26 January 2021
EMA/CHMP/47240/2021 Corr.1[1]
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 25-29 January 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

25 January 2021, 09:00 – 19:30, virtual meeting/ room 1C

26 January 2021, 08:30 – 19:30, virtual meeting/ room 1C

27 January 2021, 08:30 – 19:30, virtual meeting/ room 1C

28 January 2021, 08:30 – 19:30, virtual meeting/ room 1C

29 January 2021, 08:30 – 18:00, virtual meeting/ room 1C

Disclaimers

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

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

Note on access to documents

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

[1] Correction in section 9.1.5

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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 25-29 January 2021. See January 2021 CHMP minutes (to be published post February 2021 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 25-29 January 2021

1.3. Adoption of the minutes

CHMP minutes from meeting held on 07-10 December 2020.

ORGAM minutes from meeting held on 18 January 2021.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. salmeterol xinafoate / fluticasone propionate - EMEA/H/C/005591

for treatment of asthma

Scope: Possible oral explanation/Opinion

Action: Possible oral explanation to be held on Tuesday, 26 January 2021 at 14:00

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 27.02.2020.

See 3.1

2.1.2. salmeterol xinafoate / fluticasone propionate - EMEA/H/C/004881

for treatment of asthma

Scope: Possible oral explanation/Opinion

Action: Possible oral explanation to be held on Tuesday, 26 January 2021 at 14:00

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 27.02.2020.

See 3.1

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

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

Scope: Possible oral explanation/Opinion

Action: For adoption

See 3.1 and 15.1

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Epidyolex - cannabidiol - Orphan - EMEA/H/C/004675/II/0005

GW Pharma (International) B.V.

Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 1 year of age and older. 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 accordingly. The updated RMP version 1.1 has been submitted.
The MAH also took the opportunity to correct typographic errors and implement editorial updates as well as implement the updated ethanol statement in compliance with the EC Guideline on Excipient.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: Oral explanation to be held on Tuesday, 26 January 2021 at 16:00

Request for Supplementary Information adopted on 15.10.2020, 23.07.2020.

See 5.1

2.3.2. Trelegy Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004363/X/0012/G

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin

Scope: "Extension application to introduce a new strength (184 mcg/55 mcg/22 mcg) grouped with a type II variation (C.I.6.a) to add a new indication (asthma).
Whilst the new indication is applicable also to the existing presentations (EU/1/17/1236/001-3), the new strength is indicated only for the treatment of asthma.
The RMP (version 2.2) is updated in accordance.",

Oral explanation, opinion

Action: Oral explanation to be held on Wednesday, 27 January 2021 at 15:30

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 25.06.2020.

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. bevacizumab - EMEA/H/C/005286

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 28.05.2020.

3.1.2. salmeterol xinafoate / fluticasone propionate - EMEA/H/C/005591

for treatment of asthma

Scope: Possible oral explanation/Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 27.02.2020.

See 2.1

3.1.3. remimazolam - EMEA/H/C/005246

indicated for procedural sedation

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020, 15.10.2020. List of Questions adopted on 30.04.2020.

3.1.4. dostarlimab - EMEA/H/C/005204

treatment of mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer (EC)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020. List of Questions adopted on 23.06.2020.

3.1.5. ofatumumab - EMEA/H/C/005410

treatment of relapsing forms of multiple sclerosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 28.05.2020.

3.1.6. selinexor - Orphan - EMEA/H/C/005127

Karyopharm Europe GmbH; treatment of patients with relapsed refractory multiple myeloma (RRMM)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020, 30.01.2020, 19.09.2019. List of Questions adopted on 24.04.2019.

3.1.7. cenobamate - EMEA/H/C/005377

for the adjunctive treatment of focal onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic products.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020. List of Questions adopted on 23.07.2020.

3.1.8. bevacizumab - EMEA/H/C/005556

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.

First line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 28.05.2020.

3.1.9. pemigatinib - Orphan - EMEA/H/C/005266

Incyte Biosciences Distribution B.V.; treatment of locally advanced or metastatic cholangiocarcinoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2020. List of Questions adopted on 30.04.2020.

3.1.10. salmeterol xinafoate / fluticasone propionate - EMEA/H/C/004881

for treatment of asthma

Scope: Possible oral explanation/Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 27.02.2020.

See 2.1

3.1.11. somapacitan - Orphan - EMEA/H/C/005030

Novo Nordisk A/S; indicated for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (AGHD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020, 17.09.2020, 25.06.2020. List of Questions adopted on 30.01.2020.

3.1.12. thiotepa - EMEA/H/C/005434

conditioning treatment prior to haematopoietic progenitor cell transplantation (HPCT), treatment of solid tumours

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020. List of Questions adopted on 17.09.2020.

3.1.13. icosapent ethyl - EMEA/H/C/005398

is indicated to reduce cardiovascular risk as an adjunct to statin therapy.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020, 17.09.2020. List of Questions adopted on 26.03.2020.

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

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

Scope: Possible oral explanation/Opinion

Action: For adoption

See 2.1 and 15.1

3.1.15. Comirnaty - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735

BioNTech Manufacturing GmbH; active immunization against COVID-19 disease

Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst

Scope: Opinion was adopted at an extraordinary meeting held remotely on 21 December 2020

Action: For information

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

See 9.1

3.1.16. COVID-19 Vaccine Moderna – COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791

Moderna Biotech Spain, S.L.; indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in adults aged 18 years and older

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Hans Christian Siersted

Scope: Opinion was adopted at an extraordinary meeting held remotely on 06 January 2021

Action: For information

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

See 15.1

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

3.2.1. abiraterone acetate - EMEA/H/C/005408

treatment of metastatic prostate cancer

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 15.10.2020. List of Questions adopted on 30.01.2020.

3.2.2. hydrocortisone - Orphan - EMEA/H/C/005105

Diurnal Europe BV; replacement therapy for congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.07.2020.

3.2.3. estetrol / drospirenone - EMEA/H/C/005336

oral contraceptive

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 25.06.2020.

3.2.4. risdiplam - Orphan - EMEA/H/C/005145

Accelerated assessment

Roche Registration GmbH; treatment of spinal muscular atrophy (SMA)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 10.11.2020.

3.2.5. pralsetinib - EMEA/H/C/005413

treatment of non-small cell lung cancer (NSCLC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.09.2020.

3.2.6. estetrol / drospirenone - EMEA/H/C/005382

oral contraception

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2020.

3.2.7. ponesimod - EMEA/H/C/005163

treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.07.2020.

3.2.8. tanezumab - EMEA/H/C/005189

treatment of moderate to severe chronic pain associated with osteoarthritis (OA) in adult patients for whom treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and/or an opioid is ineffective, not tolerated or inappropriate

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.07.2020.

3.2.9. relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267

treatment of uterine fibroids

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.07.2020.

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

3.3.1. abrocitinib - EMEA/H/C/005452

Indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

Scope: List of questions

Action: For adoption

3.3.2. artesunate - Orphan - EMEA/H/C/005550

Amivas Ireland Ltd; treatment of malaria

Scope: List of questions

Action: For adoption

3.3.3. avalglucosidase alfa - Orphan - EMEA/H/C/005501

Genzyme Europe BV; for long-term enzyme replacement therapy for the treatment of patients with Pompe disease.

Scope: List of questions

Action: For adoption

3.3.4. ranibizumab - EMEA/H/C/005545

treatment of neovascular age-related macular degeneration (AMD)

Scope: List of questions

Action: For adoption

3.3.5. lonapegsomatropin - Orphan - EMEA/H/C/005367

Ascendis Pharma Endocrinology Division A/S; Treatment of growth hormone deficiency

Scope: List of questions

Action: For adoption

3.3.6. adalimumab - EMEA/H/C/005548

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn’s disease, paediatric Crohn’s disease, ulcerative colitis, uveitis, paediatric uveitis

Scope: List of questions

Action: For adoption

3.3.7. teriparatide - EMEA/H/C/004932

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture

Scope: List of questions

Action: For adoption

3.3.8. pegcetacoplan - Orphan - EMEA/H/C/005553

Apellis Ireland Limited; paroxysmal nocturnal haemoglobinuria (PNH)

Scope: List of questions

Action: For adoption

3.3.9. ripretinib - Orphan - EMEA/H/C/005614

Deciphera Pharmaceuticals (Netherlands) B.V.; Treatment of patients with advanced gastrointestinal stromal tumour (GIST)

Scope: List of questions

Action: For adoption

3.3.10. rivaroxaban - EMEA/H/C/005600

Prevention of venous thromboembolism in adult patients undergoing elective hip or knee replacement surgery and treatment of deep vein thrombosis and pulmonary embolism as well as prevention of recurrent DVT and PE in adults. Treatment of deep vein thrombosis and pulmonary embolism and prevention of recurrent DVT and PE in adults. Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors.

Scope: List of questions

Action: For adoption

3.3.11. autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogeneic glioma tumor cell lysates, inactivated - Orphan - ATMP - EMEA/H/C/003693

Epitopoietic Research Corporation-Belgium (E.R.C.); treatment of glioma

Scope: List of questions

Action: For information

3.3.12. elivaldogene autotemcel - Orphan - ATMP - EMEA/H/C/003690

Accelerated assessment

bluebird bio (Netherlands) B.V; treatment of ABCD1 genetic mutation and cerebral adrenoleukodystrophy

Scope: List of questions

Action: For information

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

3.4.1. zanubrutinib - Orphan - EMEA/H/C/004978

BeiGene Ireland Ltd; treatment of Waldenström's Macroglobulinaemia (WM).

Scope: Request by the applicant dated 22 December 2020 for an extension to the clock

stop to respond to the list of questions adopted in October 2020

Action: For adoption

List of Questions adopted on 15.10.2020.

3.4.2. leuprorelin - EMEA/H/C/005034

indicated for the treatment of hormone dependent advanced prostate cancer.

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in July 2020. This request was adopted via written procedure on 22 January 2021.

Action: For information

Scope: Request by the applicant dated 11 January 2021 for an additional extension to the clock stop to respond to the list of questions adopted in July 2020

Action: For adoption

List of Questions adopted on 23.07.2020.

3.4.3. doxorubicin hydrochloride - EMEA/H/C/005330

treatment of breast cancer, treatment of ovarian cancer, treatment of multiple myeloma, treatment of AIDS related Kaposi's sarcoma.

Scope: Request by the applicant dated 08 January 2021 for an extension to the clock stop to respond to the list of questions adopted in May 2020

Action: For adoption

List of Questions adopted on 28.05.2020.

3.4.4. doxorubicin - EMEA/H/C/005320

treatment of breast cancer, ovarian cancer, progressive multiple myeloma and AIDS-related Kaposi's sarcoma

Scope: Request from the applicant dated 11 January 2021 for an extension of clock-stop to respond to the list of outstanding issues adopted in March 2020

Action: For adoption

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

3.4.5. sildenafil - EMEA/H/C/005439

treatment of erectile dysfunction

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in June 2020

Action: For adoption

List of Questions adopted on 25.06.2020.

3.4.6. sitagliptin - EMEA/H/C/005598

treatment of type 2 diabetes mellitus

Scope: Request by the applicant dated 14 December 2020 for an extension to the clock stop to respond to the list of questions adopted in September 2020

Action: For adoption

List of questions adopted on 17.09.2020.

3.4.7. trastuzumab - EMEA/H/C/005066

treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)

Scope: Request from the applicant dated 12 December 2020 for an extension to the clock stop to respond to the list of outstanding issues adopted in December 2020

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020. List of Questions adopted on 19.09.2019.

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. dexamethasone phosphate - EMEA/H/C/005740

indicated for cerebral oedema, post-traumatic shock-lung syndrome, asthma, skin diseases, autoimmune diseases, rheumatoid arthritis, prophylaxis and treatment of post-operative or cytostatic-induced vomiting, treatment of COVID-19, eye inflammation and infection

Scope: Letter dated 20.01.2021 informing about the withdrawal of marketing authorisation application

Action: For information

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. Elebrato Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004781/X/0014/G

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin

Scope: "Extension application to introduce a new strength (184 mcg/55 mcg/22 mcg) grouped with a type II variation (C.I.6.a) to add a new indication (asthma). Whilst the new indication is applicable also to the existing presentations (EU/1/17/1237/001-3), the new strength is indicated only for the treatment of asthma. The RMP (version 2.2) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 25.06.2020.

4.1.2. Sirturo - bedaquiline - Orphan - EMEA/H/C/002614/X/0036/G

Janssen-Cilag International NV

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to add a new strength (20 mg tablets) grouped with a type II variation (C.I.6) to extend the existing Sirturo indication to include paediatric patients aged from 5 years to less than 18 years of age and weighing more than 15 kg, based on the results of the week 24 analysis of Cohort 2 (paediatric subjects aged ≥5 to <12 years) of study TMC207-C211. Sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 and the Product Leaflet are updated to support the extended indication. The RMP (version 7.1) is updated in accordance. Furthermore, the Product Information is brought in line with the latest QRD template version 10.1."

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020, 12.11.2020, 17.09.2020. List of Questions adopted on 30.04.2020.

4.1.3. Temybric Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/005254/X/0004/G

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin

Scope: "Extension application to introduce a new strength (184 mcg/55 mcg/22 mcg) grouped with a type II variation (C.I.6.a) to add a new indication (asthma).

Whilst the new indication is applicable also to the existing presentations (EU/1/19/13781237/001-3), the new strength is indicated only for the treatment of asthma. The RMP (version 2.2) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 25.06.2020.

4.1.4. Tepadina - thiotepa - EMEA/H/C/001046/X/0036

ADIENNE S.r.l.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (400 mg powder and solvent for solution for infusion)."

Action: For adoption

List of Outstanding Issues adopted on 17.09.2020. List of Questions adopted on 26.03.2020.

4.1.5. Trelegy Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004363/X/0012/G

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin

Scope: "Extension application to introduce a new strength (184 mcg/55 mcg/22 mcg) grouped with a type II variation (C.I.6.a) to add a new indication (asthma).
Whilst the new indication is applicable also to the existing presentations (EU/1/17/1236/001-3), the new strength is indicated only for the treatment of asthma. The RMP (version 2.2) is updated in accordance.",
Oral explanation, opinion

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 25.06.2020.

See 2.3

4.1.6. Trimbow - beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium - EMEA/H/C/004257/X/0012

Chiesi Farmaceutici S.p.A.; treatment of asthma, symptomatic treatment and reduction of exacerbations in adult patients with chronic obstructive pulmonary disease (COPD) with airflow limitation and who are at risk of exacerbations

Rapporteur: Janet Koenig, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Jan Neuhauser

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.12.2020. List of Questions adopted on 23.07.2020.

4.1.7. Tysabri - natalizumab - EMEA/H/C/000603/X/0116

Biogen Netherlands B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection), associated with a new strength (150 mg) and a new route of administration (subcutaneous use). The RMP (version 26.1) is updated accordingly."

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 23.07.2020.

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

No items

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

4.3.1. Akynzeo - fosnetupitant / netupitant / palonosetron - EMEA/H/C/003728/X/0031

Helsinn Birex Pharmaceuticals Limited

Rapporteur: Peter Kiely, PRAC Rapporteur: Ilaria Baldelli

Scope: "Extension application to introduce a new pharmaceutical form (concentrate 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. Benlysta - belimumab - EMEA/H/C/002015/II/0080

GlaxoSmithKline (Ireland) Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of lupus nephritis for belimumab; 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 38 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 15.10.2020.

5.1.2. Blincyto - blinatumomab - Orphan - EMEA/H/C/003731/II/0038

Amgen Europe B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová

Scope: "Extension of indication to include the use of blinatumomab as monotherapy for the treatment of paediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome negative CD19 positive B-precursor ALL as consolidation therapy; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13 of the RMP has also been submitted."

Action: For adoption

5.1.3. Brilique - ticagrelor - EMEA/H/C/001241/II/0049

AstraZeneca AB

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES), a phase III, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic stroke or transient ischaemic attack; 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 13 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 17.09.2020.

5.1.4. Epidyolex - cannabidiol - Orphan - EMEA/H/C/004675/II/0005

GW Pharma (International) B.V.

Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 1 year of age and older. 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 accordingly. The updated RMP version 1.1 has been submitted.
The MAH also took the opportunity to correct typographic errors and implement editorial updates as well as implement the updated ethanol statement in compliance with the EC Guideline on Excipient.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004),

Oral explanation

Action: For adoption

Request for Supplementary Information adopted on 15.10.2020, 23.07.2020.

See 2.3

5.1.5. Jardiance - empagliflozin - EMEA/H/C/002677/II/0055

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension of indication to include treatment of adult patients with heart failure and reduced ejection fraction for Jardiance; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9 and 5.1 of the SmPC are updated. This is based on final results from the EMPEROR HFrEF study, a phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo. The Package Leaflet and Labelling are updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.6. Jyseleca - filgotinib - EMEA/H/C/005113/II/0001

Gilead Sciences Ireland UC

Rapporteur: Kristina Dunder, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "C.I.6 (Extension of indication) C.I.6a (Extension of indication). Extension of indication to include the treatment of active ulcerative colitis in adults patients for Jyseleca.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated accordingly. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to do minor updates to the Annex II and to implement minor editorial changes in the SmPC and Package Leaflet."

Action: For adoption

5.1.7. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0090

Merck Sharp & Dohme B.V.

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

Scope: "Extension of the currently approved therapeutic indication for the treatment of relapsed or refractory classical Hodgkin lymphoma (rrcHL) in adults to an earlier line of therapy and to include paediatric patients - as follows:
Keytruda as monotherapy is indicated for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) following at least one prior therapy when ASCT is not a treatment option.
The indication is based on the study KEYNOTE-204, a randomized, open-label, Phase 3 trial evaluating Keytruda monotherapy versus Brentuximab Vedotin (BV) for the treatment of patients with rrcHL and supportive data from updated analysis of KEYNOTE-087, which was the pivotal study supporting the initial rrcHL indication."

Action: For adoption

Request for Supplementary Information adopted on 10.12.2020, 17.09.2020.

5.1.8. Nucala - mepolizumab - EMEA/H/C/003860/II/0035

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Nucala (mepolizumab). 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 7 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to update the local (IT) representative in the PL."

Action: For adoption

5.1.9. Nucala - mepolizumab - EMEA/H/C/003860/II/0036/G

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include Eosinophilic Granulomatosis with Polyangiitis

(EGPA) to Nucala (mepolizumab); 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 7 of the RMP has also been submitted.
In addition, the marketing authorisation holder took the opportunity to update the local representative (IT) in the the PL .
2 Variations : type I B.11.e.5.a.2 - To add a new pack size for pre-filled pens for Nucala, 100 mg/ml, solution for injection and another pack size for pre-filled syringes for Nucala, 100 mg/ml, solution for injection.
As a consequence, sections 6.5 and 8 of SmPCs and section 6 of the PLs are updated accordingly.
Annex IIIA is also being updated to include information relating to the new pack sizes."

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

Action: For adoption

5.1.10. Nucala - mepolizumab - EMEA/H/C/003860/II/0037

GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include hypereosinophilic syndrome (HES) for Nucala (mepolizumab); as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 (in addition 6.6 for the powder for solution for injection only) of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7 of the RMP has also been submitted.
In addition, the Marketing authorisation holder took the opportunity to update the local representative (IT) in the PL."

Action: For adoption

5.1.11. Saxenda - liraglutide - EMEA/H/C/003780/II/0026

Novo Nordisk A/S

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include treatment as an adjunct to a healthy nutrition and physical activity counselling for weight management in adolescent patients from the age of 12 years and above with body weight above 60 kg and obesity (BMI corresponding to ≥30 kg/m2 for adults), based on study NN8022-4180 that evaluated the efficacy of liraglutide 3.0 mg in adolescents aged 12 to less than 18 years with obesity. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are being updated and the Package Leaflet is updated in accordance. The application relates to paediatric studies submitted according to Article 46 of the paediatric regulation. The application included an updated RMP version 32.0."

Action: For adoption

Request for Supplementary Information adopted on 15.10.2020, 28.05.2020.

5.1.12. Siklos - hydroxycarbamide - EMEA/H/C/000689/II/0047

Addmedica S.A.S.

Rapporteur: Karin Janssen van Doorn

Scope: "Extension of indication to include treatment of severe chronic anaemia (haemoglobin level < 6 g/dL or < 7 g/dL with poor clinical or functional tolerance) in adults, adolescents and children older than 2 years suffering from sickle cell syndrome for Siklos; as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 15.10.2020.

5.1.13. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0033

Roche Registration GmbH

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: "Extension of indication to include the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumours express PD-L1 for Tecentriq based on the results of the pivotal study GO29431 (IMpower110), comparing atezolizumab monotherapy to platinum-based chemotherapy. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 12.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020.

5.1.14. Teysuno - tegafur / gimeracil / oteracil - EMEA/H/C/001242/II/0045

Nordic Group B.V.

Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include treatment of metastatic colorectal cancer in adult patients where it is not possible to initiate or continue treatment with another fluoropyrimidine. As a consequence, sections 4.1, 4.2, 4.3, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10 of the RMP has also been submitted."

Action: For adoption

5.1.15. Vaxchora - cholera vaccine, oral, live - EMEA/H/C/003876/II/0003/G

Emergent Netherlands B.V.

Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Jean-Michel Dogné

Scope: "C.I.6.a (type II): Extension of the indication for the active immunisation against disease caused by Vibrio cholerae serogroup O1, from the currently approved age range

"adults and children aged 6 years and older" to "adults and children aged 2 years and older" for Vaxchora. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.
C.I.4 (type II): to update section 5.1 of the SmPC to include long-term immunogenicity data supporting Vaxchora effectiveness at generating a protective immune response that persists for 2 years following vaccination; based on the final results from study PXVX-VC-200-006, a randomized, double-blind, placebo-controlled trial aimed to assess the safety and immunogenicity of Vaxchora in children 2 to <18 years of age.
In addition, the MAH took the opportunity to include editorial changes in the SmPC and Annex II."

Action: For adoption

Request for Supplementary Information adopted on 17.09.2020.

5.1.16. Venclyxto - venetoclax - EMEA/H/C/004106/II/0030

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Filip Josephson, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Eva Jirsová

Scope: "Extension of indication for Venclyxto (venetoclax) in combination with Hypomethylating Agents (HMAs) or Low Dose Cytarabine (LDAC) for the treatment of adult patients with newly-diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy. As a consequence, sections 4.2, 4.3, 4.4, 4.5, 4.7, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and RMP version 6.1 are also updated accordingly.", 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 15.10.2020.

5.1.17. WS1937/G Eucreas - vildagliptin / metformin hydrochloride - EMEA/H/C/000807/WS1937/0080/G Icandra - vildagliptin / metformin hydrochloride - EMEA/H/C/001050/WS1937/0083/G Zomarist - vildagliptin / metformin hydrochloride - EMEA/H/C/001049/WS1937/0082/G

Novartis Europharm Limited

Lead Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin

Scope: "Modification of approved therapeutic indication to simplify wording. Update of SmPC section 5.1 to add VERIFY study data (new study). Existing warning on drugs that may affect renal function or metformin disposition was expanded to include drugs that inhibit renal transporter (OCT2/MATE inhibitors) and corresponding update in drug interaction (section 4.4 and 4.5). PI update to QRD v10.1."

Action: For adoption

5.1.18. WS1938/G
Galvus - vildagliptin - EMEA/H/C/000771/WS1938/0066/G
Jalra - vildagliptin - EMEA/H/C/001048/WS1938/0068/G
Xiliarx - vildagliptin - EMEA/H/C/001051/WS1938/0066/G

Novartis Europharm Limited

Lead Rapporteur: Kristina Dunder

Scope: "Modification of approved therapeutic indication to simplify wording. Update of SmPC section 5.1 to add VERIFY study data (new study)."

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. Evotaz - atazanavir / cobicistat - EMEA/H/C/003904/II/0038

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Adrien Inoubli

Scope: "Extension of indication to include the use of Evotaz in combination with other antiretroviral agents in the treatment of HIV-1 infection in adolescent patients aged ≥ 12 to < 18 years, weighing ≥ 35 kg without known mutations associated with resistance to atazanavir. 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 8.0 of the RMP has also been submitted. In addition, the marketing authorisation holder took the opportunity to make minor editorial corrections."

Letter from the applicant dated 21 December 2020 requesting an extension of clock-stop to respond to the request for supplementary information adopted in December 2020.

Action: For adoption

Request for Supplementary Information adopted on 10.12.2020

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

No items

6. Ancillary medicinal substances in medical devices

6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

No items

6.2. Update of Ancillary medicinal substances in medical devices

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. autologous human t cells genetically modified ex-vivo with a lentiviral vector encoding a chimeric antigen receptor (CAR) for B-cell maturation antigen (BCMA) - H0005095

indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, whose prior regimens included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody and who had disease progression on the last regimen.

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

Action: For adoption

8.1.2. birch bark extract - H0005035

to accelerate healing in the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients from birth onwards.

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

Action: For adoption

8.1.3. oportuzumab monatox - H0005730

indicated in adults for:

- the treatment and prevention of recurrence of carcinoma-in-situ (CIS) of the urinary bladder following transurethral resection in BCG-unresponsive patients;

- the prevention of recurrence of high grade Ta and/or T1 papillary tumours following transurethral resection in BCG-unresponsive patients.

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

Action: For adoption

8.2. Priority Medicines (PRIME)

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

8.2.1. List of applications received

Action: For information

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Cresemba - isavuconazole - EMEA/H/C/002734/II/0031

Basilea Pharmaceutica Deutschland GmbH

Rapporteur: Johann Lodewijk Hillege

Scope: "Update of section 4.2 of SmPC to clarify the instructions on the start of therapy, according to current treatment guidelines for aspergillus and mucor diseases. Additionally, correction of an oversight is carried out in SmPC section 4.8 and PL section 4 of Cresemba 100 mg capsules, to reinstate "odema peripheral" as "uncommon" adverse event, which was unintentionally omitted from the PI at the time of the initial MAA. Re-instatement of text about the potential interaction between isavuconazole and protease inhibitors other than indinavir and lopinavir/ritonavir, wrongly deleted from the interactions table in SmPC section 4.5 and PL section 2 as part of a previous procedure, is also carried out."

Action: For adoption

Request for Supplementary Information adopted on 15.10.2020.

9.1.2. Siklos; Xromi - hydroxycarbamide - PSUSA/00001692/202006

Addmedica S.A.S. (Siklos), Nova Laboratories Ireland Limited (Xromi)

Siklos (EMEA/H/C/000689): Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Konstantinos Markopoulos

Xromi (EMEA/H/C/004837): Rapporteur: Konstantinos Markopoulos, Co-Rapporteur: Karin Janssen van Doorn

Scope: PRAC recommendation; PSUSA procedure

Action: For discussion

9.1.3. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0042

Roche Registration GmbH

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

"Extension of indication to include, in combination with platinum-based chemotherapy, first-line treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) for Tecentriq. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. Version 14.0 of the RMP has also been submitted."

Scope: Withdrawal of extension of indication application

Action: For information

Request for Supplementary Information adopted on 10.12.2020, 25.06.2020.

9.1.4. Comirnaty - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope: Update on procedure

Action: For discussion

See 3.1

9.1.5. WS1844
Edistride - dapagliflozin - EMEA/H/C/004161/WS1844/0039
Forxiga - dapagliflozin - EMEA/H/C/002322/WS1844/0057

Astra Zeneca AB

Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin

"Re-categorisation of the Forxiga/Edistride PASS (D169C00011): Retrospective Cohort Study on the Risk of Diabetic Ketoacidosis (DKA) to determine the effectiveness of additional risk minimisation measures in place for DKA by assessing the impact of the risk minimisation measures on the risk of DKA in T1DM patients who are treated with dapagliflozin in Europe, from a category 1 to category 3 PASS in the RMP Version 20 and removal of the following Annex IID of the PI: Obligation to conduct the following Non-interventional PASS: In order to estimate the incidence of DKA in T1DM dapagliflozin users following implementation of RMMs in Europe, the MAH should conduct and submit the results from an observational cohort study using existing data sources in European countries where dapagliflozin will be launched for T1DM."

Scope: Withdrawal of variation application

Action: For information

An oral explanation was held on 08.12.2020. Request for Supplementary Information adopted on 15.10.2020, 23.07.2020.

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

January 2021 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Election of CHMP Co-opted Member

Election of CHMP co-opted member in light of Koenraad Norga's resignation as of 30 September 2020.

Agreed areas of expertise: Pharmaco-Epidemiology; especially for methodology (bias, effect modifications etc.) and interpretation of data, in particular study designs (observational studies, RWD etc.), strengths and weaknesses.

Action: For adoption

14.1.2. Area of expertise of CHMP Co-opted Member

Agreement on area of expertise in light of the expiry of mandate of co-opted member Blanka Hirschlerova in March 2021.

Note: The area of expertise of Blanka Hirschlerova is quality (non-biologicals) and pharmacokinetics.

Action: For adoption

14.1.3. CHMP Work Plan 2021

Action: For adoption

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 11-14 January 2021

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for January 2021

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at January 2021 PDCO

Action: For information

Report from the PDCO meeting held on 26-29 January 2021

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP January 2021 meeting to CHMP for adoption:

- 06 reports on products in scientific advice and protocol assistance
- 11 reports on products in pre-authorisation procedures
- 04 reports on products in plasma master file
- 01 activities in vaccines area

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 11-14 January 2021. Table of conclusions

Action: For information

Scientific advice letters:

Disclosure of 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

14.4.1. Nitrosamines Multidisciplinary Expert Group (NMEG) on rifampicin

Scope: Report from NMEG and advice to CMDh

Action: For adoption

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

15.1.2. CHMP - Rules of Procedure

Scope: Revision of 'CHMP - Rules of Procedure' to involve international experts in CHMP COVID-19 discussions - adopted via written procedure on 18 December 2020

Action: For information

15.1.3. COVID-19 Vaccine Moderna – COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791

Moderna Biotech Spain, S.L.; indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in adults aged 18 years and older

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Hans Christian Siersted

Scope: Updated timetable adopted via written procedure on 17 December 2020

Action: For information

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

See 3.1

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

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

Scope: Conditional marketing authorisation application timetable adopted by written procedure on 9 January 2021

Action: For information

See 2.1 and 3.1.

16. Explanatory notes

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

Oral explanations *(section 2)*

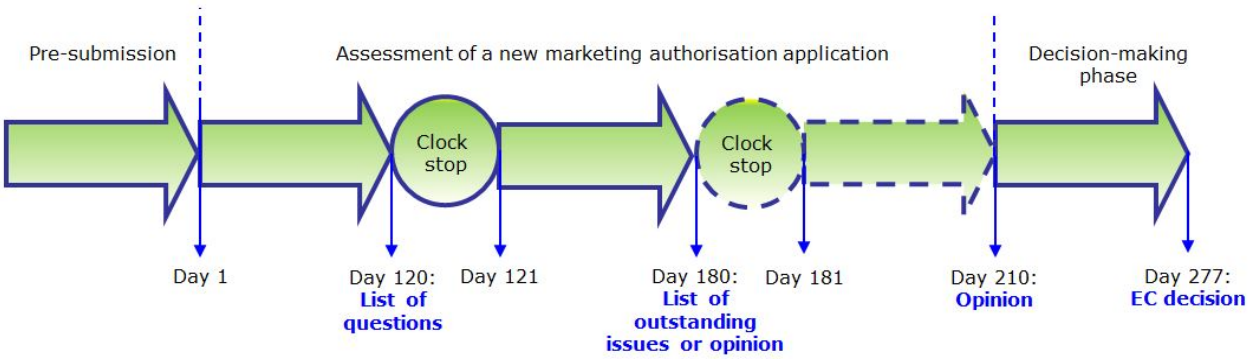
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

Extensions of marketing authorisations are applications for the change or addition of new strengths,

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

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

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

Ancillary medicinal substances in medical devices *(section 6)*

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

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

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

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a

particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2021
EMA/CHMP/49880/2021

Annex to 25-29 January 2021 CHMP Agenda

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for January 2021: **For adoption**

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

Final Outcome of Rapporteurship allocation for January 2021: **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

Lojuxta - lomitapide - EMEA/H/C/002578/S/0043
Amryt Pharmaceuticals DAC, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst
Request for Supplementary Information adopted on 10.12.2020.

Myalepta - metreleptin - EMEA/H/C/004218/S/0014, Orphan
Amryt Pharmaceuticals DAC, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Adam Przybylkowski

Raxone - idebenone - EMEA/H/C/003834/S/0023, Orphan
Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli

Vedrop - tocofersolan - EMEA/H/C/000920/S/0039
Recordati Rare Diseases, Rapporteur: Agnes

Gyurasics, PRAC Rapporteur: Melinda Palfi

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

CABOMETYX - cabozantinib - EMEA/H/C/004163/R/0018
Ipsen Pharma, Rapporteur: Bjorg Bolstad, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst

Coagadex - human coagulation factor x - EMEA/H/C/003855/R/0031, Orphan
BPL Bioproducts Laboratory GmbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst
Request for Supplementary Information adopted on 15.10.2020.

Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210/R/0054
Gilead Sciences Ireland UC, Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Ana Sofia Diniz Martins

Qtern - saxagliptin / dapagliflozin - EMEA/H/C/004057/R/0030
AstraZeneca AB, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Ilaria Baldelli

Zepatier - elbasvir / grazoprevir - EMEA/H/C/004126/R/0026
Merck Sharp & Dohme B.V., Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ana Sofia Diniz Martins

Zoely - nomegestrol acetate / estradiol - EMEA/H/C/001213/R/0055
Theramex Ireland Limited, Rapporteur: Jean-Michel Race, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Adrien Inoubli

B.2.3. Renewals of Conditional Marketing Authorisations

Deltyba - delamanid - EMEA/H/C/002552/R/0047, Orphan
Otsuka Novel Products GmbH, Rapporteur:

Christophe Focke, PRAC Rapporteur: Laurence de Fays
Request for Supplementary Information adopted on 10.12.2020.

Lorviqua - lorlatinib - EMEA/H/C/004646/R/0011
Pfizer Europe MA EEIG, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Nikica Mirošević Skvrce

Pandemic influenza vaccine H5N1 AstraZeneca - pandemic influenza vaccine (H5N1) (live attenuated, nasal) - EMEA/H/C/003963/R/0040
AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sonja Hrabcik

Rubraca - rucaparib - EMEA/H/C/004272/R/0025
Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/R/0012, Orphan, ATMP
Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, Co-Rapporteur: Egbert Flory, CHMP Coordinators: Johann Lodewijk Hillege and Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga

Zynteglo - betibeglogene autotemcel - EMEA/H/C/003691/R/0018, Orphan, ATMP
bluebird bio (Netherlands) B.V, Rapporteur: Carla Herberts, CHMP Coordinator: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

SIGNAL DETECTION

PRAC recommendations on signals adopted at the PRAC meeting held on 11-14 January 2021

Signal of abnormal weight gain

Humira - adalimumab
Rapporteur: Kristina Dunder, Co-Rapporteur: Armando Genazzani,
Scope: PRAC recommendation on a variation
Action: For adoption

Signal of adrenal crisis

Alkindi - hydrocortisone
Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Kolbeinn Gudmundsson,
Scope: PRAC recommendation on a variation, DHPC and Communication plan
Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its January 2021 meeting:

EMEA/H/C/PSUSA/00000226/202005
(apixaban)
CAPS:
Eliquis (EMEA/H/C/002148) (apixaban), Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, "17/05/2019 To: 17/05/2020"

EMEA/H/C/PSUSA/00001692/202006
(hydroxycarbamide (for centrally authorised product only))
CAPS:
Siklos (EMEA/H/C/000689) (hydroxycarbamide), Addmedica S.A.S., Rapporteur: Karin Janssen van Doorn
Xromi (EMEA/H/C/004837) (hydroxycarbamide), Nova Laboratories Ireland Limited, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Laurence de Fays, "01/07/2019 To: 28/06/2020"

EMEA/H/C/PSUSA/00002075/202004
(mitotane)
CAPS:
Lysodren (EMEA/H/C/000521) (mitotane), HRA Pharma Rare Diseases, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Eva A. Segovia, "27/04/2017 To: 27/04/2020"

EMEA/H/C/PSUSA/00009118/202005
(decitabine)
CAPS:
Dacogen (EMEA/H/C/002221) (decitabine),

Janssen-Cilag International N.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "02/05/2018 To: 01/05/2020"

EMEA/H/C/PSUSA/00010186/202005
(vedolizumab)
CAPS:
Entyvio (EMEA/H/C/002782) (vedolizumab), Takeda Pharma A/S, Rapporteur: Armando Genazzani, PRAC Rapporteur: Adam Przybylkowski, "18/05/2019 To: 18/05/2020"

EMEA/H/C/PSUSA/00010369/202006
(tedizolid phosphate)
CAPS:
Sivextro (EMEA/H/C/002846) (tedizolid phosphate), Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "20/06/2019 To: 20/06/2020"

EMEA/H/C/PSUSA/00010395/202005
('tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)))
CAPS:
Jinarc (EMEA/H/C/002788) (tolvaptan), Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Armando Genazzani, PRAC Rapporteur: Amelia Cupelli, "17/05/2019 To: 17/05/2020"

EMEA/H/C/PSUSA/00010460/202006
(blinatumomab)
CAPS:
BLINCYTO (EMEA/H/C/003731) (blinatumomab), Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová, "01/12/2019 To: 01/06/2020"

EMEA/H/C/PSUSA/00010644/202005
(atezolizumab)
CAPS:
Tecentriq (EMEA/H/C/004143) (atezolizumab), Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "17/05/2019 To: 17/05/2020"

EMEA/H/C/PSUSA/00010671/202005
(semaglutide)
CAPS:
Ozempic (EMEA/H/C/004174) (semaglutide), Novo Nordisk A/S, Rapporteur: Johann Lodewijk

Hillege **Rybelsus** (EMEA/H/C/004953) (semaglutide), Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Annika Folin	
EMEA/H/C/PSUSA/00010761/202005 (pegvaliase) CAPS: **Palynziq** (EMEA/H/C/004744) (pegvaliase), BioMarin International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, "24/11/2019 To: 23/05/2020"	
EMEA/H/C/PSUSA/00010779/202005 (avatrombopag) CAPS: **Doptelet** (EMEA/H/C/004722) (avatrombopag), Swedish Orphan Biovitrum AB (publ), Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Eva A. Segovia, "20/11/2019To: 20/05/2020"	
EMEA/H/C/PSUSA/00010848/202005 (onasemnogene abeparvovec) CAPS: **Zolgensma** (EMEA/H/C/004750) (onasemnogene abeparvovec), Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga, "24/05/2019 To: 23/05/2020"	
EMEA/H/C/PSUSA/00107800/202006 (levodopa) CAPS: **Inbrija** (EMEA/H/C/004786) (levodopa), Acorda Therapeutics Ireland Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Nikica Mirošević Skvrce, "19/12/2019 To: 20/06/2020"	

B.4. EPARs / WPARs

ELZONRIS - tagraxofusp - EMEA/H/C/005031, Orphan Stemline Therapeutics B.V., treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) 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.
Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124 Daiichi Sankyo Europe GmbH, treatment of unresectable or metastatic HER2-positive breast	For information only. Comments can be sent to the PL in case necessary.

cancer, New active substance (Article 8(3) of Directive No 2001/83/EC)	
HEPLISAV B - hepatitis b surface antigen - EMEA/H/C/005063 Dynavax GmbH, Prevention of hepatitis B virus infection, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
INREBIC - fedratinib - EMEA/H/C/005026, Orphan Celgene Europe BV, treatment of primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, 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.
Kixelle - insulin aspart - EMEA/H/C/004965 Mylan IRE Healthcare Limited, treatment of diabetes mellitus, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Lenalidomide Krka - lenalidomide - EMEA/H/C/005734 KRKA, d.d., Novo mesto, treatment of multiple myeloma and Follicular lymphoma, Generic, Duplicate, Generic of Revlimid, Duplicate of Lenalidomide Krka d.d. Novo mesto, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Lenalidomide Krka d.d. - lenalidomide - EMEA/H/C/005729 KRKA, d.d., Novo mesto, treatment of multiple myeloma, myelodysplastic syndromes and follicular lymphoma., Generic, Duplicate, Generic of Revlimid, Duplicate of Lenalidomide Krka d.d. Novo mesto, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Lenalidomide Krka d.d. Novo mesto - lenalidomide - EMEA/H/C/005348 Krka d.d. Novo mesto, treatment of multiple myeloma, Generic, Generic of Revlimid, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
LUMOXITI - moxetumomab pasudotox - EMEA/H/C/005322, Orphan AstraZeneca AB, relapsed or refractory hairy cell leukaemia (HCL) after receiving at least two prior systemic therapies, New active substance	For information only. Comments can be sent to the PL in case necessary.

(Article 8(3) of Directive No 2001/83/EC)	
Ogluo - glucagon - EMEA/H/C/005391 Xeris Pharmaceuticals Ireland Limited, treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
RETSEVMO - selpercatinib - EMEA/H/C/005375 Eli Lilly Nederland B.V., indicated for the treatment of adults with: advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy; advanced RET fusion-positive thyroid cancer who require systemic therapy and who have progressed following prior treatment. As monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, 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.
RUKOBIA - fostemsavir - EMEA/H/C/005011 ViiV Healthcare B.V., Indicated, in combination with other antiretrovirals, for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen due to resistance, intolerance or safety considerations., 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.
SIBNAYAL - potassium - EMEA/H/C/005407, Orphan Advicenne S.A., treatment of distal renal tubular acidosis (dRTA) in patients aged 6 months and older., Fixed combination application (Article 10b of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Sunitinib Accord - sunitinib - EMEA/H/C/005419 Accord Healthcare S.L.U., treatment of gastrointestinal stromal tumour (GIST) and metastatic renal cell carcinoma (MRCC) and pancreatic neuroendocrine tumours (pNET), Generic, Generic of Sutent, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
TUKYSA - tucatinib - EMEA/H/C/005263	For information only. Comments can be sent to

Seagen B.V., treatment of metastatic breast cancer or brain metastases, New active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
YUFLYMA - adalimumab - EMEA/H/C/005188 Celltrion Healthcare Hungary Kft., treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, Juvenile idiopathic arthritis, Enthesitis-related arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis, Paediatric Uveitis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

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

Abasaglar - insulin glargine - EMEA/H/C/002835/II/0035/G Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder	
AMGEVITA - adalimumab - EMEA/H/C/004212/II/0023 Amgen Europe B.V., Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 19.11.2020.	
AYVAKYT - avapritinib - EMEA/H/C/005208/II/0002, Orphan Blueprint Medicines (Netherlands) B.V., Rapporteur: Blanca Garcia-Ochoa	
Beovu - brolucizumab - EMEA/H/C/004913/II/0005/G Novartis Europharm Limited, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 10.12.2020.	
COMIRNATY - covid-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0002/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson	Positive Opinion adopted by consensus on 08.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 08.01.2021.	
Darunavir Mylan - darunavir - EMEA/H/C/004068/II/0012 Mylan S.A.S, Generic, Generic of Prezista, Rapporteur: John Joseph Borg Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Darzalex - daratumumab - EMEA/H/C/004077/II/0040, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 06.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Desloratadine ratiopharm - desloratadine - EMEA/H/C/002404/II/0025/G ratiopharm GmbH, Generic, Generic of Aerius, Rapporteur: Christophe Focke Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 15.10.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Dupixent - dupilumab - EMEA/H/C/004390/II/0038/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
EVRA - ethinylestradiol / norelgestromin - EMEA/H/C/000410/II/0048/G Janssen-Cilag International NV, Rapporteur: Paula Boudewina van Hennik Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Firmagon - degarelix - EMEA/H/C/000986/II/0038 Ferring Pharmaceuticals A/S, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0044 MSD Vaccins, Rapporteur: Kristina Dunder	
Herceptin - trastuzumab - EMEA/H/C/000278/II/0166 Roche Registration GmbH, Rapporteur: Jan	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Mueller-Berghaus Opinion adopted on 14.01.2021.	recommendation.
Herzuma - trastuzumab - EMEA/H/C/002575/II/0035/G Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0119/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 15.10.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0122 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
ILARIS - canakinumab - EMEA/H/C/001109/II/0072/G Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Inflectra - infliximab - EMEA/H/C/002778/II/0094/G Pfizer Europe MA EEIG, Duplicate, Duplicate of Remsima, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Kadcyla - trastuzumab emtansine - EMEA/H/C/002389/II/0053 Roche Registration GmbH, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Kevzara - sarilumab - EMEA/H/C/004254/II/0024/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 29.10.2020.	
Kovaltry - octocog alfa - EMEA/H/C/003825/II/0033 Bayer AG, Rapporteur: Kristina Dunder	

Lokelma - sodium zirconium cyclosilicate - EMEA/H/C/004029/II/0021/G AstraZeneca AB, Rapporteur: Romaldas Mačiulaitis Request for Supplementary Information adopted on 06.11.2020.	
Lonquex - lipegfilgrastim - EMEA/H/C/002556/II/0060 Teva B.V., Rapporteur: Outi Mäki-Ikola Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 10.12.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lucentis - ranibizumab - EMEA/H/C/000715/II/0090/G Novartis Europharm Limited, Rapporteur: Kristina Dunder	
M-M-RVAXPRO - measles, mumps and rubella vaccine (live) - EMEA/H/C/000604/II/0105 MSD Vaccins, Rapporteur: Jan Mueller-Berghaus	
MabThera - rituximab - EMEA/H/C/000165/II/0179 Roche Registration GmbH, Rapporteur: Sinan B. Sarac Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Mepsevii - vestronidase alfa - EMEA/H/C/004438/II/0019, Orphan Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Mimpara - cinacalcet - EMEA/H/C/000570/II/0068 Amgen Europe B.V., Rapporteur: Kristina Dunder Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 12.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
MVASI - bevacizumab - EMEA/H/C/004728/II/0017 Amgen Technology (Ireland) Unlimited Company, Duplicate, Duplicate of KYOMARC, Rapporteur: Bjorg Bolstad Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Mysimba - naltrexone hydrochloride /	Positive Opinion adopted by consensus on

bupropion hydrochloride - EMEA/H/C/003687/II/0042 Orexigen Therapeutics Ireland Limited, Rapporteur: Kirstine Moll Harboe Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 03.12.2020, 23.07.2020.	14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NovoSeven - eptacog alfa (activated) - EMEA/H/C/000074/II/0109/G Novo Nordisk A/S, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 22.10.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nucala - mepolizumab - EMEA/H/C/003860/II/0038 GlaxoSmithKline Trading Services Limited, Rapporteur: Peter Kiely Opinion adopted on 21.01.2021.	Positive Opinion adopted by consensus on 21.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Orfadin - nitisinone - EMEA/H/C/000555/II/0075 Swedish Orphan Biovitrum International AB, Rapporteur: Armando Genazzani	
Ozempic - semaglutide - EMEA/H/C/004174/II/0019 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
POTELIGEO - mogamulizumab - EMEA/H/C/004232/II/0008, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Paula Boudewina van Hennik Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Praluent - alirocumab - EMEA/H/C/003882/II/0058/G sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 15.10.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
ProQuad - measles, mumps, rubella and varicella vaccine (live) - EMEA/H/C/000622/II/0144 MSD Vaccins, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.01.2021.	Positive Opinion adopted by consensus on 21.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Puregon - follitropin beta -	

EMEA/H/C/000086/II/0111/G Merck Sharp & Dohme B.V., Rapporteur: Peter Kiely Request for Supplementary Information adopted on 10.12.2020.	
Puregon - follitropin beta - EMEA/H/C/000086/II/0112/G Merck Sharp & Dohme B.V., Rapporteur: Peter Kiely Request for Supplementary Information adopted on 10.12.2020.	
Puregon - follitropin beta - EMEA/H/C/000086/II/0113 Merck Sharp & Dohme B.V., Rapporteur: Peter Kiely Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Quofenix - delafloxacin - EMEA/H/C/004860/II/0007/G A. Menarini Industrie Farmaceutiche Riunite s.r.l., Rapporteur: Janet Koenig Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Remsima - infliximab - EMEA/H/C/002576/II/0096/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Repatha - evolocumab - EMEA/H/C/003766/II/0044 Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 29.10.2020, 10.09.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Rixubis - nonacog gamma - EMEA/H/C/003771/II/0035/G Baxalta Innovations GmbH, Rapporteur: Andrea Laslop Request for Supplementary Information adopted on 14.01.2021, 08.10.2020.	Request for supplementary information adopted with a specific timetable.
RoActemra - tocilizumab - EMEA/H/C/000955/II/0098/G Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Rybelsus - semaglutide - EMEA/H/C/004953/II/0007 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 12.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Sancuso - granisetron - EMEA/H/C/002296/II/0058 Kyowa Kirin Holdings B.V., Rapporteur: Simona Stankeviciute Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 10.12.2020, 12.11.2020, 04.09.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Soliris - eculizumab - EMEA/H/C/000791/II/0115/G, Orphan Alexion Europe SAS, Rapporteur: Blanca Garcia-Ochoa	
Strensiq - asfotase alfa - EMEA/H/C/003794/II/0050, Orphan Alexion Europe SAS, Rapporteur: Armando Genazzani Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 19.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Surgiflo Haemostatic Matrix Kit - human thrombin - EMEA/H/D/002301/II/0021 Presafe Denmark A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Surgiflo Haemostatic Matrix Kit - human thrombin - EMEA/H/D/002301/II/0022 Presafe Denmark A/S, Rapporteur: Jan Mueller-Berghaus	
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0051 Roche Registration GmbH, Rapporteur: Sinan B. Sarac Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Toujeo - insulin glargine - EMEA/H/C/000309/II/0117/G Sanofi-Aventis Deutschland GmbH, Duplicate, Duplicate of Lantus, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.

VITRAKVI - larotrectinib - EMEA/H/C/004919/II/0010/G Bayer AG, Rapporteur: Filip Josephson Request for Supplementary Information adopted on 15.10.2020.	
Votrient - pazopanib - EMEA/H/C/001141/II/0063/G Novartis Europharm Limited, Rapporteur: Sinan B. Sarac	
VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0051, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Xolair - omalizumab - EMEA/H/C/000606/II/0105/G Novartis Europharm Limited, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 03.12.2020.	
Zaltrap - aflibercept - EMEA/H/C/002532/II/0058/G sanofi-aventis groupe, Rapporteur: Filip Josephson Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Zavicefta - ceftazidime / avibactam - EMEA/H/C/004027/II/0023/G Pfizer Ireland Pharmaceuticals, Rapporteur: Bjorg Bolstad Request for Supplementary Information adopted on 10.12.2020, 06.11.2020, 01.10.2020.	
WS1935 **Mircera-EMEA/H/C/000739/WS1935/0083** **NeoRecormon-EMEA/H/C/000116/ WS1935/0110** Roche Registration GmbH, Lead Rapporteur: Martina Weise	
WS1942/G **Fluenz Tetra-EMEA/H/C/002617/WS1942/ 0103/G** **Pandemic influenza vaccine H5N1 AstraZeneca-EMEA/H/C/003963/WS1942/ 0038/G** AstraZeneca AB, Lead Rapporteur: Christophe Focke	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.01.2021.	
WS1943/G **Fluenz Tetra-EMEA/H/C/002617/ WS1943/0104/G** **Pandemic influenza vaccine H5N1 AstraZeneca-EMEA/H/C/003963/ WS1943/0039/G** AstraZeneca AB, Lead Rapporteur: Christophe Focke Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1954 **Infanrix hexa-EMEA/H/C/000296/ WS1954/0289** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1959 **Hexacima-EMEA/H/C/002702/WS1959/ 0109** **Hexaxim (SRD)-EMEA/H/W/002495/ WS1959/0114** **Hexyon-EMEA/H/C/002796/WS1959/ 0113** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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

Adcetris - brentuximab vedotin - EMEA/H/C/002455/II/0085, Orphan Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, "Update of the SmPC section 5.1 with the 5 year long-term follow-up and final OS results for the C25007 study in HL. Editorial updates have been also implemented in the PI."	
AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0029 sanofi-aventis groupe, Rapporteur: Martina Weise, "To update section 4.4 of the SmPC to add information on cases of drug-induced liver injury (DILI) observed in the post-marketing setting and section 4.8 of the SmPC to add of the adverse event DILI under the frequency unknown. During the assessment, it is considered that section 5.1 of the SmPC needs	Positive Opinion adopted by consensus on 21.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

to be updated to reflect new information on pharmacological effects of teriflunomide based on newly reported proprietary data and scientific literature. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the PL local representatives details." Opinion adopted on 21.01.2021. Request for Supplementary Information adopted on 24.09.2020, 14.05.2020.	
AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0032 sanofi-aventis groupe, Rapporteur: Martina Weise, "C.I.4. Update of section 4.4 of the SmPC in order to update information on the liver monitoring schedule and the use of concomitant potentially hepatotoxic drugs based on evidence from diverse clinical and post-marketing sources including results from three studies, namely TENERE/EFC10891 (Phase 3 multi-center, randomized, double-blind, open-label (for IFN β -1a), parallel-group study), Teri-PRO/LPS13567 study (Phase 4, multicenter, prospective, single-arm, open-label study) and TERIKIDS/EFC11759 (Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with 10 to 17 years of age) together with post-marketing data including real-world data from two European National Disease registries (The Danish Multiple Sclerosis Registry and Belgian Treatment in Multiple Sclerosis, or BELTRIMS registry) and one US-based database of electronic health records (Optum Humedica Database) and post-marketing experience included in the Sanofi Global pharmacovigilance database." Opinion adopted on 21.01.2021. Request for Supplementary Information adopted on 24.09.2020.	Positive Opinion adopted by consensus on 21.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0033 sanofi-aventis groupe, Rapporteur: Martina Weise, "Update of sections 4.4 and 4.8 of the SmPC regarding skin reactions in particular to drug reaction with eosinophilia and systemic symptoms (DRESS) and update of the frequency of severe skin reactions from "Not known" to "Uncommon", following a review of the Sanofi global PV database. The Package Leaflet section 4 is updated accordingly."	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 19.11.2020.	
Cosentyx - secukinumab - EMEA/H/C/003729/II/0069 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, "Update of section 5.1 of the SmPC based on final results from study CAIN457F3302; this is a randomised, double-blind, placebo-controlled study (MAXIMISE) which assessed the efficacy of secukinumab in PsA patients with axial manifestations who were naive to biologic treatment and responded inadequately to NSAIDs; the MAH took this opportunity to introduce minor editorial changes in section 5.1 of the SmPC." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Cresemba - isavuconazole - EMEA/H/C/002734/II/0030, Orphan Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.3 of the SmPC to update the description of non-clinical information following REC 002.2, based on final results from study B-7855, a 2-year carcinogenicity studies in mice. In this context, the safety margins described in section 5.3 based on PK data provided with the initial Cresemba MAA have been recalculated, corrected and expressed based on exposure (AUC; including free fraction) rather than based on body surface area (only bound fraction)." Request for Supplementary Information adopted on 14.01.2021, 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Cresemba - isavuconazole - EMEA/H/C/002734/II/0031, Orphan Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.2 of SmPC to clarify the instructions on the start of therapy, according to current treatment guidelines for aspergillus and mucor diseases. Additionally, correction of an oversight is carried out in SmPC section 4.8 and PL section 4 of Cresemba 100 mg capsules, to reinstate "odema peripheral" as "uncommon" adverse event, which was unintentionally omitted from the PI at the time of the initial MAA. Re-instatement of text about the potential interaction between isavuconazole and protease	

inhibitors other than indinavir and lopinavir/ritonavir, wrongly deleted from the interactions table in SmPC section 4.5 and PL section 2 as part of a previous procedure, is also carried out." Request for Supplementary Information adopted on 15.10.2020.	
DaTSCAN - ioflupane (123I) - EMEA/H/C/000266/II/0059 GE Healthcare B.V., Rapporteur: Alexandre Moreau, "C.I.4, Update of sections 4.2 and 5.1 of the SmPC in order to describe the possibility of quantitative reading in line with current scientific knowledge." Request for Supplementary Information adopted on 15.10.2020, 16.07.2020.	
Deltyba - delamanid - EMEA/H/C/002552/II/0045, Orphan Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, "Submission of the revised final study report from the Hollow Fiber System - Tuberculosis (HFS-TB) study listed as a Specific Obligation in the Annex II of the Product Information. This is a PK/PD study carried out using the HFS-TB model and designed to obtain the pharmacodynamic target (PDT) of delamanid in the HFS-TB, using Mycobacterium tuberculosis (Mtb) both under log-phase growth conditions and under low pH conditions (pH 5.8). The Annex II is updated accordingly. This submission addresses the post-authorisation measure SOB 009." Request for Supplementary Information adopted on 17.09.2020.	
Dupixent - dupilumab - EMEA/H/C/004390/II/0039 sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, "To update section 4.8 of the SmPC to replace tables of adverse drug reactions per indication with a consolidated table of adverse drug reactions across all approved indications as agreed in the latest PSUR (EMEA/H/C/PSUSA/00010645/202003). The Package Leaflets are updated accordingly."	
ELOCTA - efmoroctocog alfa - EMEA/H/C/003964/II/0039 Swedish Orphan Biovitrum AB (publ), Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.8 and 5.1 of the SmPC to include the	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

results of study 997HA306 in previously untreated patients which have previously been assessed as an Article 46 paediatric submission and renewal (EMEA/H/C/003964/R/0036). Additionally, minor changes are included in the Package Leaflet." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 12.11.2020, 10.09.2020.	
Enbrel - etanercept - EMEA/H/C/000262/II/0238 Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC to add headache to the list of adverse drug reactions with a frequency very common; the package leaflet is updated accordingly. In addition, the MAH took the opportunity to remove text for inflammatory bowel disease and uveitis specific to the paediatric population from section 4.4 and 4.8 of the SmPC and the package leaflet for consistency as requested by PRAC in the latest PSUSA (PSUSA/00010795/202002)." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Epivir - lamivudine - EMEA/H/C/000107/II/0114 ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, "Update of section 5.2 of the SmPC to add new information about the biotransformation of lamivudine. Furthermore, the MAH took the opportunity to introduce an excipient update in line with the SmPC guideline, a syringe and adapter instruction update in the Package Leaflet and a revision of Annex II in line with the QRD template. Moreover, minor editorial updates have been introduced throughout the Product Information." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0007/G Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, "C.I.4: To update section 5.1 of the SmPC with the description and final results from study V920-018; this is a phase 3 open-label trial conducted in Guinea to evaluate the safety and immunogenicity of Ervebo in vaccinated frontline workers 18 years of age	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

and older that was implemented as Part B of the Phase 3 ring vaccination study V920-010. With this submission, REC 20 is fulfilled. C.I.4: To update section 5.1 of the SmPC based on the result of the final study reports on the Correlate of Protection. With this submission, REC 16 is fulfilled. C.I.4: To update section 5.1 of the SmPC, based on results from the integrated summary of immunogenicity (ISI). With this submission, RECs 15 and 22 are fulfilled. C.I.13: Submission of Non-Human Primates (NHP) Correlate of Protection analysis report (non-clinical report). Analysis is based upon previous submitted NHP studies which are already part of the dossier. The MAH takes the opportunity to implement changes in the Package Leaflet following the assessment of the User Acceptance Test, procedure EMEA/H/C/004554/REC/011. With the implementation of these changes to the PL, the MAH fulfils REC011. In addition, minor editorial changes have been included in the SmPC and patient leaflet." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 15.10.2020.	
Eylea - aflibercept - EMEA/H/C/002392/II/0064 Bayer AG, Rapporteur: Alexandre Moreau, "C.1.4 to update section 5.1 of the SmPC based on the ALTAIR Study with additional long-term efficacy information on patients with wet AMD." Request for Supplementary Information adopted on 08.10.2020.	
Eylea - aflibercept - EMEA/H/C/002392/II/0065 Bayer AG, Rapporteur: Alexandre Moreau, "C.I.4, Update of section 4.2 to modify the posology in wet AMD and of 5.1 to reflect the underlying data." Request for Supplementary Information adopted on 15.10.2020.	
Eylea - aflibercept - EMEA/H/C/002392/II/0067 Bayer AG, Rapporteur: Alexandre Moreau, "C.I.4 - change in the expression of Qualitative and quantitative composition." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 14.01.2021.	
Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0119 Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Submission of the final report following CHMP conclusions on the related post-authorisation measure (MEA 57.12) from the Fabry registry, a global, observational and voluntary program designed to collect uniform and meaningful clinical data related to the onset, progression, and treated course of patients with Fabry disease. This is a long-term effectiveness study to enhance the understanding of long-term severe events and clinical continuous outcomes of Fabrazyme among 5 subgroups identified by modified Arends criteria, estimate the disease progression after Fabrazyme treatment among Classic male patients with sustained anti-agalsidase beta immunoglobulin G (IgG) antibodies (ADA); and compare the long-term effectiveness of Fabrazyme between Classic patients with lower-dose regimen and those with standard-dose regimen."	
Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0003 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, "Update of section 5.1 of the SmPC in order to introduce effectiveness information of Fluad (trivalent formulation) in the product information of Fluad Tetra based on the results from three retrospective observational studies "CORE 17-18 and 18-19", "HEOR 17-18" and "HEOR 18-19") and a randomised clinical trial "LTCF 16-17"." Request for Supplementary Information adopted on 15.10.2020.	
PRAC Led **Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0008** Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "C.I.11.b: Submission of an updated RMP version 1.9 in order to provide a consolidated RMP for adjuvanted trivalent influenza vaccine (aTIV) and adjuvanted quadrivalent influenza	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

vaccine (aQIV), including an alignment of safety concerns for aTIV and aQIV." Opinion adopted on 14.01.2021.	
Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0040 MSD Vaccins, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in relation to the post-marketing safety experience information, currently based on the post-marketing safety experience for the quadrivalent HPV vaccine, based on 4 years of post-marketing experience of the 9vHPV vaccine. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the wording regarding sodium according to the Guideline on quality aspects included in the product information for vaccines for human use EMA/CHMP/BWP/133540/2017 and to implement an editorial change in sections 5.1 and 9 of the SmPC, and the package leaflet." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 06.11.2020, 10.09.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Imbruvica - ibrutinib - EMEA/H/C/003791/II/0064, Orphan Janssen-Cilag International NV, Rapporteur: Filip Josephson, "Update of the SmPC section 5.1 to include PFS2 and data from the final analysis with long-term follow-up relevant to the Waldenström's macroglobulinaemia (WM) indication and section 4.8, to include the long-term safety cumulative data - following the submission of the addendum to the final clinical study report from study PCYC-1127-CA. In addition, an amendment to section 4.4 of the SmPC to add adequate language regarding excipients with known effect and an amendment to Table 1 of the SmPC to include a footnote by cardiac failure to reflect inclusion of events with fatal outcomes were implemented. The Package Leaflet was revised accordingly."	
Invokana - canagliflozin - EMEA/H/C/002649/II/0055 Janssen-Cilag International NV, Rapporteur: Martina Weise, "Update to sections 4.2 and 5.1 of the INVOKANA SmPC to amend posology	

information concerning the treatment of patients with eGFR between ≥30 and <45 mL/min/1.73 m2, whether or not albuminuria is present; the update is based on further analysis of previously submitted CANVAS data (studies DIA3008 and DIA4003). The Applicant has also taken the opportunity to make minor editorial changes to section 4.5."	
Iressa - gefitinib - EMEA/H/C/001016/II/0034 AstraZeneca AB, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to add Palmar-plantar erythrodysaesthesia syndrome to the list of adverse drug reactions (ADRs) with frequency uncommon; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Jevtana - cabazitaxel - EMEA/H/C/002018/II/0043/G sanofi-aventis groupe, Rapporteur: Alexandre Moreau, "Update of sections 4.8 and 5.1 of the SmPC with new clinical data from CARD study - a randomized, multicenter, Phase 4 study comparing cabazitaxel at 25 mg/m2 every 3 weeks in combination with prednisone versus alternate AR-targeted agent (abiraterone or enzalutamide) for the treatment of mCRPC patients previously treated with docetaxel and who failed a prior AR-targeted agent. Section 4.4 of the SmPC is also updated in accordance with the updated annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) regarding ethanol used as an excipient. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 15.10.2020.	
Kisplyx - lenvatinib - EMEA/H/C/004224/II/0039/G Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "C.I.13. Submission of a nonclinical (primary pharmacodynamics) study report-M14014 on the Antiproliferative Activities of Lenvatinib Mesilate and Sorafenib Tosylate in VEGF-Stimulated Growth of HUVECs. C.I.13. Submission of a nonclinical (primary	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

pharmacodynamics) study report-W-20140845 on the Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in bFGF-Induced Matrigel Plug Assay in Athymic Mice." Opinion adopted on 14.01.2021.	
Lorviqua - lorlatinib - EMEA/H/C/004646/II/0009/G Pfizer Europe MA EEIG, Rapporteur: Sinan B. Sarac, "Update of sections 4.2 and 5.2 of the SmPC in order to change the posology recommendations in patients with severe renal impairment based on the results from Study B7461010 (a phase 1, single dose open-label study to evaluate the pharmacokinetics of lorlatinib in subjects with impaired renal function). The package leaflet has been updated accordingly. Update of sections 4.4 and 4.5 of the SmPC in order to include information regarding drug-drug interaction with moderate CYP3A4/5 inducers based on study B7461026 (Phase 1, open-label, fixed sequence, 2-period study to investigate the effect of multiple doses of modafinil on the pharmacokinetics of single dose lorlatinib in healthy participants). The MAH took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 10.12.2020.	
Lyumjev - insulin lispro - EMEA/H/C/005037/II/0005 Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-Ikola, "Update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study I8B-MC-ITSA (submitted in accordance with Article 46 of regulation (EC) No 1901/2006). This study was conducted to evaluate the pharmacokinetics and glucodynamics of Lyumjev compared to Humalog in children, adolescents, and adults with Type 1 Diabetes Mellitus." Request for Supplementary Information adopted on 10.12.2020, 15.10.2020.	
Mavenclad - cladribine - EMEA/H/C/004230/II/0016 Merck Europe B.V., Rapporteur: Kirstine Moll Harboe, "C.I.4 Update of section 4.8 of the SmPC in order to add hypersensitivity to the list	Request for supplementary information adopted with a specific timetable.

of adverse drug reactions (ADRs) with frequency "common" based on a review of cumulative clinical and post-marketing data. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 14.01.2021.	
Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/II/0037 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, "Submission of the final clinical study report from study B16-439 (Phase 3b, a Multi-Center, Randomized, Open-Label, Pragmatic Study of Glecaprevir/Pibrentasvir (G/P) +/- Ribavirin for GT1 Subjects with Chronic Hepatitis C Previously Treated with an NS5A Inhibitor + Sofosbuvir Therapy). As part of the assessment, it has been requested by the CHMP to update the SmPC with resistance data from study B16-439; section 5.1 has been updated accordingly. In addition, a minor update was included to SmPC section 4.4, to include reference to study B16-439." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 19.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Mekinist - trametinib - EMEA/H/C/002643/II/0041 Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.5, 4.6 and 5.2 of the SmPC in order to add drug-drug interaction information with hormonal contraceptives and to updated relevant part of the SmPC regarding this interaction; the Package Leaflet is updated accordingly. Furthermore, the MAH took the occasion to include the information regarding the sodium content in the products in line with relevant guidelines and to bring the PI in line with the QRD template version 10.1. In addition, the MAH took the opportunity to introduce some editorial changes in the PI and to update the list of local representatives for The Netherlands in the Package Leaflet." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 03.12.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nilemdo - bempedoic acid -	Request for supplementary information adopted

EMEA/H/C/004958/II/0007 Daiichi Sankyo Europe GmbH, Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final report from clinical study 1002-050 listed as a category 3 study in the RMP (MEA). This is a multicenter open-label extension (OLE) study to assess the long-term safety and efficacy of bempedoic acid 180 mg. Study 1002-050 was a roll-over extension study of a long-term (52 weeks), randomized, double-blind, controlled study (Study 1002-040, referred to as the parent study) of bempedoic acid 180 mg once daily versus placebo with a 2:1 randomization." Request for Supplementary Information adopted on 14.01.2021.	with a specific timetable.
NINLARO - ixazomib - EMEA/H/C/003844/II/0025, Orphan Takeda Pharma A/S, Rapporteur: Armando Genazzani, "Update of the SmPC section 4.9 with additional information on Ninlaro overdose. The Package leaflet is updated accordingly." Request for Supplementary Information adopted on 26.11.2020.	
Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0007 Daiichi Sankyo Europe GmbH, Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final report from clinical study 1002-050 listed as a category 3 study in the RMP (MEA). This is a multicenter open-label extension (OLE) study to assess the long-term safety and efficacy of bempedoic acid 180 mg. Study 1002-050 was a roll-over extension study of a long-term (52 weeks), randomized, double-blind, controlled study (Study 1002-040, referred to as the parent study) of bempedoic acid 180 mg once daily versus placebo with a 2:1 randomization." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0023 Roche Registration GmbH, Rapporteur: Kirstine Moll Harboe, "To update SmPC (section 5.1) with the newly available post-hoc analysis results related to the time-to-wheelchair data performed on clinical study WA25046 (ORATORIO) in the PPMS population."	

Opsumit - macitentan - EMEA/H/C/002697/II/0039, Orphan Janssen-Cilag International N.V., Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.4, 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information of macitentan with moderate dual inhibitors of CYP3A4 and CYP2C9 based on results from a non-clnical study and a physiologically based pharmacokinetic study in healthy subjects and CYP2C9 poor metabolizers; the Package Leaflet is updated accordingly. A direct healthcare professional communication (DHPC) for this new safety information is being proposed. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Orgalutran - ganirelix - EMEA/H/C/000274/II/0046 Merck Sharp & Dohme B.V., Rapporteur: Outi Mäki-Ikola, "Update of section 4.2 of the SmPC in order to include information on handling air bubbles in the pre-filled syringes. The MAH aligned the Package Leaflet accordingly and took the opportunity to update the list of local representatives and to implement minor editorial changes in the PI." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Perjeta - pertuzumab - EMEA/H/C/002547/II/0055 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Submission of the final report from study BO25114 (JACOB). This is a double-blind, placebo-controlled, randomized, multicenter phase III study evaluating the efficacy and safety of pertuzumab in combination with trastuzumab and chemotherapy in patients with HER2-positive metastatic gastroesophageal junction and gastric cancer." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Pravafenix - fenofibrate / pravastatin sodium - EMEA/H/C/001243/II/0030 Laboratoires SMB s.a., Rapporteur: Jean-Michel Race, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information with glitazones resulting in HDL cholesterol decrease, as already mentioned in the Product Information of other products containing fenofibrate 160 mg; update of section 2 and 4.4	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

of the SmPC to correct the warning on lactose and to implement the wording on sodium, in line with the latest revision of the Excipients guideline. The Package Leaflet and the Labelling are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.2." Opinion adopted on 14.01.2021.	
Qutenza - capsaicin - EMEA/H/C/000909/II/0051/G Grunenthal GmbH, Rapporteur: Bruno Sepodes, "Update of sections 4.2 and 4.4 to delete the explicit reference to pre-treatments used in clinical trials and to opioids. Update of section 4.4 of the SmPC to include more detail on unintended exposure to capsaicin." Request for Supplementary Information adopted on 03.12.2020.	
Rekovelle - follitropin delta - EMEA/H/C/003994/II/0023 Ferring Pharmaceuticals A/S, Rapporteur: Jean-Michel Race, "Update of section 5.1 of the SmPC in order to add information on dose equivalence factor to follitropin alfa based on clinical data from literature. The MAH took the opportunity to amend section 4.4. of the SmPC with traceability information and to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 14.01.2021, 15.10.2020.	Request for supplementary information adopted with a specific timetable.
Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0036 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "Submission of the final report from study Zoster-056, in order to fulfil the post-authorisation measure MEA/FSR 006. This is a cross-vaccination study in subjects who previously received placebo in studies Zoster-006 and Zoster-022." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 01.10.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Slenyto - melatonin - EMEA/H/C/004425/II/0017 RAD Neurim Pharmaceuticals EEC SARL, Rapporteur: Kristina Dunder, "The update of the	Request for supplementary information adopted with a specific timetable.

product information to reflect information from children treated with Circadin during the French RTU program and the known safety profile of Circadin authorised for adults." Request for Supplementary Information adopted on 14.01.2021, 10.09.2020.	
Spravato - esketamine - EMEA/H/C/004535/II/0004 Janssen-Cilag International N.V., Rapporteur: Martina Weise, "to update the Spravato Product Information at section 4.2 to replace the current dosing recommendation in patients with Japanese ancestry with a statement that efficacy of Spravato in Japanese patients has not been established to date. This dosing recommendation is supported by the completed Phase 2 study 54135419TRD2005" Request for Supplementary Information adopted on 12.11.2020.	
Stivarga - regorafenib - EMEA/H/C/002573/II/0031 Bayer AG, Rapporteur: Paula Boudewina van Hennik, "Submission of final study report for Study 15982, a randomized, double blind, placebo-controlled, multicenter Phase 3 study that investigated regorafenib in subjects with hepatocellular carcinoma (HCC) after progression on sorafenib treatment." Request for Supplementary Information adopted on 26.11.2020.	
Taltz - ixekizumab - EMEA/H/C/003943/II/0038/G Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder, "Clinical studies in adult plaque psoriasis: Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long-term data in the treatment of psoriasis: RHAZ, RHBA, RHBC (3 studies of the "UNCOVER" series) were the pivotal registration studies, with response data up to 60 weeks already included in the SmPC. The current update relates to the extension data available, covering a total of 5 years. Section 5.1 of the SmPC has also been updated with information from study RHCR (known as "IXORA-R") which is a 24-week head-to-head comparison of Taltz vs guselkumab. Clinical studies in adult psoriatic arthritis: Type II- C.I.4 -Update of section 5.1 of the	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

SmPC regarding long-term data in the treatment of psoriatic arthritis: RHAP and RHBE (also known as SPIRIT-P1 and P2) were pivotal registration studies, with response data at 24 weeks and up to 52 weeks (SPIRIT-P1) already included in the SmPC. The current update relates to extension data available covering a total of 3 years. Section 5.1 of the SmPC has also been updated with longer-term data from study RHCF ("SPIRIT-H2H" Taltz vs adalimumab). Response data of up to 24 weeks are already in the SmPC and the addition of 52 week data are being proposed." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 10.12.2020, 15.10.2020.	
Taltz - ixekizumab - EMEA/H/C/003943/II/0040 Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC with long-term efficacy and safety data in axial spondyloarthritis from study RHBY - A multicenter, long-term extension study of 104 weeks, including a double-blind, placebo-controlled 40-week randomized withdrawal–retreatment period, to evaluate the maintenance of treatment effect of ixekizumab in patients with axial spondyloarthritis."	
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0030 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC to reflect the outcome of anti-drug antibody (ADA) analyses conducted across studies POPLAR, OAK, IMpower 150, IMpower 130, IMPower 131, IMpower 132, IMvigor 211, IMmotion 151, IMpower 133 and IMpassion 130, further to the CHMP recommendation." Request for Supplementary Information adopted on 14.01.2021, 08.10.2020, 23.04.2020, 05.12.2019.	Request for supplementary information adopted with a specific timetable.
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0037 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to amend the information regarding immunogenicity further to the assessment of the effect of atezolizumab neutralising	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

antibodies on the pharmacokinetics and efficacy endpoints including OS, PFS and ORR on the NSCLC studies POPLAR, OAK, IMpower 150, IMpower 130, IMPower 131 and IMpower 132 as well as on studies IMvigor 211 (UC), IMmotion 151 (RCC), IMpower 133 (SCLC) and IMpassion 130 (TNBC), as recommended by the CHMP." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 03.09.2020, 12.03.2020.	
Thalidomide Celgene - thalidomide - EMEA/H/C/000823/II/0066 Celgene Europe BV, Rapporteur: Alexandre Moreau, "Update of section 4.8 to include PML. This change is being introduced following the approval of version 11 of the Company Core Data Sheet (CCDS) for thalidomide. The PIL is updated accordingly." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0048, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC to include information on 1 additional patient with IgG anti-velaglucerase antibodies with neutralizing activity reported during extension study HGT-GCB-044, and to include vomiting as an infusion-related reaction that has been reported in post-marketing experience. Further, the MAH is updating the instructions in sections 4.2 and 6.6 of the SmPC to state that a 0.2 µm filter and a 0.22 µm filter are both considered acceptable when administering the product. In addition, the MAH took the opportunity to implement some minor editorial changes in SmPC section 5.1 and a clarification that paediatric patients included in the studies were 4 years of age and older. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 15.10.2020.	
Wakix - pitolisant - EMEA/H/C/002616/II/0023/G, Orphan Bioprojet Pharma, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Kirsti Villikka, "Update of the product information based on new clinical data from the open-label, long-term treatment of EDS (with or without cataplexy) in	Request for supplementary information adopted with a specific timetable.

narcolepsy P09-10 HARMONY III study, and the randomised, double-blind, placebo-controlled, drug abuse potential study (P16-02). The proposed update also includes results of a post-approval network meta-analysis which compares efficacy and safety of multiple treatments, multi-arm studies, and multi-criteria treatment decisions." Request for Supplementary Information adopted on 14.01.2021, 03.09.2020.	
Xydalba - dalbavancin - EMEA/H/C/002840/II/0037 Allergan Pharmaceuticals International Limited, Rapporteur: Filip Josephson, "Submission of the final report from the microbial surveillance study 14-DUR-01, listed as a category 3 study in the RMP. This is a microbial surveillance study of dalbavancin activity tested against clinical isolates collected in Europe and United States. This submission addresses the post-authorisation measure MEA 002.3." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1886/G **Aprovel-EMEA/H/C/000141/WS1886/0181/G** **CoAprovel-EMEA/H/C/000222/WS1886/0199/G** **Karvea-EMEA/H/C/000142/WS1886/0183/G** **Karvezide-EMEA/H/C/000221/WS1886/0199/G** sanofi-aventis groupe, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Group of variations consisting of: C.I.4 - Update of sections 4.4 and 4.8 of the SmPC to add information on hypoglycaemia based on a review of available data including the MAH pharmacovigilance data base and a literature review. The Package leaflet is updated accordingly. C.I.4 - Update of 4.4 and 4.5 of the SmPC to add information on a drug -drug interaction with irbesartan and repaglinide based on a review of the available data including the MAH database and a literature review. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to implement the updated annex to the European Commission guideline on Excipients in the labelling and package leaflet of medicinal	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

products for human use' to update the excipient sodium. The MAH also took the opportunity to update the list of local representatives in the PL." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 08.10.2020.	
WS1891/G **CONTROLOC Control-EMEA/H/C/001097/WS1891/0036/G** **PANTOLOC Control-EMEA/H/C/001100/WS1891/0041/G** **PANTOZOL Control-EMEA/H/C/001013/WS1891/0038/G** **SOMAC Control-EMEA/H/C/001098/WS1891/0037/G** Takeda GmbH, Lead Rapporteur: Simona Stankeviciute, "1. To update section 4.8 of the SmPC adding Hypokalaemia to the list of adverse drug reactions of Takeda's Pantoprazole containing drugs including a footnote in 4.8 that hypokalaemia may be related to the occurrence of hypomagnesaemia based on a review of the global safety database for cases containing the PT "hypocalcaemia" in patients who were treated with Takeda PPIs (Dexlansoprazole, Lansoprazole and Pantoprazole). The existing warning regarding Hypomagnesaemia in section 4.4. is proposed to be adapted accordingly. Adding also that Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia and that hypomagnesaemia associated hypocalcaemia and/or hypokalaemia improved after magnesium replacement and discontinuation of the PPI. The Package Leaflet is updated accordingly. 2. To update section 4.8 of the SmPC in order to add DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) with the frequency "unknown" based on a comprehensive review of the global safety database for all cases containing the PT "Drug reaction with eosinophilia and systemic symptoms" on all PPIs that are currently marketed by Takeda (i.e. lansoprazole, pantoprazole sodium, pantoprazole magnesium and dexlansoprazole). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the last QRD template (version 10.1), to update the list of local	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

representatives and to implement editorial corrections to the PI. The requested grouped work-sharing procedure proposed amendments to the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 29.10.2020.	
WS1917 **Kivexa-EMEA/H/C/000581/WS1917/0087** **Triumeq-EMEA/H/C/002754/WS1917/0085** **Trizivir-EMEA/H/C/000338/WS1917/0119** **Ziagen-EMEA/H/C/000252/WS1917/0114** ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, "Update of sections 4.4 of the SmPC (for Ziagen, Kivexa, Trizivir and Triumeq) and 5.2 (for Triumeq only) to add new information about the drug-drug interactions between abacavir and riociguat. The Package Leaflet is updated accordingly. Furthermore, the MAH took the opportunity to introduce an excipient update for Ziagen, Kivexa and Trizivir in line with the SmPC guideline, a syringe instruction update in the Package Leaflet of Ziagen and a revised statetment in section 6.6 of the SmPC for Triumeq in line with the QRD template. Moreover, minor editorial updates have been introduced throughout the Product Information of all four products." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 19.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1963 **Leganto-EMEA/H/C/002380/WS1963/0033** **Neupro-EMEA/H/C/000626/WS1963/0087** UCB Pharma S.A., Lead Rapporteur: Bruno Sepodes, "To update section 4.4 of the SmPC to add a warning following the update of the Company Core Data Sheet (CCDS) for rotigotine. The CCDS update consists in the addition of 2 warnings related to dopamine dysregulation syndrome and dopamine agonist withdrawal syndrome; Section 2 of the Package Leaflet is updated accordingly. Additionally, the MAH has taken the opportunity to make some editorial updates in the SmPC (section 5.1) and PL."	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.01.2021.	
WS1976 **Kisplyx-EMEA/H/C/004224/WS1976/0040** **Lenvima-EMEA/H/C/003727/WS1976/0039** Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn, "C.I.13-Submission of the final nonclinical (pharmacokinetic) study report: XT205008 on the Inhibitory potential of uridine 5´-diphosphoglucuronosyltransferase UGT-2B17 in human liver microsomes." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.3. CHMP-PRAC assessed procedures

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0017 Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.8 and 5.1 of the SmPC to provide results from the further analysis of the continuation study 261302 and the pharmacokinetics-guided dosing study 261303. The MAH took the opportunity to update the revise the "sodium statement" in section 4.4 of the SmPC per the EU Excipient Guidelines. The Package Leaflet has been updated accordingly. The RMP version 2.0 has also been submitted" Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Bronchitol - mannitol - EMEA/H/C/001252/II/0042, Orphan Pharmaxis Europe Limited, PRAC Rapporteur: Adrien Inoubli, "Submission of an updated RMP based on the new RMP template (GVP module V, revision 2). In addition, the UK CF Registry study (cat 2, PASS) has been removed from the RMP following its completion; and clinical trial as well as post-marketing exposure and safety information have been updated to reflect the results of the DPM-CF-303 study (previously assessed in EMEA/H/C/001252/II/0034) and the information presented in the latest PSUR #9 (PSUSA/ 0009226/201904)." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 29.10.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Erleada - apalutamide - EMEA/H/C/004452/II/0008	Request for supplementary information adopted with a specific timetable.

Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Tiphaine Vaillant, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study ARN-509-003 (SPARTAN) listed as a PAES in Annex II; this is a multicenter, randomised, double-blind, placebo-controlled, phase III study of ARN-509 in men with non-metastatic (M0) castration-resistant prostate cancer; the package leaflet and Annex II are updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet." Request for Supplementary Information adopted on 14.01.2021, 01.10.2020.	
Erleada - apalutamide - EMEA/H/C/004452/II/0009 Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Tiphaine Vaillant, "Update of section 5.3 of the SmPC in order to include non-clinical information based on final results from a 26-week carcinogenicity study (TOX13540) listed as a category 3 study in the RMP. The RMP version 3.2 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
EXJADE - deferasirox - EMEA/H/C/000670/II/0075 Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "The PI has been updated to remove discrepancies between SmPC and PL in sections `Pregnancy and breast-feeding' and section `Other medicines and EXJADE'. Furthermore, the Exjade SmPC and PL have been updated according to the Guidelines on excipients in the labelling and package leaflet of medicinal products for human use, Rev. 2. The MAH took also the opportunity to align the PI with the latest QRD template v. 10.1 and update the details of local representatives in EE, LV and NL. The Annex IID has been updated to reflect the	

new milestone for study CICL670E2422. In addition, the EU RMP version 18.0 for Exjade has been revised to introduce following changes: · Removal of the important identified risk, "Severe cutaneous adverse reactions (including Stevens-Johnson syndrome, Toxic epidermal necrolysis and Drug reaction with eosinophilia and systemic symptoms)" · Change to the milestone for study CICL670E2422 (Category 1) and change to RMP commitment deliverable and milestone for Study CICL670F2202 (Category 3) · Removal of the study CICL670F2429 (Category 1) due to fulfilment of the corresponding Post-Authorisation Measure · Removal of the expedited reporting requirement for the serious Adverse Drug Reactions (ADRs), 'Increase in hepatic enzymes >10 x upper limit of normal (ULN)', 'Serious rise in creatinine', 'results of renal biopsies', 'cataracts', 'hearing loss', gallstones' as agreed during PRAC PSUR Assessment (Procedure no.: EMEA/H/C/PSUSA/00000939/201910)."	
Isentress - raltegravir - EMEA/H/C/000860/II/0093 Merck Sharp & Dohme B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "Update section 4.6 of the SmPC in order to update safety information following pregnancy outcome data for raltegravir 400 mg film-coated tablet from prospective reports of pregnancy data with known outcome and time of raltegravir exposure. The updated RMP version 15.1 has also been submitted. In addition, the MAH took the opportunity to correct an inconsistency in the text describing the possibility to divide the scored 100 mg chewable tablet by harmonising the text of the footer of Tables 1 and 2 of the chewable tablets' SmPC. This was already identified in the procedure EMEA/H/C/000860/IB/0087 and is in line with the assessment done in the extension application for the chewable tablets EMEA/H/C/000860/X/0024/G. Finally, the contact details of Germany have been updated in the List of local Representatives and the PI is being brought in line with the latest QRD template (version 10.1)"	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 14.01.2021.	
Jakavi - ruxolitinib - EMEA/H/C/002464/II/0050 Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, "Update of sections 4.2 and 5.1 of the SmPC in order to update the posology and the method of administration as well as to include the A2201/EXPAND study CINC424A2201 (referred to as A2201 or "EXPAND" study). The changes are based on final results of a Catergory 3 clinical study, phase Ib study to fulfill an RMP post-approval commitment. This is a dose-finding study intended to establish the maximum safe starting dose (MSSD) of ruxolitinib tablets administered orally to patients with MF in the previous unstudied population of patients who had baseline platelet counts ≥50×109/L and <100×109/L. The Package Leaflet is updated accordingly. The RMP version 12 has also been submitted based on the results of study A2201 (category 3, additional pharmacovigilance activity), the review of safety concerns in compliance with the Good Pharmacovigilance Practices Module V, Revision 2, as well as recent PRAC outcome on PSUR (Procedure no.: EMEA/H/C/PSUSA/00010015/202002, CHMP Opinion dated 15-Oct-2020)."	
Perjeta - pertuzumab - EMEA/H/C/002547/II/0054 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Submission of the final report from study MO28047 (PERUSE) listed as an obligation in the Annex II of the Product Information. This is a multicenter, open-label, single-arm study of pertuzumab in combination with trastuzumab and a taxane in first-line treatment of patients with HER2- positive advanced (metastatic or locally recurrent) breast cancer. The RMP (version 13.0) is proposed to be updated accordingly." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Pyramax - pyronaridine / artesunate - EMEA/H/W/002319/II/0023/G Shin Poong Pharmaceutical Co., Ltd.,	Request for supplementary information adopted with a specific timetable.

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Adrien Inoubli, "Grouping of variations providing the final clinical study reports (CSR) of two completed studies: - Study SP-C-021-15: A Phase IIIb/IV cohort event monitoring study conducted in Central Africa to evaluate the safety in patients after the local registration of Pyramax (CANTAM study). This study is a Category 3 Required Additional Pharmacovigilance Activity described in the RMP (MEA 013). - SP-C-026-18: A Randomized Open-Label Exploratory Study to Determine the Efficacy of Different Treatment Regimens of Pyramax (Pyronaridine-Artesunate) In Asymptomatic Carriers Of Plasmodium Falciparum Monoinfections. This non-imposed study was conducted in Gambia and Zambia and compared asymptomatic subjects with parasitaemia dosed according to the approved label of 3-day dosing with 2-day and 1-day dosing. There have been no new safety findings from the study but the RMP has been updated to reflect its details. As a result of the additional clinical data, corresponding changes to the Product Information (SmPC and PL) are proposed with the Grouping. RMP version 17 has also been submitted, updated to reflect the results of both above-mentioned CSRs, and converted to the new RMP integrated template format (Rev 2.0.1)." Request for Supplementary Information adopted on 14.01.2021.	
Qtern - saxagliptin / dapagliflozin - EMEA/H/C/004057/II/0031 AstraZeneca AB, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ilaria Baldelli, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to reflect new data based on final results from study D1693C00001 (DECLARE). This is a multi-centre, randomised, double-blind, placebo-controlled study to evaluate the effect of dapagliflozin on cardiovascular (CV) and renal outcomes in patients with T2DM with or without established CV disease. The labelling and Package Leaflet (PL) are updated accordingly. The Risk Management Plan (RMP) v5.1 has also been updated. The MAH took the opportunity to make additional editorial changes to the PI."	
Rekovelle - follitropin delta -	Positive Opinion adopted by consensus on

EMEA/H/C/003994/II/0022 Ferring Pharmaceuticals A/S, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst, "Update of section 4.2 of the SmPC in order to introduce new anti-Müllerian hormone (AMH) assays to determine the dose of follitropin delta, following an agreed recommendation. In consequence, RMP version 5.0 was submitted and updated in line with GPV Module V rev.2. The MAH took the opportunity to amend section 4.4. of the SmPC with traceability information, to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 29.10.2020.	14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Revolade - eltrombopag - EMEA/H/C/001110/II/0063 Novartis Europharm Limited, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.2, 4.8 and 5.2 of SmPC to clarify dosing recommendations to ensure accurate treatment of patients of 'East-/Southeast-Asian' ancestry and to correct the ADR list based on currently available data, which was previously submitted and reviewed. Update of section 4.4 of the SmPC in line with the 'Excipients in the labelling and package leaflet of medicinal products for human use'. The Package leaflet has been updated accordingly. Editorial changes have also been introduced in the PI. An updated RMP has been submitted to update the final due date i.e. the date for the provision of the primary study report of CETB115E2201 (category 3) in the RMP and removal of important safety concerns, already endorsed by PRAC in the PSUSA procedure (EMEA/H/C/PSUSA/00001205/201809)." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Somavert - pegvisomant - EMEA/H/C/000409/II/0098/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Adrien Inoubli, "Variation to update the Risk Management Plan following assessment of the final results of ACROSTUDY, a multicenter, Post Authorisation Safety Study (PASS) of Somavert therapy in patients with acromegaly (procedure number EMEA/H/C/000409/II/0089), grouped with	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

variation to update of section 4.4 of the SmPC to remove the warning on growth hormone secreting tumours, consequential to the removal of pituitary tumour growth as a potential risk from the RMP. The RMP version 2.0 has been submitted and the MAH took the opportunity to update it as per the revised version of the GVP Module V Risk Management Systems, revision 2. The Package Leaflet is updated accordingly." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 29.10.2020.	
Stelara - ustekinumab - EMEA/H/C/000958/II/0081/G Janssen-Cilag International NV, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.2 of Stelara SmPC solution for injection presentations in order to change posology recommendations for patients with ulcerative colitis, and 5.1 of Stelara SmPC to update efficacy information based on 2-year results from study 3001 listed as a category 3 study in the RMP; this is a Phase 3, randomized, double blind, placebo controlled, parallel-group, multicenter protocol to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis. Update of section 5.1 of the SmPC in order to update efficacy information based on 5-year results from study 3003 listed as a category 3 study in the RMP; this is a Phase 3, randomized, double blind, placebo controlled, parallel-group, multicenter trial to evaluate the safety and efficacy of ustekinumab maintenance therapy in adult patients with moderately to severely active Crohn's disease. The RMP version 18.1 has also been submitted." Request for Supplementary Information adopted on 15.10.2020.	
Tasigna - nilotinib - EMEA/H/C/000798/II/0107 Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Submission of the 5 year data including data on late relapses from the ongoing studies ENESTfreedom (CAMN107I2201): A Phase II, single-arm, open-label, multicenter	Request for supplementary information adopted with a specific timetable.

nilotinib TFR study in patients with BCR-ABL1 positive CML-CP, who had achieved durable minimal residual disease (MRD) status on first-line nilotinib treatment and ENESTop (CAMN107A2408): A Phase II, single-arm, open-label, multicenter study, evaluating TFR in patients with BCR-ABL1-positive CML-CP who achieved a sustained molecular response of MR4.5 on nilotinib treatment after switching from imatinib to nilotinib. Consequently, the RMP version 23 is being updated to remove the additional pharmacovigilance activity 'collection and submission of data on late relapses from the ongoing studies ENESTfreedom (CAMN107I2201) and ENESTop (CAMN107A2408)' and the safety concern 'risk of resistance (in TFR)'." Request for Supplementary Information adopted on 14.01.2021.	
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0069/G Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "C.I.4 type II variation: Update of section 4.8 of the SmPC in order to add rhinorrhoea to the list of adverse drug reactions (ADRs) with frequency unknown based on a systematic review of information from clinical and non-clinical studies, post-marketing data and scientific literature. The Package Leaflet has been updated accordingly. C.I.4 type II variation: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study 109MS303 (ENDORSE) listed as a category 3 study in the RMP. This is a dose-blind, multicenter, extension study to determine the long-term safety and efficacy of two doses of BG00012 monotherapy in subjects with Relapsing-Remitting Multiple Sclerosis. The RMP version 11.1 has also been submitted." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Trumenba - meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0032 Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné, "C.I.4 To update sections 4.8 and 5.1 of	Request for supplementary information adopted with a specific timetable.

the SmPC following the interim data from the primary vaccination phase (stage 1) of study B1971057; this is a Phase 3, randomised, active-controlled, observer-blinded study to assess the immunogenicity, safety, and tolerability of bivalent rLP2086 when administered as a 2-dose regimen and a first-in-human study to describe the immunogenicity, safety, and tolerability of a bivalent rLP2086 containing pentavalent vaccine (MenABCWY) in healthy subjects ≥10 to <26 years of age. The MAH takes the opportunity to implement some editorial changes in section 4.4 of the SmPC and sections 2, 3 and 6 of the Package Leaflet in order to comply with the excipients guideline for Sodium Chloride" Request for Supplementary Information adopted on 14.01.2021.	
Vargatef - nintedanib - EMEA/H/C/002569/II/0035/G Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Agni Kapou, "Update of sections 4.5, 4.6 and 5.2 of the SmPC to reflect the results of study 1199-0340 conducted in female patients with Systemic Sclerosis associated Interstitial Lung disease (SSc-ILD), to investigate a potential interaction between nintedanib and the oral contraceptive Microgynon, a combination of ethynilestradiol and levonorgestrel. Update of sections 4.3 and 4.6 of the SmPC to introduce a new contraindication of pregnancy for Vargatef treatment. This follows the same update for Ofev (nintedanib) introduced in the context of procedure EMEA/H/C/3821/II/0026 and the request from the PRAC in the context of procedure EMEA/H/C/PSUSA/00010318/201910 to consider a similar update for Vargatef. The Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted reflecting the consequential changes to the submission of study 1199-0340, changes submitted further to the agreement on the same changes implemented for Ofev and other changes requested by the PRAC." Request for Supplementary Information adopted on 12.11.2020.	
Vargatef - nintedanib - EMEA/H/C/002569/II/0037 Boehringer Ingelheim International GmbH,	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Agni Kapou, "Submission of the final report from study LUME BioNIS listed as an obligation in the Annex II of the Product Information. This is a non-interventional study in patients eligible for treatment with Vargatef to explore whether genetic or genomic markers (alone or combined with clinical covariates) could be used to predict overall survival. The Annex II and the RMP version 8.0 are updated accordingly." Opinion adopted on 14.01.2021.	recommendation.
Xeljanz - tofacitinib - EMEA/H/C/004214/II/0028 Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan, "Submission of the final report on Biospecimen testing study, listed as a category 3 study in the RMP. This is an exploratory study to assess biomarkers related to VTE events in study A3921133. The RMP version 14.1 has also been submitted." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
Xtandi - enzalutamide - EMEA/H/C/002639/II/0049 Astellas Pharma Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.7, 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information based on final results from study MDV3100-14 (PROSPER) listed as a PAES in the Annex II; this is a phase 3, randomized, double-blind, placebo-controlled, efficacy and safety study of enzalutamide in patients with nonmetastatic castration-resistant prostate cancer; the Package Leaflet and Annex II are 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, make few editorial update and bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 26.11.2020, 03.09.2020.	
WS1965/G **Hexacima-EMEA/H/C/002702/WS1965/0110/G** **Hexaxim (SRD)-EMEA/H/W/002495/WS1965/0115/G**	Request for supplementary information adopted with a specific timetable.

Hexyon-EMEA/H/C/002796/WS1965/0114/G Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus, Lead PRAC Rapporteur: Brigitte Keller-Stanislawski, "C.I.4 (type II): Update of section 5.1 of the SmPC in order to describe the persistence of anti-HBs antibodies in subjects 6 years of age having received a hexavalent vaccine based on the final results from study A3L00052; this is a phase IV, open-label, multi-centre study in children previously vaccinated in Study A3L38a with 3 doses of either Hexacima/Hexyon/Hexaxim (Group 1) or Infanrix Hexa (Group 2). C.I.4 (type II): Update of sections 4.4 and 5.1 of the SmPC in order to reword safety and immunogenicity information regarding individuals with immunodeficiency based on the final results from study A3L44; this is a Phase III, single centre, open-label, two-arm study including HIV-exposed infected and uninfected infants vaccinated with a 3-dose infant primary series (at 6, 10, and 14 weeks of age) and a booster dose (at 15 to 18 months of age) with Hexacima/Hexyon/Hexaxim in Republic of South Africa. The updates to the SmPC were requested following assessment of these data by Article 46, EMEA/H/C/002702/P46/036 (Hexacima), EMEA/H/C/002796/P46/034 (Hexyon) and EMEA/H/W/002495/P46/036 (Hexaxim). C.I.z (type IB): Update of section 4.4 of the SmPC in order to include syncope within the precautions for use. The package leaflet is updated accordingly. In addition, the WSA took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 13.0 has also been submitted." Request for Supplementary Information adopted on 14.01.2021.	

B.5.4. PRAC assessed procedures

PRAC Led **Adasuve - loxapine - EMEA/H/C/002400/II/0032** Ferrer Internacional s.a., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "To submit the final clinical study report (CSR) for study AMDC- 204-401 EU PASS: Post-authorisation Observational Study to	Request for supplementary information adopted with a specific timetable.

Evaluate the Safety of ADASUVE -Staccato loxapine for inhalation- in Agitated Persons in Routine Clinical Care." Request for Supplementary Information adopted on 14.01.2021.	
PRAC Led **Cetrotide - cetrorelix - EMEA/H/C/000233/II/0075** Merck Europe B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of an updated RMP (version 5.2), in order to bring it in line with revision 2 of GVP module V on 'Risk management systems' including consequential removal of a number of important identified risks and important potential risk of congenital anomalies, as well as removal of missing information on infertile premenopausal women; information in the RMP has been revised based on the most recent data and the post-marketing exposure was updated." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Circadin - melatonin - EMEA/H/C/000695/II/0061** RAD Neurim Pharmaceuticals EEC SARL, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Risk Management Plan update to remove the following risks from the list of potential risks: "Drug interaction with levothyroxine" "Panic Attacks", "Potential interaction with warfarin", "Sperm motility decreased/Spermatozoa morphology abnormal" and "Withdrawal"." Request for Supplementary Information adopted on 14.01.2021, 01.10.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Conbriza - bazedoxifene - EMEA/H/C/000913/II/0054** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of Risk Management Plan (RMP) to include updated study milestones and to revise the RMP format in line with latest Good Pharmacovigilance Practices Guidance Module V, revision 2 guidelines." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 14.01.2021.	
PRAC Led **Eylea - aflibercept - EMEA/H/C/002392/II/0068** Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "The submission contains the study report of the PASS study Evaluation of Physician Knowledge of Safety and Safe Use Information for Aflibercept in Europe: A Follow-up Physician survey. The study was requested as a category 3 study. The RMP has been updated accordingly (version 27.1)." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0120** Genzyme Europe BV, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report following CHMP conclusions on the related post-authorisation measure (FU2 57.4) from the MAH Fabry Pregnancy Sub-registry, a multicenter, international, longitudinal, observational study on pregnancy outcomes for any pregnant woman enrolled in the MAH Fabry Registry who also consented to participate in the sub-registry, regardless of whether she was receiving disease therapy (such as ERT with agalsidase beta) and irrespective of the commercial product with which she may have been be treated. This study is listed as a category 3 in the RMP." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Jinarc - tolvaptan - EMEA/H/C/002788/II/0029** Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Armando Genazzani, PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Armando Genazzani, "To update the RMP for Jinarc to version 14.4 to include dehydration and pregnancy prevention programme as requiring additional risk minimisation measures in accordance with Annex II." Request for Supplementary Information adopted on 14.01.2021, 29.10.2020, 11.06.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Mavenclad - cladribine -**	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/004230/II/0015 Merck Europe B.V., Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, "C.I.11.b type II submission of an updated RMP version 1.4 in order to align to the RMP template Rev. 2. In addition, the MAH took the opportunity to include long-term safety data from the completed PREMIERE registry and remove the completed study from the pharmacovigilance plan, update of the status of the post-approval safety studies CLARION and CLEAR and update the RMP with the most recent post-approval safety data from the PBRER." Request for Supplementary Information adopted on 14.01.2021.	
PRAC Led **Ovaleap - follitropin alfa - EMEA/H/C/002608/II/0034** Theramex Ireland Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final study report for SOFIA (Safety of Ovaleap (Follitropin alfa) in Infertile Women Undergoing Superovulation for Assisted Reproductive Technologies, XM17-WH-5005) listed as a category 3 study in the RMP. This is a multi-national, comparative, prospective, non-interventional, observational cohort study. The RMP version 3.3 has also been submitted." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Revatio - sildenafil - EMEA/H/C/000638/II/0091** Upjohn EESV, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 7.0 in order to update the summary of safety concerns in line with GVP module V rev 2 guidelines. Consequently, the educational programme for the risk of hypotension is proposed to be terminated." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Tecentriq - atezolizumab -**	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP

EMEA/H/C/004143/II/0048 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the results of study WO41486 evaluating the effectiveness of the HCP brochure designed to mitigate important immune-related risks in patients receiving atezolizumab in the European Union. As a consequence, the MAH is updating section 4.4 of the SmPC, Annex II.D and the RMP. In addition, the MAH is proposing a delay in the due date for the submission of the CSR for IMvigor210 ." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 01.10.2020.	Members were in agreement with the CHMP recommendation.
PRAC Led **Vimizim - elosulfase alfa - EMEA/H/C/002779/II/0034, Orphan** BioMarin International Limited, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of an updated RMP (version 5) in order to update the safety specifications and the pharmacovigilance plan, to delete the training material and to add healthcare provider educational materials and process indicator to evaluate the distribution of the educational materials. The RMP is also brought in line with revision 2.0.1 of the guidance on the format of the EU RMP template." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0055** Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, PRAC Rapporteur: Maia Uusküla, PRAC-CHMP liaison: Alar Irs, "Update of sections 4.4 and 5.2 of the SmPC in order to include information on the use of ceftaroline in patients with cystic fibrosis, based on a pooled population pharmacokinetic (Pop PK) analysis that included data from cystic fibrosis patients treated with ceftaroline fosamil. This submission fulfils the post-authorisation measure LEG 016.1. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial changes."	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 26.11.2020.	
PRAC Led **WS1810** **Juluca-EMEA/H/C/004427/WS1810/0028** **Tivicay-EMEA/H/C/002753/WS1810/0061** **Triumeq-EMEA/H/C/002754/WS1810/0082** ViiV Healthcare B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final report from study EuroSIDA (Study 201177) listed as a category 3 study in the RMP. This is a prospective observational cohort study to monitor and compare the occurrence of hypersensitivity reaction and hepatotoxicity in patients receiving dolutegravir (with or without abacavir) and other integrase inhibitors (with or without abacavir)." Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 03.09.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1970** **Eucreas-EMEA/H/C/000807/WS1970/0081** **Galvus-EMEA/H/C/000771/WS1970/0067** **Icandra-EMEA/H/C/001050/WS1970/0084** **Jalra-EMEA/H/C/001048/WS1970/0069** **Xiliarx-EMEA/H/C/001051/WS1970/0067** **Zomarist-EMEA/H/C/001049/WS1970/0083** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP (version 15.0) in order to bring it in line with revision 2 of GVP module V on 'Risk management systems' and aligned with the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00003113/201802) adopted in October 2018. Annex II.D of the product information is updated to remove the statement around submission of an RMP update every 3 years." Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led	Positive Opinion adopted by consensus on

WS1975 **Komboglyze-EMEA/H/C/002059/WS1975/0049** **Onglyza-EMEA/H/C/001039/WS1975/0051** AstraZeneca AB, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, "To provide an updated RMP to propose a change to the milestones to 'Q1 2021' of final study report for category 3 study D1680C00016 (MEASURE-HF). Other minor changes have been included and are detailed in the summary of changes to the RMP." Opinion adopted on 14.01.2021.	14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.5. CHMP-CAT assessed procedures

Alofisel - darvadstrocel - EMEA/H/C/004258/II/0021, Orphan, ATMP Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder	
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0030, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, "Update of section 5.1 of the SmPC to include the complete data set (updated overall survival analysis) of study CCTL019B2205J, a Phase II, single arm, multicenter study to determine the efficacy and safety of Kymriah in paediatric subjects with relapsed or refractory B-cell ALL. The clinical results have already been assessed in procedure EMA/H/C/004090/P46/011. In addition, the final ATC code for tisagenlecleucel (L01XX71) has been added as an editorial change."	
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0030, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0031, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-	

Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0033, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0007/G, Orphan, ATMP Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege Request for Supplementary Information adopted on 06.11.2020.	
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0009/G, Orphan, ATMP Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege Request for Supplementary Information adopted on 04.12.2020.	

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

Idacio - adalimumab - EMEA/H/C/004475/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.01.2021. Request for Supplementary Information adopted on 12.11.2020.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1834 **Aerius-EMEA/H/C/000313/WS1834/0094** **Azomyr-EMEA/H/C/000310/WS1834/0098** **Neoclarityn-EMEA/H/C/000314/WS1834/0092** Merck Sharp & Dohme B.V., Duplicate, Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke, "The scope of	

this variation is to update the product information to comply with the revised Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use". To update sections 2, 4.4 and 6.1 (6.1 only for oral solution) of the SmPC to reflect that the guidance on excipients has been changed. Section 2 of the Package Leaflet is updated accordingly. Additionally SmPC, PIL and Labelling were updated to the latest QRD version and some minor corrections of the text introduced also affecting other sections, which do not have impact on the content." Request for Supplementary Information adopted on 10.12.2020.	
WS1940 **Adcirca-EMEA/H/C/001021/WS1940/0033** **Cialis-EMEA/H/C/000436/WS1940/0093** **Tadalafil Lilly-EMEA/H/C/004666/ WS1940/0006** Eli Lilly Nederland B.V., Lead Rapporteur: Maria Concepcion Prieto Yerro, "To include the excipient guidance in the labelling and package leaflet annex. In addition, the QRD template has also been implemented. i.e. the MAH has updated the order of presentation in line with the QRD for Cialis and Tadalafil Lilly. The details of the local representatives in Lithuania, Latvia, Estonia, France and Slovakia have been updated." Request for Supplementary Information adopted on 26.11.2020.	
WS1946 **Copalia-EMEA/H/C/000774/WS1946/0113** **Dafiro-EMEA/H/C/000776/WS1946/0117** **Exforge-EMEA/H/C/000716/WS1946/ 0112** Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1949/G **Mosquirix-EMEA/H/W/002300/WS1949/ 0050/G** **Shingrix-EMEA/H/C/004336/WS1949/ 0038/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.01.2021.	
WS1957/G **Hexacima-EMEA/H/C/002702/WS1957/0111/G** **Hexaxim (SRD)-EMEA/H/W/002495/WS1957/0116/G** **Hexyon-EMEA/H/C/002796/WS1957/0115/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	
WS1966 **Incresync-EMEA/H/C/002178/WS1966/0035** **Vipdomet-EMEA/H/C/002654/WS1966/0030** **Vipidia-EMEA/H/C/002182/WS1966/0025** Takeda Pharma A/S, Lead Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1968 **Anoro Ellipta-EMEA/H/C/002751/WS1968/0033** **Laventair Ellipta-EMEA/H/C/003754/WS1968/0036** **Relvar Ellipta-EMEA/H/C/002673/WS1968/0047** **Revinty Ellipta-EMEA/H/C/002745/WS1968/0045** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1983/G **Delstrigo-EMEA/H/C/004746/WS1983/0021/G** **Pifeltro-EMEA/H/C/004747/WS1983/0015/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Filip Josephson	
WS1985 **Aflunov-EMEA/H/C/002094/WS1985/0067** **Foclivia-EMEA/H/C/001208/WS1985/0063** Seqirus S.r.l, Lead Rapporteur: Armando Genazzani Request for Supplementary Information adopted on 14.01.2021.	Request for supplementary information adopted with a specific timetable.

WS1992/G **Nuwiq-EMEA/H/C/002813/WS1992/0038/G** **Vihuma-EMEA/H/C/004459/WS1992/0020/G** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1999 **Nuwiq-EMEA/H/C/002813/WS1999/0040** **Vihuma-EMEA/H/C/004459/WS1999/0022** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus	
WS2006 **Pregabalin Mylan-EMEA/H/C/004078/WS2006/0016** **Pregabalin Mylan Pharma-EMEA/H/C/003962/WS2006/0014** Mylan S.A.S, Generic, Generic of Lyrica, Lead Rapporteur: Alexandre Moreau, "To update section 4.8 of the SmPC to add respiratory depression with frequency of "not known" following assessment of the same change for the reference product (Lyrica). Sections 2 and 4 of the PL have been updated accordingly. In addition to the updates made to the SmPC and PIL as per the brand leader text, the applicant is taking the opportunity to amend the following details: - Update to the List of local representatives of the Marketing Authorisation Holder for Lithuania. Finally, some further minor editorial changes have been proposed for the product information texts for NO, LT and FI annexes." Opinion adopted on 14.01.2021.	Positive Opinion adopted by consensus on 14.01.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

betaine anhydrous - EMEA/H/C/005637

treatment of homocystinuria
COVID-19 Vaccine (ChAdOx1-S [recombinant]) - EMEA/H/C/005675 active immunisation to prevent COVID-19 caused by SARS CoV 2, in individuals 18 years of age and older
artesunate - EMEA/H/C/005718, Orphan B And O Pharm, Treatment of severe malaria
hepatitis B surface antigen - EMEA/H/C/005466 indicated for the prevention of infection caused by all known subtypes of the hepatitis B virus in adults.
sotorasib - EMEA/H/C/005522 treatment of locally advanced or metastatic non-small cell lung cancer
voxelotor - EMEA/H/C/004869, Orphan Global Blood Therapeutics Netherlan, Indicated for the treatment of haemolytic anaemia in adults and paediatric patients 12 years of age and older with sickle cell disease (SCD).
pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/005477 Immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae. Pneumonia caused by Streptococcus pneumoniae
bevacizumab - EMEA/H/C/005574 Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer. First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer. First line treatment of patients with advanced and/or metastatic renal cell cancer.
amivantamab - EMEA/H/C/005454 for treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy.

sapropterin - EMEA/H/C/005646
treatment of hyperphenylalaninemia (HPA)

teriparatide - EMEA/H/C/005793
treatment of osteoporosis

inebilizumab - EMEA/H/C/005818, Orphan
Viela Bio, indicated for the treatment of adults with neuromyelitis optica spectrum disorders

vildagliptin / metformin hydrochloride - EMEA/H/C/005738
treatment of type 2 diabetes mellitus

diroximel fumarate - EMEA/H/C/005437
treatment of relapsing remitting multiple sclerosis

eptinezumab - EMEA/H/C/005287
Indicated for the prophylaxis of migraine in adults

semaglutide - EMEA/H/C/005422
treatment for weight loss and weight maintenance

linzagolix choline - EMEA/H/C/005442
for the management of heavy menstrual bleeding (HMB) associated with uterine fibroids

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

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/X/0018
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Menno van der Elst, "Extension application to add a new strength of 3000 IU for RURIOCTOCOG ALFA PEGOL powder and solvent for solution for injection, for intravenous use.
Furthermore, the MAH took the opportunity to include editorial changes to update the naming convention from BAX855 to rurioctocog alfa pegol throughout the section and removed the reference to Baxalta as well as update table numbering throughout the documents in module 3. Furthermore, change omitted from the dossier following approval of variations EMEA/H/C/004195/IB/0004/G and EMEA/H/C/004195/IB/0015/G were also included."

Ozempic - semaglutide - EMEA/H/C/004174/X/0021
Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Annika Folin, "Extension application to add a new strength of 2 mg solution for injection."

Paliperidone Janssen-Cilag International - paliperidone - EMEA/H/C/005486/X/0002/G
Janssen-Cilag International N.V., Informed Consent of Xeplion, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Extension application to introduce two new strengths of 700 mg and 1000 mg prolonged-release suspension for injection, grouped with the following variations:
A.2.a - To change the (invented) name of the medicinal product
A.7
6 x C.I.7.b. - To delete the 25 mg, 50 mg, 75 mg, 100 mg and 150 mg/100 mg strengths from the Paliperidone Janssen-Cilag marketing authorisation (EU/1/20/1453/001-006)."

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

abiraterone acetate - EMEA/H/C/005649
Treatment of prostate cancer in adult men
List of Questions adopted on 12.11.2020.

abiraterone acetate - EMEA/H/C/005368
treatment of metastatic castration resistant prostate cancer
List of Questions adopted on 23.07.2020.

tralokinumab - EMEA/H/C/005255
treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy
List of Questions adopted on 17.09.2020.

AUBAGIO - teriflunomide - EMEA/H/C/002514/X/0031/G
sanofi-aventis groupe, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "1-Extension of a marketing authorisation for Aubagio to add the new strength, 7 mg film-coated tablet, for use in paediatric patients from 10 years of age and older with relapsing remitting multiple sclerosis (MS).

2- Type II (C.I.6) - Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS) for Aubagio 14 mg tablet. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance.
The MAH is requesting an extension of the market protection of one additional year in line with the guidance on elements required to support the significant clinical benefit in comparison with existing therapies of a new therapeutic indication in order to benefit from an extended (11-year) marketing protection period.
Version 6.0 of the RMP has also been submitted."
List of Questions adopted on 17.09.2020.
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Buvidal - buprenorphine - EMEA/H/C/004651/X/0008/G
Camurus AB, Rapporteur: Peter Kiely, PRAC Rapporteur: Tiphaine Vaillant, "Line extension to add a new strength of 160 mg for prolonged-release solution for injection pharmaceutical form.
In addition the MAH took the opportunity to align the PI to the latest QRD template and to implement new text regarding the content of ethanol in accordance with the EMA document "Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use" (EMA/CHMP/43486/2018) in the Package Leaflet.
Variations included:
A.4
A.5.b "
List of Questions adopted on 15.10.2020.

roxadustat - EMEA/H/C/004871
treatment of anaemia
List of Questions adopted on 17.09.2020.

risdiplam - EMEA/H/C/005145, Orphan
Roche Registration GmbH, treatment of spinal muscular atrophy (SMA)
List of Questions adopted on 10.11.2020.

Fabrazyme - agalsidase beta - EMEA/H/C/000370/X/0118/G
Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege
List of Questions adopted on 17.09.2020.

Ferriprox - deferiprone - EMEA/H/C/000236/X/0145
Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Extension application to introduce a new pharmaceutical form (gastro-resistant tablets). The RMP (version 14.0) is updated in accordance."
List of Questions adopted on 17.09.2020.

Insulin aspart Sanofi - insulin aspart - EMEA/H/C/005033/X/0003
sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Annika Folin, "Extension application to introduce a new route of administration, intravenous use, for the 10 ml vial presentations only."
List of Questions adopted on 10.12.2020.

insulin human (rDNA) - EMEA/H/C/005331
treatment of patients with diabetes mellitus who require intravenous insulin
List of Questions adopted on 23.07.2020.

istradefylline - EMEA/H/C/005308
indicated as an adjunctive treatment to levodopa-based regimens in patients with Parkinson's disease
List of Questions adopted on 30.04.2020.

selumetinib - EMEA/H/C/005244, Orphan
AstraZeneca AB, treatment of neurofibromatosis type 1 (NF1)
List of Questions adopted on 23.07.2020.

lonafarnib - EMEA/H/C/005271, Orphan
EigerBio Europe Limited, treatment of Hutchinson-Gilford Progeria Syndrome and Progeroid Laminopathies
List of Questions adopted on 23.07.2020.

Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/X/0033/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension application to introduce a new pharmaceutical form (50/20 mg coated granules in sachet),

grouped with a type II extension of indication variation (C.I.6.a) to include the treatment of children from 3 to 12 years of age for the approved Maviret 100 mg/40 mg film-coated tablets; as a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated accordingly. Version 5.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."
List of Questions adopted on 17.09.2020.

Nitisinone MDK - nitisinone - EMEA/H/C/004281/X/0007
MendeliKABS Europe Limited, Generic, Generic of Orfadin, Rapporteur: Alar Irs, PRAC Rapporteur: Amelia Cupelli, "Extension application to add a new strength of 20 mg (hard capsule)."
List of Questions adopted on 17.09.2020.

azacitidine - EMEA/H/C/004761
treatement for acute myeloid leukaemia
List of Questions adopted on 17.09.2020.

tirbanibulin mesilate - EMEA/H/C/005183
topical field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis
List of Questions adopted on 25.06.2020.

Skyrizi - risankizumab - EMEA/H/C/004759/X/0012
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Kiely, PRAC Rapporteur: Liana Gross-Martirosyan, "Extension application to add a new strength of 150 mg for solution for injection in a pre-filled syringe and pre-filled pen."
List of Questions adopted on 10.12.2020.

vericiguat - EMEA/H/C/005319
treatment of symptomatic chronic heart failure
List of Questions adopted on 15.10.2020.

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

Obizur - susoctocog alfa - EMEA/H/C/002792/S/0039
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski

Vyndaqel - tafamidis -
EMEA/H/C/002294/S/0065, Orphan
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Tiphaine Vaillant

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

Erivedge - vismodegib -
EMEA/H/C/002602/R/0050
Roche Registration GmbH, Rapporteur: Kristina Dunder, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Annika Folin

Inhixa - enoxaparin sodium -
EMEA/H/C/004264/R/0076
Techdow Pharma Netherlands B.V., Duplicate, Duplicate of Thorinane (EXP), Rapporteur: Andrea Laslop, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Menno van der Elst

Kisplyx - lenvatinib -
EMEA/H/C/004224/R/0043
Eisai GmbH, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: David Olsen

Mysildecard - sildenafil -
EMEA/H/C/004186/R/0009
Mylan S.A.S, Generic, Generic of Revatio, Rapporteur: Ondřej Slanař, PRAC Rapporteur: Menno van der Elst

Sialanar - glycopyrronium -
EMEA/H/C/003883/R/0018
Proveca Pharma Limited, Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Zane Neikena

Tenofovir disoproxil Zentiva - tenofovir disoproxil - EMEA/H/C/004120/R/0023
Zentiva k.s., Generic, Generic of Viread, Rapporteur: John Joseph Borg, PRAC Rapporteur: Adrien Inoubli

Veklury - remdesivir -
EMEA/H/C/005622/R/0015
Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Eva Jirsová

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

CRYSVITA - burosumab - EMEA/H/C/004275/II/0023, Orphan

Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to include treatment of FGF23-related hypophosphataemia in tumour-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised in patients aged 1 year and over, based on data from two ongoing open-label clinical studies, UX023T-CL201 and KRN23-002, in adults with TIO (144-week data and 88-week data are available, respectively). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated and the Package Leaflet is updated accordingly. An updated RMP version 4.0 has also been submitted. The MAH also applied for one additional year of market protection."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Esbriet - pirfenidone - EMEA/H/C/002154/II/0069, Orphan

Roche Registration GmbH, Rapporteur: Peter Kiely, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, "Extension of indication to include the treatment of unclassifiable interstitial lung disease (UILD) for Esbriet; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.0 of the RMP has also been submitted."

Firmagon - degarelix - EMEA/H/C/000986/II/0039/G

Ferring Pharmaceuticals A/S, Rapporteur: Alexandre Moreau, "Extension of indications to include :

- Extension of indication to include treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy. As a consequence, sections 4.1, 4.2, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.

- Extension of indication to include treatment as neo-adjuvant prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. As a consequence, sections 4.1, 4.2, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance."

Galafold - migalastat - EMEA/H/C/004059/II/0029, Orphan

Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ulla Wändel Liminga, "Extension of indication for Galafold (migalastat) to include long-term treatment of adolescents 12 to < 16 years with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC and sections 1 and 2 of the Package Leaflet are updated accordingly. A revised RMP version 4.0 has also been submitted."

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0099

Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Extension of indication for Keytruda to include in combination with chemotherapy, treatment of locally recurrent unresectable or metastatic triple negative breast cancer in adults whose tumours express PD L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease; as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 31.1 of the RMP has also been submitted."

Noxafil - posaconazole - EMEA/H/C/000610/II/0062

Merck Sharp & Dohme B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "Extension of indication to include primary treatment of invasive aspergillosis in adults and adolescents from 13 years of age for Noxafil gastroresistant tablet and concentrate for solution for infusion as result of conclusion of study P069 (a Phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus

Voriconazole for the Treatment of Invasive Aspergillosis); 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 16.2 of the RMP has also been submitted."

OPDIVO - nivolumab - EMEA/H/C/003985/II/0095
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to include adjuvant treatment of adult patients with resected oesophageal, or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy for OPDIVO (study CA209577) as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22.0 of the RMP has also been submitted."

OPDIVO - nivolumab - EMEA/H/C/003985/II/0096
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to use OPDIVO (nivolumab) in combination with fluoropyrimidine- and platinum-based combination chemotherapy, in first-line treatment of adult patients with advanced or metastatic gastric, gastro-oesophageal junction (GEJ) or oesophageal adenocarcinoma (study CA209649); as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 21.0 of the RMP has also been submitted."

Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0020, ATMP
CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, "Extension of the indication for use in the paediatric population (15 to 18 years)."

Ultomiris - ravulizumab - EMEA/H/C/004954/II/0010
Alexion Europe SAS, Rapporteur: Blanca Garcia-

Ochoa, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Kimmo Jaakkola, "Extension of indication to include treatment of paediatric patients with paroxysmal nocturnal haemoglobinuria (PNH) for Ultomiris; 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. In addition, Annex II is updated to reflect the addition of a PNH Parent guide. Version 2.1 of the RMP has also been submitted, in order to include the new indication."

Zeposia - ozanimod - EMEA/H/C/004835/II/0002/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon, "C.I.6 (Extension of indication)
Extension of indication to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent for Zeposia; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 5.1 of the SmPC and Annex IID 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 (MAH) took the opportunity to implement editorial changes throughout the product information.
C.I.4
Update of sections 4.4 and 4.5 of the SmPC in order to update the current SmPC description about PK interaction with BCRP inhibitors based on the study report from a drug interaction study with cyclosporine l(RPC-1063-CP-001)."

WS1952
Edistride-EMEA/H/C/004161/WS1952/0042
Forxiga-EMEA/H/C/002322/WS1952/0060

AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, "Extension of indication for Forxiga / Edistride to include treatment of children aged 10 years and adolescents with T2DM based on the results from studies MB10209/D1690C000016 and MB102-138/D1690C00017; these are paediatric studies submitted according to Article 46 of the

Paediatric Regulation. 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 21 of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0100/G
GSK Vaccines S.r.l, Rapporteur: Kristina Dunder

COMIRNATY - covid-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0002/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson
Opinion adopted on 08.01.2021.

COMIRNATY - covid-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0003/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0004
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0005
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0055
Merck Sharp & Dohme B.V., Rapporteur: Paula Boudewina van Hennik

Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0057
Merck Sharp & Dohme B.V., Rapporteur: Paula Boudewina van Hennik

Forsteo - teriparatide - EMEA/H/C/000425/II/0056
Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau

Forsteo - teriparatide -

EMEA/H/C/000425/II/0057/G
Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau

Hemoblast Bellows - thrombin - EMEA/H/D/002769/II/0008/G
BSI Group, Rapporteur: Armando Genazzani
"T.IA
T. II Submission of follow-up measure linked to EMEA/H/D/002769/IB/001. Submission of Clinical Study report of study ETC2015-002, a prospective, randomized, controlled, multicentre, pivotal, clinical investigation evaluation the safety and efficacy of HEMOBLAST Bellows in cardiothoracic, abdominal and orthopaedic lower extremity surgeries (ETC2015-002) conducted on HEMOBLAST Bellows."

Intrarosa - prasterone - EMEA/H/C/004138/II/0015
Endoceutics S.A., Rapporteur: Jean-Michel Race

Kalydeco - ivacaftor - EMEA/H/C/002494/II/0093, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro

Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0084
Genzyme Europe BV, Co-Rapporteur: Karin Janssen van Doorn

ReFacto AF - moroctocog alfa - EMEA/H/C/000232/II/0158/G
Pfizer Europe MA EEIG, Rapporteur: Kirstine Moll Harboe

Taltz - ixekizumab - EMEA/H/C/003943/II/0041
Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0073
MCM Vaccine B.V., Rapporteur: Christophe Focke

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type

B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0074
MCM Vaccine B.V., Rapporteur: Christophe Focke

Veklury - remdesivir - EMEA/H/C/005622/II/0013/G
Gilead Sciences Ireland UC, Rapporteur: Janet Koenig

Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0019, Orphan
Jazz Pharmaceuticals Ireland Limited, Rapporteur: Johanna Lähteenvuo

WS1981
Abseamed-EMEA/H/C/000727/WS1981/0093
Binocrit-EMEA/H/C/000725/WS1981/0092
Epoetin alfa Hexal-EMEA/H/C/000726/WS1981/0092
Sandoz GmbH, Lead Rapporteur: Alexandre Moreau

WS1991
Hexacima-EMEA/H/C/002702/WS1991/0112
Hexyon-EMEA/H/C/002796/WS1991/0116
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS1997
Actrapid-EMEA/H/C/000424/WS1997/0080
Fiasp-EMEA/H/C/004046/WS1997/0026
Levemir-EMEA/H/C/000528/WS1997/0102
NovoRapid-EMEA/H/C/000258/WS1997/0139
Ryzodeg-EMEA/H/C/002499/WS1997/0043
Saxenda-EMEA/H/C/003780/WS1997/0028
Tresiba-EMEA/H/C/002498/WS1997/0050
Victoza-EMEA/H/C/001026/WS1997/0058
Xultophy-EMEA/H/C/002647/WS1997/0040
Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe

WS2001
Hexacima-EMEA/H/C/002702/WS2001/0113
Hexyon-EMEA/H/C/002796/WS2001/0117
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS2016/G
Blitzima-EMEA/H/C/004723/WS2016/0039/G
Ritemvia-EMEA/H/C/004725/WS2016/0039/G
Truxima-EMEA/H/C/004112/WS2016/0042/G
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

WS2020
Blitzima-EMEA/H/C/004723/WS2020/0038
Ritemvia-EMEA/H/C/004725/WS2020/0038
Truxima-EMEA/H/C/004112/WS2020/0041
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

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

Adcetris - brentuximab vedotin - EMEA/H/C/002455/II/0086, Orphan
Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, "Update of the SmPC section 5.1 following the submission of the CSR addendum which includes long-term follow up or final OS results for the AETHERA study "A phase 3, randomised, double-blind, placebo-controlled, multicentre, clinical trial in patients with Hodgkin Lymphoma (HL) at risk of relapse or progression following ASCT"."

Akynzeo - fosnetupitant / netupitant / palonosetron - EMEA/H/C/003728/II/0034
Helsinn Birex Pharmaceuticals Limited, Rapporteur: Peter Kiely, "submission of the results of the in vitro study assessing the ability of fosnetupitant to inhibit all UGTs of interest: UGT1A1, 1A3, 1A4, 1A6, 1A9, and 2B7 following a recommendation from the CHMP."

Beovu - brolucizumab - EMEA/H/C/004913/II/0006

Novartis Europharm Limited, Rapporteur: Alexandre Moreau, "C.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data"

Bosulif - bosutinib - EMEA/H/C/002373/II/0048

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, "C.I.4
Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update safety and efficacy information based on final results from study B18711053 (a recommendation of EMEA/H/C002373/II/25/G). This is an interventional safety and efficacy study covering submission of the long-term experience results secondary endpoints (duration of MMR and CCyR, EFS and OS). The Safety Data pool is also updated with results of interventional studies, B18711048 (final CSR submitted in variation II/41) and ongoing studies B18711039 and B18711040 (listed as category 3 studies in the RMP); the Package Leaflet is updated accordingly. PSUR Annex IV associated to procedure EMEA/H/C/PSUSA/00010073/202003 (commission decision dated 14 December 2020) has been proposed for removal"

Budesonide/Formoterol Teva Pharma B.V. - budesonide / formoterol fumarate dihydrate - EMEA/H/C/004882/II/0001/G

Teva Pharma B.V., Duplicate, Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, "C.I.2.b - Updates of section 4.2 to add information on the use as reliever for allergen- and exercise-induced bronchoconstriction, section 4.4 to revise the general warning on complete withdrawal of inhaled corticosteroids, and section 6.6 to update the statement on special precautions for disposal and other handling following assessment of the same changes for the reference product DuoResp Spiromax.
C.I.3.z - update of the SmPC following a PSUR (PSUSA/00010585/201908) for the reference product DuoResp Spiromax to add 'dysphonia' as an adverse drug reaction with a frequency 'common' in section 4.8.
The Package Leaflet (PL) and Labelling are

updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the PL."

Deltyba - delamanid - EMEA/H/C/002552/II/0048, Orphan

Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, "Update of section 5.1 of the SmPC in order to include information on epidemiological cut-off and clinical breakpoint. In addition, the MAH took the opportunity to propose an editorial update in Annex II and Spanish translation of SmPC section 4.8."

Fasenra - benralizumab - EMEA/H/C/004433/II/0031

AstraZeneca AB, Rapporteur: Fátima Ventura, "C.I.13: Submission of the final report from study D3250C00037 (MELTEMI), listed as a category 3 study in the RMP. This is an open-label safety extension study to evaluate the safety and tolerability of a fixed 30 mg dose of benralizumab s.c. in severe asthma patients"

PRAC Led

Hemlibra - emicizumab - EMEA/H/C/004406/II/0021

Roche Registration GmbH, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Armando Genazzani, "Submission of an updated RMP version 2.5 in order to add thromboembolic events without concomitant aPCC as an important potential risk in the safety specifications and to update the milestones for BO40853/SURVEY study following approval of the protocol v3 (via MEA PRO 002.2)."

Imfinzi - durvalumab - EMEA/H/C/004771/II/0026

AstraZeneca AB, Rapporteur: Sinan B. Sarac, "Update of section 5.1 of the SmPC in order to update efficacy information on Overall Survival based on the 4-years follow-up analysis of the PACIFIC study (D41991C00001) submitted as recommended by the CHMP; this is a phase III, randomised, double-blind, placebo-controlled, study of Durvalumab as sequential therapy in patients with locally advanced, unresectable non-small cell lung cancer (Stage III)."

Jardiance - empagliflozin -

EMEA/H/C/002677/II/0057
Boehringer Ingelheim International GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 4.4 of the SmPC to lower the renal threshold for initiation and use of empagliflozin depending on eGFR, and of the section 5.1 wording about endpoints with reference to EMPA-REG OUTCOME study. The PL is updated accordingly."

Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0017
Bayer AG, Rapporteur: Kirstine Moll Harboe, "Submission of the final report from the pharmacokinetic study 19742 comparing the pharmacokinetic parameters of Jivi vs. Adynovi."

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0100
Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "Update of section 5.1 of the SmPC in order to update efficacy data based on interim results from study KEYNOTE-054 listed as a PAES in the Annex II; this is a randomized, double-blind, placebo-controlled phase 3 study evaluating pembrolizumab in the adjuvant therapy of patients with resected high-risk melanoma."

Lynparza - olaparib - EMEA/H/C/003726/II/0044
AstraZeneca AB, Rapporteur: Alexandre Moreau, "Update of sections 4.8, and 5.1 of the SmPC in order to provide final
PFS2 and updated interim OS data from the Phase III PAOLA-1 study; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to switch the order of the capsule and tablet formulations in Annex 1 of the QRD."

Lynparza - olaparib - EMEA/H/C/003726/II/0045
AstraZeneca AB, Rapporteur: Alexandre Moreau, "Submission of the final report from study/D0816C00012 (ORZORA) listed as PAES in the Annex II of the Product Information. This is an Open Label, Single Arm, Multi-centre Study to Assess the Clinical Effectiveness and Safety of Lynparza (Olaparib) Capsules Maintenance Monotherapy in Platinum Sensitive Relapsed somatic or germline BRCA Mutated

Ovarian Cancer Patients who are in Complete or Partial Response Following Platinum based Chemotherapy. The Annex II is updated accordingly."

Lyumjev - insulin lispro - EMEA/H/C/005037/II/0008/G

Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-Ikola, "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study I8B-MC-ITRO (PRONTO-Pump-2); this is a Phase 3 prospective, randomized, double-blind trial which compared Lyumjev to Humalog in adults with Type 1 Diabetes using continuous subcutaneous insulin infusion. The Package Leaflet is updated accordingly. The applicant also provides a phase 2 study evaluating Lyumjev in a Medtronic Pump (Study I8B-MC-ITSM) as a grouped variation."

Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0105

Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad, "To update section 5.1 Pharmacodynamic properties of the SmPC with information regarding the effectiveness of Nimenrix, to include real-world data from the Netherlands describing the impact of a single dose of Nimenrix on the prevention of meningococcal disease. In addition, a cross-reference to section 4.2 Posology and method of administration of the SmPC was included, to direct the physicians attention to the robust persistence and booser data in section 5.1 and information in section 4.4 Special warnings and precautions for use.
In addition, the MAH took the opportunity to include minor editorial changes to the SmPC."

Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0024

Roche Registration GmbH, Rapporteur: Kirstine Moll Harboe, "Type II variation application, category C.I.4, to amend the wording on Progressive Multifocal Leukoencephalopathy (PML) in the SmPC, section 4.4 Special warnings and
precautions, for compliance with PRAC Recommendations."

Odomzo - sonidegib -

EMEA/H/C/002839/II/0035
Sun Pharmaceutical Industries Europe B.V., Rapporteur: Paula Boudewina van Hennik, "submission of a pooled analysis of drug-related adverse reactions observed in 9 clinical studies with sonidegib, as reflected in the updated Core Data Sheet. As the clinical studies pertain to different therapeutic indications for which the use of Odomzo is not approved, the MAH has not considered an update of the product information."

OFEV - nintedanib -
EMEA/H/C/003821/II/0040
Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, "Update of sections 4.4. and 4.8 of the SmPC in order to add nephrotic range proteinuria as a new adverse drug reaction based on confirmed safety signal; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor corrections and editorial changes (correction of frequency category for renal failure in section 4.8 of the SmPC, correction of a typo of non-safety relevant information in section 5.1. of the SmPC and correction of typos in Annex II) in the EN PI."

Quofenix - delafloxacin -
EMEA/H/C/004860/II/0009
A. Menarini Industrie Farmaceutiche Riunite s.r.l., Rapporteur: Janet Koenig, "Submission of the final report from study PAE-DELA-01 undertaken to evaluate the impact on the breakpoints of the postantibiotic effect and the delayed re-growth of bacteria following exposure to delafloxacin. The provision of the study report addresses the post-authorisation measure MEA 001."

Remicade - infliximab -
EMEA/H/C/000240/II/0227
Janssen Biologics B.V., Rapporteur: Kristina Dunder, "Update of the breast-feeding information in section 4.6 of the SmPC to reflect the latest findings from literature regarding excretion of infliximab in human milk and the lack of impact on the development of breastfed infants. The local representative section in the Package leaflet has also been updated."

Tecentriq - atezolizumab -
EMEA/H/C/004143/II/0054

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add severe cutaneous adverse reactions (SCARs) to the list of adverse drug reactions (ADRs) with frequency uncommon, based on the review of safety data presented in a drug safety report (DSR 1105724); the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add the term pemphigoid to the description of rash in section 4.8 of the SmPC. The MAH also took the opportunity to update minor typographical errors in the SmPC and PL."

Tremfya - guselkumab - EMEA/H/C/004271/II/0026

Janssen-Cilag International N.V., Rapporteur: Agnes Gyurasics, "Update of sections 4.8 and 5.1 of the SmPC in order to implement 1-year psoriatic arthritis clinical data from the pivotal Phase 3 studies CNTO1959PSA3001 and CNTO1959PSA3002. In addition, the MAH took the opportunity to make editorial changes to the product information."

Tygacil - tigecycline - EMEA/H/C/000644/II/0116

Pfizer Europe MA EEIG, Rapporteur: Blanca Garcia-Ochoa, "Update sections 4.6 and 5.3 of the SmPC to include the conclusions from preclinical studies conducted with tigecycline in rats, which do not indicate harmful effects with respect to fertility or reproductive performance. In addition, the MAH is taking the opportunity to update the SmPC and Package Leaflet to rectify the pharmaceutical form mentioned in the excipient information from "suspension" to "solution"."

Tysabri - natalizumab - EMEA/H/C/000603/II/0123

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "C.I.4. Update of section 4.2 of the SmPC of Tysabri 300 mg IV in order to modify administration instructions based on a review of clinical study database and global safety database reports. The Package Leaflet (section 2) is updated accordingly."

Vaborem - meropenem / vaborbactam - EMEA/H/C/004669/II/0010/G

Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, "A grouped

application including 8 type II variations (C.I.4) and 1 type II variation (C.I.13):
Update of section 4.5 of the SmPC based on the results of a series of non-clinical drug-drug interaction studies undertaken with vaborbactam or meropenem. The Package Leaflet has been updated accordingly. In addition, the MAH has submitted non-clinical data on the phototoxicity potential of meropenem from a 3T3 neutral red uptake phototoxicity test."

Vargatef - nintedanib - EMEA/H/C/002569/II/0038
Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, "Update of sections 4.4 and 4.8 of the SmPC in order to add nephrotic range proteinuria to the list of adverse drug reactions (ADRs) with frequency Common, following the quarterly signal detection in EudraVigilance/EVDAS and based on MAH assessment of safety data retrieved from all completed ICTs conducted with nintedanib and the MAH Global Drug Safety System (GDSS); the Package Leaflet is updated accordingly."

Venclyxto - venetoclax - EMEA/H/C/004106/II/0032
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Update of SPC section 5.1 with new data of venetoclax in combination wtih rituximab patients with relapsed or refractory chronic lymphocytic leukemia (R/R CLL) from Study GO28667 (MURANO) interim CSR with a CCOD date of 8 May 2020. Study GO28667 is an ongoing open-label, international, multicenter, randomized, Phase III study to investigate the efficacy and safety of venetoclax in combination with rituximab (V+R) compared with bendamustine in combination with rituximab (BR) in patients with R/R CLL. The updated analysis included in this submission presents approximately 60 months of follow-up data.
The applicant is also taking advantage of this opportunity to make the below correction and propose editorial changes in the SmPC:
- Correcting the upper limit of the confidence interval of the venetoclax + obinituzumab 24-months PFS estimate (92.6 rather than 95.1) in table 5 of section 5.1 of the SmPC. Reference is made to the CSR for study

BO25323.
- Rounding the percentages across section 5.1 of the SmPC .”

Vyndaqel - tafamidis - EMEA/H/C/002294/II/0067, Orphan
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “C.I.4 Update of section 4.5 of the SmPC in order to add drug-drug interaction information with Rosuvastatin, a breast cancer resistant protein (BCRP) and organic anion transporter 3 (OAT3) substrate, based on final results from study B3461075. This is a Phase 1 interventional clinical drug-drug interaction study to estimate the effect of a multiple oral administration of Tafamidis on Rosuvastatin in pharmacokinetics (PK) in healthy participants.”

Xerava - eravacycline - EMEA/H/C/004237/II/0012
Tetraphase Pharmaceuticals Ireland Limited, Rapporteur: Filip Josephson, “Update of sections 5.3 and 6.6 of the SmPC in order to update the results of the Environmental Risk Assessment studies following their completion.”

Zejula - niraparib - EMEA/H/C/004249/II/0024, Orphan
GlaxoSmithKline (Ireland) Limited, Rapporteur: Bjorg Bolstad, “Update of sections 4.2 and 5.2 of the SmPC in order to include information based on final results from hepatic study 3000-01-003 (HEPATIC). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes in SmPC section 4.4.”

WS1969
Aprovel-EMEA/H/C/000141/WS1969/0183
CoAprovel-EMEA/H/C/000222/WS1969/0202
Karvea-EMEA/H/C/000142/WS1969/0185
Karvezide-EMEA/H/C/000221/WS1969/0202
sanofi-aventis groupe, Duplicate, Duplicate of Karvezide, Lead Rapporteur: Maria Concepcion Prieto Yerro, “Update of section 4.8 of the SmPC in order to add anemia to the list of adverse drug reactions with frequency unknown based on a review of the available data including the

MAH database and a literature review; the Package Leaflet is updated accordingly."

WS1989
Combivir-EMEA/H/C/000190/WS1989/0100
Epivir-EMEA/H/C/000107/WS1989/0116
Trizivir-EMEA/H/C/000338/WS1989/0121
ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, "Update of section 4.9 of the SmPC to revise the overdose information."

WS1990
Combivir-EMEA/H/C/000190/WS1990/0099
Dovato-EMEA/H/C/004909/WS1990/0018
Epivir-EMEA/H/C/000107/WS1990/0115
Kivexa-EMEA/H/C/000581/WS1990/0088
Triumeq-EMEA/H/C/002754/WS1990/0087
Trizivir-EMEA/H/C/000338/WS1990/0120
ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, "Update of sections 4.2 and 5.2 of the SmPC to revise the information about use of the products in patients with renal impairment."

B.6.10. CHMP-PRAC assessed procedures

Aimovig - erenumab - EMEA/H/C/004447/II/0013/G
Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, "Update of section 4.8 of the SmPC in line with revised clinical safety data. Submission of the study report from 5-year open-label study 20120178 with consequential changes to the sections 4.8 and 5.1 of the SmPC as well as an update of the EU RMP. Type IA variation to the include ATC code for erenumab. The Package Leaflet is updated accordingly."

BLINCYTO - blinatumomab - EMEA/H/C/003731/II/0039, Orphan
Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová, "C.I.13 Submission of the final report from study 20180138 classified as category 3 PASS in the RMP. This is an observational clinical study to update the OS Kaplan-Meier probability estimates and the plot last reported in the randomized Phase 3 blinatumomab 00103311

study."

CRYSVITA - burosumab - EMEA/H/C/004275/II/0021, Orphan

Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 4.2 of the SmPC in order to modify administration instructions to include the option of self/carer-administration based on results from two Phase 3 interventional clinical safety and efficacy studies; Study KRN23-003 in paediatric patients (final study report) and Study KRN23-004 in adult patients (interim report). The Package Leaflet has been updated accordingly and a new section with instructions for use has been added at the end. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and Package Leaflet. The updated RMP version 3.0 has also been submitted."

Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0016/G

Sanofi Pasteur, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, "Update of section 4.5. of the SmPC to include co-administration data on Gardasil/Cervarix/Adacel from CYD67, CYD71 and CYD66 final study reports respectively (final reports from 3 PAM MEA studies listed as category 3 studies in the RMP); these studies are dedicated to immunogenicity and safety of the concomitant administration; the Package Leaflet is updated accordingly. The RMP version 6.1. has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Eylea - aflibercept - EMEA/H/C/002392/II/0069

Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "This type II variation under category C.1.4 is to update the Posology section 4.2 of the Product Information for the indication DME based on results from the PAES VIOLET (Study 17613; (EMEA/H/C/002392/ANX/011); and to include study data to EU-PI section 5.1. The submission package also contains the AQUA CSR, a phase 4 study which served as run-in study for VIOLET."

Galafold - migalastat -

EMEA/H/C/004059/II/0030, Orphan
Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 5.1 of the SmPC based on final results from study AT1001-042 listed as category 3 in the RMP. Study AT1001-042 is an open-label, non-comparative, long-term extension study to evaluate long-term safety and efficacy of migalastat l monotherapy in subjects with Fabry disease. The updated RMP version 5 has also been submitted."

Herceptin - trastuzumab - EMEA/H/C/000278/II/0168
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.2 and 4.4 of the SmPC in order to modify the administration instructions by removing the observation time currently stipulated after administration and to amend the existing warning respectively based on final results from study SafeHER (MO28048) listed as a category 3 study in the RMP; this is a Phase III prospective, two Cohort nonrandomized, multicentre, multinational, open label study to assess the safety of assisted- and self-administered subcutaneous Herceptin as adjuvant therapy in patients with operable HER2- positive early breast cancer. The Package Leaflet is updated accordingly. The RMP version 21 has also been submitted."

Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0003, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "C.I.13: Submission of the final clinical study report for study VX18-445-007 (study 007), listed as a category 3 study in the RMP with the aim to evaluate the pharmacokinetics of Kaftrio (ELX/TEZ/IVA) in subjects with moderate hepatic impairment. The RMP version 1.2 has also been submitted."

Kalydeco - ivacaftor - EMEA/H/C/002494/II/0094, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon,

"C.I.13: Submission of the final report from study VX15-770-122 listed as a category 3 study in the RMP. This is a study in US Cystic Fibrosis Patients with the R117H-CFTR mutation to confirm the long-term safety and effectiveness of Kalydeco, including patients <18 Years of age, combining data captured in the Cystic Fibrosis Foundation Patient Registry from an interventional cohort and a non-interventional cohort. In addition, the MAH took the opportunity to propose a change of due date for study 126, listed as a category 3 in the RMP. The RMP version 10.1 has also been submitted."

Kisplyx - lenvatinib - EMEA/H/C/004224/II/0041

Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: David Olsen, "Update of sections 4.5 and 5.1 of the SmPC in order to update the drug-drug interaction with everolimus and to update the efficacy information based on the results from the study E7080-M001-221. Study 221 is a single-arm, multicenter, Phase 2 trial to evaluate the safety and efficacy of lenvatinib in combination with everolimus in subjects with unresectable advanced or metastatic non clear cell renal cell carcinoma (nccRCC) who have not received any chemotherapy for advanced disease. (MEA 008.1). The RMP version 12.1 has also been submitted."

Kisplyx - lenvatinib - EMEA/H/C/004224/II/0042

Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: David Olsen, "Submission of the final Clinical Study Report for Study E7080-G000-218. Study 218 is a randomized, open-label (formerly double-blind), Phase 2 trial to assess safety and efficacy of Lenvatinib at two different starting doses (18 mg vs 14 mg QD) in combination with Everolimus (5 mg QD) in Renal Cell Carcinoma following one prior VEGF-Targeted treatment. (MEA 007.3). The RMP 12.2 has also been submitted."

Lorviqua - lorlatinib - EMEA/H/C/004646/II/0013

Pfizer Europe MA EEIG, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of sections 4.2, 4.4 and 4.8 of

the SmPC in order to include hypertension and hyperglycaemia as new adverse drug reactions (ADRs) with frequency common and very common respectively together with recommended dose modifications and warnings, based on data from Phase 3 study B7461006, comparing lorlatinib versus crizotinib for the first line treatment of advanced ALK-positive NSCLC. In addition, the pooled safety dataset has been updated to include data from studies B7461001, a Phase 1/2 open-label, multiple-dose, dose-escalation, safety, pharmacokinetic, pharmacodynamic, and anti-tumour efficacy exploration study and B7461006. As a consequence, the frequencies of ADRs have been updated in section 4.8 of the SmPC and existing warnings on Hyperlipidaemia and Lipase and amylase increase have been amended. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted.”	
Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/II/0039 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Ana Sofia Diniz Martins, “Update of section 5.1 of the SmPC based on results from study M13-576; a non-drug interventional follow-up study to assess resistance and durability of response to AbbVie direct-acting antiviral agent (DAA) therapy (ABT-493 and/or ABT-530) in subjects who participated in Phase 2 or 3 clinical studies for the treatment of chronic hepatitis C Virus (HCV) infection. The study is included as a category 3 study in the RMP, and an updated RMP version 6.0 has also been submitted.”	
Mekinist - trametinib - EMEA/H/C/002643/II/0043 Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: David Olsen, “Submission of the final report from study 201711 listed as a category 3 study in the RMP. This is a study to identify and characterize the risk of cardiomyopathy and subsequent sequelae, including safety evaluations of patient populations at highest risk for developing these toxicities. The RMP version 17.0 has also been submitted.”	

NINLARO - ixazomib -
EMEA/H/C/003844/II/0026, Orphan
Takeda Pharma A/S, Rapporteur: Armando Genazzani, PRAC Rapporteur: Annika Folin, "Update of Annex II of the Product Information and the Risk Management Plan v. 5.1 following the completion of study C16014 comparing ixazomib plus lenalidomide and dexamethasone versus placebo plus lenalidomide and dexamethasone in adult patients with newly diagnosed multiple myeloma not eligible for stem cell transplantation (SCT) in fulfilment of SOB 003. A minor editorial change is proposed to section 4.2 Posology and Method of administration, for consistency with other sections of the SmPC. In addition, an update is proposed to the local representatives information in the Package Leaflet."

OPDIVO - nivolumab -
EMEA/H/C/003985/II/0098
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 5.1 of the SmPC in order to update overall survival information based on the final OS data for study CA209238, listed as an obligation in the Annex II and in the RMP; study CA 209238 is a Phase 3, randomised double-blind study of OPDIVO versus Yervoy in patients who have undergone complete resection of Stage IIIb/c or Stage IV melanoma; the MAH took also the occasion to update section 4.8 of the SmPC to pull the safety data sets of nivolumab as monotherapy across advanced metastatic and adjuvant settings. The Package Leaflet is updated accordingly. The RMP version 17.2 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting revisions in the PI."

Repatha - evolocumab -
EMEA/H/C/003766/II/0048
Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola, "C.I.13: Submission of the final report from study 20130286 listed as a category 3 study in the RMP. This is a double blind, randomized, placebo controlled, multicenter study
to evaluate safety, tolerability, and efficacy on LDL-C of evolocumab in HIV positive patients

with hyperlipidemia and mixed dyslipidemia.
The RMP version 6.0 has also been submitted."

Tafinlar - dabrafenib - EMEA/H/C/002604/II/0049
Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, "Submission of the final report from study 201710 listed as a category 3 study in the RMP. This is a study to perform evaluation of secondary malignancies in patients treated with dabrafenib in randomized, controlled trials. The RMP version 10.0 has also been submitted."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0053
Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Submission of the final report from study GO29322 listed as a category 3 study in the RMP. This is a Phase Ib study investigating the safety and pharmacology of atezolizumab administered with ipilimumab, interferon-alpha, or other immunemodulating therapies in patients with locally advanced or metastatic solid tumors. The RMP version 19.0 has also been submitted to remove the commitment for this study along with the safety concern and the missing information."

Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0169
Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, "Variation to update the currently approved EU Risk Management Plan for Truvada to remove the category 3 additional pharmacovigilance activity for the Registry Study GS EU 276 4487.
The Risk Management Plan (RMP) version 16.1 has been submitted."

Zercepac - trastuzumab - EMEA/H/C/005209/II/0003
Accord Healthcare S.L.U., Rapporteur: Sol Ruiz, PRAC Rapporteur: Brigitte Keller-Stanislawski

Zercepac - trastuzumab - EMEA/H/C/005209/II/0008
Accord Healthcare S.L.U., Rapporteur: Sol Ruiz, PRAC Rapporteur: Brigitte Keller-Stanislawski

B.6.11. PRAC assessed procedures

PRAC Led

Alecensa - alectinib - EMEA/H/C/004164/II/0030

Roche Registration GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Jana Lukacisinova, PRAC-CHMP liaison: Ondřej Slanař, "Submission of the final report from study (BO40643) listed as an additional pharmacovigilance activity in the RMP. This is a non-interventional post-authorisation safety study (PASS) aimed at evaluating the effectiveness of the risk minimization measures (RMMs) for the important identified risks of ILD/pneumonitis, hepatotoxicity, bradycardia, photosensitivity, severe myalgia, and CPK elevations for Alecensa ."

PRAC Led

Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0098

GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study V72_36OB, an observational PASS conducted by the Public Health England to further characterize the important potential risks of seizures (including febrile seizures), vasculitis/Kawasaki syndrome (KD), anaphylaxis (including anaphylactic shock), Acute Disseminated Encephalomyelitis (ADEM), and Glillain-Barré Syndrome (GBS) in routine UK care. The study is listed as a category 3 study in the RMP. The revised RMP version 9.0 has also been submitted."

PRAC Led

Kineret - anakinra - EMEA/H/C/000363/II/0078

Swedish Orphan Biovitrum AB (publ), Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Kirstine Moll Harboe, "Submission of the final report from study (Sobi-ANAKIN-201) listed as a category 3 study in the RMP. This is a non-interventional post-authorisation safety study to evaluate the safety of Kineret in the treatment of Cryopyrin Associated Periodic Syndromes (CAPS) in routine clinical care with

regard to serious infections, malignancies, injection site reactions, allergic reactions and medication errors, including reuse of syringe. The RMP version 5.4 has been submitted to reflect completion of this study. In addition, the RMP is updated to include information about a completed paediatric study (Sobi.ANAKIN-301) assessed as per Article 46 of Reg No 1901/2006 (EMEA/H/C/000363/P46/031). This was a randomised, double-blind, placebo-controlled, multicenter, phase 3 study which evaluated the efficacy, the safety, pharmacokinetics and immunogenicity of anakinra as compared to placebo in newly diagnosed Still's disease patients (including systemic juvenile idiopathic arthritis [SJIA] and adult-onset Still's disease [AOSD]).”

PRAC Led

Latuda - lurasidone - EMEA/H/C/002713/II/0033

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, “Type II (C.I.13) variation to submit PASS final study report for Latuda (lurasidone) 18.5 mg, 37 mg & 74 mg Film-coated tablets (equivalent to 20, 40, 80 mg lurasidone hydrochloride).”

PRAC Led

Levemir - insulin detemir - EMEA/H/C/000528/II/0101

Novo Nordisk A/S, Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Kirstine Moll Harboe, “Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy, based on final results from the non-interventional Post-Authorisation Safety Study, NN304-4016, listed as a category 3 study in the RMP. This is a diabetes pregnancy registry study conducted to assess the long-term safety of insulin use in pregnant women. The RMP version 21.0 has also been submitted.”

PRAC Led

Lonquex - lipegfilgrastim - EMEA/H/C/002556/II/0062

Teva B.V., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, “Submission of the final report

from study XM22-ONC-5002 listed as a category 3 study in the RMP. This is a drug utilisation study on the prescribing patterns of lipegfilgrastim in the EU. The RMP version 13.0 has also been submitted."

PRAC Led

Lopinavir/Ritonavir Mylan - lopinavir / ritonavir - EMEA/H/C/004025/II/0016

Mylan S.A.S, Generic, Generic of Kaletra, Rapporteur: John Joseph Borg, PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Jean-Michel Race, "Submission of an updated RMP v. 4.0 in order to implement the RMP template in accordance with GVP Module V rev. 2 and to align the safety concerns with the reference product"

PRAC Led

Nerlynx - neratinib - EMEA/H/C/004030/II/0020

Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 1.1 in order to add a new important identified risk, update data concerning the post-authorization safety studies and change of submission due date of the final Study Report of the PASS n°6201 (MEA 001), ."

PRAC Led

Neulasta - pegfilgrastim - EMEA/H/C/000420/II/0114

Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update of section 6.6 of the SmPC in order to add a new warning that the medicine should be allowed to reach room temperature before use, based on cumulative reviews of post-marketing reports of medication errors with the on-body injector."

PRAC Led

Repatha - evolocumab - EMEA/H/C/003766/II/0047

Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "C.I.3,
Update of section 4.8 of the SmPC in order to add myalgia to the list of adverse drug reactions

(ADRs) with frequency (frequency category) common following the review of nonclinical, clinical, postmarketing safety, and external spontaneous reporting databases as requested in the PSUR. The Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to add a traceability statement in line with a statement previously added to the SmPC and to propose minor updates to instructions for use of evolocumab SureClick pre-filled pen for enhanced usability."

PRAC Led

Retacrit - epoetin zeta - EMEA/H/C/000872/II/0100

Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final study report of a joint post-authorisation safety cohort study of Retacrit/Silapo (epoetin zeta) administered subcutaneously for the treatment of renal anemia (PASCO II) listed as a category 3 study in the RMP. The primary objective of the observational study was to estimate the incidence of pure red cell aplasia (PRCA), neutralising antibodies, lack of efficacy and thromboembolic events under treatment with Retacrit/Silapo (epoetin zeta).
The RMP version 16 has also been submitted."

PRAC Led

RotaTeq - rotavirus vaccine (live, oral) - EMEA/H/C/000669/II/0085

MSD Vaccins, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "To update the RMP for RotaTeq to version 7.2 to meet the requirements and updated definitions in the Guideline on good pharmacovigilance practices (GVP) module V (EMA/838713/2011; Rev 2); consequently, the list of safety concerns is updated and a reclassification of important risks is proposed. In addition, the proposed RMP version 7.2 implements the removal of hypersensitivity and severe combined immunodeficiency (SCID) from the list of safety concerns as requested by the PRAC in PSUR procedure (PSUSA/00002666/201911)."

PRAC Led

Silapo - epoetin zeta - EMEA/H/C/000760/II/0062

STADA Arzneimittel AG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final study report of a joint post-authorisation safety cohort study of Retacrit/Silapo (epoetin zeta) administered subcutaneously for the treatment of renal anemia (PASCO II) listed as a category 3 study in the RMP. The primary objective of the observational study was to estimate the incidence of pure red cell aplasia (PRCA), neutralising antibodies, lack of efficacy and thromboembolic events under treatment with Retacrit/Silapo (epoetin zeta).
The RMP version 12 has also been submitted."

PRAC Led

SIRTURO - bedaquiline - EMEA/H/C/002614/II/0042, Orphan

Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, "Submission of the final report of the PASS TMC207TBC4002, a non-interventional multi-country multidrug-resistant tuberculosis patient registry in South Africa and South Korea to monitor bedaquiline safety, utilisation, and emergence of resistance. The study is listed as a category 3 study in the RMP, and with this submission the MAH fulfills the Post Authorisation Measure MEA 010.6. The updated RMP version 8.1 has also been submitted."

PRAC Led

Tremfya - guselkumab - EMEA/H/C/004271/II/0025

Janssen-Cilag International N.V., Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 7.1 in order to amend the study population for Psoriasis registry C0168Z03 (PSOLAR) defined as Additional Pharmacovigilance Activities in the RMP. The amended protocol of the registry is included for assessment."

PRAC Led

Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0017, Orphan

Jazz Pharmaceuticals Ireland Limited, Rapporteur: Johanna Lähteenvuo, PRAC

Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, "Submission of a final CSR for post-marketing observational study of Vyxeos liposomal to assess the incidence of infusion-related reactions in adult patients. The primary objective of this study is to assess the nature, incidence, and severity of infusion-related reactions during and for up to one day following the last infusion of a five-day induction course in patients treated with the product. The secondary objective is to assess this information during and for up to one day following the last infusion of a five-day induction course in patients treated with Vyxeos."	
PRAC Led **WS1975** **Komboglyze-EMEA/H/C/002059/WS1975/0049** **Onglyza-EMEA/H/C/001039/WS1975/0051** AstraZeneca AB, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, "To provide an updated RMP to propose a change to the milestones of final study report for category 3 study D1680C00016 (MEASURE-HF). Other minor changes have been included and are detailed in the summary of changes to the RMP."	
PRAC Led **WS2000** **Leganto-MEA/H/C/002380/WS2000/0035** **Neupro-EMEA/H/C/000626/WS2000/0089** UCB Pharma S.A., Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Type II WS: C.I.11.b for RMP: Submission of a updated RMP version 5.0 in order to update RMP according to Good Pharmacovigilance Practices (GVP) Module V template (Rev 2)."	
PRAC Led **WS2011** **AZILECT-EMEA/H/C/000574/WS2011/0087** **Rasagiline ratiopharm-EMEA/H/C/003957/WS2011/0019** Teva B.V., Lead Rapporteur: Bruno Sepodes,	

Lead PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "C.I.11.b for RMP: Submission of an updated RMP version 3.0 following the completion of TV1030-CNS-50024 PASS (cat 3) Study investigating the risk of melanoma among Parkinson's Disease Patients (final study results already assessed in EMEA/H/C/WS/1749). The Applicant took the opportunity to submit a minor update to targeted follow-up questionnaire for the important potential risk of malignant melanoma and to revise the list of safety concerns and RMP format in line with GVP Module V revision 2.0.1 RMP template requirements."

B.6.12. CHMP-CAT assessed procedures

Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0041/G, ATMP
Amgen Europe B.V., Rapporteur: Olli Tenhunen, CHMP Coordinator: Johanna Lähteenvuo

Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0021/G, ATMP
CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder

Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0022, ATMP
CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, "Update of section 5.1 of the SmPC with the final results of study cod 16 HS 13, a 60-month follow up data assessing long-term efficacy and safety of Spherox.
Annex II has also been updated to reflect the completion of the study."

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

WS1962/G
Keppra-
EMEA/H/C/000277/WS1962/0191/G
UCB Pharma S.A., Lead Rapporteur: Karin

Janssen van Doorn	
WS1967/G **Incresync-EMEA/H/C/002178/WS1967/0037/G** **Vipdomet-EMEA/H/C/002654/WS1967/0032/G** **Vipidia-EMEA/H/C/002182/WS1967/0026/G** Takeda Pharma A/S, Lead Rapporteur: Johann Lodewijk Hillege, "C.I.z To bring the annexes in line with QRD version 10.1 and to updated the contact details of the local representatives in BE, DE, ES, FR, LU, LT, NL and PL. The MAH also brought the annexes of Incresync and Vipidia in line with the guidance on excipients for sodium. A.1."	
WS1979/G **Actos-EMEA/H/C/000285/WS1979/0084/G** **Competact-EMEA/H/C/000655/WS1979/0076/G** **Glubrava-EMEA/H/C/000893/WS1979/0062/G** **Glustin-EMEA/H/C/000286/WS1979/0083/G** **Tandemact-EMEA/H/C/000680/WS1979/0065/G** Takeda Pharma A/S, Lead Rapporteur: Peter Kiely, "Type IB, Category C.I.z. - Update of the Product Information (PI) with Sodium content wording in line with the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' in section 4.4 of the Summary of Product Characteristics (SmPC) and section 2 of the Package Leaflet (PL) for Competact, Glubrava and Tandemact. Type IAIN, Category A.1 Updates to the Product Information in line with the latest QRD template version 10.1 for Actos, Glustin, Competact, Glubrava and Tandemact. Minor editorial/typographical updates to local Product Information (PI), including updates to comply with EN PI and local QRD, for the following languages, for each product: - Actos: BG, CS, DA, FI, DE, HU, IS, PT, RO, ES, SV. - Competact: FI, FR, DE, PT, RO, SK, SV. - Glubrava: FI, DE, PT, ES.	

- Glustin: DA, FI, DE, HU, PT, SL.
- Tandemact: FI, DE, PT, SL, ES.
Updates to local representatives contact information in section 6 of the PL for the following countries for each of the following products:
- Actos: DE, FR, PL
- Competact: DE, FR, PL
- Glubrava: DE, ES, FR, LT, NL, PL
- Glustin: DE, ES, FR, LT, NL, PL
- Tandemact: DE, ES, FR, LT, NL
For the Danish (DA) PI only, for all products, the letters highlighted in the street name, Vallensbaek, is spelt in Danish in which the English letters "a" and "e" are replaced with the dipthong character "æ".
In addition, for the German (DE) PI, for all products, due to restricted space on the carton and in order to implement the FMD printing features, the expiry date ' Verwendbar bis' is shortened to 'Verw. bis'. This change is in alignment with local legislation for Germany and Austria."

WS1984
HyQvia-EMEA/H/C/002491/WS1984/0066
Kiovig-EMEA/H/C/000628/WS1984/0107
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

WS1987
Cervarix-EMEA/H/C/000721/WS1987/0111
Infanrix hexa-EMEA/H/C/000296/WS1987/0292
Mosquirix-EMEA/H/W/002300/WS1987/0053
Rotarix-EMEA/H/C/000639/WS1987/0119
Shingrix-EMEA/H/C/004336/WS1987/0041
Synflorix-EMEA/H/C/000973/WS1987/0155
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1988
Ambirix-EMEA/H/C/000426/WS1988/0112
Twinrix Adult-EMEA/H/C/000112/WS1988/0147
Twinrix Paediatric-EMEA/H/C/000129/WS1988/0148

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1993/G
Suboxone-EMEA/H/C/000697/WS1993/0050/G
Indivior Europe Limited, Lead Rapporteur: Janet Koenig

WS1994
Ambirix-EMEA/H/C/000426/WS1994/0113
Fendrix-EMEA/H/C/000550/WS1994/0074
Infanrix hexa-EMEA/H/C/000296/WS1994/0293
Twinrix Adult-EMEA/H/C/000112/WS1994/0148
Twinrix Paediatric-EMEA/H/C/000129/WS1994/0149
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1998/G
Abseamed-EMEA/H/C/000727/WS1998/0091/G
Binocrit-EMEA/H/C/000725/WS1998/0090/G
Epoetin alfa Hexal-EMEA/H/C/000726/WS1998/0090/G
Sandoz GmbH, Lead Rapporteur: Alexandre Moreau

WS2003
Silodyx-EMEA/H/C/001209/WS2003/0043
Urorec-EMEA/H/C/001092/WS2003/0047
Recordati Ireland Ltd, Lead Rapporteur: Armando Genazzani

WS2005/G
Hexacima-EMEA/H/C/002702/WS2005/0114/G
Hexyon-EMEA/H/C/002796/WS2005/0118/G
Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

WS2006
Pregabalin Mylan-EMEA/H/C/004078/WS2006/0016
Pregabalin Mylan Pharma-EMEA/H/C/003962/WS2006/0014

Mylan S.A.S, Generic, Generic of Lyrica, Lead Rapporteur: Alexandre Moreau, "To update section 4.8 of the SmPC to add respiratory depression with frequency of "not known" following assessment of the same change for the reference product (Lyrica). Sections 2 and 4 of the PL have been updated accordingly. In addition to the updates made to the SmPC and PIL as per the brand leader text, the applicant is taking the opportunity to amend the following details: - Update to the List of local representatives of the Marketing Authorisation Holder for Lithuania. Finally, some further minor editorial changes have been proposed for the product information texts for NO, LT and FI annexes."	
WS2007 **Atectura Breezhaler-EMEA/H/C/005067/ WS2007/0003** **Bemrist Breezhaler-EMEA/H/C/005516/ WS2007/0003** Novartis Europharm Limited, Lead Rapporteur: Peter Kiely	
WS2019 **Copalia-EMEA/H/C/000774/WS2019/0116** **Copalia HCT-EMEA/H/C/001159/WS2019/ 0091** **Dafiro-EMEA/H/C/000776/WS2019/0120** **Dafiro HCT-EMEA/H/C/001160/WS2019/ 0093** **Exforge-EMEA/H/C/000716/WS2019/ 0115** **Exforge HCT-EMEA/H/C/001068/WS2019/ 0090** Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe	
WS2021/G **Exelon-EMEA/H/C/000169/WS2021/ 0133/G** **Prometax-EMEA/H/C/000255/WS2021/ 0133/G** Novartis Europharm Limited, Lead Rapporteur: Alexandre Moreau	
WS2022/G **Copalia-EMEA/H/C/000774/WS2022/ 0115/G** **Copalia HCT-EMEA/H/C/001159/WS2022/ 0089/G**	

Dafiro-EMEA/H/C/000776/WS2022/0119/G
Dafiro HCT-EMEA/H/C/001160/WS2022/0091/G
Exforge-EMEA/H/C/000716/WS2022/0114/G
Exforge HCT-EMEA/H/C/001068/WS2022/0088/G
Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe

WS2023/G
Copalia-EMEA/H/C/000774/WS2023/0117/G
Dafiro-EMEA/H/C/000776/WS2023/0121/G
Exforge-EMEA/H/C/000716/WS2023/0116/G
Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe

WS2029
Nuwiq-EMEA/H/C/002813/WS2029/0041
Vihuma-EMEA/H/C/004459/WS2029/0023
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS1961
Mosquirix-EMEA/H/W/002300/WS1961/0052
Shingrix-EMEA/H/C/004336/WS1961/0040
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Jan Mueller-Berghaus

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMEA 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

F.1. Parallel Distribution - Pursuant to Article 9 of Council Regulation (EC) No. 2743/98 of 14 December 1998, as amended

F.2. Request for scientific opinion on justification of exceptional circumstance and for imperative grounds of public health

G. ANNEX G

G.1. Final Scientific Advice - Reports and Scientific Advice letters (MMD only)

G.2. PRIME

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

G.2.1. List of procedures concluding at 25-28 January 2021 CHMP plenary:

G.2.2. List of procedures starting in January 2021 for February 2021 CHMP adoption of outcomes

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