



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 November 2023
EMA/CHMP/460963/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 06-09 November 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

06 November 2023, 13:00 – 19:30, virtual meeting/room 1C

07 November 2023, 08:30 – 19:30, virtual meeting/room 1C

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

09 November 2023, 08:30 – 15:00, virtual meeting/room 1C

Health and safety information

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

Disclaimers

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

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

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to ongoing 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 06-09 November 2023. See November 2023 CHMP minutes (to be published post December 2023 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 06-09 November 2023

1.3. Adoption of the minutes

CHMP minutes for 09-12 October 2023.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 12 October 2023 and 30 October 2023.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. tofersen - Orphan - EMEA/H/C/005493

Biogen Netherlands B.V.; treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

Scope: Oral explanation

Action: Oral explanation to be held on 07 November 2023 at 14:00

Participation of patient representatives

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

2.2. Re-examination procedure oral explanations

2.2.1. 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: Oral explanation

Action: Oral explanation to be held on 6 November 2023 at 16:00

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.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Veltassa - patiomer - EMEA/H/C/004180/X/0031/G

Vifor Fresenius Medical Care Renal Pharma France

Scope: "Extension application to introduce a new strength (1 g powder for oral suspension), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of population from 6 to 18 years old for Veltassa based on final results from paediatric study RLY5016-206P (EMERALD); this is a phase 2, open-label, multiple dose study to evaluate the pharmacodynamic effects, safety, and tolerability of patiomer for oral suspension in children and adolescents 2 to less than 18 years of age with chronic kidney disease and hyperkalaemia. As a consequence, sections 1, 2, 4.1, 4.2, 4.8, 4.9, 5.1 and 6.5 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes."

Possible oral explanation

Action: Possible oral explanation to be held on 08 November 2023 at 16:00

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

See 4.2

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. azacitidine - EMEA/H/C/006154

Treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) and acute myeloid leukaemia (AML)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 26.04.2023.

3.1.2. paclitaxel - EMEA/H/C/006173

treatment of metastatic breast cancer

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. momelotinib - Orphan - EMEA/H/C/005768

Glaxosmithkline Trading Services Limited; treatment of disease-related splenomegaly or symptoms and anaemia

Scope: Opinion

Action: For adoption

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

3.1.4. ranibizumab - EMEA/H/C/006055

treatment of neovascular age-related macular degeneration (AMD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 23.02.2023.

3.1.5. rozanolixizumab - Orphan - EMEA/H/C/005824

UCB Pharma; Treatment of generalised myasthenia gravis (gMG)

Scope: Opinion

Action: For adoption

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

3.1.6. trametinib - Orphan - EMEA/H/C/005886

Novartis Europharm Limited; Treatment of paediatric patients aged 1 year and older with glioma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.09.2023, 25.05.2023. List of Questions adopted on 26.01.2023.

3.1.7. ustekinumab - EMEA/H/C/006101

treatment of plaque psoriasis, arthritis psoriatic, Crohn's Disease and ulcerative colitis

Scope: Opinion

Action: For adoption

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

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

3.2.1. polihexanide - Orphan - EMEA/H/C/005858

SIFI SPA; treatment of acanthamoeba keratitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.09.2022.

3.2.2. exagamglogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005763

Vertex Pharmaceuticals (Ireland) Limited; treatment of transfusion-dependent β -thalassemia and sickle cell disease

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 08.09.2023. List of Questions adopted on 17.05.2023.

3.2.3. Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006052

active immunisation for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

3.2.4. cefepime / enmetazobactam - EMEA/H/C/005431

treatment of: 1) complicated urinary tract infections (including pyelonephritis); 2) hospital-

acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); 3) patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above and 4) infections due to aerobic Gram-negative organisms in adults with limited treatment options

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

3.2.5. [Pandemic influenza vaccine \(H5N1\) \(surface antigen, inactivated, adjuvanted, prepared in cell cultures\) - EMEA/H/C/006051](#)

prophylaxis of influenza

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

3.2.6. [leniolisib - Orphan - EMEA/H/C/005927](#)

Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 24.01.2023.

3.2.7. [catumaxomab - EMEA/H/C/005697](#)

indicated for the treatment of malignant ascites

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

3.2.8. [lecanemab - EMEA/H/C/005966](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

3.2.9. [bevacizumab - EMEA/H/C/005723](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

3.2.10. paliperidone - EMEA/H/C/006185

Treatment of schizophrenia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

3.2.11. pomalidomide - EMEA/H/C/006195

in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

3.2.12. danicopan - PRIME - Orphan - EMEA/H/C/005517

Alexion Europe; Treatment of extravascular haemolysis (EVH) in patients with paroxysmal nocturnal haemoglobinuria

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

3.3.1. dasiglucagon - EMEA/H/C/006214

treatment of severe hypoglycemia in patients with diabetes

Scope: List of questions

Action: For adoption

3.3.2. levetiracetam - EMEA/H/C/006186

treatment of partial onset seizures

Scope: List of questions

Action: For adoption

3.3.3. ustekinumab - EMEA/H/C/006221

treatment of adult patients with moderately to severely active plaque psoriasis, Crohn's disease and active ulcerative colitis and active psoriatic arthritis

Scope: List of questions

Action: For adoption

3.3.4. nilotinib - EMEA/H/C/006315

treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

Scope: List of questions

Action: For adoption

3.3.5. crovalimab - EMEA/H/C/006061

treatment of paroxysmal nocturnal haemoglobinuria

Scope: List of questions

Action: For adoption

3.3.6. Respiratory syncytial virus mRNA vaccine – OPEN – EMEA/H/C/006278

Prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV)

Scope: List of questions

Action: For adoption

3.3.7. teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: List of questions

Action: For adoption

3.3.8. zolbetuximab - Orphan - EMEA/H/C/005868

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

Scope: List of questions

Action: For adoption

3.3.9. macitentan / tadalafil - EMEA/H/C/005001

treatment of pulmonary arterial hypertension (PAH) in adults patients

Scope: List of questions

Action: For adoption

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

3.4.1. apadamtase alfa - Orphan - EMEA/H/C/006198

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

Scope: Letter by the applicant dated 24.10.2023 requesting an extension to the clock stop to respond to the list of questions adopted in September 2023.

Action: For adoption

List of Questions adopted on 14.09.2023.

3.4.2. dantrolene sodium, hemiheptahydrate - Orphan - EMEA/H/C/006009

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

Scope: Letter by the applicant dated 30.10.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2023.

Action: For adoption

List of Outstanding Issues adopted on 22 June 2023. List of Questions adopted on 10.11.2022.

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

3.5.1. 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: Opinion

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.

See 2.2

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. 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 Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 22.06.2023.

4.1.2. 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 Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 20.07.2023.

4.1.3. 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 Talzena 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 Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 22.06.2023.

4.1.4. Tecentrig - atezolizumab - EMEA/H/C/004143/X/0076

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (1875 mg) and new route of administration (subcutaneous use). The RMP (version 24.0) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 30.03.2023.

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

4.2.1. Azacitidine Accord - azacitidine - EMEA/H/C/005147/X/0013

Accord Healthcare S.L.U.

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (10 mg/ml powder for solution for infusion) and a new route of administration (intravenous use). The RMP version 2 is updated in accordance."

Action: For adoption

List of Questions adopted on 26.04.2023.

4.2.2. Upravi - selexipag - EMEA/H/C/003774/X/0038

Janssen-Cilag International N.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Nathalie Gault

Scope: "Extension application to add a new strength of 100 µg film-coated tablets in HDPE bottle. The RMP (version 10.1) is updated in accordance."

Action: For adoption

List of Questions adopted on 22.06.2023.

4.2.3. Veltassa - patiomer - EMEA/H/C/004180/X/0031/G

Vifor Fresenius Medical Care Renal Pharma France

Rapporteur: Jayne Crowe, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension application to introduce a new strength (1 g powder for oral suspension), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of population from 6 to 18 years old for Veltassa based on final results from paediatric study RLY5016-206P (EMERALD); this is a phase 2, open-label, multiple dose study to evaluate the pharmacodynamic effects, safety, and tolerability of patiomer for oral suspension in children and adolescents 2 to less than 18 years of age with chronic kidney disease and hyperkalaemia. As a consequence, sections 1, 2, 4.1, 4.2, 4.8, 4.9, 5.1 and 6.5 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes."

Action: For adoption

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

See 2.3

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. Abilify Maintena - aripiprazole - EMEA/H/C/002755/X/0045

Otsuka Pharmaceutical Netherlands B.V.

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form associated with two new strengths (720 and 960 mg Prolonged-release suspension for injection). The RMP (version 12.1) is updated in accordance."

Action: For adoption

4.3.2. Reagila - cariprazine - EMEA/H/C/002770/X/0033

Gedeon Richter Plc.

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

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

Action: For adoption

4.3.3. [Spevigo - spesolimab - EMEA/H/C/005874/X/0006/G](#)

Boehringer Ingelheim International GmbH

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

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.

This line extension is grouped with a type II variation (C.I.6.a) to extend the indication for Spevigo 450 mg concentrate for solution for infusion to include treatment of generalised pustular psoriasis (GPP) flares in adolescents (from 12 years of age), based on final results from study 1368-0027 (Effisayil 2) and extrapolation; this is a multi-center, randomized, parallel group, double blind, placebo controlled, phase IIb dose-finding study to evaluate efficacy and safety of BI 655130 (spesolimab) compared to placebo in preventing GPP flares in patients with history of GPP. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet."

Action: For adoption

4.3.4. [Tepadina - thiotepa - EMEA/H/C/001046/X/0049](#)

ADIENNE S.r.l. S.U.

Rapporteur: Alexandre Moreau

Scope: "Extension application to add a new strength (200 mg powder and solvent for solution for infusion)."

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. Abecma - idecabtagene vicleucel - Orphan - ATMP - EMEA/H/C/004662/II/0031

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken, Co-Rapporteur: Heli Suila, CHMP Coordinators: Ingrid Wang and Johanna Lähteenvuo, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38 antibody and have demonstrated disease progression on the last therapy for Abecma (idecabtagene vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells.", 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 16.06.2023.

5.1.2. Aspaveli - pegcetacoplan - Orphan - EMEA/H/C/005553/II/0011

Swedish Orphan Biovitrum AB (publ)

Rapporteur: Alexandre Moreau, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adult patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) not previously treated with a complement inhibitor for Aspaveli, based on final results from study APL2-308. This is a Phase III, randomized, open-label, comparator-controlled study that enrolled adult patients with PNH who had not been treated with a complement inhibitor. 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."

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023.

5.1.3. [Ayvakyt - avapritinib - Orphan - EMEA/H/C/005208/II/0023](#)

Blueprint Medicines (Netherlands) B.V.

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include treatment of adult patients with indolent systemic mastocytosis (ISM) for avapritinib based on results from the pivotal part of study BLU-285-2203 (PIONEER), this is a 3-part, randomized, double-blind, placebo-controlled, Phase 2 study to evaluate safety and efficacy of avapritinib (BLU-285) in indolent and smoldering systemic mastocytosis with symptoms inadequately controlled with standard therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023, 26.04.2023.

5.1.4. [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 12.10.2023, 14.09.2023.

5.1.5. [Fluad Tetra - influenza vaccine \(surface antigen, inactivated, adjuvanted\) - EMEA/H/C/004993/II/0043](#)

Seqirus Netherlands B.V.

Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of indication to include adults 50 years of age and older for Fluad Tetra, based on final results from study V118_23; this is a phase 3, randomized, observer-blind, controlled, multicenter, clinical study to evaluate immunogenicity and safety of an MF59-adjuvanted quadrivalent subunit inactivated influenza vaccine in comparison with a licensed quadrivalent influenza vaccine, in adults 50 to 64 years of age. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Labelling and Package Leaflet are updated in

accordance. Version 2.9 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 20.07.2023.

5.1.6. Jardiance - empagliflozin - EMEA/H/C/002677/II/0076

Boehringer Ingelheim International GmbH

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: “Extension of indication for Jardiance to include treatment of children aged 10 years and above with type 2 diabetes based on results from study DINAMO 1218-0091; this is a double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 21.0 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 26.04.2023.

5.1.7. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0138

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication to include Keytruda in combination with gemcitabine-based chemotherapy for the first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults, based on final results from study KEYNOTE-966; this is a Phase 3 randomized, double blind study of Pembrolizumab plus Gemcitabine/Cisplatin versus Placebo plus Gemcitabine/Cisplatin as first-line therapy in participants with advanced and/or unresectable biliary tract carcinoma. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 43.1 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

5.1.8. Metalyse - tenecteplase - EMEA/H/C/000306/II/0070/G

Boehringer Ingelheim International GmbH

Rapporteur: Martina Weise

Scope: “Grouped application consisting of:

C.I.6.a (Type II): To add the new therapeutic indication Acute Ischemic Stroke (AIS) for the new 25 mg presentation. Consequently, a separate SmPC and Package Leaflet are provided

for the 25 mg presentation with the new indication. In addition, the MAH took the opportunity to implement editorial changes and minor updates to the PI of Metalyse 40 mg (8,000 U) and 50 mg (10,000 U).

B.II.e.5.c (Type II): To add the new 25 mg presentation for the sterile parenteral biological medicinal product Metalyse (tenecteplase) powder and solvent for solution for injection.

B.II.b.3.a

B.II.e.1.b.2”

Action: For adoption

5.1.9. Mounjaro - tirzepatide - EMEA/H/C/005620/II/0007

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication to include chronic weight management, including weight loss and weight maintenance, for Mounjaro, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial body mass index (BMI) of ≥ 30 kg/m² (obesity), or ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbid condition, based on a global, pivotal phase 3 study I8F-MC-GPHK (SURMOUNT-1) and five supportive phase 3 studies (SURPASS-1 to -5) in participants with T2DM and BMI ≥ 27 kg/m². SURMOUNT-1 is a phase 3, randomized, double-blind, placebo-controlled trial to investigate the efficacy and safety of tirzepatide once weekly in participants without type 2 diabetes who have obesity or are overweight with weight related comorbidities. As a consequence, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”, 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, 22.06.2023.

5.1.10. Moventig - naloxegol - EMEA/H/C/002810/II/0039

Kyowa Kirin Holdings B.V.

Rapporteur: Christophe Focke, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Rhea Fitzgerald

Scope: “Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update information regarding the use of naloxegol in OIC patients with cancer-related pain based on real-world data from non-interventional studies (NACASY, KYONAL and MOVE studies), post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 8 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 26.04.2023.

5.1.11. NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0058

MediWound Germany GmbH

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Extension of current indication for removal of eschar in adults with deep partial- and full-thickness thermal burns to the paediatric population for NexoBrid based on interim results from study MW2012-01-01 (CIDS study), listed as study MW2012-01-01 is a 3-stage, multi-centre, multi-national, randomised, controlled, open label, 2 arm study aiming to demonstrate the superiority of NexoBrid treatment over SOC treatment in paediatric patients (aged 0 to 18 years) with deep partial thickness (DPT) and full thickness (FT) thermal burns of 1% to 30% of total body surface area (TBSA).

As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 9 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023, 15.12.2022.

5.1.12. Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0031

Daiichi Sankyo Europe GmbH

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

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

Action: For adoption

5.1.13. Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0035

Daiichi Sankyo Europe GmbH

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

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for Nustendi, based on results from study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients

with, or at high risk for, cardiovascular disease who are statin intolerant; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.14. Retsevmo - selpercatinib - EMEA/H/C/005375/II/0021

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication to include the treatment of adults and adolescents 12 years and older with advanced RET fusion-positive thyroid cancer in the first-line setting for Retsevmo based on interim data from studies LIBRETTO-001 (LOXO-RET-17001) and LIBRETTO-121; LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in patients with RET-altered advanced solid tumours. LIBRETTO-121 is a Phase 1/2 study of selpercatinib in paediatric patients with advanced RET-altered solid or primary central nervous system tumours. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

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

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication for Retsevmo to include the treatment of adults with advanced or metastatic RET fusion-positive solid tumours with disease progression on or after prior systemic therapies or who have no satisfactory therapeutic options, based on interim data from study LIBRETTO-001 (LOXO-RET-17001); LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in adult and adolescent patients with advanced RET-altered tumours. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

5.1.16. Vabysmo - faricimab - EMEA/H/C/005642/II/0005

Roche Registration GmbH

Rapporteur: Jayne Crowe, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients with central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). These are global, multicenter, randomized, double-masked, active comparator-controlled, parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI."

Action: For adoption

5.1.17. [Xromi - hydroxycarbamide - EMEA/H/C/004837/II/0019](#)

Nova Laboratories Ireland Limited

Rapporteur: Anastasia Mountaki, Co-Rapporteur: Karin Janssen van Doorn, PRAC
Rapporteur: Jo Robays

Scope: "Extension of indication to include the prevention of vaso-occlusive complications of sickle cell disease in children from 6 months to 2 years of age for Xromi, based on final results from the paediatric study INV543, listed as a category 3 study in the RMP; this is a single-arm, open-label, multi-center study in children with sickle cell anaemia over 6 months of age. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 26.04.2023.

5.1.18. [WS2552 Ongentys - opicapone - EMEA/H/C/002790/WS2552/0060](#) [Ontilyv - opicapone - EMEA/H/C/005782/WS2552/0015](#)

Bial Portela & Companhia S.A.

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

Scope: "Extension of indication to include treatment of signs and symptoms of Parkinson's Disease for Ongentys/Ontilyv, based on final results from study BIA-91067-303; this is a pivotal Phase III, multicentre, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of opicapone in patients with early idiopathic Parkinson's Disease receiving treatment with L-DOPA plus a DDCI, and who are without signs of any motor complication. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.0 of the RMP has also been submitted (only applicable to Ongentys) to reflect the changes made upon approval of the informed consent application, to keep consistency between the eCTD lifecycles of the two marketing authorisations (Ongentys and Ontilyv). Furthermore, the PI is brought in line with the latest QRD template version 10.3. In addition, as part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

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

Novartis Europharm Limited

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

Scope: "Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Stage II or Stage III early breast cancer, irrespective of nodal status, in combination with an AI for Kisqali based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicenter, randomised, 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."

Third party intervention.

Action: For information

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/006372

next generation sequencing (NGS) assay for tumour mutation profiling

Scope: Request for supplementary information

Action: For adoption

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

detection of PD-L1 protein

Scope: Opinion

Action: For adoption

Request for supplementary information adopted on 12.10.2023.

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

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

Scope: Opinion

Action: For adoption

Request for supplementary information adopted on 12.10.2023, 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. mozafancogene autotemcel - Orphan - H0005537

Rocket Pharmaceuticals B.V., Fanconi anemia Type A

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

Action: For adoption

8.1.2. vorasidenib - H0006284

Treatment of patients with residual/recurrent Grade 2 glioma harbouring an isocitrate dehydrogenase 1 (IDH1) mutation or isocitrate dehydrogenase 2 (IDH2) mutation who have

undergone surgery as their only treatment

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. Arexvy - respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0002/G

GlaxoSmithkline Biologicals S.A.

Rapporteur: Patrick Vrijlandt

Scope: "Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV) based on final results from studies RSV OA=ADJ-008 and RSV OA=ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV), respectively."

Action: For adoption

9.1.2. Bylvay - odeixibat - Orphan - EMEA/H/C/004691/II/0011

Albireo

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jayne Crowe

Scope: "Extension of indication to include the treatment of cholestatic pruritus in Alagille syndrome (ALGS) in patients aged 6 months or older for Bylvay, based on final results from study A4250-012 and interim results from study A4250-015. Study A4250-012 is a 24-week, randomised, double-blind, placebo-controlled Phase III study conducted in 52 patients with a genetically confirmed diagnosis of ALGS and presence of pruritus and high serum bile acid levels at baseline. Study A4250-015 is an ongoing 72-week open-label extension trial for patients who completed study A4250-012 and evaluates the long-term safety and efficacy of Bylvay in patients with ALGS. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and Annex II of the Marketing Authorisation are updated. The Package Leaflet is updated in accordance. Version 2.4 of the RMP has also been

submitted. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet, Annex II and to the Risk Management Plan (RMP).”

Withdrawal of Type-II variation application

Action: For information

Opinion adopted on 20.07.2023. Request for Supplementary Information adopted on 22.06.2023, 30.03.2023.

9.1.3. [Nuvaxovid - Covid-19 Vaccine \(recombinant, adjuvanted\) - EMEA/H/C/005808/II/0058/G – written adoption](#)

Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

Scope: quality

Positive opinion was adopted via written procedure on 31.10.2023.

Action: For information

9.1.4. [Leqvio– Inclisiran – EMEA/H/C/005333](#)

Novartis Europharm Limited; treatment for primary hypercholesterolaemia or mixed dyslipidaemia

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

Scope: DHPC and communication plan

Action: For adoption

9.1.5. [Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0147/G](#)

Boehringer Ingelheim International GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Grouped application comprising three type II variations (C.I.4) as follows:

C.I.7.a (type IB): to delete the pharmaceutical form "powder and solvent for oral solution, 6.25 mg/ml", as agreed in procedure EMEA/H/C/000829/II/0144.

C.I.4 (type II): Update of section 4.1 of the SmPC in order to modify the indication following the deletion of the powder and solvent for oral solution; the Package Leaflet is updated accordingly. The RMP version 41.2 has also been submitted.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.”

Action: For adoption

9.1.6. [Remsima - infliximab - EMEA/H/C/002576/II/0133/G](#)

Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Kristina Dunder

Scope: "A Grouped application consisting of:

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

Action: For adoption

9.1.7. 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

Scope: "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."

Action: For adoption

Request for Supplementary Information adopted on 06.10.2023.

9.1.8. Zynrelef - bupivacaine / meloxicam - EMEA/H/C/005205

Heron Therapeutics, Zynrelef is indicated for treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Elita Poplavska

Scope: Withdrawal of marketing authorisation

Action: For information

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

PTC Therapeutics International Limited

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

Scope: Appointment of re-examination rapporteurs

Action: For adoption

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

10. Referral procedures

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

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

Advanz Pharma Limited

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

Scope: Revised timetable

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed. In addition, the EC requests the Agency/CHMP to give its opinion, as soon as possible, as to whether temporary measures are necessary to ensure the safe and effective use of this medicinal product taking into account amongst other things findings from the type II variation procedure EMEA/H/C/004093/II/0038.

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

10.5.1. Havrix - EMEA/H/A-30/1527

GlaxoSmithKline Biologicals

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

Scope: List of question

Action: For adoption

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

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

10.6.1. Azithromycin containing medicinal products for systemic use – EMEA/H/A-31/1532

MAH various (NAPs only)

Referral Rapporteur: TBC, Referral Co-Rapporteur: TBC

Scope: Start of procedure, appointment of Rapporteurs, timetable, list of questions

Action: For adoption

Need to re-evaluate the benefit-risk ratio of the approved indications considering the current scientific knowledge, the increasing resistance rate, the consumption data suggesting overuse and the different indications in the EU Member States. Furthermore, the appropriate dose and duration of administration for both oral and intravenous formulations need to be discussed as well as the adequacy of safety relevant information, information on pregnancy and breastfeeding and pharmacological properties.

The German National Competent Authority triggered a referral under Article 31 of Directive 2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended, or revoked.

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

November 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

CHMP co-opted membership

The current expertise of Jan-Mueller-Berghaus is 'Quality, safety and efficacy of biological medicinal products, including advanced therapies, and with specific emphasis on vaccines.'

The CHMP agreed that a co-opted member should be appointed in the following area of expertise: Quality, safety and efficacy of biological medicinal products, including advanced therapies, and with specific emphasis on vaccines and biosimilars. A call for nomination of a co-opted member was launched following the October 2023 plenary.

Nomination(s) received

Action: For election

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 November 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 November 2023 meeting to CHMP for adoption

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 23-26 October 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.

14.4. 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

No items

Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations (section 2)

The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications (section 3)

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 (section 4)

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures (section 5)

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices (section 6)

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 3.5)

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures (section 5.3)

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 Pharmacovigilance 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 06-09 November 2023 CHMP Agenda

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for
November 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

Atriance - nelarabine -

EMA/H/C/000752/S/0062

Sandoz Pharmaceuticals d.d., Rapporteur:
Aaron Sosa Mejia, PRAC Rapporteur: Marie
Louise Schougaard Christiansen

Mepsevii - vestronidase alfa -

EMA/H/C/004438/S/0036, Orphan

Ultragenyx Germany GmbH, Rapporteur: Patrick
Vrijlandt, PRAC Rapporteur: Maria del Pilar
Rayon

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Pazenir - paclitaxel -

EMA/H/C/004441/R/0015

ratiopharm GmbH, Generic, Generic of
Abraxane, Rapporteur: Daniela Philadelphy,
PRAC Rapporteur: Menno van der Elst

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Dectova - zanamivir -

EMA/H/C/004102/R/0017

GlaxoSmithKline Trading Services Limited,
Rapporteur: Ingrid Wang, Co-Rapporteur: Bruno
Sepodes, PRAC Rapporteur: Ulla Wändel
Liminga

Mulpleo - lusutrombopag -**EMA/H/C/004720/R/0018**

Shionogi B.V., Rapporteur: Daniela Philadelphy,
Co-Rapporteur: Ewa Balkowiec Iskra, PRAC
Rapporteur: Mari Thorn
Request for Supplementary Information adopted
on 14.09.2023.

Palynziq - pegvaliase -**EMA/H/C/004744/R/0038, Orphan**

BioMarin International Limited, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Alexandre
Moreau, PRAC Rapporteur: Rhea Fitzgerald

Skyrizi - risankizumab -**EMA/H/C/004759/R/0039**

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Finbarr Leacy, PRAC Rapporteur:
Liana Gross-Martirosyan
Request for Supplementary Information adopted
on 14.09.2023.

Trecondi - treosulfan -**EMA/H/C/004751/R/0019, Orphan**

medac Gesellschaft für klinische
Spezialpräparate mbH, Rapporteur: Fátima
Ventura, Co-Rapporteur: Aaron Sosa Mejia,
PRAC Rapporteur: Julia Pallos

B.2.3. Renewals of Conditional Marketing Authorisations**B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES**

Signal detection

PRAC recommendations on signals adopted at
the PRAC meeting held on 23-26 October 2023
PRAC:

Signal of acquired phimosis and phimosis

Edistride, Forxiga, Ebymect, Xigduo, Qtern
(CAP & NAP) – Dapagliflozin

Rapporteur: multiple, Co-Rapporteur:
multiple, PRAC Rapporteur: Mari Thorn
PRAC recommendation on a variation

Action: For adoption

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

EMA/H/C/PSUSA/0002491/202304

(pramipexole)

CAPS:

Mirapexin (EMA/H/C/000134)

(pramipexole), Boehringer Ingelheim International GmbH, Rapporteur: Thalia Marie Estrup Blicher

Sifrol (EMA/H/C/000133) (pramipexole), Boehringer Ingelheim International GmbH, Rapporteur: Thalia Marie Estrup Blicher

NAPS:

NAPs – EU,

PRAC Rapporteur: Karin Erneholm, "06/04/2022 To: 06/04/2023"

EMA/H/C/PSUSA/00010499/202303

(eftrenonacog alfa)

CAPS:

Alprolix (EMA/H/C/004142) (eftrenonacog alfa), Swedish Orphan Biovitrum AB (publ),

Rapporteur: Daniela Philadelphly, PRAC

Rapporteur: Gabriele Maurer, "20/03/2020 To: 19/03/2023"

EMA/H/C/PSUSA/00010635/202303

(avelumab)

CAPS:

Bavencio (EMA/H/C/004338) (avelumab),

Merck Europe B.V., Rapporteur: Filip Josephson,

PRAC Rapporteur: Karin Erneholm, "23/03/2022 To: 22/03/2023"

EMA/H/C/PSUSA/00010760/202303

(lorlatinib)

CAPS:

Lorviqua (EMA/H/C/004646) (lorlatinib), Pfizer

Europe MA EEIG, Rapporteur: Aaron Sosa Mejia,

PRAC Rapporteur: Nikica Mirošević Skvrce, "21/09/2022 To: 20/03/2023"

EMA/H/C/PSUSA/00010818/202303

(siponimod)

CAPS:

Mayzent (EMA/H/C/004712) (siponimod),

Novartis Europharm Limited, Rapporteur:

Thalia Marie Estrup Blicher, PRAC Rapporteur:

Maria del Pilar Rayon, "26/03/2022 To: 25/03/2023"

EMA/H/C/PSUSA/00010879/202303

(filgotinib)

CAPS:

Jyseleca (EMA/H/C/005113) (filgotinib),
Galapagos N.V., Rapporteur: Kristina Dunder,
PRAC Rapporteur: Nikica Mirošević Skvrce,
"24/09/2022 To 23/03/2023"

EMA/H/C/PSUSA/00010921/202303

(cenobamate)

CAPS:

Ontozry (EMA/H/C/005377) (cenobamate),
Angelini S.p.A., Rapporteur: Bruno Sepodes,
PRAC Rapporteur: Jo Robays, "19/05/2022 To:
26/03/2023"

EMA/H/C/PSUSA/00011003/202303

(olipudase alfa)

CAPS:

Xenpozyme (EMA/H/C/004850) (olipudase
alfa), Sanofi B.V., Rapporteur: Patrick
Vrijlandt, PRAC Rapporteur: Martin Huber,
"28/09/2022 To: 28/03/2023"

B.4. EPARs / WPARs

**Agamree - vamorolone -
EMA/H/C/005679, Orphan**

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

**in vitro diagnostic medical device -
EMA/H/D/006340**

is an 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. , Companion Diagnostics (Article 48 (3),
(4), (7), (8) of Regulation (EU) 2017/746)

For information only. Comments can be sent to
the PL in case necessary.

**Elrexio - elranatamab -
EMA/H/C/005908**

Pfizer Europe MA EEIG, treatment of adult
patients with relapsed or refractory multiple
myeloma, New active substance (Article 8(3) of
Directive No 2001/83/EC)

For information only. Comments can be sent to
the PL in case necessary.

**Elucirem - gadopiclesol -
EMA/H/C/005626**

Guerbet, for diagnostic: contrast-enhanced
magnetic resonance imaging (MRI) to improve

For information only. Comments can be sent to
the PL in case necessary.

detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate)., New active substance (Article 8(3) of Directive No 2001/83/EC)

Loargys - pegzilarginase - EMEA/H/C/005484, Orphan

Immedica Pharma AB, treatment of hyperargininemia, 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.

Rezzayo - rezafungin - EMEA/H/C/005900, Orphan

Mundipharma GmbH, treatment of invasive candidiasis, 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.

Sugammadex Lorien (WD) - sugammadex - EMEA/H/C/006115

LABORATORIOS LORIEN, S.L, reversal of neuromuscular blockade induced by rocuronium or vecuronium, Generic, Generic of Bridion, Generic application (Article 10(1) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

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

detection of HER2 antigen, Companion Diagnostics (Article 48 (3), (4), (7), (8) of Regulation (EU) 2017/746)

For information only. Comments can be sent to the PL in case necessary.

Veozza - fezolinetant - EMEA/H/C/005851

Astellas Pharma Europe B.V., treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause, 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.

Vueway - gadopiclesol - EMEA/H/C/006172

Bracco Imaging S.p.A., 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)., Duplicate, Duplicate of Elucirem, New active substance (Article 8(3) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Adjupanrix - pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) - EMEA/H/C/001206/II/0086/G

GlaxoSmithkline Biologicals SA, Informed Consent of Pandemrix (EXP), Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

Adtralza - tralokinumab - EMEA/H/C/005255/II/0010

LEO Pharma A/S, Rapporteur: Jayne Crowe
Request for Supplementary Information adopted on 31.08.2023.

Briumvi - ublituximab - EMEA/H/C/005914/II/0001

Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra

Budesonide/Formoterol Teva Pharma B.V. - budesonide / formoterol fumarate dihydrate - EMEA/H/C/004882/II/0012/G

Teva Pharma B.V., Duplicate, Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, PRAC Rapporteur: Marie Louise Schougaard Christiansen
Request for Supplementary Information adopted on 30.03.2023.

Cosentyx - secukinumab - EMEA/H/C/003729/II/0107

Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola

Dukoral - cholera vaccine (inactivated, oral) - EMEA/H/C/000476/II/0071

Valneva Sweden AB, Rapporteur: Kristina Dunder
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 26.10.2023.

Eptifibatide Accord - eptifibatide - EMEA/H/C/004104/II/0015/G

Accord Healthcare S.L.U., Generic, Generic of

Integrilin, Rapporteur: Jayne Crowe
Request for Supplementary Information adopted
on 12.05.2023.

Flucelvax Tetra - influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0039
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Request for Supplementary Information adopted
on 31.08.2023.

Flucelvax Tetra - influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0041
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Gonal-f - follitropin alfa - EMEA/H/C/000071/II/0163/G Positive Opinion adopted by consensus on 19.10.2023.
Merck Europe B.V., Rapporteur: Patrick Vrijlandt
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Hemlibra - emicizumab - EMEA/H/C/004406/II/0037
Roche Registration GmbH, Rapporteur:
Alexandre Moreau

Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0146/G Positive Opinion adopted by consensus on 26.10.2023.
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus
Opinion adopted on 26.10.2023.

Imraldi - adalimumab - EMEA/H/C/004279/II/0066/G Positive Opinion adopted by consensus on 19.10.2023.
Samsung Bioepis NL B.V., Rapporteur: Outi Mäki-Ikola
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Nepexto - etanercept - EMEA/H/C/004711/II/0023 Positive Opinion adopted by consensus on 26.10.2023.
Biosimilar Collaborations Ireland Limited,
Rapporteur: Martina Weise
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Nepexto - etanercept - EMEA/H/C/004711/II/0024
Biosimilar Collaborations Ireland Limited,
Rapporteur: Martina Weise

Request for Supplementary Information adopted
on 07.09.2023.

**Nimenrix - meningococcal group A, C,
W135 and Y conjugate vaccine -
EMA/H/C/002226/II/0129/G**

Pfizer Europe MA EEIG, Rapporteur: Ingrid
Wang

**Nplate - romiplostim -
EMA/H/C/000942/II/0089**

Amgen Europe B.V., Rapporteur: Maria
Concepcion Prieto Yerro

**Omnitrope - somatropin -
EMA/H/C/000607/II/0076**

Sandoz GmbH, Rapporteur: Patrick Vrijlandt

**Ontruzant - trastuzumab -
EMA/H/C/004323/II/0048/G**

Samsung Bioepis NL B.V., Rapporteur: Karin
Janssen van Doorn

**Orencia - abatacept -
EMA/H/C/000701/II/0158/G**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Outi Mäki-Ikola

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted
on 21.09.2023.

Positive Opinion adopted by consensus on
26.10.2023.

**Palynziq - pegvaliase -
EMA/H/C/004744/II/0039/G, Orphan**

BioMarin International Limited, Rapporteur:
Patrick Vrijlandt

**Pegasys - peginterferon alfa-2a -
EMA/H/C/000395/II/0115**

Pharmaand GmbH, Rapporteur: Filip Josephson
Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted
on 14.09.2023.

Positive Opinion adopted by consensus on
19.10.2023.

**Pergoveris - follitropin alfa / lutropin alfa -
EMA/H/C/000714/II/0087/G**

Merck Europe B.V., Rapporteur: Thalia Marie
Estrup Blicher

Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
19.10.2023.

**Perjeta - pertuzumab -
EMA/H/C/002547/II/0068/G**

Roche Registration GmbH, Rapporteur: Aaron

Sosa Mejia

Request for Supplementary Information adopted on 28.09.2023.

Phesgo - pertuzumab / trastuzumab - EMEA/H/C/005386/II/0020/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia
Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

Pyrukynd - mitapivat - EMEA/H/C/005540/II/0003/G, Orphan

Agios Netherlands B.V., Rapporteur: Alexandre Moreau
Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0068

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke

Soliris - eculizumab - EMEA/H/C/000791/II/0128/G, Orphan

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez
Request for Supplementary Information adopted on 19.10.2023, 31.08.2023.

Request for supplementary information adopted with a specific timetable.

Strensiq - asfotase alfa - EMEA/H/C/003794/II/0065/G, Orphan

Alexion Europe SAS, Rapporteur: Paolo Gasparini
Opinion adopted on 19.10.2023.

Positive Opinion adopted by consensus on 19.10.2023.

Toujeo - insulin glargine - EMEA/H/C/000309/II/0127/G

Sanofi-Aventis Deutschland GmbH, Duplicate, Duplicate of Lantus, Rapporteur: Patrick Vrijlandt

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0132

MCM Vaccine B.V., Rapporteur: Christophe Focke

XGEVA - denosumab - EMEA/H/C/002173/II/0082/G

Amgen Europe B.V., Rapporteur: Kristina Dunder
Request for Supplementary Information adopted

Request for supplementary information adopted with a specific timetable.

on 19.10.2023.

**Zaltrap - aflibercept -
EMA/H/C/002532/II/0069/G**

Sanofi Winthrop Industrie, Rapporteur: Filip Josephson

Request for Supplementary Information adopted on 19.10.2023.

Request for supplementary information adopted with a specific timetable.

**WS2522/G
Dengue Tetravalent Vaccine (Live,
Attenuated) Takeda-
EMA/H/W/005362/WS2522/0007/G**

Qdenga-

EMA/H/C/005155/WS2522/0008/G

Takeda GmbH, Lead Rapporteur: Sol Ruiz
Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted on 07.09.2023.

Positive Opinion adopted by consensus on 19.10.2023.

**WS2547
Blitzima-
EMA/H/C/004723/WS2547/0068
Truxima-
EMA/H/C/004112/WS2547/0071**

Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz
Opinion adopted on 19.10.2023.

Positive Opinion adopted by consensus on 19.10.2023.

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

**Arexvy - respiratory syncytial virus,
glycoprotein F, recombinant, stabilised in
the pre-fusion conformation, adjuvanted
with AS01E -
EMA/H/C/006054/II/0002/G**

GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, "Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV) based on final results from studies RSV OA=ADJ-008 and RSV OA=ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV), respectively."

See 9.1

**Bimervax - SARS-CoV-2 virus, variants
B.1.351-B.1.1.7, spike protein, receptor
binding domain fusion heterodimer -
EMA/H/C/006058/II/0002**

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final report from study HIPRA-HH-1 listed as a category 3 study in the RMP. This is a phase I/IIa study to evaluate safety and immunogenicity of Recombinant protein RBD fusion dimer candidate vaccine against SARS-COV-2 in adult healthy volunteers."

Request for Supplementary Information adopted on 31.08.2023.

**BLINCYTO - blinatumomab -
EMA/H/C/003731/II/0051, Orphan**

Amgen Europe B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to update immunogenicity information to remove reference to antibody testing based on an analysis of all completed clinical studies and post-marketing data."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 29.06.2023.

Positive Opinion adopted by consensus on 26.10.2023.

**Caprelsa - vandetanib -
EMA/H/C/002315/II/0059**

Sanofi B.V., Rapporteur: Alexandre Moreau, "Update of section 5.1 of the SmPC in order to update information on long-term use, based on a safety evaluation report."

**COMIRNATY - COVID-19 mRNA vaccine
(nucleoside-modified) -
EMA/H/C/005735/II/0187**

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Submission of the final report from study BNT162-01, a multi-site, open-label, first-in-human (FIH), Phase 1/2, two-part, dose-escalation trial investigating the safety and immunogenicity of four prophylactic SARS-CoV-2 RNA vaccines against COVID-19 using different dosing regimens in healthy and immunocompromised adults, listed as category 3 study in the RMP."

Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

**Dynastat - parecoxib -
EMA/H/C/000381/II/0088**

Pfizer Europe MA EEIG, Duplicate, Duplicate of

Xapit (SRD), Rapporteur: Finbarr Leacy,
"Update of section 4.4 of the SmPC in order to update skin reactions information based on literature and post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to align the Package Leaflet with the SmPC."

**Fabrazyme - agalsidase beta -
EMA/H/C/000370/II/0129**

Sanofi B.V., Rapporteur: Patrick Vrijlandt,
"Update of section 4.6 of the SmPC in order to update the safety information on pregnancy and breast-feeding based on results from AGAL02603/MS12868: "A Multicenter, Multinational Study of the Effects of Fabrazyme (agalsidase beta) Treatment on Lactation and Infants", listed as a category 3 study in the RMP, MAH safety database and literature search; the Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial changes to the PI."

Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

**IMCIVREE - setmelanotide -
EMA/H/C/005089/II/0015, Orphan**

Rhythm Pharmaceuticals Netherlands B.V.,
Rapporteur: Karin Janssen van Doorn,
"Submission of the final report from study RM-493-014. This is a phase 2 treatment trial of setmelanotide in patients with rare genetic disorders of obesity."

Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

**Keytruda - pembrolizumab -
EMA/H/C/003820/II/0139**

Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to update clinical information, based on results from study KEYNOTE-716 listed as a PAES in the Annex II. This is a randomized, double-blind phase 3 study of adjuvant therapy with pembrolizumab versus placebo in resected high-risk stage II melanoma. The Annex II is updated accordingly."

Request for Supplementary Information adopted on 31.08.2023.

**Lonquex - lipegfilgrastim -
EMA/H/C/002556/II/0080**

Positive Opinion adopted by consensus on 26.10.2023.

Teva B.V., Rapporteur: Outi Mäki-Ikola, "Update of section 4.4 of the SmPC in order to add a class-effect warning risk of Acute Myeloid Leukaemia and Myelodysplastic Syndrome in breast and lung cancer patients in conjunction with chemotherapy and/or radiotherapy based on the cumulative review of literature and MAH safety database. The Package Leaflet is updated accordingly."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 31.08.2023.

Mounjaro - tirzepatide -

EMA/H/C/005620/II/0010

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, "Update of section 4.8 of the SmPC in order to add 'anaphylactic reaction' and 'angioedema' to the list of adverse drug reactions (ADRs) with frequency rare, based on reviews of post-marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI."

Request for Supplementary Information adopted on 07.09.2023.

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) -

EMA/H/C/005808/II/0058/G

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt
Opinion adopted on 31.10.2023.

Request for Supplementary Information adopted on 12.10.2023.

Positive Opinion adopted by consensus on 31.10.2023.

See 9.1

Opzelura - ruxolitinib -

EMA/H/C/005843/II/0003

Incyte Biosciences Distribution B.V., Rapporteur: Peter Mol, "Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to update posology, safety and efficacy information based on final results from study INCB 18424-308; this is a Phase III, double-blind, vehicle-controlled, randomized withdrawal and treatment-extension study to assess the long-term efficacy and safety of ruxolitinib cream in participants with vitiligo (TRuE-V LTE). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted

Positive Opinion adopted by consensus on 19.10.2023.

on 31.08.2023.

**Paxlovid - nirmatrelvir / ritonavir -
EMA/H/C/005973/II/0049/G**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Grouped application comprising two type II variations (C.I.4) as follows:

- Update of sections 4.4 and 4.8 of the SmPC in order to clarify that toxic epidermal necrolysis has been reported with Paxlovid and to add toxic epidermal necrolysis to the list of adverse drug reactions (ADRs) with frequency Rare based on the cumulative review of MAH safety database and literature.
 - Update of sections 4.4 and 4.8 of the SmPC in order to clarify that Stevens-Johnson syndrome has been reported with Paxlovid and to add Stevens-Johnson syndrome to the list of adverse drug reactions (ADRs) with frequency Rare, based on the cumulative review of MAH safety database and literature.
- The Package Leaflet is updated accordingly."

**Phesgo - pertuzumab / trastuzumab -
EMA/H/C/005386/II/0021**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Submission of the final report from study MO40628 (PHranceSCa), a Phase II, randomized, multicenter, open-label, cross-over study to evaluate patient reported preference for Phesgo compared with intravenous pertuzumab and trastuzumab in patients with HER2-positive EBC."

**Rayvow - lasmiditan -
EMA/H/C/005332/II/0004**

Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with dabigatran and rosuvastatin based on the results from study LAIO, An Open-Label, 2-Part Study to Investigate the Effect of Lasmiditan on the Pharmacokinetics of Dabigatran and Rosuvastatin in Healthy Volunteers. The aim of study LAIO was to investigate the effect of lasmiditan on the pharmacokinetic profiles of dabigatran (a P-glycoprotein substrate) and rosuvastatin (breast cancer resistance protein substrate) in healthy volunteers. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes

to the PI.”

Remsima - infliximab -

See 9.1

EMA/H/C/002576/II/0133/G

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

RINVOQ - upadacitinib -

Positive Opinion adopted by consensus on
26.10.2023.

EMA/H/C/004760/II/0042

AbbVie Deutschland GmbH & Co. KG,

Rapporteur: Kristina Dunder, "Submission of the final report from study M13-545 listed as a category 3 study in the RMP (MEA/10).

This is a Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects with Moderately to Severely Active Rheumatoid Arthritis."

Opinion adopted on 26.10.2023.

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0065

Positive Opinion adopted by consensus on 26.10.2023.

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information with COVID-19 mRNA-1273 booster vaccine, based on final results from study ZOSTER-091; this is a phase 3, randomized, open-label, controlled, multi-center clinical study to evaluate the immune response and safety of both herpes zoster subunit vaccine (HZ/su or Shingrix) in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine (Flu D-QIV or Fluarix Quadrivalent) in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination. The Package Leaflet is updated accordingly."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 13.07.2023.

Spravato - esketamine - EMEA/H/C/004535/II/0018

Positive Opinion adopted by consensus on 19.10.2023.

Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study 54135419TRD3013 (ESCAPE). This is A Randomized, Open-label, Rater-Blinded, Active-Controlled, International, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Flexibly Dosed Esketamine Nasal Spray Compared With Quetiapine Extended-Release in Adult and Elderly Participants With Treatment-Resistant Major Depressive Disorder Who are Continuing a Selective Serotonin Reuptake Inhibitor/ Serotonin-Norepinephrine Reuptake

Inhibitor.

In addition, the MAH took the opportunity to introduce minor editorial changes, to update Annex IV and to update the list of local representatives in the Package Leaflet.”

Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted on 20.07.2023.

**Toviaz - fesoterodine -
EMA/H/C/000723/II/0068**

Positive Opinion adopted by consensus on 19.10.2023.

Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, “Update of sections 4.4 of the SmPC to amend an existing warning on angioedema and 4.8 of the SmPC in order to add hypoaesthesia oral to the list of adverse drug reactions (ADRs) with a frequency rare based on a cumulative review of safety database cases and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the QRD template v10.3.”

Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted on 13.07.2023.

**Tremelimumab AstraZeneca -
tremelimumab -
EMA/H/C/004650/II/0002**

AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the paediatric information based on final results from study D419EC00001; this is a Phase I/II, open-label, multicenter study to evaluate the safety, tolerability, and preliminary efficacy of durvalumab monotherapy or durvalumab in combination with tremelimumab in pediatric patients with advanced solid tumors and hematological malignancies.”

**Veklury - remdesivir -
EMA/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.

Verzenios - abemaciclib -

EMA/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.

Vipdomet - alogliptin / metformin -

EMA/H/C/002654/II/0044

Takeda Pharma A/S, Rapporteur: Patrick Vrijlandt, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Vitamin B12 decrease or deficiency and to update the list of adverse drug reactions (ADRs) in accordance with the recent update of the PI for Glucophage, which is the reference label for the compound metformin, and following the request by MHRA on 20 June 2022 for all products containing metformin."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 06.07.2023.

Positive Opinion adopted by consensus on 26.10.2023.

Xevudy - sotrovimab -

EMA/H/C/005676/II/0019/G

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.2, 4.8, 4.9, 5.1 and 5.2 of the SmPC in order to update posology recommendations and administration instructions and to update efficacy, pharmacokinetic and safety information, based on results from studies COMET-TAIL (phase 3 study and safety substudy; 217114), COMET-PEAK (216912), Japan-PK (217653) and BLAZE-4, and from a Population PK (PopPK) report. These clinical studies were conducted to assess the efficacy, safety and tolerability of sotrovimab given intramuscularly (IM) versus intravenously (IV) for the treatment of mild/moderate coronavirus disease 2019 (COVID-19) in high-risk, non-hospitalized patients (COMET-TAIL phase 3 study); to assess the safety and tolerability of single ascending dose of sotrovimab (COMET-TAIL safety substudy); to assess safety, tolerability, PK and

viral pharmacodynamics (PD) of sotrovimab in participants with early mild-to-moderate COVID-19 (COMET-PEAK); to assess PK, safety and tolerability of IV and IM sotrovimab in healthy Japanese and Caucasian participants (Japan-PK); and to evaluate the impact of monoclonal antibodies such as LY3819253 + sotrovimab on viral clearance and clinical outcomes in participants with COVID-19 illness (BLAZE-4). The Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 14.09.2023.

**Zavicefta - ceftazidime / avibactam -
EMA/H/C/004027/II/0033**

Pfizer Ireland Pharmaceuticals, Rapporteur:
Ingrid Wang, “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 is taking the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet.”

WS2509/G

Anoro Ellipta-

EMA/H/C/002751/WS2509/0042/G

Laventair Ellipta-

EMA/H/C/003754/WS2509/0045/G

GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Finbarr Leacy, “Grouped application comprising two type II variations (C.I.4) as follows:

- Update of section 4.8 of the SmPC in order to delete 'rash' from the list of adverse drug reactions (ADRs) with frequency uncommon based on the cumulative review of the MAH safety database, clinical trial data and literature.
 - To include significant changes to sections 2, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.5 of the SmPC, sections 4, 5, 7 and 11 of the Labelling and sections 2, 3 and 6 of the Package Leaflet for the medicinal products Anoro and Laventair containing the active substances Umeclidinium Bromide and Vilanterol following the assessment of the medicinal products Trelegy and Rolufta Ellipta, which also contains the active substances fluticasone furoate, umeclidinium bromide and vilanterol, via procedure
-

EMA/H/C/004363/R/0023 and
EMA/H/C/004654/R/0019. The same wording
is used for the combination product.
The Package Leaflet and Labelling are updated
accordingly. The Annex II is updated. In
addition, the MAH took the opportunity to
introduce minor editorial changes and to bring
the PI in line with the latest QRD template.”
Request for Supplementary Information adopted
on 14.09.2023.

WS2534

Abseamed-

EMA/H/C/000727/WS2534/0104

Binocrit-

EMA/H/C/000725/WS2534/0103

Epoetin alfa Hexal-

EMA/H/C/000726/WS2534/0103

Sandoz GmbH, Lead Rapporteur: Alexandre
Moreau, “Update of section 4.4 of the SmPC in
order to allow for iron supplementation in
accordance with patient needs and up-to-date
treatment guidelines by removing the
restrictions to exclusively use the oral route of
administration for iron supplementation. In
addition, the MAH took the opportunity to
introduce minor editorial changes to the PI,
bring it in line with the latest QRD template
version 10.3, align it with the reference product
and update instructions for use.”

Request for Supplementary Information adopted
on 31.08.2023.

WS2543

Imfinzi-EMA/H/C/004771/WS2543/0062

IMJUDO-

EMA/H/C/006016/WS2543/0003

AstraZeneca AB, Lead Rapporteur: Aaron Sosa
Mejia, “Update of sections 4.2, 4.8, 5.1 and 5.2
of the SmPC in order to include paediatric
information based on final results from study
D419EC00001 “Phase I/II, Open-Label,
Multicenter Study to Evaluate the Safety,
Tolerability, and Preliminary Efficacy of
Durvalumab Monotherapy or Durvalumab in
Combination with Tremelimumab in Pediatric
Patients with Advanced Solid Tumors and
Hematological Malignancies”. In addition, the
MAH took this opportunity to introduce editorial
changes.”

B.5.3. CHMP-PRAC assessed procedures

Brineura - cerliponase alfa -

EMA/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 12.10.2023, 25.05.2023.

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

EMA/H/C/005735/II/0188/G

BioNTech Manufacturing GmbH, Rapporteur:

Filip Josephson, PRAC Rapporteur: Menno van der Elst, "Grouped application comprising two type II variations as follows:

C.I.4 – Update of section 4.8 of the SmPC in order to update the safety information based on interim (6 months post-dose 3 in 12-15 years old) and final results from study C4591001, listed as a category 3 study in the RMP. This is a phase 1/2/3, placebo-controlled, randomised, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of COMIRNATY against COVID-19 in healthy individuals.

C.I.11.b – Update of the RMP to version 11.0 in order to revise RMP milestones of final study reports of other on-going procedures, including other administrative and editorial changes."

Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

Gavreto - pralsetinib -

EMA/H/C/005413/II/0012

Roche Registration GmbH, Rapporteur: Aaron

Sosa Mejia, PRAC Rapporteur: Ulla Wändel

Liminga, "Update of sections 4.2, 4.4 and 4.5 of the SmPC in order to amend posology recommendations, warnings and drug-drug interaction information regarding the co-administration with CYP3A4 inhibitors, P-gp inhibitors and CYP3A4 inducers based on final results from the DDI study GP43162, listed as a category 3 study in the RMP, as well as results from the physiologically based pharmacokinetic (PBPK) analyses summarised in the PBPK Report 1120689. Study GP43162 is a phase 1, open-label, fixed-sequence study to evaluate the effect of a single dose of cyclosporine on the single dose pharmacokinetics of pralsetinib in healthy subjects. The RMP version 1.6 has also been submitted."

Request for Supplementary Information adopted on 22.06.2023, 30.03.2023.

**Increlex - mecasermin -
EMA/H/C/000704/II/0080**

Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Update of sections 4.2, 4.6 and 4.8 of the SmPC in order to modify administration instructions recommendation regarding the monitoring of pre-prandial blood glucose in pre-prandial condition and in case of symptoms and to prevent the risk of lipohypertrophy, delete wording in the pregnancy section and update on number of patients with severe primary IGFD based on the cumulative review of safety database, scientific literature and clinical trials data. The Package Leaflet is updated accordingly. The RMP version 14.0 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 26.10.2023.

Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 26.10.2023.

**Lenvima - lenvatinib -
EMA/H/C/003727/II/0050**

Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information based on final results from studies E7080-G000-207 and E7080-G000-230. Study E7080-G000-207 is a multicenter, open-label, Phase 1/2

study of lenvatinib in children and adolescents with refractory or relapsed solid malignancies and young adults with osteosarcoma; Study E7080-G000-230 is a multicenter, open-label, randomized Phase 2 study to compare the efficacy and safety of lenvatinib in combination with ifosfamide and etoposide versus ifosfamide and etoposide in children, adolescents and young adults with Relapsed or Refractory Osteosarcoma (OLIE). The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted.”

Request for Supplementary Information adopted on 14.09.2023.

**LUMYKRAS - sotorasib -
EMA/H/C/005522/II/0007**

Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Update of sections 4.2 and 5.2 of the SmPC in order to update recommendations for patients with moderate to severe hepatic impairment following final results from study 20200362 listed as a category 3 PASS study in the EU RMP; this is a Phase I clinical study to evaluate the pharmacokinetics (PK) of a single oral dose of sotorasib administered in subjects with moderate or severe hepatic impairment compared with subjects who have normal hepatic function. The EU RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3.”

Request for Supplementary Information adopted on 26.10.2023, 06.07.2023, 16.03.2023.

Request for supplementary information adopted with a specific timetable.

**Myozyme - alglucosidase alfa -
EMA/H/C/000636/II/0095**

Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, “Update of sections 4.4 and 5.2 of the SmPC in order to update a warning on immunogenicity. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”
Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 14.04.2023.

Positive Opinion adopted by consensus on 26.10.2023.

**Onglyza - saxagliptin -
EMA/H/C/001039/II/0057**

Request for supplementary information adopted with a specific timetable.

AstraZeneca AB, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update safety, efficacy and pharmacokinetic information in paediatric patients with Type 2 diabetes mellitus (T2DM) aged 10 to <18 years of age based on interim results from study D1680C00019 (T2NOW). This is a 26-week, multicentre, randomised, placebo-controlled, double-blind, parallel group, Phase III trial with a 26-week safety extension period evaluating the safety and efficacy of dapagliflozin (5 and 10 mg), and, separately, saxagliptin (2.5 and 5 mg) in paediatric patients with T2DM who were between 10 and below 18 years of age. The Package Leaflet is updated accordingly. The RMP version 17.1 has also been submitted. In addition, the MAH took the opportunity bring the PI in line with the latest QRD template and to introduce editorial changes."

Request for Supplementary Information adopted on 26.10.2023.

**Pradaxa - dabigatran etexilate -
EMA/H/C/000829/II/0147/G**

See 9.1

Boehringer Ingelheim International GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "A Grouped application consisting of:

C.I.7.a (type IB): to delete the pharmaceutical form "powder and solvent for oral solution, 6.25 mg/ml", as agreed in procedure EMEA/H/C/000829/II/0144.

C.I.4 (type II): Update of section 4.1 of the SmPC in order to modify the indication following the deletion of the powder and solvent for oral solution; the Package Leaflet is updated accordingly. The RMP version 41.2 has also been submitted.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet."

**Prolia - denosumab -
EMA/H/C/001120/II/0099**

Request for supplementary information adopted with a specific timetable.

Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "Update of sections 4.4 and 4.8 of the SmPC in order to

update a warning regarding hypocalcaemia and to include reports of life-threatening events and fatal cases occurred in the post-marketing setting, particularly in patients with severe renal impairment, receiving dialysis or treatment with other calcium lowering drugs based on the cumulative review of the MAH safety database and literature. The Package Leaflet is updated accordingly. The RMP version 32.0 has also been submitted.”

Request for Supplementary Information adopted on 26.10.2023.

**Reagila - cariprazine -
EMA/H/C/002770/II/0034**

Gedeon Richter Plc., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ana Sofia Diniz Martins, “Update of sections 4.3 and 4.5 of the SmPC in order to update an existing contraindication and update drug-drug interaction information with CYP3A4 inhibitors, based on final results from study RGH-188-301 (CYPRESS) listed as a category 3 study in the RMP; this is an open-label, single-arm, fixed-sequence study to investigate the effect of erythromycin, a moderate CYP3A4 inhibitor on the pharmacokinetics of cariprazine in male patients with schizophrenia. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

**Tysabri - natalizumab -
EMA/H/C/000603/II/0136**

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, “Update of sections 4.2 and 4.4 of the SmPC to modify administration instructions and update educational guidance to enable the subcutaneous formulation to be administered outside a clinical setting by healthcare professionals based on the cumulative review of post-marketing and clinical study data. The Package Leaflet and Annex IID are updated accordingly. The RMP version 29.1 has also been submitted. In addition, the MAH took this opportunity to introduce minor editorial changes.”

Request for Supplementary Information adopted on 20.07.2023.

B.5.4. PRAC assessed procedures

PRAC Led

**Aldurazyme - Iaronidase -
EMA/H/C/000477/II/0085**

Sanofi B.V., PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "To update section 4.2 of the SmPC in order to modify the administration instructions following the assessment of procedure PSUSA/00001830/202104 based on literature review.

The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted."

Request for Supplementary Information adopted on 26.10.2023, 08.06.2023, 09.02.2023.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Benlysta - belimumab -
EMA/H/C/002015/II/0116**

GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report for the Belimumab Pregnancy registry (BEL114256) listed as a category 3 study in the RMP. This is a non-interventional study to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months preconception and/or during pregnancy. In addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with SLE and SABLE (Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus) protocol who were not exposed to belimumab and enrolled in BPR. The RMP version 45.0 has also been submitted."

Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Evusheld - tixagevimab / cilgavimab -
EMA/H/C/005788/II/0013**

AstraZeneca AB, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "The RMP is updated to version 5.0 with the removal of the commitment to conduct the

Positive Opinion adopted by consensus on 26.10.2023.

post-authorisation safety study (PASS)
D8850R00006: A post-authorization
Observational Study of Women exposed to
EVUSHELD During Pregnancy (O-STEREO).”
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

PRAC Led

Lenvima - lenvatinib -

EMA/H/C/003727/II/0053

Eisai GmbH, PRAC Rapporteur: Ulla Wändel
Liminga, PRAC-CHMP liaison: Kristina Dunder,
“Update of section 5.1 of the SmPC in order to
update safety and efficacy information for the
hepatocellular carcinoma (HCC) indication,
based on interim results from study E7080-
M000-508 (STELLAR), listed as a category 3
PASS in the RMP. This is a non-interventional
multicentre, observational, phase 4 study to
evaluate the safety and tolerability of lenvatinib
in patients with advanced or unresectable HCC.
RMP version 15.2 has also been submitted.”
Request for Supplementary Information adopted
on 26.10.2023.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

Myozyme - alglucosidase alfa -

EMA/H/C/000636/II/0093

Sanofi B.V., Rapporteur: Alexandre Moreau,
PRAC Rapporteur: Nathalie Gault, PRAC-CHMP
liaison: Alexandre Moreau, “Submission of the
final non-interventional Pompe Registry Report
2022 (MEA024 and MEA025).”
Request for Supplementary Information adopted
on 26.10.2023, 16.03.2023.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

Ozurdex - dexamethasone -

EMA/H/C/001140/II/0044

AbbVie Deutschland GmbH & Co. KG, PRAC
Rapporteur: Maria del Pilar Rayon, PRAC-CHMP
liaison: Maria Concepcion Prieto Yerro,
“Submission of an updated RMP version 12.1.”
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 08.06.2023, 16.03.2023.

Positive Opinion adopted by consensus on
26.10.2023.

PRAC Led

Remicade - infliximab -

EMA/H/C/000240/II/0243

Janssen Biologics B.V., PRAC Rapporteur: Mari

Positive Opinion adopted by consensus on
26.10.2023.

Thorn, PRAC-CHMP liaison: Kristina Dunder, "To update section 4.8 of the SmPC to add weight increased to the list of adverse drug reactions (ADRs) with frequency Uncommon following PRAC PSUR assessment report (EMA/PRAC/158162/2023-Corr.1) based on the cumulative literature review. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial changes." Opinion adopted on 26.10.2023.

PRAC Led
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0110
Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report of study P903 - US PASS (Post-authorisation safety in the US Study, NCT04958954), listed as a category 3 study in the RMP: Post-marketing safety of Spikevax vaccine in the US: Active surveillance, signal refinement and self-controlled risk interval (SCRI) signal evaluation in HealthVerity." Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

PRAC Led
Tecfidera - dimethyl fumarate - EMEA/H/C/002601/II/0082
Biogen Netherlands B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on results from study 109MS402 - Tecfidera (dimethyl fumarate) Pregnancy Exposure Registry, listed as a category 3 study in the RMP; This is an observational study and aims to address the safety concern of effects on pregnancy outcome and prospectively evaluates pregnancy outcomes in women with MS who were exposed to a Registry-specified Biogen MS product during the eligibility window for that product. The Package Leaflet is updated accordingly. The RMP version 16.0 has also been approved. In addition, the MAH has taken the opportunity to introduce editorial changes to the Product Information." Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 31.08.2023, 12.05.2023.

PRAC Led
Xeljanz - tofacitinib -
EMA/H/C/004214/II/0054
Pfizer Europe MA EEIG, PRAC Rapporteur: Liana
Gross-Martirosyan, PRAC-CHMP liaison: Peter
Mol, "Submission of an updated RMP version
31.1 in order to modify study A3921427 from
an interventional to a non-interventional study.
In addition, the MAH has taken the opportunity
to update other sections of the RMP."
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
26.10.2023.

PRAC Led
Zavesca - miglustat -
EMA/H/C/000435/II/0076
Janssen-Cilag International N.V., PRAC
Rapporteur: Mari Thorn, PRAC-CHMP liaison:
Kristina Dunder, "Update of section 4.4 of the
SmPC with information regarding the fact that
cases of Crohn's disease have been reported
post-marketing. The Package Leaflet has been
updated accordingly. In addition, the MAH took
the opportunity to implement editorial changes
in the SmPC and Package Leaflet, and to update
the contact details of the local representatives
in the Package Leaflet.
Submission of an updated RMP version 15.1 in
order to remove risks in line with GVP module V
revision 2. The MAH has also taken the
opportunity to introduce minor changes, such as
update of the post-marketing exposure data and
alignment with the latest Company EU-RMP
Template."
Request for Supplementary Information adopted
on 06.07.2023, 16.03.2023.

PRAC Led
WS2486
Emtricitabine/Tenofovir disoproxil Zentiva-
EMA/H/C/004137/WS2486/0025
Zentiva k.s., Generic, Generic of Truvada, Lead
PRAC Rapporteur: Ana Sofia Diniz Martins,
PRAC-CHMP liaison: Bruno Sepodes, "C.I.11.z -
To update the RMP for Emtricitabine/Tenofovir
disoproxil according to reference product
update, Truvada (EMA/H/C/WS2320)."

Request for Supplementary Information adopted on 31.08.2023.

PRAC Led

WS2515

Lacosamide UCB-

EMA/H/C/005243/WS2515/0018

Vimpat-EMA/H/C/000863/WS2515/0100

UCB Pharma S.A., Lead PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 17.0 in order to introduce new updates including the removal of category 3 study EP0158 due to study closure by lack of enrolment, and the removal of category 3 studies (SP848 and EP0034)."

Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

PRAC Led

WS2519/G

Advagraf-

EMA/H/C/000712/WS2519/0071/G

Modigraf-

EMA/H/C/000954/WS2519/0046/G

Astellas Pharma Europe B.V., Lead PRAC Rapporteur: Eamon O Murchu, PRAC-CHMP liaison: Jayne Crowe, "A grouped application consisting of:

Type II (C.I.13): Submission of the final report from study F506-PV-0001 listed as a category 3 study in the RMP for Advagraf and Modigraf.

This is a non-interventional post-authorisation safety study (NI-PASS) of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from Transplant Pregnancy Registry International (TPRI). The RMP version 5.0 has also been submitted.

Type IB (C.I.11.z): To include the feasibility assessment of using alternative secondary-use data sources to replicate the Transplant Pregnancy Registry International (TPRI) study as a category 3 additional pharmacovigilance activity in the RMP, including the milestones for the progress report and the final report of the feasibility assessment, related to EMA/H/C/000712/MEA/032 and EMA/H/C/000954/MEA/024."

Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

B.5.5. CHMP-CAT assessed procedures

**Carvykti - ciltacabtagene autoleucel -
EMA/H/C/005095/II/0018, Orphan,
ATMP**

Janssen-Cilag International NV, Rapporteur: Jan
Mueller-Berghaus, CHMP Coordinator: Jan
Mueller-Berghaus
Opinion adopted on 31.10.2023.
Request for Supplementary Information adopted
on 14.07.2023.

**Hemgenix - etranacogene dezaparvovec -
EMA/H/C/004827/II/0009/G, Orphan,
ATMP**

CSL Behring GmbH, Rapporteur: Silke Dorner,
CHMP Coordinator: Daniela Philadelphia
Request for Supplementary Information adopted
on 31.10.2023.

Request for supplementary information adopted
with a specific timetable.

**Kymriah - tisagenlecleucel -
EMA/H/C/004090/II/0071, Orphan,
ATMP**

Novartis Europharm Limited, Rapporteur: Rune
Kjeken, CHMP Coordinator: Ingrid Wang,
"Update of sections 5.1 and 5.2 of the SmPC in
order to update efficacy and pharmacokinetic
information based on final results from study
CCTL019B2202 (a phase II, single arm,
multicenter trial to determine the efficacy and
safety of CTL019 in pediatric patients with
relapsed and refractory B-cell acute
lymphoblastic leukemia). Submission of cellular
kinetic report for the B-cell acute lymphoblastic
leukaemia (ALL) indication based on data from
pivotal study CCTL019B2202 and the supportive
study CCTL019B2205J involving paediatric ALL
patients (partially fulfil REC).
In addition, the MAH took this opportunity to
introduce editorial changes."
Request for Supplementary Information adopted
on 31.10.2023.

Request for supplementary information adopted
with a specific timetable.

**Roctavian - valoctocogene roxaparvovec -
EMA/H/C/005830/II/0008/G, Orphan,
ATMP**

BioMarin International Limited, Rapporteur:
Violaine Closson Carella, CHMP Coordinator:
Jean-Michel Race, "Grouped application
comprising two variations as follows:
C.I.4 - Update of section 4.5 of the SmPC in
order to add drug-drug interaction information

with Isotretinoin and Efavirenz based on results from study "In vitro Drug-Drug Interaction Study: Effects of Concomitant Administration of Isotretinoin, Amphetamine, Omeprazole, Celecoxib and Selected HAART Medications with AAV5-FVIII-SQ on Cytotoxicity and AAV5-FVIII-SQ DNA and RNA Expression in Primary Human Hepatocytes".

A.6 - To change the ATC Code from B02BD1 to "not yet assigned".

Opinion adopted on 31.10.2023.

**Yescarta - axicabtagene ciloleucel -
EMA/H/C/004480/II/0063, Orphan,
ATMP**

See 9.1

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."

Request for Supplementary Information adopted on 06.10.2023.

B.5.6. CHMP-PRAC-CAT assessed procedures

**Kymriah - tisagenlecleucel -
EMA/H/C/004090/II/0075, Orphan,
ATMP**

Request for supplementary information adopted with a specific timetable.

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study CCTL019C2201 PAES in the Annex II (ANX008); this is a Phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The RMP version 6 has also been submitted. In addition, the MAH took the opportunity to update Annex II.D of the PI."

Request for Supplementary Information adopted

on 31.10.2023.

B.5.7. PRAC assessed ATMP procedures

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

WS2503/G

Afstyla-

EMA/H/C/004075/WS2503/0051/G

IDELVION-

EMA/H/C/003955/WS2503/0067/G

Respreeza-

EMA/H/C/002739/WS2503/0073/G

Voncento-

EMA/H/C/002493/WS2503/0060/G

CSL Behring GmbH, Lead Rapporteur: Jan

Mueller-Berghaus

Request for Supplementary Information adopted

on 05.10.2023.

WS2521

Riltrava Aerosphere-

EMA/H/C/005311/WS2521/0007

Trixeo Aerosphere-

EMA/H/C/004983/WS2521/0014

AstraZeneca AB, Lead Rapporteur: Finbarr

Leacy, "C.I.z - To submit the new results for the conducted fish full life-cycle study for

budesonide and an updated Environmental Risk Assessment (ERA) report."

Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted

on 31.08.2023.

WS2536

Rixathon-

EMA/H/C/003903/WS2536/0067

Riximyo-

EMA/H/C/004729/WS2536/0068

Sandoz GmbH, Lead Rapporteur: Jan Mueller-

Berghaus

Request for Supplementary Information adopted

on 14.09.2023.

WS2576

Elebrato Ellipta-

EMA/H/C/004781/WS2576/0037

Relvar Ellipta-

EMA/H/C/002673/WS2576/0064

Revinty Ellipta-

EMA/H/C/002745/WS2576/0061

Trelegy Ellipta-**EMA/H/C/004363/WS2576/0034**

GlaxoSmithKline (Ireland) Limited, Lead
Rapporteur: Maria Concepcion Prieto Yerro

WS2578**Fluenz Tetra-****EMA/H/C/002617/WS2578/0133****Pandemic influenza vaccine H5N1****AstraZeneca-****EMA/H/C/003963/WS2578/0067**

AstraZeneca AB, Lead Rapporteur: Jan Mueller-
Berghaus

WS2579/G**Fluenz Tetra-****EMA/H/C/002617/WS2579/0134/G****Pandemic influenza vaccine H5N1****AstraZeneca-****EMA/H/C/003963/WS2579/0068/G**

AstraZeneca AB, Lead Rapporteur: Christophe
Focke

WS2582**HyQvia-EMA/H/C/002491/WS2582/0092****Kiovig-EMA/H/C/000628/WS2582/0124**

Takeda Manufacturing Austria AG, Lead
Rapporteur: Jan Mueller-Berghaus

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

Mozobil - plerixafor -**EMA/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.

Withdrawal request submitted on 18.10.2023.

The MAH withdrew the procedure on 18.10.2023.

Nuvaxovid - COVID-19 vaccine (recombinant, adjuvanted) -**EMA/H/C/005808/II/0030**

Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege, "Submission of 6-month efficacy and safety interim data from the ongoing randomized, observer-blinded, placebo-controlled clinical studies 2019nCoV-501,

The MAH withdrew the procedure on 23.10.2023.

2019nCoV-301 and 2019nCoV-302.”
Request for Supplementary Information adopted
on 22.06.2023, 15.12.2022.
Withdrawal request submitted on 23.10.2023.

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

guanfacine - EMEA/H/C/006312

treatment of ADHD

apremilast - EMEA/H/C/006193

treatment of psoriatic arthritis, psoriasis,
Behçet's disease

troriluzole - EMEA/H/C/006068, Orphan

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

mirvetuximab soravtansine -

EMEA/H/C/005036, Orphan

Immunogen Biopharma (Ireland) Limited,
treatment of ovarian, fallopian tube, or primary
peritoneal cancer

tiratricol - EMEA/H/C/005220

treatment of monocarboxylate transporter 8
(MCT8) deficiency

eplontersen - EMEA/H/C/006295, Orphan

AstraZeneca AB, indicated for the treatment of
adult patients with polyneuropathy associated
with hereditary transthyretin-mediated
amyloidosis (ATTRv).

marstacimab - EMEA/H/C/006240, Orphan

Pfizer Europe Ma EEIG, Tradename is indicated
for routine prophylaxis of bleeding episodes in
patients with haemophilia A or haemophilia B

elafibranor - EMEA/H/C/006231, Orphan

Ipsen Pharma, treatment of primary biliary
cholangitis (PBC)

sotatercept - EMEA/H/C/005647, Orphan Accelerated review

Merck Sharp & Dohme B.V., treatment of
pulmonary arterial hypertension in adults

in vitro diagnostic medical device -

EMA/H/D/006341

detection of the anaplastic lymphoma kinase (ALK) protein

clascoterone - EMA/H/C/006138

indicated for the topical treatment of acne vulgaris in adults and adolescents

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

Mounjaro - tirzepatide -**EMA/H/C/005620/X/0015**

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, "Extension application to add 6 new strengths of 2.5 mg (4.17 mg/ml), 5 mg (8.33 mg/ml), 7.5 mg (12.5 mg/ml), 10 mg (16.67 mg/ml), 12.5 mg (20.83 mg/ml) and 15 mg (25 mg/ml) for Mounjaro solution for injection in pre-filled pen (KwikPen), multidose. The Package Leaflet and Labelling are updated in accordance."

Ofev - nintedanib -**EMA/H/C/003821/X/0057/G**

Boehringer Ingelheim International GmbH, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Nikica Mirošević Skvrce, "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of

the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted.”

**Opsumit - macitentan -
EMA/H/C/002697/X/0051/G, Orphan**

Janssen-Cilag International N.V., Rapporteur:
Maria Concepcion Prieto Yerro, Co-Rapporteur:
Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, “Extension application to introduce a new pharmaceutical form associated with new strengths (1 and 2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 1 month to less than 18 years of age of WHO Functional Class (FC) I to III for OPSUMIT, based on interim results from AC-055-312 study (TOMORROW). This is a multicenter, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP has also been submitted.”

**Ozempic - semaglutide -
EMA/H/C/004174/X/0043**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

**Rybelsus - semaglutide -
EMA/H/C/004953/X/0038**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,
“Extension application to introduce three new strengths of tablets (1.5 mg, 4 mg and 9 mg) for semaglutide.”

**Rybelsus - semaglutide -
EMA/H/C/004953/X/0039**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,
“Extension application to add two new strengths (25 mg and 50 mg) tablets.”

**Wegovy - semaglutide -
EMA/H/C/005422/X/0016**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

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

apremilast - EMA/H/C/006208

treatment of psoriatic arthritis, psoriasis,
Behçet's disease
List of Questions adopted on 20.07.2023.

aumolertinib - EMA/H/C/006069

treatment of non-small cell lung cancer
List of Questions adopted on 30.03.2023.

buprenorphine - EMA/H/C/006188

treatment of opioid drug dependence
List of Questions adopted on 22.06.2023.

sugemalimab - EMA/H/C/006088

treatment of adults with metastatic non-small-
cell lung cancer (NSCLC)
List of Questions adopted on 22.06.2023.

serplulimab - EMA/H/C/006170, Orphan

Henlius Europe GmbH, first-line treatment of
adult patients with extensive-stage small cell
lung cancer (ES-SCLC)
List of Questions adopted on 20.07.2023.

aprocitentan - EMA/H/C/006080

treatment of resistant hypertension
List of Questions adopted on 22.06.2023.

omecantiv mecarbil - EMA/H/C/006112

treatment of adult patients with symptomatic
chronic heart failure and reduced ejection
fraction less than 30%
List of Questions adopted on 26.04.2023.

sotorasib - EMA/H/C/005522/X/0009

Amgen Europe B.V., Rapporteur: Alexandre
Moreau, "Extension application to add a new
strength of 240 mg film-coated tablet."
List of Questions adopted on 22.06.2023.

nintedanib - EMA/H/C/006179

treatment of idiopathic pulmonary fibrosis (IPF),
chronic fibrosing interstitial lung diseases (ILDs)
and lung diseases (ILDs) systemic sclerosis
associated interstitial lung disease (SSc-ILD)
List of Questions adopted on 26.04.2023.

nivolumab - EMA/H/C/003985/X/0132

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Carolina Prieto Fernandez, PRAC Rapporteur:
Martin Huber
List of Questions adopted on 14.09.2023.

in vitro diagnostic medical device -

EMA/H/D/006373

detection of PD-L1 protein
Request for Supplementary Information adopted
on 12.10.2023.

ustekinumab - EMA/H/C/006183

treatment of Crohn's disease and Ulcerative
colitis, treatment of Crohn's disease, Ulcerative
colitis, Plaque psoriasis, Paediatric plaque
psoriasis and Psoriatic arthritis (PsA)
List of Questions adopted on 14.09.2023.

flortaucipir (18F) - EMA/H/C/006064

indicated for Positron Emission Tomography
(PET) imaging of the brain
List of Questions adopted on 20.07.2023.

teriflunomide -

EMA/H/C/005960/X/0002

Accord Healthcare S.L.U., Generic, Generic of
AUBAGIO, Rapporteur: Kristina Nadrah, PRAC
Rapporteur: Martin Huber, "Extension
application to add a new strength of 7 mg film-
coated tablets. The bioequivalence study data
were submitted."
List of Questions adopted on 20.07.2023.

in vitro diagnostic medical device -

EMA/H/D/006310

immunohistochemical assay utilising an anti-PD-
L1 monoclonal primary antibody
Request for Supplementary Information adopted
on 12.10.2023, 14.09.2023.

retifanlimab - EMA/H/C/006194, Orphan

Incyte Biosciences Distribution B.V., Treatment
of Merkel cell carcinoma (MCC).
List of Questions adopted on 20.07.2023.

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

Bylvay - odevoxibat -

EMA/H/C/004691/S/0016, Orphan

Albireo, Rapporteur: Patrick Vrijlandt, PRAC
Rapporteur: Adam Przybylkowski

Myalepta - metreleptin -

EMA/H/C/004218/S/0035, Orphan

Amryt Pharmaceuticals DAC, Rapporteur: Karin
Janssen van Doorn, PRAC Rapporteur: Adam
Przybylkowski

Zokinvy - Isoniazid -
EMA/H/C/005271/S/0008, Orphan
EigerBio Europe Limited, Rapporteur: Patrick
Vrijlandt, PRAC Rapporteur: Adam
Przybylkowski

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

Cufence - trientine -
EMA/H/C/004111/R/0016
Univar Solutions BV, Rapporteur: Daniela
Philadelphia, Co-Rapporteur: Konstantina
Alexopoulou, PRAC Rapporteur: Ana Sofia Diniz
Martins

Deltyba - delamanid -
EMA/H/C/002552/R/0070, Orphan
Otsuka Novel Products GmbH, Rapporteur:
Christophe Focke, PRAC Rapporteur: Jo Robays

Dovato - dolutegravir / lamivudine -
EMA/H/C/004909/R/0045
ViiV Healthcare B.V., Rapporteur: Filip
Josephson, Co-Rapporteur: Bruno Sepodes,
PRAC Rapporteur: David Olsen

Giapreza - angiotensin II -
EMA/H/C/004930/R/0027
Paion Deutschland GmbH, Rapporteur: Maria
Concepcion Prieto Yerro, Co-Rapporteur: Jean-
Michel Race, PRAC Rapporteur: Menno van der
Elst

JEMPERLI - dostarlimab -
EMA/H/C/005204/R/0026
GlaxoSmithKline (Ireland) Limited, Rapporteur:
Carolina Prieto Fernandez, PRAC Rapporteur:
Ana Sofia Diniz Martins

**LysaKare - L-lysine hydrochloride / L-
arginine hydrochloride -**
EMA/H/C/004541/R/0016
Advanced Accelerator Applications, Rapporteur:
Janet Koenig, Co-Rapporteur: Aaron Sosa Mejia,
PRAC Rapporteur: Adam Przybylkowski

Natpar - parathyroid hormone -
EMA/H/C/003861/R/0054, Orphan
Takeda Pharmaceuticals International AG

Ireland Branch, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Rhea Fitzgerald

**Pemazyre - pemigatinib -
EMA/H/C/005266/R/0013, Orphan**

Incyte Biosciences Distribution B.V.,
Rapporteur: Alexandre Moreau, PRAC
Rapporteur: Menno van der Elst

**Sixmo - buprenorphine -
EMA/H/C/004743/R/0017**

L. Molteni & C. dei Fratelli Alitti Societa di
Esercizio S.p.A., Rapporteur: Finbarr Leacy, Co-
Rapporteur: Petr Vrbata, PRAC Rapporteur:
Adam Przybylkowski

**Striascan - ioflupane (123i) -
EMA/H/C/004745/R/0012**

CIS BIO International, Generic, Generic of
DaTSCAN, Rapporteur: Ewa Balkowiec Iskra,
Co-Rapporteur: Simona Badoi, PRAC
Rapporteur: Tiphaine Vaillant

**Talzenna - talazoparib -
EMA/H/C/004674/R/0017**

Pfizer Europe MA EEIG, Rapporteur: Filip
Josephson, Co-Rapporteur: Hrefna
Gudmundsdottir, PRAC Rapporteur: Ana Sofia
Diniz Martins

**Ultomiris - ravulizumab -
EMA/H/C/004954/R/0040**

Alexion Europe SAS, Rapporteur: Carolina Prieto
Fernandez, Co-Rapporteur: Robert Porszasz,
PRAC Rapporteur: Kimmo Jaakkola

**Waylivra - volanesorsen -
EMA/H/C/004538/R/0026, Orphan**

Akcea Therapeutics Ireland Limited, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Karin Janssen
van Doorn, PRAC Rapporteur: Martin Huber

**Xromi - hydroxycarbamide -
EMA/H/C/004837/R/0023**

Nova Laboratories Ireland Limited, Rapporteur:
Anastasia Mountaki, PRAC Rapporteur: Jo
Robays

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

Amyvid - Florbetapir (18F) -

EMA/H/C/002422/II/0046

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Extension of indication to include monitoring response to therapy for AMYVID, based on supporting literature. As a consequence, sections 4.1 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update section 4.8 of the SmPC to reflect the current clinical trial exposures to align it with the updated RMP."

Dupixent - dupilumab -

EMA/H/C/004390/II/0079

Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Kimmo Jaakkola, "Extension of indication for DUPIXENT to include treatment of adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) with type 2 inflammation on triple therapy or double therapy if inhaled corticosteroids (ICS) are contraindicated, based on final results from study EFC15804 (BOREAS); this is a phase 3, randomized, double blind, placebo-controlled, multi-center, parallel group, 52-week study to assess the efficacy, safety and tolerability of dupilumab in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) with type 2 inflammation. 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 10.0 of the RMP has also been submitted."

Keytruda - pembrolizumab -

EMA/H/C/003820/II/0145

Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) the treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [Stage

IB2-IIB (with node-positive disease) or Stage III-IVA based on FIGO 2014] for Keytruda, based on KEYNOTE-A18: A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.1 of the RMP has also been submitted.”

Kinpeygo - budesonide -

EMA/H/C/005653/II/0008, Orphan

STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II; this is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, and tolerability of oral Nefecon compared to matching placebo in patients with primary IgAN on a background of optimized RAS inhibitor therapy. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.”

Opdivo - nivolumab -

EMA/H/C/003985/II/0137

Bristol-Myers Squibb Pharma EEIG, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, “Extension of indication to include in combination with cisplatin-based chemotherapy the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma for OPDIVO, based on interim results from study CA209901 (CheckMate901); this is a Phase 3, open-label, randomized study of nivolumab combined with ipilimumab, or with standard of care chemotherapy, versus standard of care chemotherapy in participants with previously untreated unresectable or metastatic urothelial cancer. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 35.0 of the RMP has also been submitted.”

**RYBREVANT - amivantamab -
EMA/H/C/005454/II/0010**

Janssen-Cilag International N.V., Rapporteur:
Filip Josephson, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations for RYBREVANT, based on the final results from study 61186372NSC3001 listed as a Specific Obligation in the Annex II of the Product Information; this is a global, open-label, randomized Phase 3 study of ACP compared to CP alone in participants with newly diagnosed, locally advanced or metastatic NSCLC characterized by EGFR exon 20ins. The primary objective of the PAPILLON study is to compare efficacy, as demonstrated by PFS, in participants treated with ACP versus CP alone. As a consequence, sections 4.1, 4.2, 4.8, 4.9, 5.1, 5.2 and 6.6 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 update Annex II and Annex IV of the PI. Consequently, the MAH proposes a switch from marketing authorisation under exceptional circumstances to full marketing authorisation given the fulfilment of the SOB. As part of the application, the MAH also requests an extension of the market protection by one additional year."

Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Triumeq - dolutegravir / abacavir /
lamivudine - EMA/H/C/002754/II/0116**

ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Extension of indication to include treatment of paediatric patients from 6 kg to less than 25 kg for Triumeq Dispersible Tablets, based on PK, safety, and efficacy data observed in the final results of study 205860 (IMPAACT 2019), further supported by extrapolation to data generated in adults and additional data in paediatric patients with the single entities. IMPAACT 2019 is a Phase 1/2 open-label,

multicenter, multiple dose study of dolutegravir/lamivudine/abacavir fixed dose combination tablets in treatment-experienced and treatment-naïve HIV-1-infected children less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.”

Wegovy - semaglutide -

EMA/H/C/005422/II/0017

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, “Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and BMI ≥ 27 kg/m² for WEGOVY, based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. 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)

WS2463

Imfinzi-EMA/H/C/004771/WS2463/0063

Lynparza-

EMA/H/C/003726/WS2463/0066

AstraZeneca AB, Lead Rapporteur: Carolina Prieto Fernandez, Lead PRAC Rapporteur: Amelia Cupelli, “Extension of indication for Lynparza in combination with Imfinzi for the maintenance treatment of adult patients with newly diagnosed advanced or recurrent endometrial cancer following treatment with Imfinzi and platinum-based chemotherapy, based on results from pivotal Phase III study,

D9311C00001 (DUO-E). This was a phase III, randomised, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of durvalumab in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance durvalumab with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 30 of the RMP has also been submitted.”

WS2538

Braftovi-

EMA/H/C/004580/WS2538/0034

Mektovi-

EMA/H/C/004579/WS2538/0030

Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, Lead PRAC Rapporteur: Rugile Pilviniene, “Extension of indication to include binimetinib in combination with encorafenib for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600 mutation for MEKTOVI and BRAFTOVI based on results from study PHAROS (study ARRAY-818-202) at the primary completion date; this is a Phase II, open-label, multicentre, non-comparative study (interventional). As a consequence, sections 4.1, 4.4, 4.8, 5.1, 5.2, 9 and 10 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection for Mektovi.” Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Abiraterone Krka - abiraterone acetate -

EMA/H/C/005649/II/0004

KRKA, d.d., Novo mesto, Generic, Generic of Zytiga, Rapporteur: Andreja Kranjc

Abrysvo - respiratory syncytial virus vaccine (bivalent, recombinant) -

EMA/H/C/006027/II/0001

Pfizer Europe Ma EEIG, Rapporteur: Jayne

Crowe

Bimzelx - bimekizumab -

EMA/H/C/005316/II/0023/G

UCB Pharma S.A., Rapporteur: Finbarr Leacy

Cerezyme - imiglucerase -

EMA/H/C/000157/II/0131

Sanofi B.V., Rapporteur: Patrick Vrijlandt

Comirnaty - COVID-19 mRNA vaccine

(nucleoside-modified) -

EMA/H/C/005735/II/0192

BioNTech Manufacturing GmbH, Rapporteur:

Filip Josephson

Kalydeco - ivacaftor -

EMA/H/C/002494/II/0120/G

Vertex Pharmaceuticals (Ireland) Limited,

Rapporteur: Maria Concepcion Prieto Yerro

Keytruda - pembrolizumab -

EMA/H/C/003820/II/0144

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

Gasparini

Ryzodeg - insulin aspart / insulin degludec

- EMA/H/C/002499/II/0054

Novo Nordisk A/S, Rapporteur: Kristina Dunder

Spikevax - COVID-19 mRNA vaccine

(nucleoside-modified) -

EMA/H/C/005791/II/0116/G

Moderna Biotech Spain, S.L., Rapporteur: Jan

Mueller-Berghaus

Suliqua - insulin glargine / lixisenatide -

EMA/H/C/004243/II/0037/G

Sanofi Winthrop Industrie, Rapporteur: Kristina

Dunder

Surgiflo Haemostatic Matrix Kit - human

thrombin - EMA/H/D/002301/II/0036/G

Ferrosan Medical Devices A/S, Rapporteur: Jan

Mueller-Berghaus

TachoSil - human thrombin / human

fibrinogen -

EMA/H/C/000505/II/0125/G

Corza Medical GmbH, Rapporteur: Jan Mueller-

Berghaus

Tresiba - insulin degludec -

EMA/H/C/002498/II/0060

Novo Nordisk A/S, Rapporteur: Kristina Dunder

**Trumenba - meningococcal group B vaccine
(recombinant, adsorbed) -**

EMA/H/C/004051/II/0050/G

Pfizer Europe MA EEIG, Rapporteur: Patrick
Vrijlandt

Zejula - niraparib -

EMA/H/C/004249/II/0046/G, Orphan

GlaxoSmithKline (Ireland) Limited, Rapporteur:
Ingrid Wang

WS2575

**Dengue Tetravalent Vaccine (Live,
Attenuated) Takeda-**

EMA/H/W/005362/WS2575/0009

Qdenga-

EMA/H/C/005155/WS2575/0010

Takeda GmbH, Lead Rapporteur: Sol Ruiz

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

Alkindi - hydrocortisone -

EMA/H/C/004416/II/0019

Diurnal Europe BV, Rapporteur: Karin Janssen
van Doorn, "Update of section 4.2 of the SmPC
in order to update posology recommendations in
case of incomplete dosing, following the request
by PRAC in the AR for procedure
PSUSA/00010674/202208; the Package Leaflet
is updated accordingly."

Drovelis - drospirenone / estetrol -

EMA/H/C/005336/II/0021

Chemical Works of Gedeon Richter Plc. (Gedeon
Richter Plc.), Rapporteur: Kristina Dunder,
"Update of sections 4.2 and 5.2 of the SmPC in
order to update information regarding hepatic
impairment based on final results from study
MIT-Do001-C102; this is a Phase 1, open-label,
parallel group, single-dose study to evaluate the
pharmacokinetics and safety of estetrol (E4) in
subjects with varying degrees of hepatic
function."

Dupixent - dupilumab -

EMA/H/C/004390/II/0078

Sanofi Winthrop Industrie, Rapporteur: Jan
Mueller-Berghaus, "Update of section 4.2 of the
SmPC in order to allow the use of the Dupixent
Prefilled Pen presentations for patients aged 2
to < 12 years of age based on final results of
the R668-AD-1434 sub-study; this is an

interventional open-label sub-study which purpose is to evaluate the PK, safety, immunogenicity, and efficacy of repeat doses of dupilumab (200 mg Q4W, 300 mg Q4W, and 200 mg Q2W) administered SC using a PFP with a skin pinch in children ≥ 2 to < 12 years of age. The Package Leaflet is updated accordingly. In addition, the MA took the opportunity to update the list of local representatives in the Package Leaflet.”

Fetroja - cefiderocol -

EMA/H/C/004829/II/0017

Shionogi B.V., Rapporteur: Filip Josephson, “Update of sections 4.5 and 5.2 of the SmPC in order to update drug-drug interaction information with CYP3A4 based on final results from study 2136R2118; this is a Phase 1, open-label, 1-sequence crossover, drug-drug interaction study to assess the effect of repeated doses of cefiderocol on the pharmacokinetics of midazolam in healthy adult participants.”

Kesimpta - ofatumumab -

EMA/H/C/005410/II/0013/G

Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, “A grouped application consisting of:

Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on injection-related reactions and to add ‘Hypersensitivity reactions’ to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly.

Type IB (C.I.z): Addition of a statement in the pre-filled syringes (PFS) instructions for use when PFS has been dropped on a hard surface.

Type IA (A.6): To change the ATC Code of ofatumumab from L04AA52 to L04AG12.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Lydisilka - drospirenone / estetrol -

EMA/H/C/005382/II/0021

Estetra SRL, Duplicate, Duplicate of Drovelis, Rapporteur: Kristina Dunder, “Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label,

parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in subjects with varying degrees of hepatic function.”

Skilarence - dimethyl fumarate -

EMA/H/C/002157/II/0034

Almirall S.A, Rapporteur: Janet Koenig, “Update of section 5.1 of the SmPC in order to update long-term efficacy and safety information based on final results from study M-41008-41 (Dimeskin 1); this is a phase IV non-randomised, non-interventional, open label study in adult patients with moderate to severe chronic plaque psoriasis to further assess long-term (12 months) efficacy and safety of Skilarence in routine daily practice in Spain.”

Spikevax - COVID-19 mRNA vaccine

(nucleoside-modified) -

EMA/H/C/005791/II/0114/G

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, “Grouped application consisting of:

C.I.4 (Type II): Update of sections 4.4, 4.8 and 5.1 of the SmPC to update the safety information regarding the administration of Spikevax to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, based on updated clinical literature and internal data; the Package Leaflet is updated accordingly.

C.I.Z (Type IB): To update section 6.6 of the SmPC in order to clarify the handling instructions for the pre-filled syringes; the Package Leaflet is updated accordingly.”

Translarna - ataluren -

EMA/H/C/002720/II/0074, Orphan

PTC Therapeutics International Limited, Rapporteur: Peter Mol, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations in the paediatric population, to update the summary of safety profile and to update efficacy, safety and pharmacokinetic information on the paediatric population based on the final results from study PTC124-GD-048-DMD “A Phase 2, multiple-dose, open-label study evaluating the safety and PK of ataluren in patients with nmDMD aged

≥6 months to <2 years old" (MEA-018). The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0134

MCM Vaccine B.V., Rapporteur: Christophe Focke, "Update of section 4.8 of the SmPC in order to add Extensive swelling of vaccinated limb to the list of adverse drug reactions (ADRs) with frequency rare and to update its description based on the cumulative review of clinical studies, literature and safety database. The Package Leaflet is updated accordingly."

Vaxzevria - covid 19 vaccine (chadox1 s [recombinant]) - EMEA/H/C/005675/II/0095

AstraZeneca AB, Rapporteur: Sol Ruiz, "Update of sections 4.1, 4.4 and 5.1 of the SmPC in order to update clinical information, following a critical evaluation of the benefit-risk profile of Vaxzevria against currently circulating variants of concern based on available data and structured benefit risk assessment."

VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMEA/H/C/005754/II/0007/G

Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, "A grouped application consisting of: Type II (C.I.4): Update of section 4.8 of the SmPC in order to include additional safety data based on safety update reports from studies VAT00008 booster extension and VAT00002 Cohort 2, in order to fulfil REC 20. Type IA (A.6): To change the ATC Code of the COVID-19 protein subunit vaccine from J07BX03 to J07BN04."

Yselty - linzagolix choline - EMEA/H/C/005442/II/0010

Theramex Ireland Limited, Rapporteur: Finbarr Leacy, "Submission of the final report from study PRIMROSE 3 (20-OBE2109-007), listed as a category 3 study in the RMP. This is a long-term follow-up study to assess bone mineral

density in subjects with uterine fibroids completing the Phase 3 studies of linzagolix, PRIMROSE 1 or PRIMROSE 2.”

Ztalmy - ganaxolone -

EMA/H/C/005825/II/0002, Orphan

Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, “Submission of the final report from study 1042-HME-1001 listed as post-authorisation measure (PAM) recommendation. This is an interventional Phase 1 Single Dose, Open-Label Crossover Comparative Bioavailability Study of Two Oral Formulations of Ganaxolone. The primary objective of this study was to evaluate and compare the pharmacokinetics of a new ganaxolone formulation (hot-melt extrusion [HME]) with ganaxolone oral suspension after a single oral dose administration under fed conditions.”

B.6.10. CHMP-PRAC assessed procedures

Gavreto - pralsetinib -

EMA/H/C/005413/II/0017

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.2 and 5.2 of the SmPC in order to include information regarding moderate and severe hepatic impairment based on final results from study GP43163 listed as a category 3 study in the RMP; this is a Phase I, open-label, single-dose study to evaluate the pharmacokinetics and safety of pralsetinib in subjects with moderate or severe hepatic impairment compared to healthy subjects. The RMP version 1.8 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the marketing authorisation renewal date in Annex I.”

Vpriv - velaglucerase alfa -

EMA/H/C/001249/II/0063

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, “Update of section 4.2 of the SmPC in order to add information to support at-home self-administration of VPRIV by a trained patient and/or a caregiver based on post-marketing

data and literature. The Package Leaflet and Annex IID are updated accordingly. The updated RMP version 13.0 has also been submitted.”

B.6.11. PRAC assessed procedures

PRAC Led

WS2569

Corlantor-

EMA/H/C/000598/WS2569/0059

Ivabradine Anpharm-

EMA/H/C/004187/WS2569/0019

Procoralan-

EMA/H/C/000597/WS2569/0058

Les Laboratoires Servier, Lead PRAC

Rapporteur: Menno van der Elst, PRAC-CHMP

liaison: Patrick Vrijlandt, “C.I.11.z - To update

the RMP to delete the obsolete products

(Ivabradine Egis and Ivabradine Proterapia) that

are still mentioned in the RMP.”

B.6.12. CHMP-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel /

lisocabtagene maraleucel -

EMA/H/C/004731/II/0032, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Concetta Quintarelli, CHMP Coordinator: Paolo

Gasparini

Libmeldy - atidarsagene autotemcel -

**EMA/H/C/005321/II/0021, Orphan,
ATMP**

Orchard Therapeutics (Netherlands) B.V.,

Rapporteur: Emmely de Vries, CHMP

Coordinator: Peter Mol

Strimvelis - autologous CD34+ enriched

cell fraction that contains CD34+ cells

transduced with retroviral vector that

encodes for the human ADA cDNA

sequence - EMA/H/C/003854/II/0039,

Orphan, ATMP

Fondazione Telethon ETS, Rapporteur: Sol Ruiz,

CHMP Coordinator: Maria Concepcion Prieto

Yerro

Yescarta - axicabtagene ciloleucel -

EMA/H/C/004480/II/0065, Orphan,

ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-

Berghaus, CHMP Coordinator: Jan Mueller-

Berghaus, "Update of section 4.8 of the SmPC in order to add Infusion Related Reactions to the list of adverse drug reactions (ADRs) with frequency Common, based on a cumulative review of the MAH safety database, clinical trials and post-marketing data. The Package Leaflet is updated accordingly."

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2572/G

Herceptin-

EMA/H/C/000278/WS2572/0191/G

MabThera-

EMA/H/C/000165/WS2572/0200/G

Roche Registration GmbH, Lead Rapporteur: Jan Mueller-Berghaus

WS2581/G

Fluenz Tetra-

EMA/H/C/002617/WS2581/0136/G

Pandemic influenza vaccine H5N1

AstraZeneca-

EMA/H/C/003963/WS2581/0070/G

AstraZeneca AB, Lead Rapporteur: Christophe Focke

WS2589

Ongentys-

EMA/H/C/002790/WS2589/0062

Ontilyv-EMA/H/C/005782/WS2589/0017

Bial - Portela & C^a, S.A., Lead Rapporteur: Martina Weise

WS2592/G

Nuwiq-

EMA/H/C/002813/WS2592/0056/G

Vihuma-

EMA/H/C/004459/WS2592/0038/G

Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS2602/G

Eucreas-

EMA/H/C/000807/WS2602/0104/G

Icandra-

EMA/H/C/001050/WS2602/0109/G

Zomarist-

EMA/H/C/001049/WS2602/0106/G

Novartis Europharm Limited, Lead Rapporteur:

Kristina Dunder

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers

E.1.1. Annual Update

E.1.2. Variations

E.1.3. Initial PMF Certification

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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