09 October 2023
EMA/CHMP/421839/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 09-12 October 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

09 October 2023, 09:00 – 19:30, virtual meeting/room 1C

10 October 2023, 08:30 – 19:30, virtual meeting/room 1C

11 October 2023, 08:30 – 19:30, virtual meeting/room 1C

12 October 2023, 08:30 – 13:00, virtual meeting/room 1C

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 09-12 October 2023. See October 2023 CHMP minutes (to be published post November 2023 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 09-12 October 2023.

1.3. Adoption of the minutes

CHMP minutes for 11-14 September 2023.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. sparsentan - Orphan - EMEA/H/C/005783

Vifor France; for the treatment of primary immunoglobulin A nephropathy (IgAN).

Scope: Oral explanation

Action: Oral explanation to be held on 11 October 2023 at 11:00

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

2.2. Re-examination procedure oral explanations

2.2.1. Albrioza - sodium phenylbutyrate / ursodoxicoltaurine - Orphan - EMEA/H/C/005901

Amylyx Pharmaceuticals EMEA B.V.; treatment of amyotrophic lateral sclerosis (ALS)

Scope: Oral explanation

Action: Oral explanation to be held on 10 October 2023 at 14:00

Participation of patient representatives

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

Opinion on 22.06.2023. List of Outstanding Issues adopted on 23.02.2023, 10.11.2022. List

of Questions adopted on 23.06.2022.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Imfinzi - durvalumab - EMEA/H/C/004771/II/0057

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi as treatment of adults with unresectable hepatocellular carcinoma (uHCC), based on final results from study D419CC00002 (HIMALAYA); this was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma (HIMALAYA). 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 9, Succession 1 of the RMP has also been submitted. In addition, the PI is brought in line with the latest QRD template version 10.3."

Scope: Oral explanation

Action: Oral explanation to be held on 11 October 2023 at 16:00

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

See 5.1

2.3.2. Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0038, Orphan

Advanz Pharma Limited

Rapporteur: Carolina Prieto Fernandez

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from studies 747-302 and 747-401, listed as specific obligations in the Annex II, as well as results from real-world evidence (RWE) studies evaluating analyses of hepatic clinical outcomes. Study 747-302 is a confirmatory double-blind, randomised, placebo-controlled multicentre study investigating the clinical benefit associated with Ocaliva treatment in patients with PBC who are either unresponsive or intolerant to UDCA treatment based on clinical endpoints, while study 747-401 is a double-blind, randomised, placebo-controlled study evaluating the safety and pharmacokinetics of Ocaliva in patients with PBC and moderate to severe hepatic impairment. The Annex II and Package Leaflet are updated accordingly."

Scope: Oral explanation

Action: Oral explanation to be held on 10 October 2023 at 16:00

Request for Supplementary Information adopted on 30.03.2023.

See 9.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. vamorolone - Orphan - EMEA/H/C/005679

Santhera Pharmaceuticals (Deutschland) GmbH; treatment of Duchenne muscular dystrophy (DMD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 23.02.2023.

3.1.2. elranatamab - PRIME - Orphan - EMEA/H/C/005908

Pfizer Europe MA EEIG; Treatment of adult patients with relapsed or refractory multiple myeloma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 25.05.2023.

3.1.3. gadopiclenol - EMEA/H/C/005626

for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.04.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

3.1.4. pegzilarginase - Orphan - EMEA/H/C/005484

Immedica Pharma AB; treatment of hyperargininemia

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 15.12.2022.

3.1.5. rezafungin - Orphan - EMEA/H/C/005900

Mundipharma GmbH; treatment of invasive candidiasis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 15.12.2022.

3.1.6. fezolinetant - EMEA/H/C/005851

treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.06.2023. List of Questions adopted on 26.01.2023.

3.1.7. gadopiclenol - EMEA/H/C/006172

for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.04.2023, 10.11.2022.

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

3.2.1. concizumab - EMEA/H/C/005938

routine prophylaxis to prevent or reduce the frequency of bleeding in patients with: haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors ≥ 12 years of age; haemophilia B (congenital factor IX deficiency) with FIX inhibitors of any age

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

3.2.2. dabigatran etexilate - EMEA/H/C/005922

prevention of venous thromboembolic events

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 25.05.2023, 23.02.2023. List of Questions adopted on 23.06.2022.

3.2.3. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165

indicated for in vitro labelling of kits for radiopharmaceutical preparation

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.12.2021.

3.2.4. epinephrine - EMEA/H/C/006139

Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.02.2023.

3.2.5. dopamine hydrochloride - PUMA - EMEA/H/C/006044

Treatment of hypotension in neonates, infants and children

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.03.2023.

3.2.6. omaveloxolone - Orphan - EMEA/H/C/006084

Reata Ireland Limited; Treatment of Friedreich’s ataxia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

3.2.7. pegcetacoplan - EMEA/H/C/005954

Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

3.2.8. toripalimab - EMEA/H/C/006120

Combination treatment for metastatic or recurrent locally advanced nasopharyngeal carcinoma and for metastatic or recurrent oesophageal squamous cell carcinoma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.03.2023.

3.2.9. etrasimod - EMEA/H/C/006007

treatment of patients with moderately to severely active ulcerative colitis (UC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.03.2023.

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

3.3.1. liquid ethanolic extract 30 per cent (W/W) of allium cepa fresh bulb and citrus limon fresh fruit / dry aqueous extract of paullinia cupana seed / dry hydroethanolic extract of theobroma cacao seed - EMEA/H/C/004155

treatment of alopecia areata in children and adolescents

Scope: List of questions

Action: For adoption

3.3.2. fruquintinib - EMEA/H/C/005979

treatment of metastatic colorectal cancer

Scope: List of questions

Action: For adoption

3.3.3. meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165

indicated for active immunisation to prevent invasive disease caused by Neisseria meningitidis groups A, B, C, W, and Y

Scope: List of questions

Action: For adoption

3.3.4. ustekinumab - EMEA/H/C/005918

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

Scope: List of questions

Action: For adoption

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

3.4.1. arpraziquantel - Article 58 - EMEA/H/W/004252

treatment of schistosomiasis in children

Scope: Letter by the applicant dated 22.09.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

Action: For adoption

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 30.03.2023.

3.4.2. bimatoprost - EMEA/H/C/005916

indicated for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma (OAG) or ocular hypertension (OHT) who are unsuitable for topical IOP-lowering medications.

Scope: Letter by the applicant dated 29.09.2023 requesting an extension to the clock stop to respond to the list of questions adopted in July 2023.

Action: For adoption

List of Questions adopted on 20.07.2023.

3.4.3. eribulin - EMEA/H/C/006134

treatment of breast cancer and liposarcoma

Scope: Letter by the applicant dated 22.09.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

Action: For adoption

List of outstanding issues adopted on 14.09.2023. List of Questions adopted on 23.02.2023.

3.4.4. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/006053

indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

Scope: Letter by the applicant dated 29.09.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023

The CHMP agreed to the request by via written procedure on 03 October 2023.

Action: For information

List of outstanding issues adopted on 14.09.2023. List of Questions adopted on 26.04.2023.

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

3.5.1. Albrioza - sodium phenylbutyrate / ursodoxicoltaurine - Orphan - EMEA/H/C/005901

Amylyx Pharmaceuticals EMEA B.V.; treatment of amyotrophic lateral sclerosis (ALS)

Scope: Opinion

Action: For adoption

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

Opinion on 22.06.2023. List of Outstanding Issues adopted on 23.02.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

See 2.2

Participation of patient representatives

3.5.2. 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

Scope: List of experts for SAG

Action: For adoption

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

Opinion adopted on 20.07.2023. List of Outstanding Issues adopted on 25.05.2023, 23.02.2023. List of Questions adopted on 15.09.2022.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. trastuzumab duocarmazine - EMEA/H/C/005654

treatment of HER2 (Human Epidermal Growth Factor Receptor 2)-positive metastatic breast cancer

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on

10.11.2022.

3.7.2. sugammadex - EMEA/H/C/006115

reversal of neuromuscular blockade induced by rocuronium or vecuronium

Scope: Withdrawal of marketing authorisation application

Action: For information

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

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. Vyepti - eptinezumab - EMEA/H/C/005287/X/0011

H. Lundbeck A/S

Rapporteur: Jan Mueller-Berghaus

Scope: "Line extension application to add a new strength (300 mg concentrate for solution for infusion)."

Action: For adoption

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. Entyvio - vedolizumab - EMEA/H/C/002782/X/0075

Takeda Pharma A/S

Rapporteur: Paolo Gasparini

Scope: quality

Action: For adoption

List of Questions adopted on 26.04.2023.

4.2.2. Eylea - aflibercept - EMEA/H/C/002392/X/0084/G

Bayer AG

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

Scope: "Extension application to add a new strength of Aflibercept 114.3 mg/ml solution for injection (in a vial), to be indicated in adults for the (1) treatment of neovascular (wet) age-related macular degeneration (nAMD) and (2) visual impairment due to diabetic macular oedema (DME), grouped with a type II variation (B.II.g.2) to introduce a post-approval change management protocol to add a new presentation for Aflibercept solution 114.3 mg/ml in a single-use pre-filled syringe for intravitreal injection."

Action: For adoption

List of Questions adopted on 22.06.2023.

4.2.3. Kalydeco - ivacaftor - EMEA/H/C/002494/X/0115/G

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Monica Martinez Redondo

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

Action: For adoption

List of Questions adopted on 25.05.2023.

4.2.4. Skyrizi - risankizumab - EMEA/H/C/004759/X/0033

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy

Scope: "Extension application to add a new strength of 90 mg solution for injection in pre-filled syringe, indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy."

Action: For adoption

List of Questions adopted on 20.07.2023.

4.2.5. Talzenna - talazoparib - EMEA/H/C/004674/X/0015/G

Pfizer Europe MA EEIG

Rapporteur: Filip Josephson, Co-Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application for Talzenna to introduce a new strength of 0.1 mg hard capsules, grouped with a type II variation (C.I.6.a) in order to extend the indication for Talzenna in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), based on final results from study C3441021 (TALAPRO-2) as well as supplemental data from study C3441006 (TALAPRO-1). Study C3441021 (TALAPRO-2) is a randomized, double-blind, placebo-controlled, phase 3 study of talazoparib in combination with enzalutamide in mCRPC, while study C3441006 (TALAPRO-1) is a phase 2, open-label, response rate study of talazoparib in men with DNA repair defects and mCRPC who previously received taxane-based chemotherapy and progressed on at least one novel hormonal agent. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.5, 4.7, 4.8, 5.1, 5.2, 6.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

List of Questions adopted on 22.06.2023.

4.2.6. Viagra - sildenafil - EMEA/H/C/000202/X/0115

Upjohn EESV

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible film)."

Action: For adoption

List of Questions adopted on 26.01.2023.

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

4.3.1. 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

4.3.2. Menveo - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/X/0119

GSK Vaccines S.r.l

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection). The RMP (version 11.0) is updated in accordance."

Action: For adoption

4.3.3. 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

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

No items

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

No items

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

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

Takeda Pharma A/S

Rapporteur: Peter Mol, PRAC Rapporteur: Menno van der Elst

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."

Action: For adoption

5.1.2. Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0012

Pfizer Europe MA EEIG

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of indication to include infants, children and adolescents from 6 weeks to less than 18 years of age for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae, based on final results from studies B7471003, B7471011, B7471012, B7471013 and B7471014. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

5.1.3. Beyfortus - nirsevimab - EMEA/H/C/005304/II/0005

AstraZeneca AB

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of children up to 24 months of age who remain vulnerable to severe Respiratory Syncytial Virus (RSV) disease through their second RSV season for Beyfortus, based on interim results from studies D5290C00005 and D5290C00008.
Study D5290C00005 (MEDLEY) is a Phase II/III, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus in high-risk children. Study D5290C00008 (MUSIC) is a Phase II, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetics, and occurrence of antidrug antibody for Beyfortus in immunocompromised children ≤ 24 Months of Age.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 2.1 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 20.07.2023.

5.1.4. Bimzelx - bimekizumab - EMEA/H/C/005316/II/0020

UCB Pharma S.A.

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

5.1.5. Brukinsa - zanubrutinib - EMEA/H/C/004978/II/0014

BeiGene Ireland Ltd

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include in combination with obinutuzumab treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic treatments for Brukinsa; based on results from studies BGB-3111-212 and BGB-3111-GA101-001. BGB-3111-212 is an ongoing international, Phase 2, open-label, randomized (2:1), active control study of zanubrutinib plus obinutuzumab (Arm A) versus obinutuzumab monotherapy (Arm B) in patients with R/R FL. The primary efficacy endpoint is overall response rate (ORR); while BGB-3111-GA101-001 is a Phase 1b Study to Assess Safety, Tolerability and Antitumor Activity of the Combination of BGB-3111 with

Obinutuzumab in Subjects with B-Cell Lymphoid Malignanciesa. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. 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 22.06.2023.

5.1.6. Evkeeza - evinacumab - EMEA/H/C/005449/II/0011

Ultragenyx Germany GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include the treatment of paediatric patients with homozygous familial hypercholesterolaemia (HoFH) aged 5 years and older for Evkeeza, based on interim results from study R1500-CL-17100, as well as supportive information from an updated interim analysis of study R1500-CL-1719, and an extrapolation analysis (including population PK, population PK/PD, and simulation analyses). R1500-CL-17100 is an ongoing multicentre, three-part, single-arm, open-label study evaluating the efficacy, safety, and tolerability of evinacumab in paediatric patients aged ≥ 5 to 11 years with HoFH. 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 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder took the opportunity to introduce minor editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

5.1.7. Imfinzi - durvalumab - EMEA/H/C/004771/II/0057

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi as treatment of adults with unresectable hepatocellular carcinoma (uHCC), based on final results from study D419CC00002 (HIMALAYA); this was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma (HIMALAYA). 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 9, Succession 1 of the RMP has also been submitted. In addition, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

See 2.3

5.1.8. Jemperli - dostarlimab - EMEA/H/C/005204/II/0023

GlaxoSmithKline (Ireland) Limited

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include in combination with platinum-containing chemotherapy the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy, based on results from study 213361 (RUBY) Part 1, listed as a Specific Obligation in the Annex II; this is a phase 3, randomized, double-blind, multicenter study of dostarlimab (TSR-042) plus carboplatin-paclitaxel versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 3.0 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. 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 20.07.2023.

5.1.9. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0135

Merck Sharp & Dohme B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include in combination with chemotherapy the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastrooesophageal junction adenocarcinoma in adults based on study KEYNOTE-859, a randomized, double-blind phase 3 trial, evaluating Keytruda in combination with chemotherapy compared to placebo in combination with chemotherapy for the first-line treatment of patients with HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 42.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023, 22.06.2023.

5.1.10. 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

5.1.11. Orencia - abatacept - EMEA/H/C/000701/II/0152

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include the prophylaxis of acute Graft versus Host Disease (aGvHD) in the adult and paediatric population for Orencia, based on final results from studies IM101311 - Abatacept Combined With a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis and IM101841 - Overall Survival In 7/8 HLA-Matched Hematopoietic Stem Cell Transplantation Patients Treated With Abatacept Combined With A Calcineurin Inhibitor And Methotrexate - An Analysis Of The Center For International Blood And Marrow Transplant Research (Cibmtr) Database. 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 and Labelling are updated in accordance. Version 28.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 30.03.2023.

5.1.12. Praluent - alirocumab - EMEA/H/C/003882/II/0078

Sanofi Winthrop Industrie

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of paediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia (HeFH) as an adjunct to diet, alone or in combination with other LDL-C lowering therapies, based on final results from study EFC14643 listed as a category 3 study in the RMP; this is a randomized, double-blind, placebo-controlled study followed by an open-label treatment period to evaluate the efficacy and safety of alirocumab in children and adolescents with heterozygous familial hypercholesterolemia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP is also submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023.

5.1.13. Prevymis - letermovir - Orphan - EMEA/H/C/004536/II/0033/G

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Kirsti Villikka

Scope: "Grouped application consisting of 1) Extension of indication to include treatment of prophylaxis of cytomegalovirus in kidney transplant recipients (KTR) for Prevymis, based on final results from study P002MK8228; this is a Phase III, randomized, double-blind, active comparator-controlled study to evaluate the efficacy and safety letermovir versus valganciclovir for the prevention of Human Cytomegalovirus (CMV) Disease in adult kidney transplant recipients. 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 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes; 2) Update of section 4.2 of the SmPC in order to update duration of treatment recommendation based on final results from study P040MK8228; this is a Phase III randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of letermovir (LET) prophylaxis when extended from 100 days to 200 days post-transplant in cytomegalovirus (CMV) seropositive recipients (R+) of an allogeneic hematopoietic stem cell transplant (HSCT)."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023.

5.1.14. Reblozyl - luspatercept - Orphan - EMEA/H/C/004444/II/0021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jo Robays

Scope: "Extension of indication to include treatment of adult patients with anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS), who may require RBC transfusions for Reblozyl, based on results from study ACE-536-MDS-002 (COMMANDS), an active-controlled, open-label, randomized Phase 3 study comparing the efficacy and safety of luspatercept vs epoetin alfa in adult subjects with anemia due to IPSS-R very low, low or intermediate risk MDS, who are ESA naïve and require RBC transfusions, and studies ACE-536-MDS-001(MEDALIST), ACE-536-MDS-004 , A536-03, A536-05 and ACE-536-LTFU-001; 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 2.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023.

5.1.15. Rubraca - rucaparib - EMEA/H/C/004272/II/0036

Zr Pharma& GmbH

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include maintenance treatment of adult patients with advanced (FIGO Stages III and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first-line platinum-based chemotherapy for Rubraca, based on interim results from study CO-338-087 (ATHENA); this is a Phase III, randomized, double-blind, dual placebo controlled study of rucaparib as monotherapy and in combination with nivolumab in patients with newly diagnosed EOC, FTC, or PPC who have responded to their first-line treatment (surgery and platinum-based chemotherapy). 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 6.3 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 14.09.2023, 25.05.2023, 15.12.2022.

5.1.16. Veyvondi - vonicog alfa - EMEA/H/C/004454/II/0030

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include "prophylactic treatment to prevent or reduce the frequency of bleeding episodes" for Veyvondi based on final results from study 071301 and interim results from study SHP677-304. Study 071301 is a prospective, phase 3, open-label, international multicenter study on efficacy and safety of prophylaxis with rVWF in severe von Willebrand disease; while study SHP677-304 is a phase 3B, prospective, open-label, uncontrolled, multicenter study on long term safety and efficacy of rVWF in paediatric and adult subjects with severe von Willebrand disease. As a consequence, sections 4.1, 4.2, 4.4, 5.1, 5.2, 6.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023.

5.1.17. Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0037

Merck Sharp & Dohme B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of the paediatric population (1 to 18 years of age) for Zinplava, based on final results from study MK-6072-001 (MODIFY III) listed as a category 3 study in the RMP; this is a phase 3, randomised, placebo-controlled, parallel-group, multi-site, double-blind trial evaluating the safety, tolerability, pharmacokinetics (PK) and efficacy of a single infusion of bezlotoxumab in paediatric participants from 1 to <18 years of age receiving antibacterial drug treatment for Clostridioides difficile infection (CDI). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 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 22.06.2023.

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/006340

in vitro diagnostic device for laboratory use, intended for the qualitative detection of BRAF V600 mutations in DNA extracted from formalin-fixed, paraffin-embedded human tissue.

Scope: Opinion

Action: For adoption

List of Questions adopted on 14.09.2023.

6.3.2. in vitro diagnostic medical device - EMEA/H/D/006373

detection of PD-L1 protein

Scope: List of Questions

Action: For adoption

6.3.3. in vitro diagnostic medical device - EMEA/H/D/006308

detection of HER2 antigen

Scope: Opinion

Action: For adoption

List of Questions adopted on 14.09.2023.

6.3.4. in vitro diagnostic medical device - EMEA/H/D/006310

immunohistochemical assay utilising an anti-PD-L1 monoclonal primary antibody

Scope: Opinion

Action: For adoption

List of Questions adopted on 14.09.2023.

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. resmetirom – H0006220

Treatment of adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with liver fibrosis

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. Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/S/0004

SIGA Technologies Netherlands B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber

Scope: "Annual reassessment of Marketing Authorisation for Tecovirimat SIGA (exceptional circumstances)."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023, 20.07.2023, 25.05.2023.

9.1.2. Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/II/0006

SIGA Technologies Netherlands B.V.

PRAC Led; PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise

Scope: "Change of specific obligation (exceptional circumstances) listed in Annex IIE."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023, 25.05.2023, 14.04.2023.

9.1.3. Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0038, Orphan

Advanz Pharma Limited

Rapporteur: Carolina Prieto Fernandez

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from studies 747-302 and 747-401, listed as specific obligations in the Annex II, as well as results from real-world evidence (RWE) studies evaluating analyses of hepatic clinical outcomes. Study 747-302 is a confirmatory double-blind, randomised, placebo-controlled multicentre study investigating the clinical benefit associated with Ocaliva treatment in patients with PBC who are either unresponsive or intolerant to UDCA treatment based on clinical endpoints, while study 747-401 is a double-blind, randomised, placebo-controlled study evaluating the safety and pharmacokinetics of Ocaliva in patients with PBC and moderate to severe hepatic impairment. The Annex II and Package Leaflet are updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 30.03.2023.

See 2.3

9.1.4. WS2409
Lixiana-EMEA/H/C/002629/WS2409/0042
Roteas-EMEA/H/C/004339/WS2409/0029

Daiichi Sankyo Europe GmbH

Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Nathalie Gault

Scope: "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC with available paediatric data based on final results from study DU176b-D-U312; this is a phase 3, open-label, randomised, multicentre, controlled trial to evaluate the pharmacokinetics and pharmacodynamics of edoxaban and to compare the efficacy and safety of edoxaban with standard-of-care anticoagulant therapy in paediatric subjects from birth to less than 18 years of age with confirmed venous thromboembolism (VTE). The Package Leaflet and Labelling are updated accordingly. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to bring the PI in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 30.03.2023.

9.1.5. Rebetol – ribavirin – EMEA/H/C/000246

Merck Sharp & Dohme B.V.; Rebetol is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. Rebetol is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) for paediatric patients (children 3 years of age and older and adolescents) not previously treated and without liver decompensation.

Rapporteur: Jean-Michel Race, Co-Rapporteur: Bruno Sepodes

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.6. Qarziba - dinutuximab beta - EMEA/H/C/003918/II/0043, Orphan

Recordati Netherlands B.V.

Rapporteur: Peter Mol

Scope: "Update of sections 4.1, 4.2 and 5.1 of the SmPC based on final results from study APN311-202V3 listed as a Specific Obligation in the Annex II of the Product Information. This is a Phase I/II dose schedule finding study of Ch14.18/CHO continuous infusion combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma. In addition, the MAH took the opportunity to update Annex II section E. The Package Leaflet is updated accordingly.

Action: For adoption

Request for Supplementary Information adopted on 26.04.2023, 15.09.2022.

9.1.7. Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0045

Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

Scope: "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen - adolescent boosting vaccination based on interim results from study 2019nCOV-301(IR) listed as a category 3 study in the RMP; this is a Phase 3, randomised, observer-blinded, placebo- controlled study to evaluate the efficacy, safety, and immunogenicity of SARS CoV-2 rS with Matrix-M adjuvant in adult participants ≥ 18 years of age with a paediatric expansion (12 to < 18 years of age). The Package Leaflet is updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

9.1.8. Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0058/G

Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

Scope: quality variation

Action: For adoption

9.1.9. Pepaxti - melphalan flufenamide - EMEA/H/C/005681/II/0002

Oncopeptides AB

Rapporteur: Peter Mol, Co-Rapporteur: Elita Poplavska, PRAC Rapporteur: Martin Huber

"Extension of indication to include treatment of patients with Multiple Myeloma who have received at least two prior lines of therapies for Pepaxti, based on final results from study OP-103 OCEAN; this is a randomized, open-label phase III study in patients with relapsed or refractory multiple myeloma following two to four lines of prior therapies and who were refractory to lenalidomide and the last line of 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 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Scope: Withdrawal of extension of indication application

Action: For information

Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 22.06.2023, 30.03.2023.

9.1.10. COVID-19 Vaccine (inactivated, adjuvanted) Valneva - SARS-CoV-2 virus, strain Wuhan hCoV-19/Italy/INMI1-isl/2020, inactivated - EMEA/H/C/006019

Valneva Austria GmbH; COVID-19 Vaccine (inactivated, adjuvanted) Valneva is indicated for

active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 to 50 years of age

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Alar Irs

Scope: Notification to withdraw the marketing authorisation

Action: For information

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

Novartis Europharm Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Peter Mol

Scope: "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))."

Action: For discussion

9.1.12. Degarelix Accord - degarelix acetate - EMEA/H/C/006048

Accord Healthcare S.L.U.; treatment of prostate cancer

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Tiphaine Vaillant

Scope: Third party intervention

Action: For information

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Firmagon

Opinion adopted on 20.07.2023. List of Outstanding Issues adopted on 26.04.2023. List of Questions adopted on 10.11.2022.

9.1.13. Pregabalin Sandoz GmbH – pregabalin – EMEA/H/C/004070

Sandoz GmbH; treatment of epilepsy and generalised anxiety disorder (GAD)

Rapporteur: Tomas Radimersky

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.14. Integrilin – eptifibatide – EMEA/H/C/00230

GlaxoSmithKline (Ireland) Limited; prevention of early myocardial infarction

Rapporteur: Alexandre Moreau, Co-Rapporteur: Paolo Gasparini

Scope: DHPC and communication plan

Action: For adoption

9.1.15. Translarna - ataluren - EMEA/H/C/002720/R/0071, Orphan

PTC Therapeutics International Limited

Re-examination Rapporteur: TBC, Re-examination Co-Rapporteur: TBC

Scope: Draft Re-examination timetable, appointment of re-examination rapporteurs

Action: For adoption

Opinion adoption on 14.09.2023. Request for Supplementary Information adopted on 25.05.2023.

9.1.16. Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan

GlaxoSmithKline (Ireland) Limited

Re-examination Rapporteur: TBC, Re-examination Co-Rapporteur: TBC

Scope: Draft Re-examination timetable, appointment of re-examination rapporteurs

Action: For adoption

Opinion adoption on 14.09.2023. Request for Supplementary Information adopted on 26.04.2023.

9.1.17. Pazenir – paclitaxel – EMEA/H/C/004441

Ratiopharm GmbH

Rapporteur: Daniela Philadelphy

Scope: DHPC and communication plan

Action: For adoption

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

No items

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

10.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

10.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) of Commission Regulation (EC) No 1084/2003

No items

10.10. Procedure under Article 29 of Regulation (EC) 1901/2006

No items

10.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) of Commission Regulation No 1234/2008

No items

11. Pharmacovigilance issue

11.1. Early Notification System

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

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by PROXY

No items

14.1.2. CHMP membership

No items

14.1.3. Strategic review and learning meeting (SRLM) under Spanish EU presidency

Update on the SRLM, to be held 17-18 October 2023 in Madrid

CHMP: Maria Conception Prieto Yerro

Action: For information

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 October 2023

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

Agenda of the October 2023 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 October 2023 meeting to CHMP for adoption:

- 12 reports on products in scientific advice and protocol assistance
- 6 reports on products in pre-authorisation procedures

- 1 report on products in post-authorisation procedures
- 1 report on products in plasma master file

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 18-19 September 2023.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 25-28 September 2023. 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.

14.3.4. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

Guideline (Rev. 6) on the clinical evaluation of anticancer medicinal products following GCG review and adoption of the ONCWP.

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

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

15.1.1. Health Threats and ETF Update

Action: For information

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)*

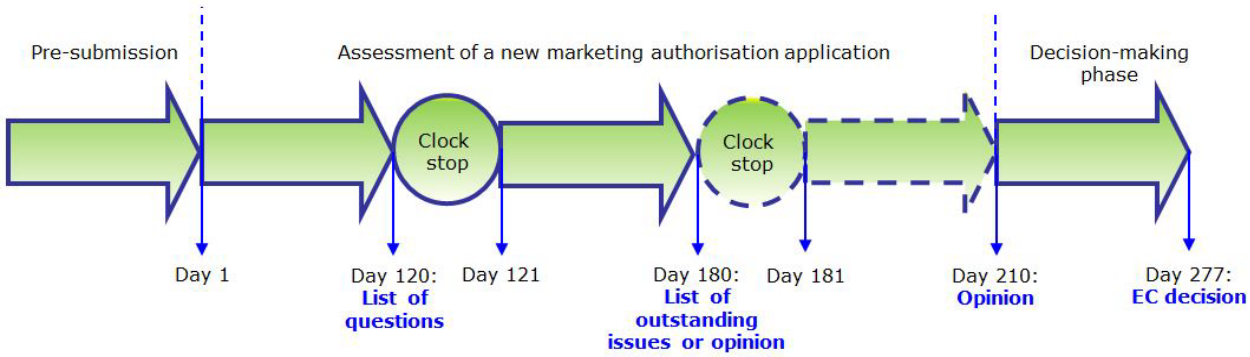
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

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Annex to 09-12 October 2023 CHMP Agenda

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for October 2023: **For adoption**	

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

Final Outcome of Rapporteurship allocation for October 2023: **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

MVABEA - ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/S/0019 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	
Qarziba - dinutuximab beta - EMEA/H/C/003918/S/0053, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Gabriele Maurer	
Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/S/0004 SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 14.09.2023, 20.07.2023, 25.05.2023.	See 9.1
ZABDENO - ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/S/0017 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	

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

Atazanavir Krka - atazanavir - EMEA/H/C/004859/R/0004
KRKA, d.d., Novo mesto, Generic, Generic of Reyataz, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Nathalie Gault

Besremi - ropeginterferon alfa-2b - EMEA/H/C/004128/R/0031
AOP Orphan Pharmaceuticals GmbH, Rapporteur: Janet Koenig, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ana Sofia Diniz Martins
Request for Supplementary Information adopted on 20.07.2023.

Febuxostat Krka - febuxostat - EMEA/H/C/004773/R/0008
KRKA, d.d., Novo mesto, Generic, Generic of Adenuric, Rapporteur: John Joseph Borg, PRAC Rapporteur: Jan Neuhauser

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

GHRYVELIN - macimorelin - EMEA/H/C/004660/R/0020
Atnahs Pharma Netherlands B.V., Rapporteur: Martina Weise, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Liana Gross-Martirosyan
Request for Supplementary Information adopted on 14.09.2023.

Vizimpro - dacomitinib - EMEA/H/C/004779/R/0011
Pfizer Europe MA EEIG, Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Eva Skovlund, PRAC Rapporteur: Menno van der Elst

B.2.3. Renewals of Conditional Marketing Authorisations

Hemgenix - etranacogene dezaparvovec - EMEA/H/C/004827/R/0007, Orphan, ATMP

CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP

Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Concetta Quintarelli, CHMP Coordinators: Jan Mueller-Berghaus and Paolo Gasparini, PRAC Rapporteur: Rhea Fitzgerald

Retsevmo - selpercatinib - EMEA/H/C/005375/R/0026

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst

SIRTURO - bedaquiline - EMEA/H/C/002614/R/0054, Orphan

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Tecartus - brexucabtagene autoleucel - EMEA/H/C/005102/R/0034, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Rune Kjeken, CHMP Coordinators: Jan Mueller-Berghaus and Ingrid Wang, PRAC Rapporteur: Menno van der Elst

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 25-28 September 2023 PRAC:

Signal of cutaneous vasculitis

Azacitidine Accord, Azacitidine Betapharm, Azacitidine Mylan, Onureg, Vidaza (CAP) - azacitidine

Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Menno van der Elst
PRAC recommendation on a variation
Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its October 2023 meeting:

EMEA/H/C/PSUSA/00002511/202301
(pregabalin)
CAPS:
Lyrica (EMEA/H/C/000546) (pregabalin), Upjohn EESV, Rapporteur: Peter Mol
Pregabalin Pfizer (EMEA/H/C/003880) (pregabalin), Upjohn EESV, Rapporteur: Peter Mol, PRAC Rapporteur: Liana Gross-Martirosyan, "01/02/2021 To: 31/01/2023"

EMEA/H/C/PSUSA/00002667/202302
(rotigotine)
CAPS:
Neupro (EMEA/H/C/000626) (rotigotine), UCB Pharma S.A., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, "16/02/2020 To: 15/02/2023"

EMEA/H/C/PSUSA/00009204/202301
(ivacaftor)
CAPS:
Kalydeco (EMEA/H/C/002494) (ivacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Monica Martinez Redondo, "24/01/2020 To: 23/01/2023"

EMEA/H/C/PSUSA/00010730/202302
(tezacaftor / ivacaftor)
CAPS:
Symkevi (EMEA/H/C/004682) (tezacaftor / ivacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Rhea Fitzgerald, "12/02/2022 To: 11/02/2023"

EMEA/H/C/PSUSA/00010745/202302
(apalutamide)

CAPS:
Erleada (EMEA/H/C/004452) (apalutamide), Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Tiphaine Vaillant, "14/02/2022 To: 13/02/2023"

EMEA/H/C/PSUSA/00010795/202302
(etanercept)
CAPS:
Benepali (EMEA/H/C/004007) (etanercept), Samsung Bioepis NL B.V., Rapporteur: Christian Gartner
Enbrel (EMEA/H/C/000262) (etanercept), Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro
Erelzi (EMEA/H/C/004192) (etanercept), Sandoz GmbH, Rapporteur: Peter Mol
Nepexto (EMEA/H/C/004711) (etanercept), Biosimilar Collaborations Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Monica Martinez Redondo, "02/02/2020 To: 02/02/2023"

EMEA/H/C/PSUSA/00010823/202302
(upadacitinib)
CAPS:
RINVOQ (EMEA/H/C/004760) (upadacitinib), AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, "14/08/2022 To: 14/02/2023"

EMEA/H/C/PSUSA/00011000/202302
(ciltacabtagene autoleucel)
CAPS:
CARVYKTI (EMEA/H/C/005095) (ciltacabtagene autoleucel), Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays, "27/08/2022 To: 27/02/2023"

EMEA/H/C/PSUSA/00011010/202302
(teclistamab)
CAPS:
Tecvayli (EMEA/H/C/005865) (teclistamab), Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Jana Lukacisinova, "23/08/2022 To: 22/02/2023"

B.4. EPARs / WPARs

Aqumeldi - enalapril maleate - EMEA/H/C/005731, PUMA Proveca Pharma Limited, treatment of heart failure, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Catiolanze - latanoprost - EMEA/H/C/005933 Santen Oy, Reduction of elevated intraocular pressure (IOP), Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Ebglyss - lebrikizumab - EMEA/H/C/005894 Almirall, S.A., treatment of moderate-to-severe atopic dermatitis in adults and adolescents, 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.
Finlee - dabrafenib - EMEA/H/C/005885, Orphan Novartis Europharm Limited, Treatment of glioma, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Herwenda - trastuzumab - EMEA/H/C/005769 Sandoz GmbH, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC), Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
VANFLYTA - quizartinib - EMEA/H/C/005910 Daiichi Sankyo Europe GmbH, Treatment of adult patients with diagnosed acute myeloid leukaemia (AML), 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.
Yorvipath - palopegteriparatide - EMEA/H/C/005934, Orphan Ascendis Pharma Bone Diseases A/S, PTH replacement therapy indicated for the treatment of hypoparathyroidism 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.
Zilbrysq - zilucoplan - EMEA/H/C/005450, Orphan UCB Pharma S.A., treatment of generalised myasthenia gravis in adults, New active substance (Article 8(3) of Directive No	For information only. Comments can be sent to the PL in case necessary.

2001/83/EC)	
Zoonotic Influenza Vaccine Seqirus - zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006375 Seqirus S.r.l., active immunisation against H5 subtype of Influenza A virus, Informed Consent of Aflunov, Informed consent application (Article 10c 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

Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0050 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0005/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0007/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Byooviz - ranibizumab - EMEA/H/C/005545/II/0012/G Samsung Bioepis NL B.V., Rapporteur: Christian Gartner Opinion adopted on 05.10.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 05.10.2023.
DaTSCAN - ioflupane (123i) - EMEA/H/C/000266/II/0066/G GE Healthcare B.V., Rapporteur: Alexandre	

Moreau	
Erleada - apalutamide - EMEA/H/C/004452/II/0032/G Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez Opinion adopted on 21.09.2023. Request for Supplementary Information adopted on 13.07.2023.	Positive Opinion adopted by consensus on 21.09.2023.
Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/II/0020/G Novo Nordisk A/S, Rapporteur: Daniela Philadelphy Opinion adopted on 05.10.2023. Request for Supplementary Information adopted on 20.07.2023.	Positive Opinion adopted by consensus on 05.10.2023.
Hemangiol - propranolol - EMEA/H/C/002621/II/0025 Pierre Fabre Medicament, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Herceptin - trastuzumab - EMEA/H/C/000278/II/0189 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.09.2023. Request for Supplementary Information adopted on 20.07.2023.	Positive Opinion adopted by consensus on 21.09.2023.
Iasibon - ibandronic acid - EMEA/H/C/002025/II/0025 Pharmathen S.A., Generic, Generic of Bondronat, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 21.09.2023.	Request for supplementary information adopted with a specific timetable.
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0064, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 29.06.2023.	Positive Opinion adopted by consensus on 28.09.2023.
IVF Media G5 Series - human albumin solution - EMEA/H/D/000003/II/0008 Vitrolife Sweden AB, Rapporteur: Filip Josephson	

Kadcyla - trastuzumab emtansine - EMEA/H/C/002389/II/0069/G Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 05.10.2023, 13.07.2023.	Request for supplementary information adopted with a specific timetable.
Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0042/G, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol	
KANJINTI - trastuzumab - EMEA/H/C/004361/II/0023 Amgen Europe B.V., BREDA, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.09.2023. Request for Supplementary Information adopted on 06.07.2023.	Positive Opinion adopted by consensus on 21.09.2023.
Lacosamide Accord - lacosamide - EMEA/H/C/004443/II/0023/G Accord Healthcare S.L.U., Generic, Generic of Vimpat, Rapporteur: John Joseph Borg Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Lokelma - sodium zirconium cyclosilicate - EMEA/H/C/004029/II/0032 AstraZeneca AB, Rapporteur: Larisa Gorobets Request for Supplementary Information adopted on 31.08.2023.	
Metalyse - tenecteplase - EMEA/H/C/000306/II/0069/G Boehringer Ingelheim International GmbH, Rapporteur: Martina Weise Opinion adopted on 21.09.2023. Request for Supplementary Information adopted on 20.07.2023.	Positive Opinion adopted by consensus on 21.09.2023.
MINJUVI - tafasitamab - EMEA/H/C/005436/II/0012/G, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Orencia - abatacept - EMEA/H/C/000701/II/0158/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 21.09.2023.	
Orencia - abatacept - EMEA/H/C/000701/II/0161/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola	
Ovitrelle - choriogonadotropin alfa - EMEA/H/C/000320/II/0089 Merck Europe B.V., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Pemetrexed Accord - pemetrexed - EMEA/H/C/004072/II/0025 Accord Healthcare S.L.U., Generic, Generic of Alimta, Rapporteur: John Joseph Borg Opinion adopted on 28.09.2023.	Positive Opinion adopted by consensus on 28.09.2023.
Perjeta - pertuzumab - EMEA/H/C/002547/II/0068/G Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
PreHevbri - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005466/II/0006 VBI Vaccines B.V., Rapporteur: Jan Mueller-Berghaus	
Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0215/G Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder Opinion adopted on 05.10.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 05.10.2023.
Ranivisio - ranibizumab - EMEA/H/C/005019/II/0005 Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 05.10.2023. Request for Supplementary Information adopted on 29.06.2023.	Positive Opinion adopted by consensus on 05.10.2023.
Ranivisio - ranibizumab - EMEA/H/C/005019/II/0006 Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 05.10.2023.	Positive Opinion adopted by consensus on 05.10.2023.

Request for Supplementary Information adopted on 29.06.2023.	
Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0066/G CSL Behring GmbH, Rapporteur: Kristina Dunder Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 13.07.2023.	Positive Opinion adopted by consensus on 28.09.2023.
Ryeqo - relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267/II/0019/G Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
Ryeqo - relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267/II/0020/G Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
Skytrofa - lonapegsomatropin - EMEA/H/C/005367/II/0019/G, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt	
TAVNEOS - avacopan - EMEA/H/C/005523/II/0010, Orphan Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder	
TEZSPIRE - tezepelumab - EMEA/H/C/005588/II/0009/G AstraZeneca AB, Rapporteur: Finbarr Leacy	
Uptravi - selexipag - EMEA/H/C/003774/II/0039 Janssen-Cilag International N.V., Rapporteur: Martina Weise Request for Supplementary Information adopted on 07.09.2023.	
Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0131 MCM Vaccine B.V., Rapporteur: Christophe	Request for supplementary information adopted with a specific timetable.

Focke Request for Supplementary Information adopted on 28.09.2023.	
Vyepti - eptinezumab - **EMEA/H/C/005287/II/0012** H. Lundbeck A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
WS2507 **Bondronat-** **EMEA/H/C/000101/WS2507/0092** **Bonviva-** **EMEA/H/C/000501/WS2507/0076** Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 07.09.2023, 06.07.2023.	
WS2526/G **Infanrix hexa-** **EMEA/H/C/000296/WS2526/0335/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	
WS2542/G **Ongentys-** **EMEA/H/C/002790/WS2542/0059/G** **Ontilyv-** **EMEA/H/C/005782/WS2542/0014/G** Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise Request for Supplementary Information adopted on 14.09.2023.	

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

Ameluz - 5-aminolevulinic acid - **EMEA/H/C/002204/II/0055** Biofrontera Bioscience GmbH, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.8, 5.1 and 6.6 of the SmPC in order to include artificial daylight lamps as an additional light source for photodynamic therapy in combination with Ameluz for the treatment of actinic keratoses based on final results from non-clinical study PT-0042-A and literature (investigator-initiator trials). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. "	

Request for Supplementary Information adopted on 25.05.2023.	
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0006 Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final report from study HAN-01 listed as a category 3 study in the RMP (MEA/006). This is a phase IIb, randomised, controlled, observer-blinded study to evaluate safety and immunogenicity of a recombinant protein RBD fusion dimer candidate vaccine against SARS-CoV-2 in adult healthy volunteers." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0008 Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final report from study HIPRA-HH-10 listed as a category 3 study in the RMP. This is a phase 2b, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion dimer candidate (PHH-1V) against SARS-CoV-2, in adults fully vaccinated with adenovirus vaccine against COVID-19."	
Braftovi - encorafenib - EMEA/H/C/004580/II/0031 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information on effect of encorafenib in combination with binimetinib on the single oral dose PK of specific CYP isozymes substrates, and effect of multiple doses of modafinil, a moderate CYP3A4 inducer, on the multiple oral dose PK of encorafenib administered with binimetinib based on final results from arm 1 and 3 of clinical study ARRAY-818-103/C4221003 (REC). ARRAY-818-103/ C4221003 study is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other	Request for supplementary information adopted with a specific timetable.

BRAF V600-E and/or K-mutant advanced solid tumours." Request for Supplementary Information adopted on 21.09.2023.	
Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0037 Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, "Submission of the final clinical study report addendum for study DS8201-A-U303 (DESTINY-Breast04) in order to fulfil the recommendation to submit the final OS analysis. U303 is a phase 3, multicentre, randomised, open-label, active-controlled trial of trastuzumab deruxtecan (T-DXd), an anti-HER2-antibody drug conjugate (ADC), versus treatment of physician's choice for HER2-low, unresectable and/or metastatic breast cancer subjects."	
Fetcroja - cefiderocol - EMEA/H/C/004829/II/0016 Shionogi B.V., Rapporteur: Filip Josephson, "Update of sections 4.2 and 6.2 of the SmPC in order to update the information on incompatibility in line with the PRAC recommendation adopted for EMEA/H/C/PSUSA/00010849/202211. The package leaflet was revised accordingly, to introduce information intended for healthcare professionals." Opinion adopted on 05.10.2023.	Positive Opinion adopted by consensus on 05.10.2023.
Filsuvez - birch bark extract - EMEA/H/C/005035/II/0006, Orphan Amryt Pharmaceuticals DAC, Rapporteur: Kristina Dunder, "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study EASE (BEB-13); this is a double-blind, randomised, placebo (vehicle) controlled trial to evaluate efficacy and safety of birch bark extract on top of standard of care in children from birth to less than 18 years of age (and adults) with epidermolysis bullosa. In addition, the MAH took the opportunity to introduce minor changes to the PI."	
INREBIC - fedratinib - EMEA/H/C/005026/II/0017, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.5 of	Request for supplementary information adopted with a specific timetable.

the SmPC in order to update drug-drug interaction information with dual inhibitors of CYP3A4 and CYP2C19, based on final results from study FEDR-CP-004; this is a phase 1, open-label study to evaluate the effect of a dual CYP2C19 and CYP3A4 inhibitor, fluconazole, on the pharmacokinetics of fedratinib in healthy adult subjects." Request for Supplementary Information adopted on 05.10.2023, 31.08.2023.	
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))."	See 9.1
JCOVDEN - COVID-19 Vaccine Janssen (ad26.cov2.s) - EMEA/H/C/005737/II/0074/G Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "Grouped application comprising two type II variations (C.I.13) as follows: - Submission of the final report from study TOX15258 - Ad26.COV2.S (Prophylactic COVID-19 Vaccine): A Transcriptomics Exploratory Study in Cambodian Cynomolgus Monkey. - Submission of the report from study TV-TEC-236300 - Biophysical studies on interactions between human platelet 4 and Ad26.COV2.S."	
Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0028 Bayer AG, Rapporteur: Thalia Marie Estrup Blicher, "Submission of the final report from study 19764 (PMI) listed as a category 3 study in the RMP as well as pooled data from phase 3 studies 13024 (PROTECT VIII) and 15912 (PROTECT Kids). Study 19764 is a multicenter, single group, uncontrolled, open-label interventional post-marketing investigation	Positive Opinion adopted by consensus on 28.09.2023.

(PMI) to assess safety and efficacy of Jivi treatment in patients with hemophilia A." Opinion adopted on 28.09.2023.	
Kisqali - ribociclib - EMEA/H/C/004213/II/0041/G Novartis Europharm Limited, Rapporteur: Filip Josephson, "Grouped application comprising two type II variations as follows: - Update of section 5.2 of the SmPC in order to update absorption information based on final results from study CLEE011A2117, a Phase I, single center, two-period, two-treatment, open label, randomized crossover study to investigate the absolute bioavailability of a single oral dose of 600 mg of ribociclib relative to an intravenous (i.v.) infusion of 150 mg ribociclib in healthy subjects. - Update of sections 4.2 and 4.5 of the SmPC in order to update the recommended dose modification when ribociclib is administered in combination with CYP3A4 inhibitors and update the drug-drug interaction information on substances that may increase ribociclib plasma concentrations based on the updated PBPK modelling. In addition, the MAH took this opportunity to introduce minor editorial changes to the Package Leaflet." Request for Supplementary Information adopted on 22.06.2023.	
Mektovi - binimetinib - EMEA/H/C/004579/II/0027 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of the final report from study ARRAY 818-103 on Arms 1 and 3. This is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours, to assess drug drug interactions between encorafenib + binimetinib combination and midazolam (CYP3A4 substrate), caffeine (CYP1A2 substrate), omeprazole (CYP2C19 substrate), losartan (CYP2C9 substrate), dextromethorphan (CYP2D6 substrate) and modafinil (moderate CYP3A4 inducer)." Request for Supplementary Information adopted on 21.09.2023.	Request for supplementary information adopted with a specific timetable.
Mozobil - plerixafor -	Request for supplementary information adopted

EMEA/H/C/001030/II/0051 Sanofi B.V., Rapporteur: Peter Mol, "Update of section 4.6 of the SmPC in order to update information regarding duration of contraception after cessation of treatment; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor update to the Labelling section." Request for Supplementary Information adopted on 28.09.2023.	with a specific timetable.
Mylotarg - gemtuzumab ozogamicin - EMEA/H/C/004204/II/0030, Orphan Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy, pharmacokinetic and safety information based on interim results from study WI203680 - MyeChild 01-International Randomised Phase III Clinical Trial in Children With Acute Myeloid Leukaemia – Incorporating an Embedded Dose Finding Study for Gemtuzumab Ozogamicin in Combination With Induction Chemotherapy. This is a dose finding sub-study aimed to identify the optimum tolerated number of doses of GO 3 mg/m2 (up to a maximum of 3 doses) which can be combined safely with AraC plus mitoxantrone or liposomal DAUNO in induction therapy." Request for Supplementary Information adopted on 31.08.2023.	
NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0045 Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen - adolescent boosting vaccination based on interim results from study 2019nCOV-301(IR) listed as a category 3 study in the RMP; this is a Phase 3, randomised, observer-blinded, placebo- controlled study to evaluate the efficacy, safety, and immunogenicity of SARS CoV-2 rS with Matrix-M adjuvant in adult participants ≥ 18 years of age with a pediatric expansion (12 to < 18 years of age). The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.	See 9.1

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0058/G Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt	See 9.1
Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0038, Orphan Advanz Pharma Limited, Rapporteur: Carolina Prieto Fernandez, "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from studies 747-302 and 747-401, listed as specific obligations in the Annex II, as well as results from real-world evidence (RWE) studies evaluating analyses of hepatic clinical outcomes. Study 747-302 is a confirmatory double-blind, randomised, placebo-controlled multicentre study investigating the clinical benefit associated with Ocaliva treatment in patients with PBC who are either unresponsive or intolerant to UDCA treatment based on clinical endpoints, while study 747-401 is a double-blind, randomised, placebo-controlled study evaluating the safety and pharmacokinetics of Ocaliva in patients with PBC and moderate to severe hepatic impairment. The Annex II and Package Leaflet are updated accordingly." Request for Supplementary Information adopted on 30.03.2023.	See 9.1
Ozurdex - dexamethasone - EMEA/H/C/001140/II/0045 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC in order to add "Central serous chorioretinopathy" to the list of adverse drug reactions (ADRs) with frequency "uncommon" based on a safety signal and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and design changes to the Package Leaflet; and to bring the PI in line with the latest QRD template version 10.3."	
Qarziba - dinutuximab beta - EMEA/H/C/003918/II/0043, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol, "Update of sections 4.1, 4.2 and 5.1 of the SmPC based on final results from study APN311-202V3 listed as a Specific Obligation in the Annex II of the Product Information. This is	See 9.1.

a Phase I/II dose schedule finding study of Ch14.18/CHO continuous infusion combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma. In addition, the MAH took the opportunity to update Annex II section E. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 26.04.2023, 15.09.2022.	
Scemblix - asciminib - EMEA/H/C/005605/II/0008, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add interaction information between asciminib and OATP1B and BCRP substrates, based on results from three PBPK simulation reports: DMPK-R2001088, DMPK-R2270328 and DMPK-R2300226. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 21.09.2023.	Request for supplementary information adopted with a specific timetable.
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."	
Skyrizi - risankizumab - EMEA/H/C/004759/II/0035 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Update of sections 4.8 and 5.1 of the SmPC for 150 mg solution for injection in pre-filled pen and pre-filled syringe and 75 mg solution for injection in pre-filled syringe based on final results from study M15-997; this is a Phase 3, single-arm, multicenter, open label study to assess the safety and efficacy of risankizumab for maintenance in moderate to severe plaque type psoriasis. In addition, the MAH took the opportunity to implement editorial changes to the SmPC for all strengths / pharmaceutical forms." Opinion adopted on 21.09.2023. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 21.09.2023.

on 29.06.2023.	
Veklury - remdesivir - EMEA/H/C/005622/II/0052 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update non-clinical information based on results from the non-clinical studies PC-540-2045 and PC-540-2046. In addition, the MAH took the opportunity to implement editorial changes in the SmPC." Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Verzenios - abemaciclib - EMEA/H/C/004302/II/0028 Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC in order to add a new warning on "arterial thromboembolic events", based on a safety review. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMEA/H/C/005754/II/0006 Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC in order to add 'Hypersensitivity and anaphylactic reactions' to the list of adverse drug reactions (ADRs) with frequency 'Not known', based on post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI." Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
Zaltrap - aflibercept - EMEA/H/C/002532/II/0070 Sanofi Winthrop Industrie, Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update information regarding the duration of contraceptive use after cessation of treatment. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 05.10.2023.	Positive Opinion adopted by consensus on 05.10.2023.
WS2544 Ebymect-	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/004162/WS2544/0064
Komboglyze-
EMEA/H/C/002059/WS2544/0057
Xigduo-EMEA/H/C/002672/WS2544/0074
AstraZeneca AB, Lead Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Vitamin B12 decrease/deficiency' and to change the frequency of 'Vitamin B12 decrease/deficiency' in the list of adverse drug reactions (ADRs) from frequency 'very rare' to 'common'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."
Request for Supplementary Information adopted on 21.09.2023.

B.5.3. CHMP-PRAC assessed procedures

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

Brineura - cerliponase alfa -
EMEA/H/C/004065/II/0039, Orphan
BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 9 of the SmPC in order to state that clinical data are available for patients aged 1 year and older and to include updates to the frequency of adverse reactions, immunogenicity, pharmacokinetic, and paediatric population sections based on the final results from studies 190-203, listed as a specific obligation and 190-202 (submitted in P46/013).
Study 190-203 was a Phase 2, open-label, multicenter study in pediatric patients < 18 years of age with CLN2 disease, confirmed by deficiency of TPP1 enzyme activity and mutation of the CLN2 gene.
The Package Leaflet, Annex II and Annex IV are

updated accordingly. The RMP version 4.0 has also been submitted." Request for Supplementary Information adopted on 25.05.2023.	
EVUSHELD - tixagevimab / cilgavimab - EMEA/H/C/005788/II/0009/G AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising two type II variations (REC 23) as follows: C.I.4 - Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and satefy information based on final results from study TACKLE (D8851C00001). C.I.4 - Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information based on final results from studies PROVENT (D8850C00002) and STORM CHASER (D8850C00003). The RMP version 4.1 has also been submitted." Request for Supplementary Information adopted on 20.07.2023.	
Kuvan - sapropterin - EMEA/H/C/000943/II/0078 BioMarin International Limited, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from study KOGNITO, listed as a category 3 study in the RMP. This is a Phase IV Open-Label, Single-Cohort Study of the Long-Term Neurocognitive Outcomes in 4 to 5 Year-Old Children with Phenylketonuria Treated with Sapropterin Dihydrochloride (Kuvan) for 7 Years. The RMP version 16.0 has also been submitted." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
LIVTENCITY - maribavir - EMEA/H/C/005787/II/0004, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Submission of the final report from study SHP620-302 listed as a category 3 study in the RMP. This is a Phase III, multicenter, randomized, double-blind, double-dummy, active-controlled study of maribavir compared to valganciclovir for the treatment of asymptomatic Cytomegalovirus (CMV) Infection in Hematopoietic Stem Cell Transplant recipients. The RMP version 2.0 has	

also been submitted." Request for Supplementary Information adopted on 25.05.2023.	
Lynparza - olaparib - EMEA/H/C/003726/II/0061 AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Amelia Cupelli, "Update of sections 4.8 and 5.1 of the SmPC in order to update the overall survival and safety information, based on the final results from study D081SC00001 (PROpel), listed as a PAES in the Annex II; this is a randomised, double-blind, placebo-controlled, multicentre phase III study of olaparib plus abiraterone relative to placebo plus abiraterone as first-line therapy in men with metastatic castration resistant prostate cancer; the Annex II is updated in accordance. The RMP version 27.1 is approved. In addition, the MAH took the opportunity to revise the list of local representatives in the package leaflet" Opinion adopted on 05.10.2023. Request for Supplementary Information adopted on 31.08.2023, 06.07.2023.	Positive Opinion adopted by consensus on 05.10.2023.
Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0094 Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, "Update of section 4.2 of the SmPC in order to add home infusion upon request by PRAC following the assessment of PSUSA/00000086/202109 I based on a cumulative search of the MAH Global Pharmacovigilance database and literature. The Package Leaflet and Annex II are updated accordingly. The RMP version 10.0 has also been submitted." Request for Supplementary Information adopted on 26.04.2023.	
Onpattro - patisiran - EMEA/H/C/004699/II/0034, Orphan Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from study ALN-TTR02-006 (study 006), listed a category 3 study in the RMP. This is a multicenter, open-label, extension study to evaluate the long-term safety and efficacy of patisiran in patients with familial amyloidotic polyneuropathy who have completed a prior clinical study with patisiran.	Request for supplementary information adopted with a specific timetable.

The RMP version 2.2 has also been submitted." Request for Supplementary Information adopted on 28.09.2023.	
TAGRISSO - osimertinib - EMEA/H/C/004124/II/0052 AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst, "Update of section 5.1 of the SmPC in order to update efficacy information (final OS data) based on final results from study D5164C00001 (ADAURA) listed as a PAES in the Annex II; this is a Phase III, double-blind, randomised, placebo-controlled study, designed to assess the efficacy and safety of osimertinib versus placebo in patients with stage IB-IIIA epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC) who have undergone complete tumour resection, with or without postoperative adjuvant chemotherapy. The RMP version 15 has also been submitted. In addition, the MAH took the opportunity to update Annex II section D of the PI and to implement editorial changes to the SmPC." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 28.09.2023.
Tegsedi - inotersen - EMEA/H/C/004782/II/0038, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.8 of the SmPC in order to modify the warning on liver monitoring and drug-induced liver injury and to add 'drug-induced liver injury' to the list of adverse drug reactions (ADRs) with frequency not known, following the request in the Assessment Report for PAM procedure EMEA/H/C/004782/LEG/008. The Annex II and Package Leaflet are updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
Vaborem - meropenem / vaborbactam - EMEA/H/C/004669/II/0020 Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, PRAC	Positive Opinion adopted by consensus on 28.09.2023.

Rapporteur: Maria del Pilar Rayon, "Submission of the final reports from Global Microbiology Surveillance Study and Molecular Surveillance Report, listed as a category 3 study in the RMP. The RMP version 2.0 has also been submitted." Opinion adopted on 28.09.2023.	
Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0043/G Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Valentina Di Giovanni, "Grouped application consisting of: C.I.13: Submission of the final report from study GS-US-320-0108 listed as category 3 studies in the RMP. This is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Negative, Chronic Hepatitis B. The RMP version 10.1 has also been submitted. C.I.13: Submission of the final report from study GS-US-320-0110 listed as category 3 studies in the RMP. This is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Positive, Chronic Hepatitis B. The RMP version 10.1 has also been submitted." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
Vyvgart - efgartigimod alfa - EMEA/H/C/005849/II/0006, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.5 of the SmPC in order to amend an existing warning on use of vaccination and update drug-drug interaction information on vaccines based on final results from study ARGX-113-2102; this is a phase 1, randomized, open-label, placebo-controlled, parallel-group study to evaluate the immune response to PNEUMOVAX 23 in healthy participants receiving efgartigimod IV 10 mg/kg or placebo. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 28.09.2023.	Positive Opinion adopted by consensus on 28.09.2023.

Request for Supplementary Information adopted on 06.07.2023.	
XOSPATA - gilteritinib - EMEA/H/C/004752/II/0013, Orphan Astellas Pharma Europe B.V., Rapporteur: Ingrid Wang, PRAC Rapporteur: Martin Huber, "Update of sections 4.2 and 5.2 in order to update the information on renal impairment based on final results from study 2215-CL-0114, listed as a category 3 study in the RMP. Study 2215-CL-0114 is a phase 1, single-dose, open-label study to investigate the effect of renal impairment on gilteritinib pharmacokinetics, safety and tolerability in 9 participants with severe renal impairment compared to 8 participants with normal renal function. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes." Request for Supplementary Information adopted on 22.06.2023.	
WS2409 **Lixiana-EMEA/H/C/002629/WS2409/0042** **Roteas-EMEA/H/C/004339/WS2409/0029** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Nathalie Gault, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC with available paediatric data based on final results from study DU176b-D-U312; this is a phase 3, open-label, randomised, multicentre, controlled trial to evaluate the pharmacokinetics and pharmacodynamics of edoxaban and to compare the efficacy and safety of edoxaban with standard-of-care anticoagulant therapy in paediatric subjects from birth to less than 18 years of age with confirmed venous thromboembolism (VTE). The Package Leaflet and Labelling are updated accordingly. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 30.03.2023.	See 9.1
WS2451 **Bondronat-** **EMEA/H/C/000101/WS2451/0090**	

Bonviva- **EMEA/H/C/000501/WS2451/0075** Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Lead PRAC Rapporteur: Karin Erneholm, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add information regarding the risk of "Atypical fractures of other long bones"; based on literature. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 12.05.2023.	

B.5.4. PRAC assessed procedures

PRAC Led **Arixtra - fondaparinux sodium - EMEA/H/C/000403/II/0087** Mylan Ire Healthcare Limited, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To update section 4.8 of the SmPC to update the ADR table following the assessment of PSUSA (EMEA/H/C/PSUSA/00001467/202112). The Package Leaflet is updated accordingly." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 06.07.2023, 14.04.2023.	Positive Opinion adopted by consensus on 28.09.2023.
PRAC Led **CABOMETYX - cabozantinib - EMEA/H/C/004163/II/0033** Ipsen Pharma, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Peter Mol, "Submission of the final report from study F-FR-60000-001 (CASSIOPE) listed as a category 3 study in the RMP. This is a prospective, non-imposed and non-interventional study of cabozantinib tablets in adults with advanced renal cell carcinoma (RCC) following prior vascular endothelial growth factor (VEGF)-targeted therapy. The RMP version 7.0 has also been submitted." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 08.06.2023.	Positive Opinion adopted by consensus on 28.09.2023.
PRAC Led	Request for supplementary information adopted

Caelyx pegylated liposomal - doxorubicin - EMEA/H/C/000089/II/0107 Baxter Holding B.V., PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "Submission of an updated RMP version 6.1 in order to align to GVP Module V Revision 2 requirements, following a request received within the Assessment Report for procedure EMEA/H/C/PSUSA/00001172/202111." Request for Supplementary Information adopted on 28.09.2023.	with a specific timetable.
PRAC Led **Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0036** Daiichi Sankyo Europe GmbH, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the final report from study 'EU survey of relevant healthcare professionals on understanding of key risk minimisations measures pertaining to ILD/pneumonitis' listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Eurartesim - piperaquine tetraphosphate / artenimol - EMEA/H/C/001199/II/0040/G** Alfasigma S.p.A., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "C.I.13: Submission of the final report from the effectiveness evaluation survey for Eurartesim (protocol no. 3366) listed as a category 3 study in the RMP. This is a European multi-centre online survey to assess physician understanding of the revised edition of the educational material. Consequential changes to RMP version 16.1 have been implemented. C.I.11.b: Submission of an updated RMP version 16.1 in order to delete "Severe Malaria" from the Missing Information." Request for Supplementary Information adopted on 28.09.2023, 08.06.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **EXJADE - deferasirox - EMEA/H/C/000670/II/0085** Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of an updated RMP version	Positive Opinion adopted by consensus on 28.09.2023.

21.2 in order to include the physician survey CICL670A2429 as a PASS category 3, based on the submission of a draft version of the protocol for the physician survey CICL670A2429. The Annex IID is updated to remove one sentence related to 'surveillance programme' and to introduce a minor correction to the guide for healthcare professionals." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 08.06.2023.	
PRAC Led **Fasenra - benralizumab - EMEA/H/C/004433/II/0049/G** AstraZeneca AB, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Grouped application consisting of: 1) Submission of an updated RMP version 5 in order to remove the safety concern of missing information on use in pregnant and lactating women. Consequently, the MAH proposes to remove study D3250R00026 as an additional pharmacovigilance activity, and to remove the commitment to conduct additional pharmacovigilance for the use of benralizumab in pregnant and lactating women with severe eosinophilic asthma. 2) Submission of an updated RMP version 5 in order to remove the safety concern of important potential risk of serious infections." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 06.07.2023.	Positive Opinion adopted by consensus on 28.09.2023.
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 28.09.2023.	Request for supplementary information adopted with a specific timetable.

PRAC Led **Plenadren - hydrocortisone - EMEA/H/C/002185/II/0043** Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study SHP617-400 (EU AIR) listed as a category 3 PASS in the RMP; this is a European multi-centre, multi-country, post-authorisation, observation study (registry) of patients with chronic adrenal insufficiency. The RMP version 4.0 has also been submitted." Opinion adopted on 28.09.2023.	Positive Opinion adopted by consensus on 28.09.2023.
PRAC Led **Reblozyl - luspatercept - EMEA/H/C/004444/II/0023, Orphan** Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report from study ACE-536-MDS-005 listed as a category 3 study in the RMP. This is a non-interventional post-authorisation safety study (PASS) to evaluate the effectiveness of the additional risk minimisation measure (aRMM) for Reblozyl among Healthcare Providers (HCPs) in the EU/EEA. The RMP version 3.0 has been submitted in order to reflect the completion of the study and to remove the HCP checklist as routine aRMM. The Annex II is updated accordingly." Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **REKAMBYS - rilpivirine - EMEA/H/C/005060/II/0019** Janssen-Cilag International N.V., PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 4.2 in order to update the risk characterisation information for the missing information "use in pregnancy" based on interim data of the Antiretroviral Pregnancy Register (APR), listed as a category 3 study in the RMP; and to align the milestones and due dates of this study following the outcome of procedure EMEA/H/C/PSUSA/00010901/202209. In addition, the MAH took the opportunity to update the status and the interim report	Positive Opinion adopted by consensus on 28.09.2023.

milestones for the studies DUS and COMBINE-2." Opinion adopted on 28.09.2023.	
PRAC Led **Revlimid - lenalidomide - EMEA/H/C/000717/II/0126** Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from study CC-5013-MDS-010 listed as an obligation in the Annex II of the Product Information. This is a prospective non-interventional post-authorisation safety study (PASS), designed as a disease registry of patients with transfusion dependent IPSS low or intermediate-1-risk myelodysplastic syndromes (MDS) and isolated del(5q). Section 4.8 of the SmPC is updated with the adverse drug reaction of anaemia in patients with myelodysplastic syndromes. Section D of the Annex II and the RMP (version 39.1) are updated accordingly." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 08.06.2023.	Positive Opinion adopted by consensus on 28.09.2023.
PRAC Led **Stelara - ustekinumab - EMEA/H/C/000958/II/0101/G** Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Update of section 4.4 of the SmPC in order to remove a warning on cardiovascular events based on final results from non-interventional PASS studies NDI-MACE (CNTO1275PSO4005) and Quantify MACE (PCSIMM004697), listed as category 3 studies in the RMP (MEA/053 and MEA/054). NDI-MACE is a Nordic Database Initiative for Exposure to Ustekinumab: A Review and Analysis of Major Adverse Cardiovascular Events from the Swedish and Danish National Registry Systems; Quantify MACE is an Observational Longitudinal Post-authorisation Safety Study of STELARA in the Treatment of Psoriasis and Psoriatic Arthritis: Analysis of Major Adverse Cardiovascular Events (MACE) using Swedish National Health Registers. The Package Leaflet is updated accordingly. The RMP version 27.1 has also been submitted." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 28.09.2023.	
PRAC Led **Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/II/0006** SIGA Technologies Netherlands B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of substantial updates to the protocol of study SIGA-246-021 listed as a specific obligation in the Annex II of the Product Information in order to reflect the transfer of sponsorship from SIGA Technologies, Inc. to the NIH Division of Microbiology and Infection Disease protocol. This is a phase 4, observational field study to evaluate safety and clinical benefit in tecovirimat-treated patients following exposure to variola virus and clinical diagnosis of smallpox disease. The Annex II and the RMP submitted version 1.2 are updated accordingly." Request for Supplementary Information adopted on 14.09.2023, 25.05.2023, 14.04.2023.	See 9.1
PRAC Led **VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0061** Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of an updated RMP version 12 in order to remove certain risks from the list of safety concerns." Request for Supplementary Information adopted on 28.09.2023, 06.07.2023, 14.04.2023, 09.02.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2270 Vfend-EMEA/H/C/000387/WS2270/0147** Pfizer Europe MA EEIG, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Patrick Vrijlandt, "Update of Annex II and RMP to include the results from final clinical study report (CSR) following the completion of a non-interventional (NI) post-authorisation safety study (PASS): A1501103 "An Active Safety Surveillance Program to Monitor Selected Events in Patients with Long-term Voriconazole Use". MEA091 is fulfilled with this procedure. In addition, the MAH took this opportunity to introduce editorial changes to the RMP and	Positive Opinion adopted by consensus on 28.09.2023.

transition from the EMA GVP 1 template to the new template GVP 2.1. The frequency categories for the ADRs 'periostitis', 'phototoxicity' and 'squamous cell carcinoma (SCC)' of the skin in the ADR table in section 4.8 of the Vfend SmPC and section 4 of the Vfend Package Leaflet were amended. Version 6.3 of the RMP is approved with this procedure." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 12.05.2023, 12.01.2023, 01.09.2022.	
PRAC Led **WS2517** **Edistride-** **EMEA/H/C/004161/WS2517/0063** **Forxiga-** **EMEA/H/C/002322/WS2517/0084** AstraZeneca AB, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 30 in order to remove the potential important risk for Lower Limb Amputation." Opinion adopted on 28.09.2023.	Positive Opinion adopted by consensus on 28.09.2023.
PRAC Led **WS2546** **Brimica Genuair-** **EMEA/H/C/003969/WS2546/0039** **Duaklir Genuair-** **EMEA/H/C/003745/WS2546/0040** Covis Pharma Europe B.V., Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "C.I.11.z - To provide a new version of the RMP to update the milestone for PASS study D6560R00004 regarding Arrythmia final report ." Request for Supplementary Information adopted on 14.09.2023.	
PRAC Led **WS2548** **Bretaris Genuair-** **EMEA/H/C/002706/WS2548/0051** **Eklira Genuair-** **EMEA/H/C/002211/WS2548/0052** Covis Pharma Europe B.V., Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "C.I.11.z - To provide a new version of the RMP to update the milestone for PASS study D6560R00004	

regarding Arrythmia final report .” Request for Supplementary Information adopted on 14.09.2023.	

B.5.5. CHMP-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0019, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Opinion adopted on 06.10.2023. Request for Supplementary Information adopted on 16.06.2023.	
Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0028/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Opinion adopted on 06.10.2023.	
CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0023, Orphan, ATMP Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, Request for Supplementary Information adopted on 06.10.2023.	Request for supplementary information adopted with a specific timetable.
Upstaza - eladocagene exuparvovec - EMEA/H/C/005352/II/0014/G, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Maura O'Donovan, CHMP Coordinator: Finbarr Leacy, “Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update information on safety and efficacy, based on final results from studies NTUH-AADC-010 and NTUH-AADC-011. NTUH-AADC-010 is an open-label, single arm, externally controlled trial to evaluate safety, efficacy, pharmacodynamics and immunogenicity of AGIL-AADC in children from 18 months to less than 18 years of age with severe AADC deficiency, while NTUH-AADC-011 is an open-label, single arm, externally controlled trial to evaluate efficacy and safety of AGIL-AADC in children from 18 months to less than 6 years of	

age with severe AADC deficiency. In addition, sections 4.5, 4.9 and 6.6 of the SmPC are updated in order to provide better clarification and guidance for the medical practice. The Package Leaflet is updated accordingly. The MAH also took the opportunity to update the due date of the final report of study AADC-1602 in the Annex II, considering the 10-year follow up of the last patient in study AADC-011, and to introduce minor editorial changes to the PI."	
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0063, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, , "Update of section 5.1 of the SmPC in order to include new clinical data based on Overall Survival (OS) Primary Analysis from study KTE-C19-107 (ZUMA-7); this is a phase 3, randomized, open-label study evaluating the efficacy of axicabtagene ciloleucel versus standard of care therapy in subjects with relapsed/refractory diffuse large B cell lymphoma (DLBCL) in the 2nd line setting. In addition, the MAH took the opportunity to submit a consolidated Environmental Risk Assessment (ERA) document."	
WS2558/G **Tecartus-EMEA/H/C/005102/WS2558/0036/G** **Yescarta-EMEA/H/C/004480/WS2558/0064/G** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, Opinion adopted on 05.10.2023.	Positive Opinion adopted by consensus on 05.10.2023.

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

WS2408 **Riarify-EMEA/H/C/004836/WS2408/0027** **Trydonis-EMEA/H/C/004702/WS2408/0030** Chiesi Farmaceutici S.p.A., Informed Consent of	

Trimbow, Lead Rapporteur: Janet Koenig	
WS2503/G **Afstyla-** **EMEA/H/C/004075/WS2503/0051/G** **IDELVION-** **EMEA/H/C/003955/WS2503/0067/G** **Respreeza-** **EMEA/H/C/002739/WS2503/0073/G** **Voncento-** **EMEA/H/C/002493/WS2503/0060/G** CSL Behring GmbH, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
WS2524 **Galvus-EMEA/H/C/000771/WS2524/0079** **Jalra-EMEA/H/C/001048/WS2524/0082** **Xiliarx-EMEA/H/C/001051/WS2524/0080** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder, "C.I.z - To provide an updated Environmental Risk Assessment (ERA) report for OECD TG308 and OECD TG218 studies." Request for Supplementary Information adopted on 31.08.2023.	
WS2527/G **Infanrix hexa-** **EMEA/H/C/000296/WS2527/0334/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
WS2528/G **Eucreas-** **EMEA/H/C/000807/WS2528/0101/G** **Icandra-** **EMEA/H/C/001050/WS2528/0106/G** **Zomarist-** **EMEA/H/C/001049/WS2528/0103/G** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder, "C.I.z - To provide the Environmental Risk Assessment (ERA) report for vildalgiptin to add data from OECD TG308 and OECD TG218 studies. C.I.z - To provide the Environmental Risk Assessment (ERA) report for metformin to add FOCUS_DEGKINv2 SFO calculated DT50 values." Request for Supplementary Information adopted on 31.08.2023.	
WS2532/G	Positive Opinion adopted by consensus on

Hexacima- **EMEA/H/C/002702/WS2532/0152/G** **Hexyon-** **EMEA/H/C/002796/WS2532/0156/G** Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 28.09.2023.”	28.09.2023.
WS2540 **Biktarvy-** **EMEA/H/C/004449/WS2540/0057** **Descovy-** **EMEA/H/C/004094/WS2540/0064** **Genvoya-** **EMEA/H/C/004042/WS2540/0088** **Odefsey-** **EMEA/H/C/004156/WS2540/0062** **Vemlidy-** **EMEA/H/C/004169/WS2540/0044** Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
WS2553/G **Delstrigo-** **EMEA/H/C/004746/WS2553/0036/G** **Pifeltro-** **EMEA/H/C/004747/WS2553/0028/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Filip Josephson Opinion adopted on 28.09.2023.	Positive Opinion adopted by consensus on 28.09.2023.
WS2555/G **Kisplyx-** **EMEA/H/C/004224/WS2555/0057/G** **Lenvima-** **EMEA/H/C/003727/WS2555/0052/G** Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn	
WS2561/G **Olanzapine Glenmark-** **EMEA/H/C/001085/WS2561/0041/G** **Olanzapine Glenmark Europe-** **EMEA/H/C/001086/WS2561/0038/G** **Olazax-** **EMEA/H/C/001087/WS2561/0033/G** **Olazax Disperzi-** **EMEA/H/C/001088/WS2561/0035/G** Glenmark Arzneimittel GmbH, Generic, Generic	

of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau	
WS2562 **Nilemdo-EMEA/H/C/004958/WS2562/0032** **Nustendi-EMEA/H/C/004959/WS2562/0036** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
WS2565 **Blitzima-EMEA/H/C/004723/WS2565/0069** **Truxima-EMEA/H/C/004112/WS2565/0072** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
WS2567 **Glyxambi-EMEA/H/C/003833/WS2567/0054** **Synjardy-EMEA/H/C/003770/WS2567/0075** Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 05.10.2023.	Positive Opinion adopted by consensus on 05.10.2023.
WS2568 **Nuwiq-EMEA/H/C/002813/WS2568/0055** **Vihuma-EMEA/H/C/004459/WS2568/0037** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
WS2570 **Lantus-EMEA/H/C/000284/WS2570/0131** **Suliqua-EMEA/H/C/004243/WS2570/0036** **Toujeo-EMEA/H/C/000309/WS2570/0126** Sanofi-Aventis Deutschland GmbH, Lead Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

aflibercept - EMEA/H/C/006150 treatment of age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO), due to diabetic macular oedema (DME) and due to myopic choroidal neovascularisation (myopic CNV) or central RVO)
erdafitinib - EMEA/H/C/006050 treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC)
insulin lispro - EMEA/H/C/006158 treatment of diabetes mellitus
insulin aspart - EMEA/H/C/006187 treatment of diabetes mellitus
amino acids - EMEA/H/C/005557, Orphan Recordati Rare Diseases, treatment of decompensation episodes in MSUD patients
pomalidomide - EMEA/H/C/006273 treatment of adult patients with multiple myeloma
pomalidomide - EMEA/H/C/006314 treatment of multiple myeloma
pomalidomide - EMEA/H/C/006302 in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM)
pomalidomide - EMEA/H/C/006294 treatment of adults with multiple myeloma
imetelstat - EMEA/H/C/006105, Orphan Geron Netherlands B.V., treatment of adult patients with transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS) with ring sideroblasts
ustekinumab - EMEA/H/C/005805 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

Bimzelx - bimekizumab - EMEA/H/C/005316/X/0021
UCB Pharma S.A., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Gross-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."

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."

Eurartesim - piperaquine tetraphosphate / artenimol - EMEA/H/C/001199/X/0041
Alfasigma S.p.A., Rapporteur: Janet Koenig, "Extension application to introduce a new pharmaceutical form associated with 2 new strengths (80 mg/10 mg and 160 mg/20 mg

dispersible tablets)."

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)."

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."

PHEBURANE - sodium phenylbutyrate - EMEA/H/C/002500/X/0037
Eurocept International B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 1.1) is updated in accordance."

Skyrizi - risankizumab - EMEA/H/C/004759/X/0043/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Gross-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.”

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

in vitro diagnostic medical device - EMEA/H/D/006340 in vitro diagnostic device for laboratory use, intended for the qualitative detection of BRAF V600 mutations in DNA extracted from formalin-fixed, paraffin-embedded human tissue. Request for Supplementary Information adopted on 14.09.2023.
in vitro diagnostic medical device - EMEA/H/D/006308 detection of HER2 antigen Request for Supplementary Information adopted on 14.09.2023.
in vitro diagnostic medical device - EMEA/H/D/006310 immunohistochemical assay utilising an anti-PD-L1 monoclonal primary antibody Request for Supplementary Information adopted on 14.09.2023.

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

Brineura - cerliponase alfa - EMEA/H/C/004065/S/0042, Orphan BioMarin International Limited, Rapporteur: Martina Weise, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Mari Thorn
IMVANEX - smallpox vaccine (live modified vaccinia virus ankara) - EMEA/H/C/002596/S/0095 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer
Increlex - mecasermin - EMEA/H/C/000704/S/0081 Ipsen Pharma, Rapporteur: Outi Mäki-Ikola,

PRAC Rapporteur: Kirsti Villikka

Lojuxta - lomitapide -
EMEA/H/C/002578/S/0057
Amryt Pharmaceuticals DAC, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Menno van der Elst

Strensiq - asfotase alfa -
EMEA/H/C/003794/S/0066, Orphan
Alexion Europe SAS, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Rhea Fitzgerald

Upstaza - eladocagene exuparvovec -
EMEA/H/C/005352/S/0017, Orphan, ATMP
PTC Therapeutics International Limited, Rapporteur: Maura O'Donovan, CHMP Coordinator: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer

Vyndaqel - tafamidis -
EMEA/H/C/002294/S/0090, Orphan
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Tiphaine Vaillant

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

Ambrisentan Mylan - ambrisentan -
EMEA/H/C/004985/R/0009
Mylan Pharmaceuticals Limited, Generic, Generic of Volibris, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Maria del Pilar Rayon

Doptelet - avatrombopag -
EMEA/H/C/004722/R/0018
Swedish Orphan Biovitrum AB (publ), Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Monica Martinez Redondo

Esperoct - turoctocog alfa pegol -
EMEA/H/C/004883/R/0022
Novo Nordisk A/S, Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Gabriele Maurer

Grasustek - pegfilgrastim -
EMEA/H/C/004556/R/0014
Juta Pharma GmbH, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Martina Weise,

PRAC Rapporteur: Menno van der Elst

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

Kisqali - ribociclib - EMEA/H/C/004213/II/0045

Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "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."

Palforzia - defatted powder of arachis hypogaea L., semen (peanuts) - EMEA/H/C/004917/II/0014/G

Aimmune Therapeutics Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kirsti Villikka, "Grouped variation consisting of:
C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomized, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON) to evaluate the safety and efficacy of peanut powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections

4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling were updated accordingly. Version 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet. As part of the application the MAH is requesting a 1-year extension of the market protection. B.II.e.5.a: Introduction of a new pack-size " Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
TAGRISSO - osimertinib - EMEA/H/C/004124/II/0053 AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include TAGRISSO in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations, based on final results from study FLAURA2 (D5169C00001); this is a Phase III, open-label, randomized study of osimertinib with or without platinum plus pemetrexed chemotherapy, multicentre study to assess the efficacy and safety of TAGRISSO as first-line treatment in patients with EGFR mutation-positive, locally advanced or metastatic NSCLC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 16 of the RMP has also been submitted."	
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0081 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension of indication to include, in combination with bevacizumab, adjuvant treatment of adult patients with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation for TECENTRIQ, based on final results from study WO41535 (IMbrave050); this is a phase III, randomized, multi-centre, international, open-label study,	

conducted to evaluate the efficacy and safety of adjuvant therapy of atezolizumab in combination with bevacizumab in patients with completely resected or ablated HCC who were at high risk for disease recurrence. 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 28.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0082

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension of indication to include first-line treatment of adult patients with non-small cell lung cancer (NSCLC) who are ineligible for platinum-based chemotherapy and who do not have EGFR mutant or ALK-positive disease, who have: locally advanced unresectable NSCLC not amenable for definitive chemoradiotherapy, or metastatic NSCLC, for TECENTRIQ, based on final results from study MO29872 (IPSOS); this is a phase 3, open-label, multicenter, randomized study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment naive advanced or recurrent (stage IIIB not amenable for multimodality treatment) or metastatic (stage IV) non-small cell lung cancer who are deemed unsuitable for platinum-containing therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. Version 29.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

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, "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."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Briumvi - ublituximab - EMEA/H/C/005914/II/0003
Propharma Group The Netherlands B.V., Rapporteur: Ewa Balkowiec Iskra

Diacomit - stiripentol - EMEA/H/C/000664/II/0045/G
BIOCODEX, Rapporteur: Alar Irs

Ibandronic Acid Teva - ibandronic acid - EMEA/H/C/001195/II/0021
Teva B.V., Generic, Generic of Bondronat, Bonviva, Rapporteur: Hrefna Gudmundsdottir

Ilumetri - tildrakizumab - EMEA/H/C/004514/II/0052
Almirall S.A, Rapporteur: Jan Mueller-Berghaus

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0143
Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini

Orgalutran - ganirelix - EMEA/H/C/000274/II/0057/G
Organon N.V., Rapporteur: Outi Mäki-Ikola

Ovaleap - follitropin alfa - EMEA/H/C/002608/II/0039
Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt

Pluvicto - lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483/II/0010
Novartis Europharm Limited, Rapporteur: Janet Koenig

Polivy - polatuzumab vedotin -
EMEA/H/C/004870/II/0026, Orphan
Roche Registration GmbH, Rapporteur:
Alexandre Moreau

Shingrix - herpes zoster vaccine
(recombinant, adjuvanted) -
EMEA/H/C/004336/II/0069
GlaxoSmithkline Biologicals SA, Rapporteur:
Christophe Focke

TRODELVY - sacituzumab govitecan -
EMEA/H/C/005182/II/0029
Gilead Sciences Ireland UC, Rapporteur: Jan
Mueller-Berghaus

Xofigo - radium-223 -
EMEA/H/C/002653/II/0053
Bayer AG, Rapporteur: Janet Koenig

Yselty - linzagolix choline -
EMEA/H/C/005442/II/0009
Theramex Ireland Limited, Rapporteur: Finbarr
Leacy

Ziextenzo - pegfilgrastim -
EMEA/H/C/004802/II/0030/G
Sandoz GmbH, Rapporteur: Christian Gartner

WS2574
Nilemdo-
EMEA/H/C/004958/WS2574/0033
Nustendi-
EMEA/H/C/004959/WS2574/0037
Daiichi Sankyo Europe GmbH, Lead Rapporteur:
Patrick Vrijlandt

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

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 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 metabolising 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 metabolising 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 metabolising system (S-9).”	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0029, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, “Submission of the final report from study GWCP18055. This is a randomized, double-blind, placebo- and positive-controlled, parallel group trial to investigate the effects of multiple therapeutic and supratherapeutic doses of cannabidiol (GWP42003-P) in the fed state on the QT/QTc interval in healthy subjects.”	
Ervebo - recombinant vesicular stomatitis virus - zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0034 Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, “Update of section 5.1 of the SmPC in order to update long-term of immunogenicity information and safety results based on final results from study V920-009 (Partnership for Research on Ebola Vaccines in Liberia). In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”	
Evrysdi - risdiplam - EMEA/H/C/005145/II/0017 Roche Registration GmbH, Rapporteur: Bruno Sepodes, “Update of section 5.1 of the SmPC in order to add information on cardiac electrophysiology based on final results from study BP42817 (QTc Study), listed as a category	

3 PASS in the RMP. This is a Phase 1, double-blind, placebo and positive controlled crossover study to investigate the effects of risdiplam on QTc interval in healthy subjects."

Evrysdi - risdiplam - EMEA/H/C/005145/II/0018
Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of section 5.3 of the SmPC in order to update carcinogenicity information based on final results from study 8447237. This is a 104 Week Oral (Gavage) Administration Carcinogenicity Study in the Wistar Rat to investigate the tumorigenic potential of Evrysdi. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

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."

Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/II/0056
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, "Update of section 5.1 of the SmPC in order to add a statement regarding concordance of SVR4 and SVR12, based on post-hoc analysis of the data from the Phase 2 and 3 clinical trials."

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."

Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0072
Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 4.6 of the

SmPC in order to update information on pregnancy based on literature and post-marketing data."

Xultophy - insulin degludec / liraglutide - EMEA/H/C/002647/II/0050
Novo Nordisk A/S, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add Dizziness and Delayed gastric emptying to the list of adverse drug reactions (ADRs) with frequency common and unknown, respectively, based on the cumulative review of clinical studies data, post-marketing data, class labels and biological plausibility. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0063
Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, "Update of section 4.8 of the SmPC in order to add 'Kounis Syndrome' to the list of adverse drug reactions (ADRs). The Package Leaflet is updated accordingly. 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."

WS2502
CoAprovel- EMEA/H/C/000222/WS2502/0214
Karvezide- EMEA/H/C/000221/WS2502/0214
Sanofi Winthrop Industrie, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.3 of the SmPC in order to update information on hydrochlorothiazide monocomponent based on literature review."

B.6.10. CHMP-PRAC assessed procedures

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 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."

Piqray - alpelisib - EMEA/H/C/004804/II/0022/G

Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst, "Grouped application comprising two type II variations (C.I.4) as follows:
- Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information on prophylactic use of metformin for hyperglycaemia based on the results from study CBYL719CES01T (METALLICA). METALLICA is a Phase II study aimed to evaluate the effect of prophylactic use of metformin for hyperglycaemia in HR-positive, HER2-negative, PIK3CA-mutated advanced breast cancer patients treated with alpelisib plus endocrine therapy.
- Update of section 4.8 of the SmPC in order to add "uveitis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on a cumulative review of the MAH safety database and literature.
The Package Leaflet and Annex II are updated accordingly. The RMP version 7.0 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led

HEPLISAV B - Hepatitis B surface antigen

(rDNA) - EMEA/H/C/005063/II/0031
Dynavax GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study DV2-HBV-28 - Post-marketing observational surveillance study to evaluate pregnancy outcomes among women who receive HEPLISAV-B or Engerix-B; HBV-28 was conducted using the same patient population as two observational post-marketing surveillance studies designed to evaluate the incidence of AMI (HBV-25) or new-onset immunemediated diseases, herpes zoster, and anaphylaxis (HBV-26) in recipients of HEPLISAV-B compared with recipients of Engerix-B. The primary objective of this study was to describe and compare pregnancy outcomes in recipients of HEPLISAV-B and recipients of Engerix-B.The Package Leaflet is updated accordingly. The RMP version 1.4 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."

PRAC Led
Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0054
ViiV Healthcare B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from non-interventional PASS study COMBINE-2 listed as a category 3 study in the RMP. This is a real-world evidence study to evaluate effectiveness of two drug regimen, antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor. The RMP version 6.0 has also been submitted in order to remove the important identified risk of ''drug resistance''."

PRAC Led
MabThera - rituximab - EMEA/H/C/000165/II/0199
Roche Registration GmbH, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa Mejia, "Submission of the final report for study BE29950 (RIVAS), listed as a category 3 study in the RMP. This is a prospective, single center, secondary data use, long-term surveillance, non-interventional PASS with the objective to

better characterise the risk profile of MabThera by collecting long term safety data in patients with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have been treated with rituximab (MabThera) or other available non-rituximab therapies. The RMP version 24.0 has also been submitted."	
PRAC Led **Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0127** Pfizer Europe MA EEIG, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Submission of an updated RMP version 9.0 in order to remove the important potential risks 'Change in meningococcal epidemiology/serogroup replacement' and 'Lack of Efficacy' from the list of the safety concerns, to remove 'Long-term persistence of the vaccine response and need for a booster dose' as missing information and to remove 'Use during pregnancy' from the list of safety concerns."	
PRAC Led **Nivestim - filgrastim - EMEA/H/C/001142/II/0074/G** Pfizer Europe MA EEIG, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Grouped application consisting of: C.I.13: Submission of the final report from non-interventional PASS study ZOB-NIV-1513/C1121008 listed as a category 3 study in the RMP. This is a multinational, multi-centre, prospective, non-interventional, post-authorisation safety study in Healthy Donors (HDs) exposed to nivestim (biosimilar filgrastim) for Haematopoietic Stem Cell (HSC) Mobilisation (NEST). The RMP version 12 has also been submitted. C.I.11 for RMP: Submission of an updated RMP version 12.0 in order to align it with the reference product, Neupogen, RMP v. 6.3 dated June 2022. "	
PRAC Led **Revatio - sildenafil - EMEA/H/C/000638/II/0107** Upjohn EESV, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 8.0 in order to remove "Long-term Mortality" as	

missing information based on the completion of Study A1481324 - A multinational, multicentre study to assess the effects of oral sildenafil on mortality in adults with pulmonary arterial hypertension (PAH). In addition, the MAH took the opportunity to reflect the completion of the Studies A1481324 and A1481319."

PRAC Led

Simponi - golimumab - EMEA/H/C/000992/II/0117/G

Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Grouped application consisting of:
C.I.13: Submission of the final report from study UC Nordic (MK-8259-013) listed as a category 3 study in the RMP. This is a Non-interventional Observational Longitudinal Post Authorization Safety Study (PASS) of SIMPONI in Treatment of Ulcerative Colitis using Nordic National Health Registries.
C.I.13: Submission of the final report from study ENEIDA (MK-8259-042) listed as a category 3 study in the RMP. This is a Post-Authorisation Safety Study (PASS) of Golimumab in UC Using the Spanish ENEIDA Registry.
The RMP version 27.1 has also been submitted."

PRAC Led

Sprycel - dasatinib - EMEA/H/C/000709/II/0090

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Aaron Sosa Mejia, "Submission of an updated RMP version 18.0 in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects."

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 10.1 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's Vedrop registry) from the pharmacovigilance plan."	
PRAC Led **Zaltrap - aflibercept -** **EMEA/H/C/002532/II/0071** Sanofi Winthrop Industrie, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 5.0 in order to update the Risk Minimisation Measures and List of Safety Concerns removing "Nephrotic syndrome", "Cardiac failure and ejection fraction decreased", "Posterior reversible encephalopathy syndrome", "Thrombotic microangiopathy" and "Osteonecrosis of jaw" of the important identified risks, "Reproductive and developmental toxicity" as an important potential risk and "Safety in patients with severe hepatic impairment" of the missing information, following the assessment of PSUSA/00010019/202108."	
PRAC Led **WS2571** **Glyxambi-** **EMEA/H/C/003833/WS2571/0055** **Jardiance-** **EMEA/H/C/002677/WS2571/0082** **Synjardy-** **EMEA/H/C/003770/WS2571/0076** Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Submission of the final report from study 1245-0201. This is an observational post-authorization safety study (PASS) to assess the risk of acute pancreatitis in type 2 diabetes mellitus (T2DM) patients newly initiating empagliflozin compared to other oral non-incretin/non-sodium glucose co-transporter-2 inhibitors (SGLT2i)-containing glucose lowering drugs. The RMP versions 22.0, 15.0 and 10.0 have also been submitted for Jardiance, Synjardy and Glyxambi, respectively."	

B.6.12. CHMP-CAT assessed procedures

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2576
Elebrato Ellipta-
EMEA/H/C/004781/WS2576/0037
Relvar Ellipta-
EMEA/H/C/002673/WS2576/0064
Revinty Ellipta-
EMEA/H/C/002745/WS2576/0061
Trelegy Ellipta-
EMEA/H/C/004363/WS2576/0034
GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro

WS2578
Fluenz Tetra-
EMEA/H/C/002617/WS2578/0133
Pandemic influenza vaccine H5N1
AstraZeneca-
EMEA/H/C/003963/WS2578/0067
AstraZeneca AB, Lead Rapporteur: Jan Mueller-Berghaus

WS2579/G
Fluenz Tetra-
EMEA/H/C/002617/WS2579/0134/G
Pandemic influenza vaccine H5N1
AstraZeneca-
EMEA/H/C/003963/WS2579/0068/G
AstraZeneca AB, Lead Rapporteur: Christophe Focke

WS2582
HyQvia-EMEA/H/C/002491/WS2582/0092
Kiovig-EMEA/H/C/000628/WS2582/0124
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

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

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

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