA/H/C/002754/II/0116

ViiV Healthcare B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include treatment of paediatric patients from 6 kg to less than 25 kg for Triumeq Dispersible Tablets, based on PK, safety, and efficacy data observed in the final results of study 205860 (IMPAACT 2019), further supported by extrapolation to data generated in adults and additional data in paediatric patients with the single entities. IMPAACT 2019 is a Phase 1/2 open-label, multicenter, multiple dose study of dolutegravir/lamivudine/abacavir fixed dose combination tablets in treatment-experienced and treatment-naïve HIV-1-infected children less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22.0 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."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

5.1.19. Vabysmo - Faricimab - EMEA/H/C/005642/II/0005

Roche Registration GmbH

Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients with central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). These are global, multicenter, randomized, double-masked, active comparator-controlled,

parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 09.11.2023.

5.1.20. Valdoxan - Agomelatine - EMEA/H/C/000915/II/0051

Les Laboratoires Servier

Rapporteur: Eva Skovlund, PRAC Rapporteur: Pernille Harg

Scope: "Extension of indication to include new therapeutic indication in adolescents aged 12 to 17 years for the treatment of moderate to severe major depressive episodes, if depression is unresponsive to psychological therapy alone, for Valdoxan, further to the results of the phase 2 (CL2-20098-075) and phase 3 (CL3-20098-076) paediatric clinical studies included in the Paediatric Investigation Plan number EMEA-001181-PIP-11; As a consequence, the 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. The updated RMP version 25.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023, 22.06.2023, 26.01.2023.

5.1.21. Veklury - Remdesivir - EMEA/H/C/005622/II/0053/G

Gilead Sciences Ireland UC

Rapporteur: Janet Koenig (DE) (MNAT with AT for Quality), PRAC Rapporteur: Eva Jirsová

Scope: "Grouped application comprising two extensions of indication to include treatment of paediatric patients weighing at least 1.5 kg for VEKLURY, based on final results from study GS-US-540-5823; this is a Phase 2/3 single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of remdesivir in participants from birth to < 18 years of age with 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 8.1 of the RMP has also been submitted."

Action: For adoption

5.1.22. Xtandi - Enzalutamide - EMEA/H/C/002639/II/0063

Astellas Pharma Europe B.V.

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy, for Xtandi, based on final results from study MDV3100-13 (EMBARK); this is a phase 3, randomized, efficacy and safety study of enzalutamide plus

leuprolide, enzalutamide monotherapy, and placebo plus leuprolide in men with high-risk nonmetastatic prostate cancer progressing after definitive therapy. 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 18.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023.

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006470

to detect amplification of the HER2/neu gene via quantitative fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer and adenocarcinomas of the stomach (including gastroesophageal junction) tissue specimens

Scope: List of questions

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006454

To detect PD-L1 protein

Scope: List of questions

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. sargramostim - H0006411

To increase survival in adult and paediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

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. Adcetris - brentuximab vedotin - Orphan - EMEA/H/C/002455/II/0109

Takeda Pharma A/S

Rapporteur: Peter Mol, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) treatment of adult patients with previously untreated CD30+ peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) for Adcetris based on the final overall survival results of Echelon-2 (SGN035-014), A randomized, double-blind, placebo-controlled, phase 3 study of brentuximab vedotin and CHP (A+CHP) versus CHOP in the frontline treatment of patients with CD30-positive mature T-cell lymphomas. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 19.0 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."

Withdrawal of extension of indication application.

Action: For information

9.1.2. Cuprymina – copper (64Cu) chloride – EMEA/H/C/002136

A.C.O.M. - Advanced Center Oncology Macerata; radiopharmaceutical (radiolabelling of carrier molecules)

Rapporteur: Paolo Gasparini, Co-Rapporteur: Janet Koenig

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0072, Orphan, ATMP

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: quality

Withdrawal of Type II variation application

Action: For information

Request for Supplementary Information adopted on 08.09.2023.

9.1.4. Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044

AstraZeneca AB

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

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce

minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3."

Action: For adoption

9.1.5. Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0028

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: ""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 LIBRETTO-431 (JZJC) listed as a specific obligation in the Annex II (SOB/002); this is a randomized Phase 3 study comparing selpercatinib to platinum-based and pemetrexed therapy with or without pembrolizumab in patients with locally advanced or metastatic, RET-fusion-positive NSCLC. The Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II."

Action: For adoption

Request for Supplementary Information adopted on 07.03.2024.

9.1.6. Rinvoq - upadacitinib - EMEA/H/C/PSUSA/00010823/202302

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Petar Mas

Scope: PRAC recommendation on PSUSA

Action: For adoption

See 2.3

9.1.7. WS2552
Ongentys - Opicapone - EMEA/H/C/002790/WS2552/0060
Ontilyv - Opicapone - EMEA/H/C/005782/WS2552/0015

Bial Portela & Companhia S.A.

Lead Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of signs and symptoms of Parkinson's Disease for Ongentys/Ontilyv, based on final results from study BIA-91067-303; this is a pivotal Phase III, multicentre, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of opicapone in patients with early idiopathic Parkinson's Disease receiving treatment with L-DOPA plus a DDCI, and who are without signs of any motor complication. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.0 of the RMP has also been submitted (only applicable to Ongentys) to reflect the changes made upon approval of the informed consent application, to keep consistency between the eCTD lifecycles of the two marketing authorisations (Ongentys and Ontilyv). Furthermore, the PI is brought in line with the latest QRD template version 10.3. In addition, as part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market

protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Withdrawal of extension of indication application

Action: For information

Request for Supplementary Information adopted on 09.11.2023.

9.1.8. Remsima - Infliximab - EMEA/H/C/002576/II/0133/G

Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola

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

Action: For discussion

Request for Supplementary Information adopted on 09.11.2023.

9.1.9. Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675

AstraZeneca AB; prevention of COVID-19

Rapporteur: Sol Ruiz

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

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

10.1.1. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065

Orexigen Therapeutics Ireland Limited

Referral Rapporteur: Thalia Marie Estrup Blicher, Referral Co-Rapporteur: Daniela Philadelphy

Scope: Revised timetable

Action: For adoption

List of outstanding issues adopted on 14.12.2023. List of questions adopted on 14.09.2023.

10.1.2. Ocaliva - obeticholic acid - EMEA/H/A-20/1531

Advanz Pharma Limited

Referral Rapporteur: Carolina Prieto Fernandez, Referral Co-Rapporteur: Paolo Gasparini

Scope: Revised timetable, list of experts for AHEG

Action: For adoption

List of outstanding issues adopted on 25.01.2024. List of questions adopted on 12.10.2023.

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

10.2.1. Colistimethate sodium (CMS) – EMEA/H/A-5(3)/1524

Various MAHs

Referral Rapporteur: Martina Weise, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: List of outstanding issues / opinion

Action: For adoption

Review of the ratio of polymyxins E1 and E2 in colistin starting material and of the (sulfomethylation) composition profile of CMS finished product.

List of outstanding issues adopted on 22.02.2024. List of questions adopted on 22.06.2023.

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

No items

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

10.4.1. Micrazym – porcine pancreas enzymes - EMEA/H/A-29(4)/1535

Avva Pharmaceuticals Ltd.

Referral Rapporteur: Patrick Vrijlandt, Referral Co-Rapporteur: Martina Weise

Scope: List of outstanding issues / opinion

Action: For adoption

Decentralised Procedure number: NL/H/5258/001-002/DC, notification sent by the Agency of The Netherlands dated 21 December 2023 notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC.

List of questions adopted on 25.01.2024.

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

10.5.1. Havrix – Hepatitis A virus (inactivated, adsorbed) - EMEA/H/A-30/1527

GlaxoSmithKline Biologicals

Referral Rapporteur: Maria Grazia Evandri, Referral Co-Rapporteur: Lyubina Racheva

Scope: List of outstanding issues / opinion

Action: For adoption

Harmonisation exercise for Havrix and associated names. Product Information harmonisation was triggered by the MAH.

List of questions adopted on 09.11.2023.

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

10.7.1. Synapse Labs Pvt. Ltd. – various – EMEA/H/A-31/1529

Various MAHs

Scope: Opinion

Action: For adoption

Article 31 procedure triggered by the Agency of Medicines and Medical Devices (AEMPS) in Spain, concerning the contract research organisation (CRO) Synapse Labs Pvt. Ltd., located in Kharadi, Pune, India.

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

10.11.1. Lorazepam Macure – lorazepam - EMEA/H/A-13/1536

Macure Pharma ApS

Referral Rapporteur: Peter Mol, Referral Co-Rapporteur: Kristina Dunder

Scope: List of questions / opinion

Action: For adoption

Variation number in decentralised procedure: NL/H/4353/001/II/004, notification sent by the Agency of The Netherlands dated 01 February 2024 notifying of the start of a referral under Article 13(1) of Regulation No 1234/2008.

11. Pharmacovigilance issue

11.1. Early Notification System

March 2024 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

No items

14.2. Coordination with EMA Scientific Committees

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 March 2024

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

Agenda of the March 2024 PDCO plenary meeting.

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: Francesca Luciani

Reports from BWP March 2024 meeting to CHMP for adoption:

- 12 reports on products in scientific advice and protocol assistance
- 16 reports on products in pre-authorisation procedures
- 01 report on products in post-authorisation procedures

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 04-07 March 2024. 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. Ad-hoc Influenza Working Group

Scope: EU Strain selection for the Influenza Vaccines for the Season 2024/2025: Report from the Ad Hoc Influenza working group to the BWP

Action: For adoption

Scope: EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2024/2025

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. Update of the Business Pipeline report for the human scientific committees

Q1-2024 initial marketing authorisation application submissions with eligibility request to central procedure

Action: For information

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

15. Any other business

15.1. AOB topic

No items

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)*

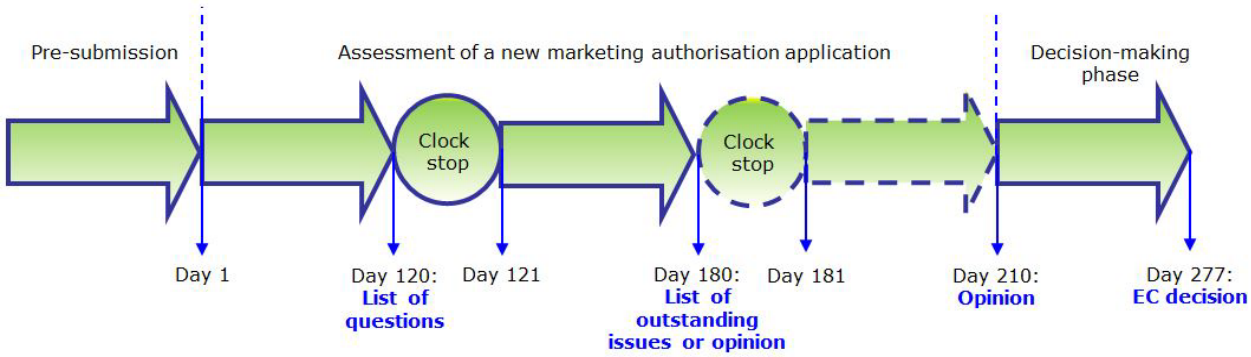
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

18 March 2024
EMA/CHMP/82669/2024

Annex to 18-21 March 2024 CHMP Agenda

Pre-submission and post-authorisations issues

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for March 2024: **For adoption**

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Defitelio - Defibrotide - EMEA/H/C/002393/S/0064, Orphan
Gentium S.r.l., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Cufence - Trientine - EMEA/H/C/004111/R/0016
Univar Solutions BV, Rapporteur: Daniela Philadelphy, Co-Rapporteur: Konstantina Alexopoulou, PRAC Rapporteur: Ana Sofia Diniz Martins
Request for Supplementary Information adopted on 25.01.2024.

Deferasirox Mylan - Deferasirox - EMEA/H/C/005014/R/0013
Mylan Pharmaceuticals Limited, Generic, Generic of EXJADE, Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Tiphaine

Vaillant

Giapreza - Angiotensin II - EMEA/H/C/004930/R/0027
Paion Deutschland GmbH, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 25.01.2024.

Nuceiva - Botulinum toxin type A - EMEA/H/C/004587/R/0037
Evolus Pharma B.V., Rapporteur: Finbarr Leacy, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski

Xromi - Hydroxycarbamide - EMEA/H/C/004837/R/0023
Nova Laboratories Ireland Limited, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Jo Robays
Request for Supplementary Information adopted on 25.01.2024.

B.2.3. Renewals of Conditional Marketing Authorisations

Columvi - Glofitamab - EMEA/H/C/005751/R/0003, Orphan
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jana Lukacisinova

Lytgobi - Futibatinib - EMEA/H/C/005627/R/0003
Taiho Pharma Netherlands B.V., Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga

Rozlytrek - Entrectinib - EMEA/H/C/004936/R/0020
Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its March 2024 meeting:

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - Dengue tetravalent vaccine (live, attenuated) - EMEA/H/W/005362/PSUV/0011 (without

RMP) Takeda GmbH, PRAC Rapporteur: Liana Martirosyan, "reporting period 19-Feb-2023 to 18-Aug-2023"	
EMEA/H/C/PSUSA/00010119/202307 (Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)) CAPS: **IMVANEX** (EMEA/H/C/002596) (Smallpox vaccine (live modified vaccinia virus Ankara)), Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "31/01/2023 To: 31/07/2023"	
EMEA/H/C/PSUSA/00010544/202308 (palbociclib) CAPS: **IBRANCE** (EMEA/H/C/003853) (Palbociclib), Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "02/08/2022 To: 02/08/2023"	
EMEA/H/C/PSUSA/00010823/202308 (upadacitinib) CAPS: **RINVOQ** (EMEA/H/C/004760) (Upadacitinib), AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "14/02/2023 To: 14/08/2023"	See 2.3 and 9.1
EMEA/H/C/PSUSA/00010843/202307 (darolutamide) CAPS: **NUBEQA** (EMEA/H/C/004790) (Darolutamide), Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser, "30/01/2023 To: 30/07/2023"	
EMEA/H/C/PSUSA/00010877/202307 (leuprorelin (depot formulations)) CAPS: **Camcevi** (EMEA/H/C/005034) (Leuprorelin), Accord Healthcare S.L.U., Rapporteur: Johanna Lähteenvuo NAPS: **NAPs** - EU, PRAC Rapporteur: Amelia Cupelli, "24/05/2022 To: 31/07/2023"	
EMEA/H/C/PSUSA/00010980/202307 (anifrolumab) CAPS:	

Saphnelo (EMEA/H/C/004975) (Anifrolumab), AstraZeneca AB, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Liana Martirosyan, "30/01/2023 To: 29/07/2023"	
EMEA/H/C/PSUSA/00010983/202308 (voxelotor) CAPS: **Oxbryta** (EMEA/H/C/004869) (Voxelotor), Pfizer Europe Ma EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jo Robays, "14/02/2023 To: 13/08/2023"	
EMEA/H/C/PSUSA/00011034/202308 (dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.]) CAPS: **Qdenga** (EMEA/H/C/005155) (Dengue tetravalent vaccine (live, attenuated)), Takeda GmbH, Rapporteur: Sol Ruiz, PRAC Rapporteur: Liana Martirosyan, "18/02/2023 To: 18/08/2023"	

B.4. EPARs / WPARs

Apremilast Accord - Apremilast - EMEA/H/C/006208 Accord Healthcare S.L.U., treatment of psoriatic arthritis, psoriasis, Behçet's disease, Generic, Generic of Otezla, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Celldemic - Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006052 Seqirus Netherlands B.V., active immunisation for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
EXBLIFEP - cefepime / enmetazobactam - EMEA/H/C/005431 Advanz Pharma Limited, treatment of: 1)	For information only. Comments can be sent to the PL in case necessary.

complicated urinary tract infections (including pyelonephritis); 2) hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); 3) patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above and 4) infections due to aerobic Gram-negative organisms in adults with limited treatment options, New active substance (Article 8(3) of Directive No 2001/83/EC)	
FILSPARI - Sparsentan - EMEA/H/C/005783, Orphan Vifor France, for the treatment of primary immunoglobulin A nephropathy (IgAN)., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Incellipan - Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006051 Seqirus Netherlands B.V., prophylaxis of influenza, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Krazati - adagrasib - EMEA/H/C/006013 Mirati Therapeutics B.V., treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Nintedanib Accord - Nintedanib - EMEA/H/C/006179 Accord Healthcare S.L.U., treatment of idiopathic pulmonary fibrosis (IPF), chronic fibrosing interstitial lung diseases (ILDs) and lung diseases (ILDs) systemic sclerosis associated interstitial lung disease (SSc-ILD), Generic, Generic of Vargatef, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Pomalidomide Viatris - pomalidomide - EMEA/H/C/006195 Viatris Limited, in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM), Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Pyzchiva - Ustekinumab -	For information only. Comments can be sent to

EMEA/H/C/006183 Samsung Bioepis NL B.V., treatment of Crohn's disease, Ulcerative colitis, Plaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA), Similar biological application (Article 10(4) of Directive No 2001/83/EC)	the PL in case necessary.
Qalsody - Tofersen - EMEA/H/C/005493, Orphan Biogen Netherlands B.V., treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase 1 (SOD1) gene, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tizveni - Tislelizumab - EMEA/H/C/005542 Beigene Ireland Limited, treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in adults, treatment of locally advanced or metastatic squamous non-small cell lung cancer in adults, locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Voydeya - Danicopan - EMEA/H/C/005517, Orphan Alexion Europe, Treatment of extravascular haemolysis (EVH) in patients with paroxysmal nocturnal haemoglobinuria, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
ZYNYZ - Retifanlimab - EMEA/H/C/006194, Orphan Incyte Biosciences Distribution B.V., Treatment of Merkel cell carcinoma (MCC)., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0015, Orphan Swedish Orphan Biovitrum AB (publ),

Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 25.01.2024.	
BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0007/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 18.01.2024, 16.11.2023, 05.10.2023.	Positive Opinion adopted by consensus on 07.03.2024.
Braftovi - Encorafenib - EMEA/H/C/004580/II/0035/G Pierre Fabre Medicament, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Budesonide/Formoterol Teva Pharma B.V. - Budesonide / Formoterol fumarate dihydrate - EMEA/H/C/004882/II/0012/G Teva Pharma B.V., Duplicate, Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, PRAC Rapporteur: Marie Louise Schougaard Christiansen Request for Supplementary Information adopted on 09.11.2023, 30.03.2023.	
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0202 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 25.01.2024.	Positive Opinion adopted by consensus on 29.02.2024.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0205 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Dovprela - Pretomanid - EMEA/H/C/005167/II/0020, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.

Empliciti - Elotuzumab - EMEA/H/C/003967/II/0037/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol Request for Supplementary Information adopted on 15.02.2024.	
Enrylaze - Crisantaspase - EMEA/H/C/005917/II/0003/G Jazz Pharmaceuticals Ireland Limited, Rapporteur: Peter Mol Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Eptifibatide Accord - Eptifibatide - EMEA/H/C/004104/II/0015/G Accord Healthcare S.L.U., Generic, Generic of Integrilin, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 08.02.2024, 26.10.2023, 12.05.2023.	
EXPAREL liposomal - Bupivacaine - EMEA/H/C/004586/II/0018 Pacira Ireland Limited, Rapporteur: Elita Poplavska Request for Supplementary Information adopted on 25.01.2024.	
Foclivia - Pandemic Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/001208/II/0084/G Seqirus S.r.l, Rapporteur: Maria Grazia Evandri Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 29.02.2024.
Gliolan - 5-aminolevulinic acid - EMEA/H/C/000744/II/0026/G Photonamic GmbH & Co. KG, Rapporteur: Bruno Sepodes Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Hetlioz - Tasimelteon - EMEA/H/C/003870/II/0037, Orphan Vanda Pharmaceuticals Netherlands B.V., Rapporteur: Jayne Crowe Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0150/G	

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
Ibandronic Acid Teva - Ibandronic acid - EMEA/H/C/001195/II/0021 Teva B.V., Generic, Generic of Bondronat, Bonviva, Rapporteur: Hrefna Gudmundsdottir Request for Supplementary Information adopted on 29.02.2024, 16.11.2023.	Request for supplementary information adopted with a specific timetable.
Ilumetri - Tildrakizumab - EMEA/H/C/004514/II/0052 Almirall S.A, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 30.11.2023.	Positive Opinion adopted by consensus on 29.02.2024.
Kanuma - Sebelipase alfa - EMEA/H/C/004004/II/0048, Orphan Alexion Europe SAS, Rapporteur: Karin Janssen van Doorn Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0149 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
Kisqali - Ribociclib - EMEA/H/C/004213/II/0048/G Novartis Europharm Limited, Rapporteur: Filip Josephson	
Klisyri - Tirbanibulin - EMEA/H/C/005183/II/0014/G Almirall, S.A., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Kovaltry - Octocog alfa - EMEA/H/C/003825/II/0044/G Bayer AG, Rapporteur: Kristina Dunder	
Ledaga - Chlormethine - EMEA/H/C/002826/II/0035/G, Orphan Helsinn Birex Pharmaceuticals Limited, Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 06.07.2023.	
LIVMARLI - Maralixibat - EMEA/H/C/005857/II/0008/G, Orphan Mirum Pharmaceuticals International B.V.,	Positive Opinion adopted by consensus on 14.03.2024.

Rapporteur: Martina Weise Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 07.12.2023.	
MINJUVI - Tafasitamab - EMEA/H/C/005436/II/0014/G, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 25.01.2024.	Positive Opinion adopted by consensus on 07.03.2024.
Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0130/G Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang Request for Supplementary Information adopted on 11.01.2024.	
Nulojix - Belatacept - EMEA/H/C/002098/II/0090/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 18.01.2024.	Positive Opinion adopted by consensus on 29.02.2024.
Pedmarqsi - Sodium thiosulfate - EMEA/H/C/005130/II/0002/G Fennec Pharmaceuticals (EU) Limited, Rapporteur: Elita Poplavska Request for Supplementary Information adopted on 01.02.2024.	
Rotarix - Rotavirus vaccine (live, oral) - EMEA/H/C/000639/II/0132/G GlaxoSmithKline Biologicals S.A., Rapporteur: Christophe Focke Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0024, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 01.02.2024.	Positive Opinion adopted by consensus on 07.03.2024.
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0116/G Moderna Biotech Spain S.L., Rapporteur: Jan	Positive Opinion adopted by consensus on 07.03.2024.

Mueller-Berghaus Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 25.01.2024, 14.12.2023.	
Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0013/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 18.01.2024.	Positive Opinion adopted by consensus on 14.03.2024.
TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0125/G Corza Medical GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 14.12.2023.	Positive Opinion adopted by consensus on 29.02.2024.
TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0030/G Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus	
Tysabri - Natalizumab - EMEA/H/C/000603/II/0141/G Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 07.03.2024.	Positive Opinion adopted by consensus on 07.03.2024.
Vitrolife IVF media - Recombinant human albumin solution - EMEA/H/D/004693/II/0005 Vitrolife Sweden AB, Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Yargesa - Miglustat - EMEA/H/C/004016/II/0014 Piramal Critical Care B.V., Generic, Generic of Zavesca, Rapporteur: Daniela Philadelphy	
Zometa - Zoledronic acid - EMEA/H/C/000336/II/0103/G Phoenix Labs Unlimited Company, Rapporteur: Thalia Marie Estrup Blicher	
Zoonotic Influenza Vaccine Seqirus - Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) -	

EMEA/H/C/006375/II/0001 Seqirus S.r.l., Informed Consent of Aflunov, Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 22.02.2024, 25.01.2024.	
WS2596 **Infanrix hexa-EMEA/H/C/000296/WS2596/0341** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
WS2630 **Hefiya-EMEA/H/C/004865/WS2630/0052** **Hyrimoz-EMEA/H/C/004320/WS2630/0051** Sandoz GmbH, Lead Rapporteur: Christian Gartner Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
WS2638 **Luveris-EMEA/H/C/000292/WS2638/0098** **Pergoveris-EMEA/H/C/000714/WS2638/0089** Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher	

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

AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0002/G GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, "Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV) based on final results from studies RSV OA=ADJ-008 and RSV OA=ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV), respectively." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 07.03.2024, 09.11.2023.

BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0013

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to change posology recommendations in individuals 16 years of age and older, amend an existing warning on hypersensitivity and anaphylaxis, delete insomnia and back pain from the list of adverse drug reactions (ADRs), change frequency of odynophagia, abdominal pain and injection site hypersensitivity from Uncommon to Rare and update immunogenicity information based on final results from study HIPRA-HH-2 (PART A and PART B) listed as a category 3 study in the RMP; HIPRA-HH-2 was a Phase IIb, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial in adults fully vaccinated against COVID-19. The objective was to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion heterodimer vaccine candidate (PHH-1V) against SARS-CoV-2 (Part A). An extension to the study was introduced to add a fourth dose as described below (Part B)."

Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0025

UCB Pharma S.A., Rapporteur: Finbarr Leacy, "Update of section 5.1 of the SmPC in order to add long-term efficacy data based on the interim results (week 144 data) from study PS0014 listed as a category 3 study in the RMP (MEA/005); this is an ongoing, multicenter, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult study participants with moderate to severe plaque PSO who completed 1 of the 3 completed feeder studies (PS0008, PS0009, and PS0013)."
Request for Supplementary Information adopted on 25.01.2024.

Brukinsa - Zanubrutinib - EMEA/H/C/004978/II/0018

BeiGene Ireland Ltd, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2 and 4.5 of the SmPC in order to update information with

regards to concomitant use of moderate CYP3A inducers based on final results from the drug-drug interaction study BGB-3111-112; this is a phase 1, open-label, fixed-sequence study to investigate the effect of the moderate CYP3A inducer rifabutin on the pharmacokinetics of zanubrutinib in healthy male subjects."	
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0048, Orphan Ablynx NV, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information on paediatric patients based on results from study OBS17325 - Retrospective Data Collection of Pediatric Patients with Immune Thrombotic Thrombocytopenic Purpura (iTTP) Treated with Caplacizumab. The primary objective of this study was to describe the effectiveness and safety of caplacizumab in pediatric patients with iTTP." Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0203 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to update the safety information based on interim (6MPD3 in 6mo-12yo) results from study C4591007, listed as a category 3 study in the RMP. This is an interventional "Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children."" Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Cyramza - Ramucirumab - EMEA/H/C/002829/II/0053 Eli Lilly Nederland B.V., Rapporteur: Peter Mol, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety data on paediatric patients following the outcome of Article 46 procedure EMEA/H/C/002829/P46/009 and based on results from study J1S-MC-JV02 (JV02). This is a randomized, open-label, phase 1/2 study	

evaluating ramucirumab in paediatric patients and young adults with relapsed, recurrent, or refractory synovial sarcoma. In addition, the MAH took the opportunity to implement editorial updates to the SmPC and the Package Leaflet."	
Duavive - Estrogens conjugated / Bazedoxifene - EMEA/H/C/002314/II/0036 Pfizer Europe MA EEIG, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the wording regarding interactions with other medicinal products and to align with the updated CMDh Core SmPC. 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 bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Dupixent - Dupilumab - EMEA/H/C/004390/II/0078 Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2 of the SmPC in order to allow the use of the Dupixent Prefilled Pen presentations for patients aged 2 to < 12 years of age based on final results of the R668-AD-1434 sub-study; this is an interventional open-label sub-study which purpose is to evaluate the PK, safety, immunogenicity, and efficacy of repeat doses of dupilumab (200 mg Q4W, 300 mg Q4W, and 200 mg Q2W) administered SC using a PFP with a skin pinch in children ≥2 to <12 years of age. The Package Leaflet is updated accordingly. In addition, the MA took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 14.12.2023.	
Epidyolex - Cannabidiol - EMEA/H/C/004675/II/0028/G, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Grouped application comprising three type II variations (C.I.13) as follows: - Submission of the final report from study GWTX21068 – Genotoxicity study with 7-OH-CBD (Bacterial Reverse Mutation Assay). The	Positive Opinion adopted by consensus on 14.03.2024.

objective of this study was to evaluate the ability of GWP4200370 (also known as 7-COOH-CBD) to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolizing system (S-9). - Submission of the final report from study GWTX21028 – Genotoxicity study with 7-COOH-CBD (Bacterial Reverse Mutation Assay). The objective of this study was to evaluate the ability of GWP4200307 to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolizing system (S-9). - Submission of the final report from GWTX18015 – Genotoxicity study with 7-COOH-CBD (Rat Micronucleus and Alkaline Comet Assay). The objective of this study was to evaluate the ability of GWP4200370 (also known as 7-COOH-CBD) to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolizing system (S-9)." Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 23.11.2023.	
Fabrazyme - Agalsidase beta - EMEA/H/C/000370/II/0129 Sanofi B.V., Rapporteur: Patrick Vrijlandt, "Update of section 4.6 of the SmPC in order to update the safety information on pregnancy and breast-feeding based on results from AGAL02603/MSC12868: "A Multicenter, Multinational Study of the Effects of Fabrazyme (agalsidase beta) Treatment on Lactation and Infants", listed as a category 3 study in the RMP, MAH safety database and literature search; the Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial changes to the PI." Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 26.10.2023.	Positive Opinion adopted by consensus on 14.03.2024.
Gardasil 9 - Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0069	

Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update long-term effectiveness information based on results from the 4th interim report for study V503-021, listed as a category 3 study in the RMP. This is a registry-based extension of protocol V503-001 in countries with centralized cervical cancer screening infrastructures to evaluate the long-term effectiveness, immunogenicity, and safety of 9vHPV vaccine as administered to 16- to 26-year-old women. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet."
Request for Supplementary Information adopted on 25.01.2024.

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

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.4 and 5.1 of the SmPC in order to add new warnings on 'Major adverse cardiac events (MACE)', 'Thrombosis', and 'Second primary malignancies', following an Art. 20 Class Referral involving JAK inhibitors approved to treat rheumatoid arthritis and to update efficacy information regarding the effects of ruxolitinib in relation to thromboembolic events based on recently published data from MAJIC-PV study (a randomized, controlled open-label study in polycythemia vera (PV))."
Request for Supplementary Information adopted on 25.01.2024, 12.10.2023.

JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0075/G

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "A grouped application consisting of six Type II variations, as follows: C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on results on updated genomic sequencing data from study VAC31518COV3001 listed as a category 3 study in the RMP. This is a randomized, double-blind, placebo-controlled Phase 3 study to assess the efficacy and safety of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18

years and older. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to section 6.1 of the SmPC and to the Package Leaflet. C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on results on updated genomic sequencing data from study VAC31518COV3009 listed as a category 3 study in the RMP. This is a Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, reactogenicity, and immunogenicity of 2 doses of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older. C.I.13: Submission of the final report from VAC31518COV2008 listed as a category 3 study in the RMP. This is a randomized, double-blind, Phase 2 study to evaluate the immunogenicity, reactogenicity and safety of Ad26.COV2.S administered as booster vaccination in adults 18 years of age and older who have previously received primary vaccination with Ad26.COV2.S or BNT162b2. C.I.13: Submission of the final report from the open label phase of study VAC31518COV3001 listed as a category 3 study in the RMP. C.I.13: Submission of the final report from VAC31518COV4002 listed as a category 3 study in the RMP. This is an observational post-authorization study to assess the effectiveness of Ad26.COV2.S for prevention of COVID-19 using real-world data.”	
Kalydeco - Ivacaftor - EMEA/H/C/002494/II/0124 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, “Submission of the final report from Post-Authorisation Effectiveness Study (PAES) VX15-770-125 listed as a category 3 study in the RMP (ANX/024). This is an observational study to evaluate the long-term effectiveness and safety of kalydeco in children with cystic fibrosis who have a specified CFTR gating mutation and are aged 2 through 5 years at therapy initiation.” Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Keytruda - Pembrolizumab -	

EMEA/H/C/003820/II/0147 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-B61; this is a Phase 2, Single-arm, Open-label Clinical Trial of Pembrolizumab Plus Lenvatinib in Participants with First-line Advanced/Metastatic Non-clear Cell Renal Cell Carcinoma (nccRCC)." Request for Supplementary Information adopted on 01.02.2024.	
Kisplyx - Lenvatinib - EMEA/H/C/004224/II/0058 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-B61; this is a phase 2, single-arm, open-label clinical trial of pembrolizumab plus lenvatinib in participants with first-line advanced/metastatic non-clear cell Renal Cell Carcinoma (nccRCC). In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 01.02.2024.	
Leqvio - Inclisiran - EMEA/H/C/005333/II/0022 Novartis Europharm Limited, Rapporteur: Martina Weise, "Update of the Package Leaflet (Annex III.B) in order to include complete Instructions For Use for Healthcare Professionals for the pre-filled syringe without needle guard and to update the Instructions For Use for Healthcare Professionals for the pre-filled with needle guard." Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
LIVTENCITY - Maribavir - EMEA/H/C/005787/II/0008, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, "Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on the updated Population PK analysis data. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 16.11.2023.	
Myozyme - Alglucosidase alfa -	Positive Opinion adopted by consensus on

EMEA/H/C/000636/II/0098 Sanofi B.V., Rapporteur: Alexandre Moreau, "To update section 4.8 of the SmPC to add burning sensation, syncope and asthma to the list of adverse drug reactions (ADRs) with frequency common, not known and not known respectively, following the assessment of procedure II/93 based on the cumulative review of clinical studies, MAH safety database and literature search. The Package Leaflet is updated accordingly." Opinion adopted on 14.03.2024.	14.03.2024.
Orladeyo - Berotralstat - EMEA/H/C/005138/II/0017/G BioCryst Ireland Limited, Rapporteur: Finbarr Leacy, "A grouped application comprised of two type II variations, as follows: C.I.4: Update of section 4.5 of the SmPC in order to remove the recommendation for close monitoring for adverse events with concomitant use of P-gp and BCRP inhibitors based on final safety results from the drug-drug interaction study BCX7353-119, as well as to update the effects of cyclosporine on berotralstat. Study BCX7353-119 is a phase 1 drug-drug interaction study to evaluate the effect of cyclosporine on the pharmacokinetics of berotralstat in healthy subjects. C.I.13: Submission of the final reports from parts 2 and 3 of study BCX7353-301; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of two dose levels of BCX7353 as an oral treatment for the suppression of events in subjects with hereditary angioedema. In addition, the MAH took the opportunity to add additional wording for patients with severely reduced kidney function in the Package Leaflet and to introduce minor editorial changes to the PI, as per previous guidance."	
QUVIVIQ - Daridorexant - EMEA/H/C/005634/II/0013/G Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, "Update of sections 4.4, 4.5 and 5.1 of the SmPC in order to reflect the conclusions of studies ID-075-121, ID-078-122 and ID-078-118, respectively. The Package Leaflet was updated accordingly. Study	Request for supplementary information adopted with a specific timetable.

ID-078-121 is a randomized, double-blind, placebo-controlled, 2-way crossover study to investigate the effects of daridorexant on nighttime respiratory function and sleep in subjects with severe obstructive sleep apnea; Study ID-078-122 is a prospective, open-label, single-dose Phase 1 study to measure daridorexant in breast milk of healthy lactating women; and study ID-078-118 is a single-center, randomized, double-blind, single-dose, 3-way crossover study to compare the effects of daridorexant and placebo on postural stability, the auditory awakening threshold, and cognitive function in the middle of the night following evening administration to healthy adult and elderly subjects." Request for Supplementary Information adopted on 07.03.2024, 01.02.2024.	
Remsima - Infliximab - EMEA/H/C/002576/II/0133/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising three type II variations (C.I.4) as follows: - Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information based on Week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (crohn's disease), listed as a category 3 study in the RMP; Study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease. - Update of sections 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.	See 9.1

- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study). The RMP version 16.1 has also been submitted. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI." Request for Supplementary Information adopted on 09.11.2023.	
Repatha - Evolocumab - EMEA/H/C/003766/II/0069 Amgen Europe B.V., Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC to include Real World Data information based on final results from study 20130296; this is an observational study to describe the clinical characteristics of patients on initiation of Repatha, with a secondary objective to describe the treatment patterns of Repatha use over time." Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0045 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Submission of the final report from study M15-555, listed as a category 3 study in the RMP. This is phase 3, randomized, double-blind study comparing upadacitinib (ABT-494) monotherapy to methotrexate (MTX) in subjects with moderately to severely active rheumatoid arthritis with inadequate response to MTX." Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 30.11.2023.	Positive Opinion adopted by consensus on 29.02.2024.
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0049 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to include long-term efficacy and safety information (up to week 104 data) from study M19-944 (Study 2); this is a	Request for supplementary information adopted with a specific timetable.

phase 3, randomized, double-blind study evaluating the long-term safety, tolerability, and efficacy of upadacitinib 15 mg QD in subjects with nr-axSpA who completed the double-blind period on study drug." Request for Supplementary Information adopted on 14.03.2024.	
Rivastigmine 1A Pharma - Rivastigmine - EMEA/H/C/001181/II/0042 1 A Pharma GmbH, Informed Consent of Exelon, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on the risk of QT prolongation based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Rivastigmine HEXAL - Rivastigmine - EMEA/H/C/001182/II/0042 Hexal AG, Informed Consent of Exelon, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on the risk of QT prolongation based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Rivastigmine Sandoz - Rivastigmine - EMEA/H/C/001183/II/0042 Sandoz GmbH, Informed Consent of Exelon, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on the risk of QT prolongation based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0014 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from study R10933-10987-COV-2118 (COV-2118) - A Phase 2 Randomized, Open-Label, Parallel Group Study to Assess the Immunogenicity, Safety, and Tolerability of	Positive Opinion adopted by consensus on 29.02.2024.

Moderna mRNA-1273 Vaccine Administered with Casirivimab+Imdevimab in Healthy Adult Volunteers." Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 11.01.2024.	
Scemblix - Asciminib - EMEA/H/C/005605/II/0009, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of section 5.3 of the SmPC in order to update preclinical safety data based on final results from study R1570226: this is a 2-year rat carcinogenicity study. In addition, the MAH took the opportunity to implement editorial changes to the SmPC." Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 21.09.2023.	Positive Opinion adopted by consensus on 29.02.2024.
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0121/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "A grouped application consisting of three Type II variations, as follows: C.I.4: Update of sections 4.5, 4.8 and 5.1 of the SmPC to add drug-drug interaction information of Co-administration of Spikevax (mRNA-1273), including its variant formulations with herpes zoster (shingles) vaccine, based on final results from Clinical Study 217670 (NCT05047770). This is a phase 3, randomized, open-label, controlled, multi-center clinical study to evaluate the immune response and safety of both herpes zoster subunit vaccine (HZ/su or Shingrix) in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine (Flu D-QIV or Fluarix Quadrivalent) in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination. C.I.4: Update of sections 4.5, 4.8 and 5.1 of the SmPC to add drug-drug interaction information of Co-administration of Spikevax (mRNA-1273), including its variant formulations with influenza vaccines (standard), based on final results from Clinical Study 217670 (NCT05047770). This is a phase 3, randomized, open-label, controlled, multi-center clinical study, sponsored by	

GlaxoSmithKline Biologicals, to evaluate the immune response and safety of both herpes zoster subunit vaccine (HZ/su or Shingrix) in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine (Flu D-QIV or Fluarix Quadrivalent) in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination.
C.I.4: Update of sections 4.5, 4.8 and 5.1 of the SmPC to add drug-drug interaction information of Co-administration of the variants of Spikevax (mRNA-1273) with influenza (high-dose) vaccines, based on final results from Clinical Study QHD00028 (NCT04969276). This is a Phase II, open-label study, to 'Assess the Safety and Immunogenicity of Fluzone High-Dose Quadrivalent (Influenza Vaccine), 2021-2022 Formulation and a Third Dose of Moderna COVID-19 Vaccine (mRNA-1273 Vaccine) Administered Either Concomitantly or Singly in Adults 65 Years of Age and Older Previously Vaccinated With a 2-dose Schedule of Moderna COVID-19 Vaccine'."

Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0002

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.4 and 4.8 of the SmPC in order to update an existing warning and add 'Stevens-Johnson Syndrome (SJS)' and 'Toxic epidermal necrolysis (TEN)' to the list of adverse drug reactions (ADRs). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0052

Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2 and 4.8 of the SmPC in order to add information regarding fever in infants 2 months of age based on final results from study C3511002; this is a Phase 2b trial to assess the safety, tolerability, and immunogenicity of MenABCWY in healthy infants 2 and 6 months of age. In addition, the MAH is taking this opportunity to implement a minor editorial update to SmPC section 4.4 to add a 'Traceability' subheading, in line with the QRD

product information template version 10.3. Furthermore, as suggested in the linguistic review phase of variation procedure EMEA/H/C/004051/II/0037, the MAH is adding an 'Excipients' subheading to SmPC section 4.4."	
Ultomiris - Ravulizumab - EMEA/H/C/004954/II/0043/G Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, "A grouped application comprised of a Type II variation and a Type IA variation, as follows: Type II (C.I.4): Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update clinical information regarding the atypical haemolytic uremic syndrome (aHUS) indication, based on final results from studies ALXN1210-aHUS-311 and ALXN1210-aHUS-312. ALXN1210-aHUS-311 is a phase 3, open-label, uncontrolled, multicenter, single treatment arm study in adolescent and adult patients with evidence of TMA who are naïve to complement inhibitor treatment, while ALXN1210- aHUS-312 is a phase 3, open-label, uncontrolled, multicenter, single treatment arm study in pediatric patients with evidence of TMA who are naïve to complement inhibitor treatment (Cohort 1) or are clinically stable after having been treated with eculizumab (Cohort 2). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. Type IA (A.6): To change the ATC Code for ravulizumab from L04AA43 to L04AJ02." Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0099 AstraZeneca AB, Rapporteur: Sol Ruiz, "Submission of the final report from study D8111R00017 (COVIDRIVE) listed as a category 3 PAES in the RMP. This is a post-authorisation retrospective cohort study to evaluate the effectiveness of the AZD1222 vaccine to prevent serious COVID-19 infection in conditions of usual care." Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
Veklury - Remdesivir -	Request for supplementary information adopted

EMEA/H/C/005622/II/0054/G Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Grouped application to update section 5.2 of the SmPC to update pharmacokinetic information based on results from two Population PK Study reports, QP-2023-1074 and CTRA-2023-1084. QP-2023-1074 is a population pharmacokinetic analysis of Sulfobutylether-β-cyclodextrin (SBECD) in adults with normal and impaired renal function following remdesivir administration. CTRA-2023-1084 is a population pharmacokinetic analysis for remdesivir and metabolites (GS-704277 and GS-441524) after administration of remdesivir in adults." Request for Supplementary Information adopted on 14.03.2024.	with a specific timetable.
Venclyxto - Venetoclax - EMEA/H/C/004106/II/0047 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Submission of the final report from study GO28667 (MURANO) listed as a category 3 study in the RMP. This is a Multicenter, Phase III, Open-Label, Randomized Study in Relapsed/Refractory Patients with Chronic Lymphocytic Leukemia to Evaluate the Benefit of GDC-0199 (ABT-199) Plus Rituximab Compared with Bendamustine Plus Rituximab." Request for Supplementary Information adopted on 08.02.2024.	
Volibris - Ambrisentan - EMEA/H/C/000839/II/0067 GlaxoSmithKline (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, "To update sections 4.8 and 5.1 of the SmPC following the assessment of Art 46 procedure (EMEA/H/C/000839) based on final results from study AMB114588; this is an open-label, long term extension study for treatment of pulmonary arterial hypertension in paediatric patients aged 8 years up to 18 years who have participated in AMB112529 and in whom continued treatment with ambrisentan is desired. In addition, the MAH took the opportunity to implement minor editorial changes to Annex II and to the Package Leaflet." Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 14.03.2024.

Xeljanz - Tofacitinib - EMEA/H/C/004214/II/0059 Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, "Update of section 4.4 of the SmPC in order to update serious infections section based on post-marketing data and literature. In addition, the MAH has taken the opportunity to implement changes to improve readability and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 14.03.2024.	Request for supplementary information adopted with a specific timetable.
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0002, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, "Submission of the final report from study 1042-HME-1001 listed as post-authorisation measure (PAM) recommendation. This is an interventional Phase 1 Single Dose, Open-Label Crossover Comparative Bioavailability Study of Two Oral Formulations of Ganaxolone. The primary objective of this study was to evaluate and compare the pharmacokinetics of a new ganaxolone formulation (hot-melt extrusion [HME]) with ganaxolone oral suspension after a single oral dose administration under fed conditions." Request for Supplementary Information adopted on 14.03.2024, 14.12.2023.	Request for supplementary information adopted with a specific timetable.
WS2603 **Eucreas-EMEA/H/C/000807/WS2603/0105** **Galvus-EMEA/H/C/000771/WS2603/0082** **Icandra-EMEA/H/C/001050/WS2603/0110** **Jalra-EMEA/H/C/001048/WS2603/0085** **Xiliarx-EMEA/H/C/001051/WS2603/0083** **Zomarist-EMEA/H/C/001049/WS2603/0107** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add 'Cholecystitis' to the list of adverse drug reactions (ADRs) with frequency 'Not known'. The Package Leaflet is updated accordingly." Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 11.01.2024.	Negative Opinion adopted by consensus on 29.02.2024.

WS2626 Mirapexin-EMEA/H/C/000134/WS2626/0107 Sifrol-EMEA/H/C/000133/WS2626/0098 Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add 'spontaneous penile erection' to the list of adverse drug reactions (ADRs) with frequency rare, based on the outcome of a cumulative review. The Package Leaflet is updated accordingly. In addition, the 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 updated QRD template version 10.3." Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.

B.5.3. CHMP-PRAC assessed procedures

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0018/G Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising two type II variations as follows: C.I.13: Submission of the final report from study D5290C00004 (MELODY) listed as a category 3 study in the RMP. This is a phase III study, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of MEDI8897, a monoclonal antibody with an extended half-life against respiratory syncytial virus, in healthy late preterm and term infants. C.I.13: Submission of the final report from study D5290C00005 (MEDLEY) listed as a category 3 study in the RMP. This is a phase II/III study, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus (nirsevimab) in high-risk children. The RMP version 2.3 has also been submitted." Request for Supplementary Information adopted on 07.03.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0201 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Liana	Request for supplementary information adopted with a specific timetable.

Martirosyan, "Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to update information regarding concomitant vaccine administration with influenza vaccine based on final results from study C4591030 listed as a category 3 study in the RMP. This is an interventional phase 3, randomized, observer-blind trial to evaluate the safety and immunogenicity of BNT162b2 and quadrivalent seasonal influenza vaccine when administered separately or concomitantly in adults 18 to 64 years of age. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted." Request for Supplementary Information adopted on 07.03.2024.	
Dovprela - Pretomanid - EMEA/H/C/005167/II/0019/G, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Martirosyan, "Grouped application comprising two variations as follows: Type II (C.I.4) – Update of sections 4.1 and 5.1 of the SmPC in order to rephrase the indication wording to align with the current WHO definitions. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Type IB (C.I.11.z) - Submission of an updated RMP version 2.0 in order to align the safety concerns following the assessment of procedure EMEA/H/C/005167/11/0013." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
Fintepla - Fenfluramine - EMEA/H/C/003933/II/0022/G, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "A grouped application comprised of three Type II variations, as follows: C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to modify the list of adverse drug reactions based on a revised safety ADR methodology for Dravet and Lennox-Gastaut syndromes, which includes pooled analyses encompassing studies ZX008-1503 and ZX008-1601 cohort B. The Package Leaflet is updated accordingly. C.I.4: Update of section 5.1 of the SmPC in	

order to update clinical efficacy information for Dravet syndrome based on final results from study ZX008-1503 listed as a category 3 study in the RMP. This is an open-label extension trial to assess the long-term safety of ZX008 (fenfluramine hydrochloride) oral solution as an adjunctive therapy in children and young adults with Dravet syndrome. C.I.4: Update of section 5.1 of the SmPC in order to update clinical efficacy information for Lennox-Gastaut syndrome based on final results from study ZX008-1601 Part 1 cohort B and interim results for study ZX008-1601 Part 2 cohort B. Study 1601 Part 1 was an international, randomized, double-blind, parallel-group, placebo-controlled study in subjects with LGS 2 to 35 years of age, while study 1601 Part 2 is a long-term, open-label, flexible-dose extension for subjects who completed study 1601 Part 1. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information, including to section 4.2 of the SmPC."	
Idefirix - Imlifidase - EMEA/H/C/004849/II/0019, Orphan Hansa Biopharma AB, Rapporteur: Martina Weise, PRAC Rapporteur: Bianca Mulder, "Update of section 5.1 of the SmPC in order to include the description of the final results from PAES study 17-HMedIdeS-14 listed as a specific obligation in the Annex II (SOB/002); this is a prospective, observational long-term follow-up study of patients treated with imlifidase (IdeS) prior to kidney transplantation. The primary objective of this trial was to evaluate graft survival in patients who have undergone kidney transplantation after imlifidase administration in earlier trials and relates to both safety and efficacy. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to update section E of Annex II and to implement editorial changes to sections 4.4, 4.6 and 9 of the SmPC. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.

Ilumetri - Tildrakizumab - EMEA/H/C/004514/II/0054 Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski, "Update of section 5.1 of the SmPC in order to update clinical and safety information based on long-term results from the extension periods of the pivotal clinical studies MK-3222-010 (A 64-Week, Phase 3, Randomized, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222/MK-3222), Followed by an Optional Long-Term Safety Extension Study, in Subjects with Moderate-to-Severe Chronic Plaque Psoriasis (Protocol No. MK-3222-010)) and MK-3222-011 (A 52-Week, Phase 3, Randomized, Active Comparator and Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222 / MK-3222), Followed by an Optional Long-Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis). The RMP version 1.4 has also been submitted." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0100 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of section 5.1 of the SmPC in order to add vaccine effectiveness data, and the removal of the two open specific obligations (POX-MVA-039 (SOB02) and SEMVAc (SOB03)), based on the IMVANEX vaccine effectiveness data in real-world use during the 2022 monkeypox outbreak. Consequently, the MAH proposes a switch from exceptional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Isturisa - Osilodrostat - EMEA/H/C/004821/II/0017/G, Orphan Recordati Rare Diseases, Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon, "Grouped application comprising two	Positive Opinion adopted by consensus on 07.03.2024.

type II variations (C.I.4) as follows: - Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study LINC4 (study CLCI699C2302 - A Phase III, multi-center, randomized, double-blind, 48 week study with an initial 12 week placebo-controlled period to evaluate the safety and efficacy of osilodrostat in patients with Cushing's disease). - Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study LINC3 (study CLCI699C2301 - A Phase III, multi-center, double-blind, randomized withdrawal study of LCI699 following a 24 week, single-arm, open-label dose titration and treatment period to evaluate the safety and efficacy of LCI699 for the treatment of patients with Cushing's disease). The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the PI." Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 30.11.2023.	
Juluca - Dolutegravir / Rilpivirine - EMEA/H/C/004427/II/0057/G ViiV Healthcare B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Nathalie Gault, "Grouped application comprising two type II variations as follows: C.I.13: Submission of the final report from study 201636 (SWORD 1) listed as a category 3 study in the RMP. This is a phase III, randomized, multicenter, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine from current INI-, NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed. C.I.13: Submission of the final report from study 201637 (SWORD 2) listed as a category 3 study in the RMP. This is a phase III, randomized, multicenter, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine from current INI-, NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected	Request for supplementary information adopted with a specific timetable.

adults who are virologically suppressed. The RMP version 7.0 has also been submitted." Request for Supplementary Information adopted on 07.03.2024.	
Jyseleca - Filgotinib - EMEA/H/C/005113/II/0031/G Galapagos N.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "Grouped application comprising two variations as follows: Type II (C.I.4): Update of sections 4.8 and 5.1 of the SmPC to update the safety mean duration exposure and efficacy information based on final results (up to Week 432) from study GLPG0634-CL-205 (DARWIN 3) listed as a category 3 study in the RMP (MEA/009); this is a phase II, open-label, long-term follow-up safety and efficacy study to evaluate the long-term safety and tolerability of filgotinib for the treatment of Rheumatoid Arthritis in patients who received treatment in their parent studies. The RMP version 6.1 has also been submitted. Type IA (A.6): To change the ATC code for Janus-associated kinase (JAK) inhibitor from L04AA45 filgotinib to L04AF04 filgotinib." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
Kuvan - Sapropterin - EMEA/H/C/000943/II/0078 BioMarin International Limited, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu, "Submission of the final report from study KOGNITO, listed as a category 3 study in the RMP. This is a Phase IV Open-Label, Single-Cohort Study of the Long-Term Neurocognitive Outcomes in 4 to 5 Year-Old Children with Phenylketonuria Treated with Sapropterin Dihydrochloride (Kuvan) for 7 Years. The RMP version 16.0 has also been submitted." Request for Supplementary Information adopted on 11.01.2024, 28.09.2023.	
Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4	See 9.1

randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3."	
Onglyza - Saxagliptin - EMEA/H/C/001039/II/0057 AstraZeneca AB, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to include safety, efficacy and pharmacokinetic information in paediatric patients with Type 2 diabetes mellitus (T2DM) aged 10 to <18 years of age based on interim results from study D1680C00019 (T2NOW). This is a 26-week, multicentre, randomised, placebo-controlled, double-blind, parallel group, Phase III trial with a 26-week safety extension period evaluating the safety and efficacy of dapagliflozin (5 and 10 mg), and separately, saxagliptin (2.5 and 5 mg) in paediatric patients with T2DM who were between 10 and below 18 years of age. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity bring the PI in line with the latest QRD template, to introduce editorial changes and to update the contact details of the local representative in the Netherlands in the Package Leaflet. The RMP version 17.1 was agreed during the procedure." Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 26.10.2023.	Positive Opinion adopted by consensus on 29.02.2024.
Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0028 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, "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 LIBRETTO-431 (JZJC) listed as a specific obligation in the Annex II (SOB/002); this is a randomized Phase	Request for supplementary information adopted with a specific timetable. See 9.1

3 study comparing selpercatinib to platinum-based and pemetrexed therapy with or without pembrolizumab in patients with locally advanced or metastatic, RET-fusion-positive NSCLC. The Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II." Request for Supplementary Information adopted on 07.03.2024.	
RoActemra - Tocilizumab - EMEA/H/C/000955/II/0121 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study ZUMA-8 (PAM). This is a phase 1 multicenter study evaluating the safety and tolerability of KTE-X19 in adult subjects with Relapsed/Refractory Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma. The RMP version 29.0 has also been submitted." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0015 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive analysis of the results from the drug pregnancy registry cohort (PDC study GV44373), listed as a category 3 PASS in the RMP, as well as data from clinical studies and post-marketing surveillance. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0096 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the SmPC based on final results from study D7220C00001; this is a phase 2/3 partially double-blinded, randomised,	Positive Opinion adopted by consensus on 07.03.2024.

multinational, active-controlled study in both previously vaccinated and unvaccinated adults to determine the safety and immunogenicity of AZD2816, a vaccine for the prevention of COVID-19 caused by variant strains of SARS-CoV-2. The RMP version 8 succession number 3 was submitted to consolidate the updates made in the RMP as part of two parallel procedures (EMEA/H/C/005675/II/0096 and EMEA/H/C/005675/II/0097). In addition, the MAH took the opportunity to update in the EU-RMP the submission milestone date for study D8111R00010." Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 08.02.2024.	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0097 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final report from study D8110C00001 listed as a category 3 study in the RMP (SOB/020). This is a phase III, randomised, placebo-controlled study of AZD1222 (Vaxzevria) conducted in the US, Peru and Chile. The purpose of the final CSR addendum is to provide long-term safety data through to study completion and include the second year of follow-up post-first dose and final day 730 visit. The RMP version 8 succession number 3 was submitted to consolidate the updates made in RMP as part of two parallel procedures (EMEA/H/C/005675/II/0096 and EMEA/H/C/005675/II/0097). In addition, the MAH took the opportunity to update in the EU-RMP the submission milestone date for study D8111R00010." Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 07.03.2024.
Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0014, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.4 of the SmPC in order to amend an existing warning on infusion reactions and hypersensitivity reactions, and update of section 5.1 of the SmPC to update the mechanism of	Request for supplementary information adopted with a specific timetable.

action of efgartigimod in relation to albumin; based on final results from study ARGX-113-1705 listed a category 3 study in the RMP. This is a long-term, single-arm, open-label, multicenter, phase 3 follow-on study of ARGX-113-1704 to evaluate the safety and tolerability of ARGX-113 in patients with myasthenia gravis having generalized muscle weakness. The RMP version 2.2 has also been submitted." Request for Supplementary Information adopted on 07.03.2024, 11.01.2024.	
Xevudy - Sotrovimab - EMEA/H/C/005676/II/0026 Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Liana Martirosyan, "To update sections 4.2, 4.8 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study COMET-PACE (215226), a category 3 study in the RMP; this is an open-label, non-comparator, multicentre study to describe the pharmacokinetics (PK), pharmacodynamics (PD; viral load) and safety following a single intravenous or intramuscular dose of sotrovimab in paediatric participants with mild to moderate COVID-19 at high risk of disease progression. The RMP version 1.1 has also been updated." Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 07.03.2024.
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0005, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.2 of the SmPC in order to update dosing instructions in severe hepatic impairment based on data from phase I study 1042-IHF-1001. The RMP version 1.3 has also been submitted."	
WS2631 Kisplyx-EMEA/H/C/004224/WS2631/0059 Lenvima- EMEA/H/C/003727/WS2631/0054 Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn, Lead PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC for Kisplyx and sections 4.8 and 5.1 of the SmPC for Lenvima, in order to	

reflect the results of two completed paediatric clinical studies E7080-G000-216 and E7080-G000-231. Study 231 is a Phase 2, open-label, multicenter basket study to evaluate the antitumor activity and safety of Lenvatinib in children, adolescents, and young adults with relapsed or refractory solid malignancies. Study 216 is a Phase 1/2, multicenter, open-label, single arm study of lenvatinib in combination with everolimus in pediatric subjects (and young adults aged ≤21 years) with relapsed or refractory malignant solid tumors. The Package Leaflet for Kisplyx is updated accordingly. The RMP version 15.3 has also been submitted." Request for Supplementary Information adopted on 22.02.2024.	
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2593/0012 Qdenga-EMEA/H/C/005155/WS2593/0013 Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.5 of the SmPC in order to add co-administration information with HPV vaccine based on final results from study DEN-308 listed as a category 3 study in the RMP (MEA003/MEA004); this is a Phase 3, open-label, randomized trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous dengue tetravalent vaccine (live, attenuated) (TDV) and an intramuscular recombinant 9-valent human papillomavirus (9vHPV) vaccine in subjects aged ≥9 to <15 years in an endemic country for dengue; the Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes and to update the text on PSUR submissions in Annex II for Dengue tetravalent vaccine." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **Enbrel - Etanercept - EMEA/H/C/000262/II/0254** Pfizer Europe MA EEIG, Rapporteur: Maria	Request for supplementary information adopted with a specific timetable.

Concepcion Prieto Yerro, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC in order to update the frequency of Adverse Drug Reaction (ADR) `Glomerulonephritis' from `Not Known' to `Rare' following PSUSA/00010795/202302 procedure, based on available evidence from clinical trials, literature, and post-marketing data. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 07.03.2024.	
PRAC Led **Entyvio - Vedolizumab - EMEA/H/C/002782/II/0081** Takeda Pharma A/S, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study Vedolizumab-5001 (OTIS Entyvio Pregnancy Exposure Registry); this is a non-interventional study to monitor planned and unplanned pregnancies in female patients with ulcerative colitis or Crohn's disease. In addition, the MAH took the opportunity to introduce minor changes and corrections to the PI and bring it in line with the latest QRD template." Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 07.03.2024.
PRAC Led **HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0096** Baxalta Innovations GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of sections 4.8 and 5.1 of the SmPC in order to update long-term safety information based on final results from studies 161406 "Non-Interventional Post-Marketing Safety Study on the Long-Term Safety of HYQVIA (Global)" listed as category 3 a study in the RMP and 161302 "Non-Interventional Post-Authorization Safety Study on the Long-Term Safety of HyQvia in Subjects Treated with HyQvia". Both studies were non-interventional, prospective, uncontrolled, multicenter, open-label, post-authorisation	Request for supplementary information adopted with a specific timetable.

studies. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3, to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 07.03.2024.	
PRAC Led **Intuniv - Guanfacine - EMEA/H/C/003759/II/0033/G** Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of the final reports from the Drug Utilisation Study of Intuniv (guanfacine extended release) in European countries: a prescriber survey (EUPAS18739) and a retrospective database study (EUPAS18735), listed as category 3 studies in the RMP. The RMP version 4.0 has also been submitted." Request for Supplementary Information adopted on 07.03.2024, 28.09.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Nplate - Romiplostim - EMEA/H/C/000942/II/0091** Amgen Europe B.V., PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of an updated RMP version 22 in order to include the latest safety information collected until 31 July 2023 (data lock point). The main change consists of removing the neutralising antibodies that cross-react with endogeneous thrombopoietin (eTPO)." Opinion adopted on 07.03.2024.	Positive Opinion adopted by consensus on 07.03.2024.
PRAC Led **NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0060** Novavax CZ, a.s., PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 4.2 after approval of adapted COVID-19 vaccine by new strain, Omicron XBB.1.5." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.

PRAC Led **SARCLISA - Isatuximab - EMEA/H/C/004977/II/0027** Sanofi Winthrop Industrie, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Update of section 4.8 of the SmPC in order to add 'Thrombocytopenia' and 'Anaemia' to the list of adverse drug reactions (ADRs) and to amend the frequency of all remaining ADRs with their appropriate frequencies, following PRAC request in the outcome of the PSUSA procedure PSUSA/00010851/202303." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0031** Gilead Sciences Ireland UC, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of an updated RMP version 3.1 in order to propose the removal of safety concerns." Request for Supplementary Information adopted on 07.03.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Vedrop - Tocofersolan - EMEA/H/C/000920/II/0047** Recordati Rare Diseases, PRAC Rapporteur: Melinda Palfi, PRAC-CHMP liaison: Beata Maria Jakline Ullrich, "Submission of an updated RMP version 10.2 in order to remove all important potential risks and missing information from the list of safety concerns, to align with the new RMP format according to Good Pharmacovigilance Practices Module V Revision 2 and to remove one closed post-authorisation safety study of category 2 (Recordati Rare Diseases' Vedrop registry) from the pharmacovigilance plan." Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 30.11.2023.	Positive Opinion adopted by consensus on 07.03.2024.

B.5.5. CHMP-CAT assessed procedures

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G, ATMP	

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini	

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

WS2518/G **Combivir-** **EMEA/H/C/000190/WS2518/0110/G** **Epivir-** **EMEA/H/C/000107/WS2518/0127/G** **Kivexa-** **EMEA/H/C/000581/WS2518/0097/G** **Trizivir-** **EMEA/H/C/000338/WS2518/0132/G** ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, Opinion adopted on 07.03.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 07.03.2024.
WS2584 **HyQvia-EMEA/H/C/002491/WS2584/0094** **Kiovig-EMEA/H/C/000628/WS2584/0125** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 29.02.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 29.02.2024.
WS2614 **Cegfila-EMEA/H/C/005312/WS2614/0019** **Pelmeg-EMEA/H/C/004700/WS2614/0027** Mundipharma Corporation (Ireland) Limited, Lead Rapporteur: Karin Janssen van Doorn Opinion adopted on 14.03.2024. Request for Supplementary Information adopted on 07.12.2023.	Positive Opinion adopted by consensus on 14.03.2024.
WS2635 **Hexacima-** **EMEA/H/C/002702/WS2635/0155** **Hexyon-** **EMEA/H/C/002796/WS2635/0159** **MenQuadfi-** **EMEA/H/C/005084/WS2635/0032** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-	

Berghaus	
WS2644/G **Entresto-** **Neparvis-** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 14.03.2024.	Positive Opinion adopted by consensus on 14.03.2024.
WS2661 **Mirapexin-** **EMEA/H/C/000134/WS2661/0108** **Sifrol-EMEA/H/C/000133/WS2661/0099** Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 29.02.2024.	Request for supplementary information adopted with a specific timetable.
WS2666/G **Ongentys-** **EMEA/H/C/002790/WS2666/0065/G** **Ontilyv-** **EMEA/H/C/005782/WS2666/0020/G** Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise	

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Tocilizumab - EMEA/H/C/006196 treatment of rheumatoid arthritis (RA)
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
Datopotamab - EMEA/H/C/006081 treatment of adult patients with locally advanced or metastatic non squamous non-small cell lung cancer (NSCLC)
Pegfilgrastim - EMEA/H/C/006407 treatment of neutropenia
Resminostat - EMEA/H/C/006259

treatment of patients with advanced stage mycosis fungoides (MF) and Sézary syndrome (SS)
Seladelpar lysine dihydrate - EMEA/H/C/004692 is a peroxisome proliferator receptor delta (PPARδ) activator indicated for the treatment of primary biliary cholangitis (PBC) including pruritus in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA.
Nirogacestat - EMEA/H/C/006071, Orphan Springworks Therapeutics Ireland Limited, treatment of desmoid tumours
Aflibercept - EMEA/H/C/006339 treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)
Resmetirom - EMEA/H/C/006220 for the treatment of adults with nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis
Aflibercept - EMEA/H/C/006551 treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)
Ustekinumab - EMEA/H/C/006444 for the treatment of Crohn’s disease and ulcerative colitis

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

Aqumeldi - Enalapril maleate - EMEA/H/C/005731/X/0001/G Proveca Pharma Limited, Rapporteur: John Joseph Borg, PRAC Rapporteur: Mari Thorn, “Extension application to add a new strength of 1 mg orodispersible tablet grouped with a type IB variation (C.I.z) to correct the SmPC to remove the recommended dose of epinephrine from section 4.4.”

BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/X/0014/G
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich

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

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

Axitinib - EMEA/H/C/006206
treatment of adult patients with advanced renal cell carcinoma (RCC)
List of Questions adopted on 20.07.2023.

Erdafitinib - EMEA/H/C/006050
treatment of adult patients with locally advancedunresectableor metastatic urothelial carcinoma (UC)
List of Questions adopted on 25.01.2024.

Bimzelx - Bimekizumab - EMEA/H/C/005316/X/0021
UCB Pharma S.A., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "Extension application to add a new strength of 320 mg (160 mg/ml) for bimekizumab solution for injection in pre-filled syringe or pre-filled pen, for subcutaneous (SC) administration."
List of Questions adopted on 25.01.2024.

Cresemba - Isavuconazole - EMEA/H/C/002734/X/0042/G, Orphan
Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "Extension application to add a new strength of 40 mg hard capsule to be used in paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and

older for CRESEMBA 200 mg powder, based on final results from studies 9766-CL-0107 and 9766-CL-0046. Study 9766-CL-0046 is a Phase 1, open-label, multicenter study to evaluate the PK, safety and tolerability of intravenous and oral isavuconazonium sulfate in paediatric patients. This study was conducted in two sequential parts: Part 1 with three intravenous dosing cohorts, and Part 2 with two oral dosing cohorts. Study 9766-CL-0107 is a Phase 2, open-label, non-comparative, multicenter study to evaluate the safety and tolerability, efficacy, and PK of isavuconazole for the treatment of invasive aspergillosis or mucormycosis in paediatric patients aged 1 to < 18 years.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance.
Version 9.1 of the RMP has also been submitted."
List of Questions adopted on 25.01.2024.

Enzalutamide - EMEA/H/C/006299
treatment of prostate cancer
List of Questions adopted on 14.12.2023.

Donanemab - EMEA/H/C/006024
to slow disease progression in adult patients with Alzheimer's disease (AD).
List of Questions adopted on 14.12.2023.

Mektovi - Binimetinib - EMEA/H/C/004579/X/0029
Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Extension application to add a new strength of 45 mg (film-coated tablets)."
List of Questions adopted on 25.01.2024.

Nilotinib - EMEA/H/C/006315
treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)
List of Questions adopted on 09.11.2023.

Ocrevus - Ocrelizumab - EMEA/H/C/004043/X/0039
Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (920 mg) and new route of administration (subcutaneous use).
The RMP (version 9.0) is updated in

accordance."
List of Questions adopted on 25.01.2024.

Odronextamab - EMEA/H/C/006215, Orphan
Regeneron Ireland Designated Activity Company, treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)
List of Questions adopted on 14.12.2023.

Crovalimab - EMEA/H/C/006061
treatment of paroxysmal nocturnal haemoglobinuria
List of Questions adopted on 09.11.2023.

Pomalidomide - EMEA/H/C/006273
treatment of adult patients with multiple myeloma
List of Questions adopted on 25.01.2024.

Pomalidomide - EMEA/H/C/006314
treatment of multiple myeloma
List of Questions adopted on 25.01.2024.

Pomalidomide - EMEA/H/C/006294
treatment of adults with multiple myeloma
List of Questions adopted on 25.01.2024.

Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278
Prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV)
List of Questions adopted on 09.11.2023.

Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Extension application to introduce three new strengths of tablets (1.5 mg, 4 mg and 9 mg) for semaglutide."
List of Questions adopted on 22.02.2024.

Skyrizi - Risankizumab - EMEA/H/C/004759/X/0043/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "Extension application to a new strength of 180 mg of risankizumab (solution for injection in cartridge) grouped with a type II variation extension of indication

(C.I.6.a) to include treatment of adult patients with moderately to severely active ulcerative colitis, for SKYRIZI, based on final results from studies M16-067 substudy 2: a phase 2b/3 multicenter, randomized, double-blind, placebo-controlled induction study to evaluate the efficacy and safety of risankizumab in subjects with moderately to severely active ulcerative colitis, and M16-066 substudy 1: a multicenter, randomized, double-blind, placebo controlled 52-week maintenance and an open-label extension study of the efficacy and safety of risankizumab in subjects with ulcerative colitis, as well as DDI study M19-974. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC for the Skyrizi 600 mg concentrate for solution for infusion, and sections 1, 2, 4.1, 4.2, 4.8, 5.1, 5.2, 5.3, 6.5 and 6.6 of the SmPC for the Skyrizi 360 mg solution for injection in cartridge are updated. The Annex II, Labelling and Package Leaflets are updated in accordance. Version 5.0 of the RMP has also been submitted."
List of Questions adopted on 25.01.2024.

Sotatercept - EMEA/H/C/005647, Orphan
Merck Sharp & Dohme B.V., treatment of pulmonary arterial hypertension in adults
List of Questions adopted on 23.01.2024.

Macitentan / Tadalafil - EMEA/H/C/005001
treatment of pulmonary arterial hypertension (PAH) in adult patients
List of Questions adopted on 09.11.2023.

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

Ebvallo - Tabelecleucel - EMEA/H/C/004577/S/0008, Orphan, ATMP
Pierre Fabre Medicament, Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Amelia Cupelli

ELZONRIS - Tagraxofusp - EMEA/H/C/005031/S/0025, Orphan
Stemline Therapeutics B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Obizur - Susoctocog alfa - EMEA/H/C/002792/S/0056

Baxalta Innovations GmbH, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Gabriele Maurer

Tecovirimat SIGA - Tecovirimat - EMEA/H/C/005248/S/0010
SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber

Voraxaze - Glucarpidase - EMEA/H/C/005467/S/0025, Orphan
SERB S.A.S., Rapporteur: Petr Vrbata, PRAC Rapporteur: Martin Huber

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

Arsenic trioxide Accord - Arsenic trioxide - EMEA/H/C/005175/R/0009
Accord Healthcare S.L.U., Generic, Generic of TRISENOX, Rapporteur: Alar Irs, PRAC Rapporteur: Tiphaine Vaillant

Bortezomib Fresenius Kabi - Bortezomib - EMEA/H/C/005074/R/0010
Fresenius Kabi Deutschland GmbH, Generic, Generic of VELCADE, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Amelia Cupelli

Kinpeygo - Budesonide - EMEA/H/C/005653/R/0010, Orphan
STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen

RINVOQ - Upadacitinib - EMEA/H/C/004760/R/0051
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

TALVEY - Talquetamab - EMEA/H/C/005864/R/0005, Orphan
Janssen-Cilag International N.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Barbara Kovacic Bytyqi

Tecvayli - Teclistamab - EMEA/H/C/005865/R/0010
Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, Co-Rapporteur: Paolo

Gasparini, PRAC Rapporteur: Jana Lukacisinova

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

BLINCYTO - Blinatumomab - EMEA/H/C/003731/II/0056, Orphan Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jana Lukacisinova, "Extension of indication to include treatment as part of consolidation therapy for the treatment of patients with Philadelphia chromosome negative CD19 positive B-cell precursor ALL for BLINCYTO. The proposed indication is supported by efficacy data from Studies E1910, 20120215, and AALL1331, safety data for Studies E1910, 20120215, AALL1331, MT103-202, and MT103-203, and Pharmacokinetic data for Studies 20120215, AALL1331, MT103-202, MT103-203, and 20190360. 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 18.0 of the RMP has also been submitted."	
Dupixent - Dupilumab - EMEA/H/C/004390/II/0083 Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, "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."

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

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Ulla Wändel Liminga, "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-center 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."

RYBREVANT - Amivantamab - EMEA/H/C/005454/II/0013

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include amivantamab in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations (EGFRm NSCLC), based on results from study 73841937NSC3003 (MARIPOSA). This is a randomized, open-label, Phase 3 study that compares the efficacy and safety of the combination of amivantamab and lazertinib (Arm A) versus osimertinib monotherapy (Arm B) and lazertinib monotherapy (Arm C) in participants with EGFRm NSCLC. The primary objective of the MARIPOSA study was to assess the efficacy of

the combination of amivantamab and lazertinib (Arm A), compared with osimertinib (Arm B), as measured by PFS assessed by BICR in adult participants with EGFRm NSCLC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the EU RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Sialanar - Glycopyrronium - EMEA/H/C/003883/II/0029 Proveca Pharma Limited, Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Zane Neikena, "Extension of indication to include treatment of children aged from 2 years and older for SIALANAR, based on the interim results from study PRO/GLY/005. This is a retrospective analysis of real world data from children aged under 3 years treated with glycopyrronium for severe drooling. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. 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)	
Synjardy - Empagliflozin / Metformin - EMEA/H/C/003770/II/0078 Boehringer Ingelheim International GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, "Extension of indication to include the treatment of children aged 10 years and above with type 2 diabetes for Synjardy, based on the final results from study 1218-0091 (DINAMO) - A double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period	

up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 16.0 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."

Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0006

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include in combination with platinum and fluoropyrimidine-based chemotherapy the first-line treatment of adult patients with human epidermal growth factor receptor-2 (HER-2)-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma for TEVIMBRA, based on results from the phase 3 study BGB-A317-305 (study 305); this is a global, randomized, double-blind, placebo-controlled study at the approved registrational dosing regimen for Tevimbra (200 mg administered IV Q3W), in combination with platinum and fluoropyrimidine-based chemotherapy, in adult patients with HER-2 negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. 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 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Yselty - Linzagolix choline - EMEA/H/C/005442/II/0013

Theramex Ireland Limited, Rapporteur: Finbarr Leacy, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Martin Huber, "Extension of indication to include treatment of endometriosis-associated pain in adult women of reproductive age for YSELTY, based on final results from studies Edelweiss 3 (18-OBE2109-003) and Edelweiss 6 (19-OBE2109-006) as well as additional supporting studies. Edelweiss 3 is a pivotal phase 3, randomised, double-blind,

placebo-controlled, safety and efficacy study to evaluate linzagolix with add-back therapy as a therapy for pain associated with endometriosis, while Edelweiss 6 is an open-label extension study including patients who completed Edelweiss 3 pivotal study regardless of their previous treatment assignment and met the eligibility criteria. 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 1.1 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 market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Atosiban SUN – Atosiban - EMA/VR/0000167976 Sun Pharmaceutical Industries (Europe) B.V., Rapporteur: John Joseph Borg	
AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0009/G GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt	
BUCCOLAM - Midazolam - EMEA/H/C/002267/II/0062/G Neuraxpharm Pharmaceuticals S.L., Rapporteur: Peter Mol	
Buvidal - Buprenorphine - EMEA/H/C/004651/II/0025 Camurus AB, Rapporteur: Finbarr Leacy	
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0212/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson	
Ervebo - Recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0035 Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke	

Evenity - Romosozumab -
EMEA/H/C/004465/II/0023
UCB Pharma S.A., Rapporteur: Kristina Dunder

Evenity - Romosozumab -
EMEA/H/C/004465/II/0024
UCB Pharma S.A., Rapporteur: Kristina Dunder

Gilenya - Fingolimod -
EMEA/H/C/002202/II/0088
Novartis Europharm Limited, Rapporteur: Alexandre Moreau

LUTATHERA - Lutetium (177Lu) oxodotreotide -
EMEA/H/C/004123/II/0048, Orphan
Advanced Accelerator Applications, Rapporteur: Janet Koenig

Nucala - Mepolizumab -
EMEA/H/C/003860/II/0066/G
GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) -
EMEA/H/C/005808/II/0063/G
Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt

OXERVATE - Cenegermin -
EMEA/H/C/004209/II/0059, Orphan
Dompe farmaceutici S.p.A., Rapporteur: Maria Concepcion Prieto Yerro

Ozempic - Semaglutide -
EMEA/H/C/004174/II/0044/G
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

Rotarix - Rotavirus vaccine (live, oral) -
EMEA/H/C/000639/II/0133/G
GlaxoSmithKline Biologicals S.A., Rapporteur: Christophe Focke

SomaKit TOC - Edotreotide -
EMEA/H/C/004140/II/0028, Orphan
Advanced Accelerator Applications, Rapporteur: Maria Concepcion Prieto Yerro

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) -
EMEA/H/C/005791/II/0123/G
Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) -

EMEA/H/C/005791/II/0124/G
Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus

TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0032
Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus

TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0033
Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus

Vazkepa - Icosapent ethyl - EMEA/H/C/005398/II/0023/G
Amarin Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise

Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0017, Orphan
Argenx, Rapporteur: Thalia Marie Estrup Blicher

Wegovy - Semaglutide - EMEA/H/C/005422/II/0020/G
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

WS2550
Aldara-EMEA/H/C/000179/WS2550/0089
Zyclara-EMEA/H/C/002387/WS2550/0031
Viatris Healthcare Limited, Lead Rapporteur: Ewa Balkowiec Iskra

WS2642/G
Riltrava Aerosphere-EMEA/H/C/005311/WS2642/0011/G
Trixeo Aerosphere-EMEA/H/C/004983/WS2642/0018/G
AstraZeneca AB, Lead Rapporteur: Finbarr Leacy

WS2659/G
Riarify-EMEA/H/C/004836/WS2659/0032/G
Trimbow-EMEA/H/C/004257/WS2659/0039/G
Trydonis-EMEA/H/C/004702/WS2659/0036/G
Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig

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

Biktarvy - Bictegravir / Emtricitabine /

Tenofovir alafenamide - EMEA/H/C/004449/II/0059

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, "Update of sections 4.4, 4.5, 4.6, 5.1 and 5.2 of the SmPC in order to update information on pregnancy and update the dosing recommendations with polyvalent caution-containing products for pregnant patients based on final results from GS-US-380-5310; A Phase 1b, Open-label study to Evaluate the Pharmacokinetics (PK), Safety and Efficacy of B/F/TAF in HIV-1 infected, Virologically Suppressed, Pregnant Women in their Second and Third Trimesters; study GS-US-380-3909 and the Antiretroviral Pregnancy Registry. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes."

Cetrotide - Cetrorelix - EMEA/H/C/000233/II/0091

Merck Europe B.V., Rapporteur: Martina Weise, "Type II C.I.4 To update section 6.6 of the SmPC to amend the administered dose of cetrorelix from 'dose of at least 0.23 mg' to 'dose of 0.21 mg' based on the representative dose study conducted to evaluate the administered dose after reconstitution."

Erleada - Apalutamide - EMEA/H/C/004452/II/0036

Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, "- to update the method of administration for Erleada 60 mg film-coated tablets provided in the SmPC section 4.2 (and related section of the PL) to allow patients to take tablets with non-fizzy beverage or soft food, or by a nasogastric feeding tube; hence, aligning the vehicles for administration between the two Erleada strengths (i.e. 60 mg and 240 mg).
The MAH took the opportunity to introduce the following editorial changes:
- Irish country code has been added in the contact information of the local representative;
- New link for reporting of adverse events in section 4.8 of the SmPC and section 4 of the PL has been provided."

Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0152

Merck Sharp & Dohme B.V., Rapporteur: Paolo

Gasparini, "Update of section 5.1 of the SmPC in order to update efficacy information based on interim results from study KEYNOTE-564; this is a phase 3, randomized, double-blind, placebo-controlled clinical trial of pembrolizumab as monotherapy in the adjuvant treatment of renal cell carcinoma post nephrectomy."	
Kisqali - Ribociclib - EMEA/H/C/004213/II/0049 Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.2 and 4.4 of the SmPC in order to update the ECG monitoring recommendations in patients with advanced or metastatic breast cancer (aBC) treated with ribociclib based on the continuing and comprehensive assessments of QT/QTcF effects in patients with cancer from studies A2301 (MONALEESA-2), E2301 (MONALEESA-7) and F2301 (MONALEESA-3). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes."	
NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0066 Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-101 Part 2 listed as a category 3 study in the RMP (MEA 010.2). This is a 2-part, phase 1/2, randomized, observer-blinded study to evaluate the safety and immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with or without Matrix-M adjuvant in healthy participants."	
Oncaspar - Pegaspargase - EMEA/H/C/003789/II/0053/G Les Laboratoires Servier, Rapporteur: Alexandre Moreau, "A grouped application comprised of a Type II variation and a Type IB variation, as follows: - Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to add 'Hepatic veno-occlusive disease (VOD)' as a warning and new safety risk, following an internal signal evaluation. The Package Leaflet is updated accordingly. - Type IB (C.I.3.z): Update of sections 4.4 and 4.8 of the SmPC in order to add 'Antithrombin	

III decreased' to the list of adverse drug reactions with frequency 'Very common' and to update the frequency of 'Neutrophil count decreased' from 'Not known' to 'Very common', following the outcome of the PAM procedure P46/008. The Package Leaflet is updated accordingly."

Onivyde pegylated liposomal - Irinotecan hydrochloride trihydrate - EMEA/H/C/004125/II/0035, Orphan

Les Laboratoires Servier, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to add "Interstitial lung disease (including pneumonitis)" 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."

Opfolda - Miglustat - EMEA/H/C/005695/II/0010/G

Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "A grouped application comprised of two Type II variations, as follows:
C.I.4: Update of section 5.2 of the SmPC in order to update drug metabolism information based on the final report of the in vitro transporter study 8496647 as well as the population PK study AMC0206. Study 8496647 was for the evaluation of miglustat as a substrate and inhibitor of a panel of human drug transporters.
C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update reproductive and developmental toxicology information based on reassessment of non-clinical data.
In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0052/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application comprised of 2 Type II Variations, as follows:
C.I.4: Update of section 4.5 of the SmPC in order to include more detailed dosing information within the clinical comments for the drug-drug interactions (DDIs) related to venetoclax, apixaban, saxagliptin and

cariprazine and to remove the reference to the dabigatran SmPC in the dabigatran DDI clinical comments. C.I.4: Update of section 5.2 of the SmPC in order to include additional information related to the rosuvastatin DDI, based on the final results from study C4671052; this is a phase 1, randomized, fixed sequence, multiple dose, open-label study to estimate the effect of nirmatrelvir/ritonavir on rosuvastatin pharmacokinetics in healthy adult participants."	
Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0030 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Slipped Capital Femoral Epiphysis/ Slipped Upper Femoral Epiphysis (SCFE/SUFE) in Paediatric Patients' and to add it to the list of adverse drug reactions (ADRs) with frequency 'Common', based on a safety topic report. The Package Leaflet is updated accordingly."	
Revestive - Teduglutide - EMEA/H/C/002345/II/0064, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to add the recommendation of upper GI endoscopy or other imaging before and during the treatment with teduglutide per clinical discretion as a precaution to 'Gastrointestinal neoplasia including hepatobiliary tract' based on the cumulative review of literature. In addition, the MAH took the opportunity to introduce minor editorial changes and to bring the PI in line with the latest QRD template."	
Reyataz - Atazanavir - EMEA/H/C/000494/II/0139 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.3 and 4.5 of the SmPC in order to reclassify the drug-drug-interaction information to a contraindication for the co-administration with antineoplastic agents (encorafenib and ivosidenib), as well as, for the co-administration with the anticonvulsant agents (carbamazepine, phenobarbital and phenytoin); based on post-marketing data and literature. The Package	

Leaflet is updated accordingly."

Scemblix - Asciminib - EMEA/H/C/005605/II/0013/G, Orphan

Novartis Europharm Limited, Rapporteur: Janet Koenig, "Grouped application comprising three type II variations as follows:
C.I.4 - Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with P-gp Substrates based on the final results from studies 2301078, CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.
C.I.4 - Update of section 4.8 of the SmPC in order to update the Summary of the safety profile and safety information based on final results from study CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.
C.I.4 - Update of section 5.1 of the SmPC in order to update safety information based on final results from study CABL001A2301.
The Package Leaflet is updated accordingly."

Uptravi - Selexipag - EMEA/H/C/003774/II/0042/G

Janssen-Cilag International N.V., Rapporteur: Martina Weise, "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 multicenter, open-label, single-arm study to evaluate the safety, tolerability and 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 multicenter, 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."

Veklury - Remdesivir - EMEA/H/C/005622/II/0056
Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update antiviral activity information based on the final results from the nonclinical study PC-540-2048 on the antiviral activity of remdesivir against SARS-CoV-2 Omicron XBF, XBB.1.16, FL.22, XBB.2.3.2, EG.5.1, EG.1.2, BA.2.86 and XBB.1.9.2 subvariants."

VELCADE - Bortezomib - EMEA/H/C/000539/II/0102
Janssen-Cilag International N.V., Rapporteur: Paolo Gasparini, "Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy and preclinical clinical information following EMA/CHMP/SWP/74077/2020 rev. 1* dated 30 March 2023. 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 10.3."

Venclyxto - Venetoclax - EMEA/H/C/004106/II/0048
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update safety and efficacy information on paediatric population following the assessment of procedure P46/018 based on final results from study M13-833 - A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients With Relapsed or Refractory Malignancies. The Package Leaflet is updated accordingly."

Verzenios - Abemaciclib - EMEA/H/C/004302/II/0033
Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC

in order to include the final OS data based on final results from study MONARCH3 (I3Y-MC-JPBM). This is a randomized, double-blind, placebo-controlled, phase 3 trial of nonsteroidal aromatase inhibitors (anastrozole or letrozole) plus LY2835219, a CDK4/6 Inhibitor, or placebo in postmenopausal women with hormone receptor-positive, HER2-Negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting."

WS2612
Finlee-EMEA/H/C/005885/WS2612/0003
Mekinist-
EMEA/H/C/002643/WS2612/0062
Spexotras-
EMEA/H/C/005886/WS2612/0001
Tafinlar-
EMEA/H/C/002604/WS2612/0065
Novartis Europharm Limited, Lead Rapporteur: Peter Mol, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Tumour lysis syndrome and add Tumour lysis syndrome to the list of adverse drug reactions (ADRs) with frequency Not known based on the review of MAH global database, clinical trials database and literature. 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 10.3 and to introduce editorial changes."

WS2650
Imfinzi-EMEA/H/C/004771/WS2650/0065
IMJUDO-
EMEA/H/C/006016/WS2650/0006
AstraZeneca AB, Lead Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2 and 4.4 of the SmPC in order to simplify current dosing recommendations."

B.6.10. CHMP-PRAC assessed procedures

Akeega - Niraparib / Abiraterone acetate - EMEA/H/C/005932/II/0003
Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of adverse drug reactions and to update information from MAGNITUDE study based on

final results from study 64091742PCR3001 (MAGNITUDE) listed as a PAES in the Annex II. This is a phase 3 randomized, placebo-controlled, double-blind, multicenter study which assessed the efficacy and safety of niraparib 200 mg in combination with AA 1,000 mg once daily plus prednisone or prednisolone 10 mg daily (AAP)a, compared with placebo plus AAP in men with mCRPC and HRR gene alterations, approximately half of whom had BRCA gene alterations and comprised the prespecified BRCA subgroup.
The Annex II and Package Leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."

Eylea - Aflibercept - EMEA/H/C/002392/II/0090

Bayer AG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault, "Update of sections 4.8 and 5.1 of the SmPC in order to update safety and clinical information based on results from studies PULSAR (20968) and PHOTON (21091).
PULSAR (20968) is an ongoing pivotal Phase 3 study to investigate the efficacy and safety of HD aflibercept at treatment intervals of 12 weeks and longer for indication neovascular age-related macular degeneration (nAMD).
PHOTON (21091), is an ongoing pivotal Phase 2/3 study to investigate the efficacy and safety of HD aflibercept at treatment intervals of 12 weeks and longer for indication Diabetic Macular Edema (DME).
The Package Leaflet is updated accordingly. The RMP version 34.1 has also been submitted. In addition, the MAH took the opportunity to implement an editorial update in section 6.6 of the SmPC to align the text with other similar products. "

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, multicenter, 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."

Orkambi - Lumacaftor / Ivacaftor - EMEA/H/C/003954/II/0088

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Eamon O Murchu, "Submission of the final report from study VX19-809-124 (study 124), listed as a category 3 study in the RMP. This is a Phase 3, open-label, rollover study to evaluate the long-term safety and tolerability of lumacaftor/ivacaftor in cystic fibrosis subjects homozygous for F508del who were 1 to <2 years of age at treatment initiation and who completed the Safety Follow Up (SFU) visit in study 122 (Part B) or were lumacaftor/ivacaftor naïve. The RMP version 11.5 has also been submitted."

Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0023/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Gabriele Maurer, "A grouped application comprised of 2 Type II variations and 1 Type IA variation, as follows:
Type II variation (C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information, based on the final report from study WO40324 (FeDeriCa) listed as a category 3 study in the RMP. This is a phase 3, randomized, multicenter, open-label, two-arm study to evaluate the pharmacokinetics, efficacy, and safety of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in combination with chemotherapy in patients with HER2-positive early breast cancer.
Type II variation (C.I.4): Update of section 4.8 of the SmPC in order to only present specific Phesgo safety data by updating the summary of safety profile and the tabulated list of adverse reactions to reflect this information. The Package Leaflet is updated accordingly.
Type IA variation (A.6): To change the ATC

code of pertuzumab and trastuzumab from L01XY02 to L01FY01.
The RMP version 3.0 has also been submitted.
In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to update the list of local representatives in the Package Leaflet."

B.6.11. PRAC assessed procedures

PRAC Led
Amlodipine-Valsartan Mylan - Amlodipine / Valsartan - EMEA/H/C/004037/II/0021
Mylan Pharmaceuticals Limited, Generic, Generic of Exforge, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of an updated RMP version 4.0 in order to align the safety concerns with the latest version of RMP for Amlodipine/Valsartan available in the public domain and to bring the RMP in line with the latest RMP template."

PRAC Led
ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0018, Orphan
Swedish Orphan Biovitrum AB (publ), PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 2.1 in order to revise the category 3 PASS Sobi.PEGCET-301 and Sobi.PEGCET-302."

PRAC Led
Avamys - Fluticasone furoate - EMEA/H/C/000770/II/0051/G
GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Grouped application comprising two type II variations as follows:
C.I.11.b – Submission of an updated RMP version 12 in order to remove Headache, Nasal events (including: epistaxis, nasal ulceration, nasal septum perforation and other nasal events), Hypersensitivity, Cataract and glaucoma as Important Identified Risks; to remove Taste and smell disorders, Pyrexia, Systemic corticosteroids effect: adrenal suppression, Systemic corticosteroid effect: growth retardation, Psychiatric effects as

Important Potential Risks and to remove Use in pregnancy and lactation, Off-label use (sinusitis and children < 6 years of age) as missing information. C.I.11.b – Submission of an updated RMP version 12 in order to remove targeted follow up questionnaires. In addition, the MAH took this opportunity to align the RMP template with GVP Module V Revision 2.”	
PRAC Led **Beovu - Brolucizumab - EMEA/H/C/004913/II/0028** Novartis Europharm Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, “Update of section 4.8 of the SmPC in order to add ‘Scleritis’ to the list of adverse drug reactions (ADRs) with frequency ‘Not known’, following the recommendation by PRAC in the outcome for the signal assessment of Scleritis. The Package Leaflet is updated accordingly.”	
PRAC Led **Cholestagel - Colesevelam - EMEA/H/C/000512/II/0053** CHEPLAPHARM Arzneimittel GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, “Submission of an updated RMP version 2.0 in order to remove important identified and potential risks, as well as missing information to bring it in line with GVP module V. Additionally, epidemiological data on indication and target population, clinical data and post-marking exposure data was updated.”	
PRAC Led **Efient - Prasugrel - EMEA/H/C/000984/II/0037** Substipharm, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, “Submission of an updated RMP version 13 in order to remove of a region-specific additional risk-minimisation activity following previous PSUSA procedure (EMEA/H/C/PSUSA/00002499/202102), as well as to align content and format with new requirements according to GVP Module V Rev. 2. In addition, the MAH took the opportunity to	

update Annex II of the PI and to update the list of local representatives in the Package Leaflet."

PRAC Led

Lysodren - Mitotane - EMEA/H/C/000521/II/0030

HRA Pharma Rare Diseases, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Update of section 4.4 of the SmPC in order amend an existing warning on hepatic impairment based on a cumulative review of cases with increase of transaminases >5 ULN and the outcome of these elevations after mitotane discontinuation, following the request by PRAC in the PSUSA/00002075/202304."

PRAC Led

Moventig - Naloxegol - EMEA/H/C/002810/II/0043

Kyowa Kirin Holdings B.V., PRAC Rapporteur: Eamon O Murchu, PRAC-CHMP liaison: Finbarr Leacy, "Submission of the final report from the PASS study D3820R0008 listed as a category 3 study in the RMP. This is a US post-marketing, comparative, observational study to evaluate the cardiovascular safety of Naloxegol in patients with non-cancer pain in comparison to other treatments for opioid induced constipation. The RMP version 9.0 has also been submitted."

PRAC Led

Remicade - Infliximab - EMEA/H/C/000240/II/0247

Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 22.1 in order to remove reference to the immunogenicity substudy as part of protocol REMICADEPIB4002 in Part III. The MAH proposes to discontinue the Dutch portion of the immunogenicity substudy, which is part of protocol REMICADEPIB4002."

PRAC Led

VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMEA/H/C/005754/II/0010

Sanofi Pasteur, PRAC Rapporteur: Jana Lukacisinova, PRAC-CHMP liaison: Petr Vrbata, "Submission of an updated RMP version 2.1 in

order to update the list of safety concerns with the removal of Vaccine Associated Enhanced Disease (VAED) including Vaccine Associated Enhanced Respiratory Disease (VAERD) as an important potential risk. In addition, the MAH is taking the opportunity to change anaphylactic reaction risk characterisation from potential to identified risk, to update clinical trial exposure (VAT00008 open label extension), to update signal detection and literature screening strategy, to update the CSR due dates for VAT0002 and VAT00008, to remove category 3 study VAT00006, to cancel category 3 study VAT00007, to discontinue category 3 study VAT00012, to cancel category 3 study VBA00003 following availability of UK HSA data and to update the adverse events of special interest (AESI) preferred terms list."

PRAC Led
WS2671
Finlee-EMEA/H/C/005885/WS2671/0005
Spexotras-
EMEA/H/C/005886/WS2671/0004
Tafinlar-
EMEA/H/C/002604/WS2671/0067
Novartis Europharm Limited, Lead PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Eva Skovlund, "Update of section 4.8 of the SmPC for Tafinlar, Finlee and Spexotras in order to add 'Atrioventricular (AV) block' and 'Bundle branch block' to the list of adverse drug reactions (ADRs), following the PRAC recommendation in the PSUR for Mekinist (PSUSA/00010262/202305). The Package Leaflet is updated accordingly."

B.6.12. CHMP-CAT assessed procedures

ROCTAVIAN - Valoctocogene roxaparvovec - EMEA/H/C/005830/II/0010, Orphan, ATMP
BioMarin International Limited, Rapporteur: Violaine Closson Carella, CHMP Coordinator: Jean-Michel Race, "Submission of the final report from study BMN270-302 listed as a category 3 study in the RMP. This is a phase 3 open-label, single-arm study to evaluate the efficacy and safety of BMN 270, an adeno-associated virus vector–mediated gene transfer of human factor VIII at a dose of 4E13 vg/kg in

hemophilia A patients with residual FVIII levels ≤ 1 IU/dL receiving prophylactic FVIII infusions."

WS2646
Tecartus-
EMEA/H/C/005102/WS2646/0042
Yescarta-
EMEA/H/C/004480/WS2646/0073
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus

B.6.13. CHMP-PRAC-CAT assessed procedures

WS2632
Tecartus-
EMEA/H/C/005102/WS2632/0041
Yescarta-
EMEA/H/C/004480/WS2632/0072
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, Lead PRAC Rapporteur: Karin Erneholm, "Update of sections 4.2 and 5.1 of the SmPC in order to update the safety monitoring timelines based on data from clinical studies, post-marketing studies and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to sections 2.2, 6.3 and 6.6 and to update sections 4.4 and 4.5 of the SmPC to align the language across both products."

B.6.14. PRAC assessed ATMP procedures

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

WS2633/G
Hexacima-
Hexyon-
Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

WS2639
Glyxambi-
EMEA/H/C/003833/WS2639/0059
Jentadueto-
EMEA/H/C/002279/WS2639/0072
Trajenta-
EMEA/H/C/002110/WS2639/0054

Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt

WS2640
Infanrix hexa-
EMEA/H/C/000296/WS2640/0343
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2645/G
Avamys-
EMEA/H/C/000770/WS2645/0052/G
Elebrato Ellipta-
EMEA/H/C/004781/WS2645/0039/G
Relvar Ellipta-
EMEA/H/C/002673/WS2645/0066/G
Revinty Ellipta-
EMEA/H/C/002745/WS2645/0063/G
Trelegy Ellipta-
EMEA/H/C/004363/WS2645/0036/G
GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy

WS2648/G
Mircera-
EMEA/H/C/000739/WS2648/0098/G
NeoRecormon-
EMEA/H/C/000116/WS2648/0123/G
Roche Registration GmbH, Lead Rapporteur: Martina Weise

WS2654
Aerius-EMEA/H/C/000313/WS2654/0106
Azomyr-
EMEA/H/C/000310/WS2654/0110
Neoclarityn-
EMEA/H/C/000314/WS2654/0104
Organon N.V., Duplicate, Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke, "To update section 4.4 of the SmPC and section 2 of the package leaflet to correct the content of benzyl alcohol and the content of propylene glycol to comply with the Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use".
In addition, the MAH has taken the opportunity to update section 4.8 of the SmPC and section 4 of the package leaflet to correct the link to QRD Appendix V for the national reporting system.
Furthermore, the MAH has taken the opportunity to update the package leaflet with

details of the local representative for Austria. Lastly, the MAH has taken the opportunity to introduce minor editorial corrections to the PI in the following language: CS.”	
WS2657 **HyQvia-EMEA/H/C/002491/WS2657/0097** **Kiovig-EMEA/H/C/000628/WS2657/0127** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus	
WS2660/G **Entresto-EMEA/H/C/004062/WS2660/0059/G** **Neparvis-EMEA/H/C/004343/WS2660/0057/G** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt	
WS2674 **Nuwiq-EMEA/H/C/002813/WS2674/0060** **Vihuma-EMEA/H/C/004459/WS2674/0042** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus	
WS2675 **Hefiya-EMEA/H/C/004865/WS2675/0053** **Hyrimoz-EMEA/H/C/004320/WS2675/0052** Sandoz GmbH, Duplicate, Duplicate of Hyrimoz, Lead Rapporteur: Christian Gartner	

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

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.

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