27 July 2020
EMA/CHMP/389029/2020 Rev[1]
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 20-23 July 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

20 July 2020, 09:00 – 19:30, room 1C/ virtual meeting

21 July 2020, 08:30 – 19:30, room 1C/ virtual meeting

22 July 2020, 08:30 – 19:30, room 1C/ virtual meeting

23 July 2020, 08:30 – 15:00, room 1C/ virtual meeting

Disclaimers

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

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

Note on access to documents

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

[1] Changes in section 7.1

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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 20-23 July 2020. See July 2020 CHMP minutes (to be published post September 2020 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 20-23 July 2020.

1.3. Adoption of the minutes

ORGAM minutes for 13 July 2020.

CHMP minutes for 22-25 June 2020.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. amikacin - Orphan - EMEA/H/C/005264

Insmed Netherlands B.V.; treatment of lung infection as part of combination antibacterial drug regiment in adults.

Scope: Oral explanation,

Updated draft list of experts for the SAG on Anti-Infectives meeting adopted via written procedure on 3 July 2020, Report from the SAG on Anti-Infectives meeting held on 10 July 2020

Action: Oral explanation to be held on Tuesday, 21 July 2020 at 14:00

List of Outstanding Issues adopted on 25.06.2020, 30.04.2020. List of Questions adopted on 14.11.2019.

2.1.2. emapalumab - Orphan - EMEA/H/C/004386

Swedish Orphan Biovitrum AB (publ); treatment of paediatric patients with primary haemophagocytic lymphohistiocytosis (HLH).

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday, 21 July 2020 at 09:00

List of Outstanding Issues adopted on 25.06.2020, 27.06.2019. List of Questions adopted

on 13.12.2018.

2.1.3. filgotinib - EMEA/H/C/005113

treatment of adult patients with moderately to severely active rheumatoid arthritis.

Scope: Possible oral explanation/ Opinion

Action: Oral explanation to be held on Tuesday, 21 July 2020 at 16:00

List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 12.12.2019.

2.1.4. bupivacaine / meloxicam - EMEA/H/C/005205

for application into the surgical site to reduce postoperative pain.

Scope: Oral explanation

Action: Oral explanation to be held on Monday, 20 July 2020 at 16:00

List of Outstanding Issues adopted on 30.04.2020, 27.02.2020. List of Questions adopted on 25.07.2019.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

2.4.1. Ibuprofen Kabi – EMEA/H/A-29(4)/1498

Fresenius Kabi Deutschland GmbH

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Paula Boudewina van Hennik

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday, 21 July 2020 at time 11:00

Summary: Decentralised Procedure number: DE/H/6040/001/DC, notification by the German Agency notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC.

See 10.4

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. crizanlizumab - Orphan - EMEA/H/C/004874

Novartis Europharm Limited; treatment of sickle cell disease.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.04.2020. List of Questions adopted on 17.10.2019.

3.1.2. arsenic trioxide - EMEA/H/C/005218

treatment of relapsed acute promyelocytic leukaemia (APL).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 12.12.2019.

3.1.3. avapritinib - Orphan - EMEA/H/C/005208

Blueprint Medicines (Netherlands) B.V.; treatment of gastrointestinal stromal tumours.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.04.2020. List of Questions adopted on 14.11.2019.

3.1.4. belantamab mafodotin - Orphan - EMEA/H/C/004935

GlaxoSmithKline (Ireland) Limited; treatment of patients with relapsed or refractory multiple myeloma.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.06.2020. List of Questions adopted on 28.04.2020.

3.1.5. acalabrutinib - Orphan - EMEA/H/C/005299

AstraZeneca AB; treatment of adult patients with chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 27.02.2020.

3.1.6. dapivirine - Article 58 - EMEA/H/W/002168

reducing the risk of HIV-1 infection via vaginal intercourse in sexually active HIV-uninfected women.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.07.2019, 26.04.2019, 18.10.2018. List of Questions adopted on 09.11.2017.

3.1.7. tagraxofusp - Orphan - EMEA/H/C/005031

TMC Pharma (EU) Limited; treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.03.2020, 25.06.2019. List of Questions adopted on 24.04.2019.

3.1.8. bevacizumab - EMEA/H/C/005181

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 28.05.2020. List of Questions adopted on 30.01.2020.

3.1.9. fampridine - EMEA/H/C/005359

treatment of multiple sclerosis.

Scope: Opinion

Action: For adoption

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

12.12.2019.

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

3.2.1. meningococcal group a, c, w135 and y conjugate vaccine - Article 28 - EMEA/H/C/005084

immunisation against Neisseria meningitidis serogroups A, C, W-135 and Y.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.2. melphalan - EMEA/H/C/005173

high-dose used alone or in combination with other cytotoxic drugs and/or total body irradiation is indicated in the treatment of: multiple myeloma, malignant lymphoma (Hodgkin, non-Hodgkin lymphoma), acute lymphoblastic and myeloblastic leukaemia, childhood neuroblastoma, ovarian adenocarcinoma, mammary adenocarcinoma.

in combination with other cytotoxic drugs and/or total body irradiation, in adult and paediatric population, is indicated as conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (HSCT) in haematological diseases.

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 25.07.2019.

3.2.3. rilpivirine - EMEA/H/C/005060

treatment of human immunodeficiency virus type 1 (HIV-1).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

3.2.4. influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159

prevention of influenza disease.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.5. cabotegravir - EMEA/H/C/004976

treatment of human immunodeficiency virus type 1 (HIV-1).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

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

3.3.1. bevacizumab - EMEA/H/C/005327

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: List of questions

Action: For adoption

3.3.2. abiraterone acetate - EMEA/H/C/005368

treatment of metastatic castration resistant prostate cancer.

Scope: List of questions

Action: For adoption

3.3.3. bevacizumab - EMEA/H/C/005611

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: List of questions

Action: For adoption

3.3.4. leuprorelin - EMEA/H/C/005034

indicated for the treatment of hormone dependent advanced prostate cancer.

Scope: List of questions

Action: For adoption

3.3.5. 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: List of questions

Action: For adoption

3.3.6. 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 questions

Action: For adoption

3.3.7. insulin human (rDNA) - EMEA/H/C/005331

treatment of patients with diabetes mellitus who require intravenous insulin.

Scope: List of questions

Action: For adoption

3.3.8. selumetinib - Orphan - EMEA/H/C/005244

AstraZeneca AB; treatment of neurofibromatosis type 1 (NF1).

Scope: List of questions

Action: For adoption

3.3.9. lonafarnib - Orphan - EMEA/H/C/005271

Accelerated assessment

EigerBio Europe Limited; treatment of Hutchinson-Gilford progeria syndrome and progeroid laminopathies.

Scope: List of questions

Action: For adoption

3.3.10. berotralstat - Orphan - EMEA/H/C/005138

BioCryst Ireland Limited; prevention of hereditary angioedema (HAE).

Scope: List of questions

Action: For adoption

3.3.11. lumasiran - Orphan - EMEA/H/C/005040

Accelerated assessment

Alnylam Netherlands B.V.; primary hyperoxaluria type 1 (PH1).

Scope: List of questions

Action: For adoption

3.3.12. 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 questions

Action: For adoption

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

treatment of uterine fibroids.

Scope: List of questions

Action: For adoption

3.3.14. 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 questions

Action: For adoption

3.3.15. adalimumab - EMEA/H/C/005188

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.

Scope: List of questions

Action: For adoption

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

3.4.1. dasatinib - EMEA/H/C/005446

treatment of leukaemia.

Scope: Letter from the applicant dated 14 July 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in June 2020.

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. List of Questions adopted on 17.10.2019.

3.4.2. dasatinib - EMEA/H/C/005317

treatment of leukaemia.

Scope: Letter from the applicant dated 14 July 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in June 2020.

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. List of Questions adopted on 17.10.2019.

3.4.3. dostarlimab - EMEA/H/C/005204

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

Scope: Letter from the applicant dated 16 July 2020 requesting an extension of clock-stop to respond to the list of questions adopted in June 2020.

Action: For adoption

List of questions adopted on 25.06.2020.

3.4.4. istradefylline - EMEA/H/C/005308

indicated as an adjunctive treatment to levodopa-based regimens in patients with Parkinson’s disease.

Scope: Letter from the applicant dated 6 July 2020 requesting an extension of clock-stop to respond to the list of questions adopted in April 2020.

Action: For adoption

List of questions adopted on 30.04.2020.

3.4.5. ofatumumab - EMEA/H/C/005410

treatment of relapsing forms of multiple sclerosis.

Scope: Request to Biostatistics Working Party (BSWP)

Action: For adoption

List of Questions adopted on 28.05.2020.

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

3.6.1. Cabazitaxel Accord - cabazitaxel - EMEA/H/C/005178

Accord Healthcare S.L.U.; treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen.

Scope: Letter from the EC on the opinion adopted in April 2020.

Action: For discussion

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

Opinion adopted on 30.04.2020. List of Outstanding Issues adopted on 26.03.2020, 27.02.2020. List of Questions adopted on 19.09.2019.

3.6.2. Kaftrio - elexacaftor / tezacaftor / ivacaftor - Orphan - EMEA/H/C/005269

Vertex Pharmaceuticals (Ireland) Limited; treatment of cystic fibrosis.

Scope: Update on Kaftrio

Action: For information

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

Opinion adopted on 25.06.2020. Oral explanation held on 23.06.2020. List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 28.01.2020.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. abicipar pegol - EMEA/H/C/005103

treatment of neovascular (wet) age-related macular degeneration (AMD).

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 14.11.2019.

3.7.2. aripiprazole - EMEA/H/C/005062

treatment of schizophrenia, or of moderate to severe manic episodes in bipolar I disorder with sensor to measure medication adherence.

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 25.07.2019.

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. Pemetrexed Hospira - pemetrexed - EMEA/H/C/003970/X/0021

Pfizer Europe MA EEIG

Rapporteur: Alar Irs

Scope: "Extension application to introduce a new pharmaceutical form with its associated strength (25 mg/ml concentrate for solution for infusion)."

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. List of Questions adopted on 27.02.2020.

4.1.2. Pradaxa - dabigatran etexilate - EMEA/H/C/000829/X/0122/G

Boehringer Ingelheim International GmbH

Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Anette Kirstine Stark

Scope: "Extension application to add two new pharmaceutical forms for Pradaxa (coated granules (20 mg, 30 mg, 40 mg, 50 mg, 110 mg, 150 mg) and powder and solvent for oral solution (6.25 mg/ml)), grouped with:

-A type II variation (C.I.6.a) - Extension of indication to include new indication for Pradaxa 75 mg, 110 mg, 150 mg capsules based on the paediatric trials 1160.106 and 1160.108. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.7, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet and labelling are updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the package leaflet. The RMP version 37.0 has also been submitted.

-Type IB (B.I.b.1.c)

-Type IA (B.I.b.1.b)

-Type IB (B.I.b.1.d)

-Type IA (B.I.b.2.a)

-Type IA (B.I.b.1.d)

-Type IA (B.I.d.1.a.1)

-Type IA (B.II.d.1.a)

-Type IB (B.II.d.1.d)

-Type IA (B.II.d.2.a)

-Type IA (B.II.c.1.c)"

Action: For adoption

List of Questions adopted on 27.02.2020.

4.1.3. Trulicity - dulaglutide - EMEA/H/C/002825/X/0045

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Ilaria Baldelli

Scope: "Extension application to introduce two new strengths of 3 mg and 4.5 mg solution for injection."

Action: For adoption

List of Questions adopted on 26.03.2020.

4.1.4. Ultomiris - ravulizumab - EMEA/H/C/004954/X/0004/G

Alexion Europe SAS

Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Agnes Gyurasics

Scope: "Extension application to add a new strength (1100 mg in 11 ml vial, concentration 100 mg/ml) for Ultomiris concentrate for solution for infusion, grouped with a Type II application (B.II.z) for a new presentation (300 mg in 3 ml vial, concentration 100 mg/ml) including changes in the active substance concentration, excipients composition and concentrations, and minor differences in the last two steps of the manufacturing process."

Action: For adoption

List of Questions adopted on 30.04.2020.

4.1.5. Xarelto - rivaroxaban - EMEA/H/C/000944/X/0074/G

Bayer AG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form, granules for oral suspension, 1 mg/ml.
Extension of indication to include treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years following initiation of standard anticoagulation treatment for Xarelto 15 and 20 mg tablets.
As a consequence, sections 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated accordingly.
In addition, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC is updated for all other dose strengths (2.5/10/ and 15/20 mg initiation packs) of Xarelto and corresponding sections of the package leaflet. Section 4.4 has been updated with regard to sodium content according to Annex to the European Commission guideline on 'Excipients in the labelling and package

leaflet of medicinal products for human use' (SANTE-2017-11668).
The RMP version 12.1 has also been submitted."

Action: For adoption

List of Questions adopted on 30.04.2020.

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. Hulio - adalimumab - EMEA/H/C/004429/X/0016

Mylan S.A.S

Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to add a new strength of 20 mg solution for injection.
The RMP (version 3.1) is updated in accordance."

Action: For adoption

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

Chiesi Farmaceutici S.p.A.

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

Scope: "Extension application to add a new pharmaceutical form (inhalation powder) associated with new strength (88µg / 5µg / 9µg).
The RMP (version 6.2) is updated in accordance."

Action: For adoption

4.3.3. 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

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

4.4.1. Lacosamide Accord - lacosamide - EMEA/H/C/004443/X/0007

Accord Healthcare S.L.U.

Rapporteur: John Joseph Borg, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form (solution for infusion), a new strength (10mg/ml) and a new route of administration (intravenous use).",

Letter from the applicant dated 16 July 2020 requesting an extension of clock-stop to respond to the list of questions adopted in March 2020.

Action: For adoption

List of questions adopted on 26.03.2020.

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. Crysvita - burosumab - Orphan - EMEA/H/C/004275/II/0010/G

Kyowa Kirin Holdings B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of adults with X-linked hypophosphataemia (XLH), and modification of the currently approved indication in children and adolescents, by removing the qualification 'with growing skeletons', in order to include treatment in all children with radiographic evidence of bone disease.
The application provides new week-48 data from study UX023-CL304; a randomised, double-blind, placebo-controlled, phase 3 study with open-label extension to assess the efficacy and safety of KRN23 in adults with XLH.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated and the package leaflet is updated in accordance. Furthermore, the PI is brought in line with the latest QRD template version 10.1.
The updated RMP version 2.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 30.01.2020.

5.1.2. Dupixent - dupilumab - EMEA/H/C/004390/II/0027

sanofi-aventis groupe

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

Scope: "Extension of indication to include atopic dermatitis patients from 6 years to 11 years. Consequently, the sections 4.1, 4.2, 4.8, 5.1 and 5.2 are updated. The package leaflet is updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

5.1.3. 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 marketing authorisation holder (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: For adoption

5.1.4. Humira - adalimumab - EMEA/H/C/000481/II/0198

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of moderately to severely active ulcerative colitis in paediatric patients for HUMIRA; as a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC for 40mg/0.8mL, 40mg/0.4mL and 80mg/0.8mL presentations are updated. Furthermore, sections 5.1 and 5.2 of the SmPC for 20mg/0.2mL are updated. The package leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted."

Action: For adoption

5.1.5. HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0056

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to replace the therapeutic indications of replacement therapy in hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia and multiple myeloma and hypogammaglobulinaemia in patients with HSCT, by the therapeutic indication of replacement therapy in secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of <4 g/l. for HyQvia; as a consequence, sections 4.1 and 4.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020.

5.1.6. Imbruvica - ibrutinib - Orphan - EMEA/H/C/003791/II/0059

Janssen-Cilag International NV

Rapporteur: Filip Josephson, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication in chronic lymphocytic leukaemia (CLL) to add combination with rituximab as follows; in combination with rituximab or obinutuzumab for the treatment of adult patients with previously untreated CLL.
This extension of the approved CLL indication is based on results from the phase 3 Eastern Cooperative Oncology Group-American College of Radiology Imaging Network (ECOG ACRIN) study E1912 (also referred to as PCYC-1126e-CA).
The SmPC is revised to include information related to the new indication. The package leaflet has been revised accordingly. Minor editorial changes have been implemented in Annex II and Annex IIIA. An updated RMP has been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

5.1.7. Imfinzi - durvalumab - EMEA/H/C/004771/II/0014/G

AstraZeneca AB

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include the use of Imfinzi in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC). The proposed indication is supported by study D419QC00001 (CASPIAN), an ongoing phase III randomised, multicentre, open-label, comparative study designed to determine the efficacy and safety of durvalumab, or durvalumab and tremelimumab, in combination with etoposide and platinum-based chemotherapy (EP) for the first-line treatment of patients with ES-SCLC.
In addition, the marketing authorisation holder (MAH) proposes to update sections 4.4 and 4.8 of the SmPC to update the safety information based on the Durvalumab Pan-Tumour Pool, a safety dataset comprising of 9 clinical studies building on the existing safety

database and summarising the safety information for durvalumab monotherapy characterised across tumour types in the durvalumab clinical program to date. The package leaflet is updated in accordance. The RMP version 2S1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020, 27.02.2020.

5.1.8. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/II/0085

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include the combination regimen of the ivacaftor 150 mg tablets with elexacaftor/tezacaftor/ivacaftor fixed dose combination (FDC) tablets for the treatment of adults and adolescents aged 12 years and older with cystic fibrosis who have at least one F508del mutation in the CFTR gene; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 8.8 of the RMP has also been submitted."

Action: For adoption

5.1.9. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/II/0086

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to extend the indication of Kalydeco (ivacaftor) granules in the treatment of infants aged at least 4 months, toddlers and children weighing 5 kg to less than 25 kg with cystic fibrosis who have one of the following gating (class III) mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 8.9 of the RMP has also been submitted."

Action: For adoption

5.1.10. Latuda - lurasidone - EMEA/H/C/002713/II/0029

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication for the treatment of schizophrenia in adolescent from 13 to less than 18 years. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated accordingly. In addition, the marketing authorisation holder (MAH) takes the opportunity to update the PI according to the excipient guideline and update the list of local representatives in the package leaflet. The RMP version 8 has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 26.03.2020.

5.1.11. NovoThirteen - catridecacog - EMEA/H/C/002284/II/0026/G

Novo Nordisk A/S

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension of indication to include treatment of bleeding episodes in patients with congenital factor XIII A-subunit deficiency as well as minor surgery based on the results of study NN1841-3868 and the PRO-RBDD registry. As a consequence, sections 4.1, 4.2, 4.4, 4.6, 5.1 and 5.2 of the SmPC and the RMP version 15 has been submitted. Annex IID and the package leaflet have been updated accordingly.
Furthermore, the PI is brought in line with the latest QRD template version. Minor editorial updates have also been made.", 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 30.04.2020.

5.1.12. Olumiant - baricitinib - EMEA/H/C/004085/II/0016

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include a new indication in the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy for Olumiant; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated.
The package leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the package leaflet.
Minor editorial changes were brought to the labelling. Furthermore, the Annex II is brought in line with the latest QRD template version 10.1.
The RMP version 8.1 has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020, 26.03.2020.

5.1.13. Opdivo - nivolumab - EMEA/H/C/003985/II/0080

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) after prior

fluoropyrimidine- and platinum-based chemotherapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 16.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

5.1.14. Prezista - darunavir - EMEA/H/C/000707/II/0107

Janssen-Cilag International NV

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension of indication for Prezista (darunavir) (800 mg) in combination with COBI (150 mg) for the treatment of HIV-1 infection in adolescents (aged 12 years and older with body weight at least 40 kg). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC and section 3 of the package leaflet are being updated accordingly. The updated RMP version 27.1 has also been submitted."

Action: For adoption

5.1.15. Recarbrio - imipenem / cilastatin / relebactam - EMEA/H/C/004808/II/0001

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of hospital-acquired pneumonia (HAP) including ventilator-associated pneumonia (VAP), with or without concurrent bacteraemia in adults for Recarbrio; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The package leaflet is updated in accordance. Furthermore, the marketing authorisation holder (MAH) made editorial corrections and brought the PI in line with the latest QRD template version 10.1. Version 1.1 of the RMP has also been submitted."

Action: For adoption

5.1.16. Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0022

GlaxoSmithkline Biologicals SA

Rapporteur: Christophe Focke, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sonja Hrabcik

Scope: "Extension of indication to include a new population for Shingrix: adults 18 years of age or older at increased risk of Herpes Zoster supported by the clinical studies Zoster-002 (MEA 001), Zoster -039 (MEA 002), Zoster -041 (MEA 003), Zoster -028 (MEA 004), Zoster -001 and Zoster -015.
As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated in order to delete a warning and to add new safety and efficacy information. The package leaflet is updated in accordance. The RMP version 2.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

5.1.17. Votubia - everolimus - Orphan - EMEA/H/C/002311/II/0061

Novartis Europharm Limited

Rapporteur: Janet Koenig

Scope: "To modify the approved therapeutic indication (adjunctive treatment of patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex, TSC) to include the new population of patients from 6 months to less than 2 years of age.
As a consequence, sections 4.1, 4.2, 5.1, 5.2 of the SmPC and sections 1 and 2 of the package leaflet are updated accordingly.
Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 12.12.2019.

5.1.18. Zavicefta - ceftazidime / avibactam - EMEA/H/C/004027/II/0015

Pfizer Ireland Pharmaceuticals

Rapporteur: Bjorg Bolstad, Co-Rapporteur: Simona Stankeviciute, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include paediatric patients aged 3 months to less than 18 years for Zavicefta (for the treatment of cIAI and cUTI), based on data from paediatric studies D4280C00014, C3591004 and C3591005 and the population PK modelling/simulation analyses (CAZ-MS-PED-01 and CAZ-MS-PED-02).
As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated in order to reflect this additional population, the paediatric posology, paediatric safety information, the description of the clinical trials and handling instructions for paediatric dosing. The package leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to correct the sodium content to SmPC sections 2 and 4.4 and PL section 2 and the volumes of distribution of ceftazidime and avibactam in SmPC section 5.2. Furthermore, the MAH is also introducing a correction in the Czech SmPC to add missing values in the table in SmPC section 5.1.
The RMP version 3.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020, 25.07.2019.

5.1.19. Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0048

Pfizer Ireland Pharmaceuticals

Rapporteur: Alar Irs

Scope: "Extension of indication for the treatment of community acquired pneumonia (CAP) to include concurrent bacteraemia due to Streptococcus pneumoniae (SP) for all age groups, based on the results of previously submitted studies: FOCUS 1 (study P903-08) and

FOCUS 2 (study P903-09), paediatric CAP study (study P903-31) and relevant post-marketing safety experience with ceftaroline for bacteraemic Streptococcus pneumoniae CAP. As a consequence, sections 4.1 and 5.1 of the SmPC are updated accordingly. No RMP has been provided within this application."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2019.

5.1.20. WS1782
Lacosamide UCB - lacosamide - EMEA/H/C/005243/WS1782/0006
Vimpat - lacosamide - EMEA/H/C/000863/WS1782/0088

UCB Pharma S.A.

Lead Rapporteur: Filip Josephson, Lead Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include the treatment as adjunctive therapy of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy for Lacosamide UCB and Vimpat; consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. The RMP version 15.0 has also been submitted.
Furthermore, the PI is brought in line with the latest QRD template version 10.1. The marketing authorisation holder (MAH) also takes the opportunity to align the PI of Lacosamide UCB with the PI of Vimpat and to implement some corrections in BG, CS, DA, FR, DE, HU, PL and ES."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

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

No items

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

No items

6. 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)

7.1.1. Remdesivir - EMEA/H/K/5622/CU

Gilead Sciences Ireland UC

Scope: Update on the compassionate use programme

Action: For information

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

Opinion adopted on 25.06.2020.

7.1.2. Sofosbuvir - EMEA/H/K/003891/CU

Gilead Sciences International

Scope: Update on the compassionate use programme

Action: For information

Opinion adopted on 24.10.2013.

7.1.3. Sofosbuvir/Ledipasvir - EMEA/H/K/003892/CU

Gilead Sciences International

Scope: Update on the compassionate use programme

Action: For information

Opinion adopted on 20.02.2014.

7.1.4. Daclatasvir – EMEA/H/K/003867/CU

Bristol-Myers Squibb

Scope: Update on the compassionate use programme

Action: For information

Opinion adopted on 21.11.2013.

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. artesunate - H0005550

initial treatment of severe or complicated malaria, in adults and children.

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

Action: For adoption

8.1.2. autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, sub family D (ALD), member 1, (ABCD1) cDNA - Orphan - H0003690

bluebird bio (Netherlands) B.V; treatment of patients less than 18 years of age with early cerebral adrenoleukodystrophy for whom a human leukocyte antigen (HLA) - matched sibling haematopoietic stem cell (HSC) donor is not available.

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. Desloratadine ratiopharm - desloratadine - EMEA/H/C/002404/II/0023/G

ratiopharm GmbH

Rapporteur: Koenraad Norga, Co-Rapp: Peter Kiely, PRAC Rapporteur: Jean-Michel Dogné

Scope: "C.I.5.b - Change in the legal status of desloratadine ratiopharm from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' in view of the safety profile of desloratadine ratiopharm and the post-marketing experience already available with other medicinal products containing similar long acting histamine antagonists. The RMP version 1.0 has also been submitted. In addition, the marketing authorisation holder (MAH) also took the opportunity to bring the PI in line with the latest QRD template (version 10.1), to update the list of local representatives in the package leaflet and to make editorial changes.
C.I.6.b - To delete the therapeutic indication in adolescents aged 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria. Section 4.1 of the SmPC and section 1 of the package leaflet are updated accordingly."

Action: For discussion

Request for Supplementary Information adopted on 26.03.2020.

9.1.2. Duzallo - allopurinol/lesinurad - EMEA/H/C/004412

Grunenthal GmbH

Rapporteur: Kristina Dunder, Co-Rapporteur: Tomas Radimersky

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Edistride - dapagliflozin - EMEA/H/C/004161/R/0038

AstraZeneca AB

Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Annika Folin

Scope: Renewal of marketing authorisations for unlimited validity

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 28.05.2020.

9.1.4. Erleada - apalutamide - EMEA/H/C/004452/II/0006

Janssen-Cilag International N.V.

Rapporteur: Blanca Garcia-Ochoa

Scope: "Update of section 4.8 of the SmPC to add interstitial lung disease to the list of adverse drug reactions (ADRs) with frequency unknown based on a safety review; the package leaflet is updated accordingly. The marketing authorisation holder (MAH) also took the opportunity to update the PI in line with the QRD template 10.1."

Action: For discussion

Request for Supplementary Information adopted on 05.06.2020.

9.1.5. Fortacin - lidocaine / prilocaine - EMEA/H/C/002693/II/0030

Recordati Ireland Ltd

Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Change in the legal status of Fortacin from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' in view of the safety profile of Fortacin, the post-marketing experience already available with other medicinal products containing amide local anaesthetics and in view of making the product more accessible to the target population. Furthermore, the PI is being brought in line with the latest QRD template (version 10.1). The RMP version 3.1 has also been submitted."

Action: For discussion

Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.

9.1.6. Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0016
Dovato - dolutegravir / lamivudine - EMEA/H/C/004909/II/0001
Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0069
Tivicay - dolutegravir - EMEA/H/C/002753/II/0052

ViiV Healthcare B.V.

Lead Rapporteur: Filip Josephson

Scope: "Update of section 4.6 of the SmPC in order to update the safety information regarding the occurrence of neural tube defects with the DTG-containing regimens based on interim analysis from Tsepamo study. This is a birth outcomes surveillance study being conducted in Botswana that was designed to evaluate adverse birth outcomes by HIV status and antiretroviral regimen, and to determine if there is an increased risk of neural tube defects among infants exposed to efavirenz at conception. This surveillance system captures all antiretroviral exposure including dolutegravir. The SmPC is updated accordingly. The RMP is not submitted.",

PRAC advice

Action: For adoption

9.1.7. Kanuma - sebelipase alfa - EMEA/H/C/004004/II/0026/G, Orphan

Alexion Europe SAS

Rapporteur: Bart Van der Schueren, Co-Rapporteur: Fátima Ventura

Scope: Grouped variations consisting of

1) update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the clinical information based on the pooled safety and efficacy analysis of already submitted studies (namely study LAL-CL04: an open label multicentre extension study to evaluate the long-term safety, tolerability, and efficacy of sebelipase alfa (SBC-102) in adult subjects with liver dysfunction due to lysosomal acid lipase deficiency (LAL-D) who previously received treatment in study LAL-CL01; study LAL-CL03: an open label, multicentre, dose escalation study to evaluate the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of SBC-102 in children with growth failure due to LAL-D; study LAL-

CL06: a multicentre, open-label study of sebelipase alfa in patients with LAL-D; study LAL-CL08: a phase 2, open label, multicentre study to evaluate the safety, tolerability, efficacy, and pharmacokinetics of sebelipase alfa in infants with rapidly progressive LAL-D; study LAL-CL02: a multicentre, randomised, placebo-controlled study of SBC-102 in patients with LAL-D) and updated population pharmacokinetic (PK) analyses in children and adults. The package leaflet and the RMP (version 4.0) are updated accordingly. Annex II is also updated to remove the obligation related to the provision of study LAL-CL08;

2) submission of the final report from study LAL-EA01: an open-label study with sebelipase alfa 1 mg/kg every other week for up to 78 weeks or until drug commercialisation in the United States (US) patients who did not otherwise qualify for an active sebelipase alfa trial (expanded access protocol).

Action: For adoption

Request for supplementary information adopted on 26.03.2020.

9.1.8. Qutenza - capsaicin - EMEA/H/C/000909/II/0048

Grunenthal GmbH

Rapporteur: Bruno Sepodes

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to amend the posology based on PACE and STRIDE studies. The package leaflet is updated accordingly."

Correction of Opinion

Action: For information

Opinion adopted on 30.04.2020. Request for Supplementary Information adopted on 27.02.2020, 12.12.2019.

9.1.9. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0036

Roche Registration GmbH

Rapporteur: Sinan B. Sarac

Scope: "Submission of the final report from study GO28915 (OAK) listed as a category 3 study in the RMP. This is a Phase III, open-label multicenter, randomised study to investigate the efficacy and safety of atezolizumab (anti−PD-L1 antibody) compared with docetaxel in patients with NSCLC after failure with platinum-containing chemotherapy. In addition, the marketing authorisation holder (MAH) submitted integrated analyses of the potential relationship of ADA and safety we based on studies IMvigor210, IMvigor211, OAK, POPLAR, IMpower150, IMpower130, IMpower131, IMpower132, IMpower133 and IMpassion130 as recommended by the CHMP."

Action: For adoption

Request for Supplementary Information adopted on 12.03.2020.

9.1.10. WS1587/G Abasaglar-EMEA/H/C/002835/WS1587/0028/G Humalog-EMEA/H/C/000088/WS1587/0178/G

Eli Lilly Nederland B.V.

Lead Rapporteur: Kristina Dunder

Scope: "Type II variation. B.IV.z.
Type IAIN B. II.e.5.a.1"

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 14.11.2019, 19.09.2019

9.1.11. Zurampic - lesinurad - EMEA/H/C/003932

Grunenthal GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

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

10.1.1. Yondelis - EMEA/H/C/0773/A-20/0060

MAH: Pharma Mar S.A.

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Blanca Garcia-Ochoa

Scope: Opinion

Action: For adoption

European Commission triggered a referral procedure under Article 20 of Regulation (EC) No 726/2004 to request CHMP to assess study OVC-3006, which failed to meet its endpoints in the indication of ovarian cancer, and its impact on the benefit risk balance for the centrally authorised medicinal product(s) Yondelis (trabectedin).

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

10.2.1. Presence of nitrosamine impurities in human medicinal products containing chemically synthesised active pharmaceutical ingredients EMEA/H/A-5(3)/1490

MAHs: various

Referral Rapporteur: Martina Weise, Referral Co-Rapporteurs: Kristina Dunder

Scope: Implementation of the Nitrosamine Art. 5.3 referral outcome

Action: For information

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

No items

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

10.4.1. Ibuprofen Kabi – EMEA/H/A-29(4)/1498

MAH: Fresenius Kabi Deutschland GmbH

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Paula Boudewina van Hennik

Scope: Oral explanation

Action: For adoption

Summary: Decentralised procedure number: DE/H/6040/001/DC, notification by the German Agency notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC.

See 2.4

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

10.5.1. Varilrix - EMEA/H/A-30/1499

MAH: GlaxoSmithKline Biologicals

Referral Rapporteur: Jan Mueller-Berghaus, Referral Co-Rapporteurs: Sol Ruiz

Scope: List of questions

Action: For adoption

Harmonisation exercise for Varilrix and associated names. Product information harmonisation was triggered by the MAH.

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

10.6.1. Panexcell Clinical Laboratories Priv. Ltd - Multiple NAPs (EMEA/H/A-31/1494)

MAHs: various

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Jayne Crowe

Scope: Opinion

Action: For adoption

Article 31 procedure triggered by the German Federal Institute of Drugs and Medical Devices (BfArM) concerning the contract research organisation (CRO) Panexcell Clinical Laboratories Priv. Ltd. located in Navi Mumbai 400 701, India

10.6.2. Ranitidine - EMEA/H/A-31/1491

MAHs: various

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

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Daniela Melchiorri

Scope: Appointment of re-examination rapporteurs

Action: For information

Tests performed in a random selection of ranitidine API batches and finished products available in the EU have shown levels of NDMA which raise concerns.
European Commission triggered on 12 September 2019 a referral procedure under Article 31 of Directive 2001/83/EC to evaluate the relevance of these findings, the potential root causes and their impact on the benefit-risk balance of medicinal products containing ranitidine.

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

July 2020 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

Action: For information

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

No items

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 6-9 July 2020

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for July 2020

Action: For adoption

14.2.2. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 14-16 July 2020

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 July 2020 meeting to CHMP for adoption:

- 15 reports on products in scientific advice and protocol assistance
- 12 reports on products in pre-authorisation procedures
- 1 report on products in plasma master file

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 2-3 June 2020

Table of Decisions of the NRG meeting held on 30 June - 1 July 2020

Action: For adoption

14.3.3. Quality Working Party (QWP)

Chair(s): Blanka Hirschlerova

QWP response to questions from CMDh on acceptability of the proposed in-use period of 3 months for TAPTIQOM 15 micrograms/ml + 5 mg/ml eye drops, solution

Action: For adoption

14.3.4. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 06-09 July 2020. 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

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

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)*

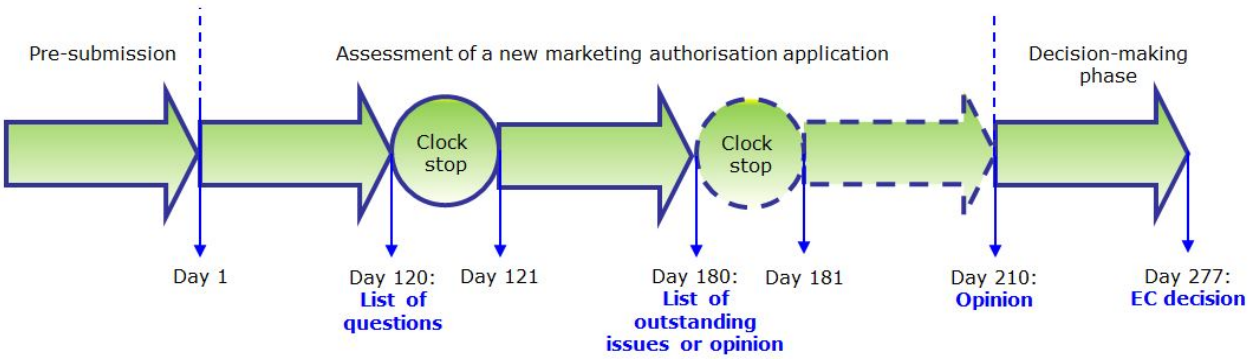
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

20 July 2020
EMA/CHMP/388052/2020

Annex to 20-23 July 2020 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 July 2020: **For adoption**

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

Final Outcome of Rapporteurship allocation for July 2020: **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

Chenodeoxycholic acid Leadiant - chenodeoxycholic acid - EMEA/H/C/004061/S/0014, Orphan
Leadiant GmbH, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Adam Przybylkowski

Elaprase - idursulfase - EMEA/H/C/000700/S/0087
Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Aripiprazole Accord - aripiprazole - EMEA/H/C/004021/R/0019
Accord Healthcare S.L.U., Generic of Abilify,

Rapporteur: John Joseph Borg, PRAC
Rapporteur: Ana Sofia Diniz Martins
Request for Supplementary Information adopted on 28.05.2020.

Episalvan - birch bark extract - EMEA/H/C/003938/R/0018
Amryt GmbH, Rapporteur: Kristina Dunder, Co-Rapporteur: Natalja Karpova, PRAC Rapporteur: Zane Neikena

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Briviact - brivaracetam - EMEA/H/C/003898/R/0025
UCB Pharma S.A., Rapporteur: Filip Josephson, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Adam Przybylkowski
Request for Supplementary Information adopted on 28.05.2020.

Cinacalcet Mylan - cinacalcet - EMEA/H/C/004014/R/0011
Mylan S.A.S, Generic of Mimpara, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ulla Wändel Liminga
Request for Supplementary Information adopted on 28.05.2020.

Edistride - dapagliflozin - EMEA/H/C/004161/R/0038
AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Annika Folin
Request for Supplementary Information adopted on 25.06.2020, 28.05.2020.

See agenda 9.1

Eptifibatide Accord - eptifibatide - EMEA/H/C/004104/R/0010
Accord Healthcare S.L.U., Generic of Integrilin, Rapporteur: Jayne Crowe, PRAC Rapporteur: Adrien Inoubli

Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/R/0069
Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ilaria Baldelli
Request for Supplementary Information adopted on 28.05.2020.

Jevtana - cabazitaxel -

EMEA/H/C/002018/R/0042
sanofi-aventis groupe, Rapporteur: Alexandre Moreau, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Tiphaine Vaillant

Kovaltry - octocog alfa - EMEA/H/C/003825/R/0030
Bayer AG, Rapporteur: Kristina Dunder, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski

Lopinavir/Ritonavir Mylan - lopinavir / ritonavir - EMEA/H/C/004025/R/0014
Mylan S.A.S, Generic of Kaletra, Rapporteur: John Joseph Borg, PRAC Rapporteur: Adrien Inoubli

Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/R/0056
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald
Request for Supplementary Information adopted on 28.05.2020.

Pemetrexed Accord - pemetrexed - EMEA/H/C/004072/R/0012
Accord Healthcare S.L.U., Generic of Alimta, Rapporteur: John Joseph Borg, PRAC Rapporteur: Tiphaine Vaillant

Rasagiline Mylan - rasagiline - EMEA/H/C/004064/R/0006
Mylan S.A.S, Generic of AZILECT, Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Ana Sofia Diniz Martins

Spectrila - asparaginase - EMEA/H/C/002661/R/0018
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Jan Neuhauser
Request for Supplementary Information adopted on 25.06.2020.

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and Haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/R/0065
MCM Vaccine B.V., Rapporteur: Christophe Focke, Co-Rapporteur: Bjorg Bolstad, PRAC

Rapporteur: Brigitte Keller-Stanislawski

Zalviso - sufentanil - EMEA/H/C/002784/R/0016
Grunenthal GmbH, Rapporteur: Milena Stain, PRAC Rapporteur: Adam Przybylkowski
Request for Supplementary Information adopted on 26.03.2020.

B.2.3. Renewals of Conditional Marketing Authorisations

Adcetris - brentuximab vedotin - EMEA/H/C/002455/R/0079, Orphan
Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst

Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/R/0004
Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Menno van der Elst

NINLARO - ixazomib - EMEA/H/C/003844/R/0021, Orphan
Takeda Pharma A/S, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 06-09 July 2020:

Signal of Kaposi´s sarcoma

AMGEVITA, AMSPARITY, HALIMATOZ, HEFIYA, HULIO, HUMIRA, HYRIMOZ, IDACIO, IMRALDI, CIMZIA, BENEPALI, ENBREL, ERELZI, SIMPONI, FLIXABI, INFLECTRA, REMICADE, REMSIMA, ZESSLY (CAP) – tumour necrosis factor (TNF) inhibitors

Rapporteur: various, Co-Rapporteur: various

PRAC recommendation on a variation

Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its July 2020 meeting:

EMEA/H/C/PSUSA/00000805/201912
(clofarabine)
CAPS:
Evoltra (EMEA/H/C/000613) (clofarabine), Genzyme Europe BV, Rapporteur: Alexandre Moreau
Ivozall (EMEA/H/C/005039) (clofarabine), ORPHELIA Pharma SAS, Rapporteur: Simona Badoi
NAPS:
CLOFARABINE NEON HEALTHCARE - NEON HEALTHCARE LIMITED, PRAC Rapporteur: Tiphaine Vaillant, "Period covered from 14/11/2019 to 28/12/2019"

EMEA/H/C/PSUSA/00001838/201912
(lenalidomide)
CAPS:
Lenalidomide Accord (EMEA/H/C/004857) (lenalidomide), Accord Healthcare S.L.U., Rapporteur: Ewa Balkowiec Iskra
Revlimid (EMEA/H/C/000717) (lenalidomide), Celgene Europe BV, Rapporteur: Alexandre Moreau
NAPS:
NAPs – EU
PRAC Rapporteur: Tiphaine Vaillant, "Period covered from 26/12/2018 to 26/12/2019"

EMEA/H/C/PSUSA/00001892/201912
(liraglutide)
CAPS:
Saxenda (EMEA/H/C/003780) (liraglutide), Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege
Victoza (EMEA/H/C/001026) (liraglutide), Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, "Period covered from 01/01/2019 to 31/12/2019"

EMEA/H/C/PSUSA/00010322/201912
(olaparib)
CAPS:
Lynparza (EMEA/H/C/003726) (olaparib), AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Amelia Cupelli, "Period covered from 16/12/2018 to 15/12/2019"

EMEA/H/C/PSUSA/00010341/201912 (secukinumab) CAPS: **Cosentyx** (EMEA/H/C/003729) (secukinumab), Novartis Europharm Limited, Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Eva A. Segovia, "Period covered from 26/12/2018 to 25/12/2019"
EMEA/H/C/PSUSA/00010391/201912 (lutetium (177Lu) chloride) CAPS: **EndolucinBeta** (EMEA/H/C/003999) (lutetium (177Lu) chloride), ITM Medical Isotopes GmbH, Rapporteur: Peter Kiely **Lumark** (EMEA/H/C/002749) (lutetium (177Lu) chloride), I.D.B. Holland B.V., Rapporteur: Jean-Michel Race NAPS: **NAPs** - EU "Period covered from 19/12/2018 to 19/12/2019"
EMEA/H/C/PSUSA/00010647/201912 (dimethyl fumarate (psoriasis)) CAPS: **Skilarence** (EMEA/H/C/002157) (dimethyl fumarate), Almirall S.A, Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin, "Period covered from 24/06/2019 to 23/12/2019"
EMEA/H/C/PSUSA/00010671/201911 (semaglutide) CAPS: **Ozempic** (EMEA/H/C/004174) (semaglutide), Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Annika Folin, "Period covered from 01/06/2019 to 30/11/2019"
EMEA/H/C/PSUSA/00107800/201912 (levodopa) CAPS: **Inbrija** (EMEA/H/C/004786) (levodopa), Acorda Therapeutics Ireland Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Nikica Mirošević Skvrce, "Period covered from 21/12/2018 to 20/12/2019"

B.4. EPARs / WPARs

Aybintio - bevacizumab - EMEA/H/C/005106	For information only. Comments can be sent to the PL in case necessary.

Samsung Bioepis NL B.V., 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., Similar biological application (Article 10(4) of Directive No 2001/83/EC)	
Gencebok - caffeine citrate - EMEA/H/C/005435 Gennisium Pharma, treatment of primary apnoea, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Idefirix - imlifidase - EMEA/H/C/004849, Orphan Hansa Biopharma AB, Idefirix is indicated for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor., 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.
Kaftrio - elexacaftor / tezacaftor / ivacaftor - EMEA/H/C/005269, Orphan Vertex Pharmaceuticals (Ireland) Limited, treatment of cystic fibrosis, 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.
LIVOGIVA - teriparatide - EMEA/H/C/005087 Theramex Ireland Limited, treatment of osteoporosis, 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.
Methylthioninium chloride Cosmo - methylthioninium chloride - EMEA/H/C/002776 Cosmo Technologies Ltd, is indicated as an aid for the enhanced visualisation and detection of colorectal lesions in adult patients undergoing screening / surveillance colonoscopy for colorectal cancer., Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Pretomanid FGK - pretomanid - EMEA/H/C/005167, Orphan	For information only. Comments can be sent to the EPL in case necessary.

FGK Representative Service GmbH, treatment of tuberculosis, New active substance (Article 8(3) of Directive No 2001/83/EC)	
QUTAVINA - teriparatide - EMEA/H/C/005388 EuroGenerics Holdings B.V., treatment of osteoporosis, Duplicate of Livogiva, 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.
Turalio - pexidartinib - EMEA/H/C/004832, Orphan Daiichi Sankyo Europe GmbH, treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT), also referred to as giant cell tumour of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS), 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.
Veklury - remdesivir - EMEA/H/C/005622 Gilead Sciences Ireland UC, treatment of coronavirus disease 2019 (COVID-19), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Abilify Maintena - aripiprazole - EMEA/H/C/002755/II/0036/G Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes
Advate - octocog alfa - EMEA/H/C/000520/II/0107 Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 30.04.2020.
ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0013 Baxalta Innovations GmbH, Rapporteur: Andrea Laslop
ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0014/G

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop	
ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0015/G Baxalta Innovations GmbH, Rapporteur: Andrea Laslop	
Cinacalcet Mylan - cinacalcet - EMEA/H/C/004014/II/0009 Mylan S.A.S, Generic, Generic of Mimpara, Rapporteur: Tomas Radimersky Request for Supplementary Information adopted on 02.07.2020, 30.04.2020.	Request for supplementary information adopted with a specific timetable.
Dupixent - dupilumab - EMEA/H/C/004390/II/0031/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus	
Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210/II/0049/G Gilead Sciences Ireland UC, Rapporteur: Filip Josephson	
Fasenra - benralizumab - EMEA/H/C/004433/II/0028/G AstraZeneca AB, Rapporteur: Fátima Ventura	
Fasenra - benralizumab - EMEA/H/C/004433/II/0029/G AstraZeneca AB, Rapporteur: Fátima Ventura	
Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0014 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 10.07.2020.	Positive Opinion adopted by consensus on 10.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0101 AstraZeneca AB, Rapporteur: Christophe Focke Opinion adopted on 10.07.2020.	Positive Opinion adopted by consensus on 10.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0038/G MSD Vaccins, Rapporteur: Kristina Dunder	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0111/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	

Request for Supplementary Information adopted on 19.03.2020, 12.12.2019.	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0116 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0041/G, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
ILARIS - canakinumab - EMEA/H/C/001109/II/0069/G Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 02.07.2020.	Request for supplementary information adopted with a specific timetable.
Ilumetri - tildrakizumab - EMEA/H/C/004514/II/0012/G Almirall S.A, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 14.05.2020.	
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0047/G Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus	
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0049 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus	
Inflectra - infliximab - EMEA/H/C/002778/II/0088/G Pfizer Europe MA EEIG, Duplicate of Remsima, Rapporteur: Outi Mäki-Ikola Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
JETREA - ocriplasmin - EMEA/H/C/002381/II/0050 Oxurion NV, Rapporteur: Kristina Dunder	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0088 Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lamzede - velmanase alfa -	Request for supplementary information adopted

EMEA/H/C/003922/II/0012/G, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 09.07.2020.	with a specific timetable.
MabThera - rituximab - EMEA/H/C/000165/II/0173/G Roche Registration GmbH, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
Menveo - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0094/G GSK Vaccines S.r.l, Rapporteur: Johann Lodewijk Hillege	
Mepsevii - vestronidase alfa - EMEA/H/C/004438/II/0013/G, Orphan Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 05.06.2020, 17.04.2020.	
Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0042 Orexigen Therapeutics Ireland Limited, Rapporteur: Kirstine Moll Harboe	
Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0098 Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 14.05.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0099/G Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad	
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0010/G Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 28.05.2020, 17.04.2020.	

Ongentys - opicapone - EMEA/H/C/002790/II/0028/G Bial - Portela & Cª, S.A., Rapporteur: Martina Weise Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ontruzant - trastuzumab - EMEA/H/C/004323/II/0024/G Samsung Bioepis NL B.V., Rapporteur: Koenraad Norga	
Orencia - abatacept - EMEA/H/C/000701/II/0140/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
Pazenir - paclitaxel - EMEA/H/C/004441/II/0007 ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Milena Stain	
Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0068 Merck Europe B.V., Rapporteur: Kirstine Moll Harboe Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
Perjeta - pertuzumab - EMEA/H/C/002547/II/0049/G Roche Registration GmbH, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
POTELIGEO - mogamulizumab - EMEA/H/C/004232/II/0005/G, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Paula Boudewina van Hennik Request for Supplementary Information adopted on 07.05.2020.	
Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0190 Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder	
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0163 CSL Behring GmbH, Rapporteur: Jan Mueller-	

Berghaus	
ReFacto AF - moroctocog alfa - EMEA/H/C/000232/II/0153/G Pfizer Europe MA EEIG, Rapporteur: Kirstine Moll Harboe	
Remsima - infliximab - EMEA/H/C/002576/II/0088/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0041 CSL Behring GmbH, Rapporteur: Kristina Dunder	
Revatio - sildenafil - EMEA/H/C/000638/II/0090/G Upjohn EESV, Rapporteur: Johann Lodewijk Hillege	
Ritonavir Mylan - ritonavir - EMEA/H/C/004549/II/0007/G Mylan S.A.S, Generic, Generic of Norvir, Rapporteur: John Joseph Borg Request for Supplementary Information adopted on 17.04.2020.	
Skyrizi - risankizumab - EMEA/H/C/004759/II/0010/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Kiely	
Somavert - pegvisomant - EMEA/H/C/000409/II/0095 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Stelara - ustekinumab - EMEA/H/C/000958/II/0080/G Janssen-Cilag International NV, Rapporteur: Jayne Crowe Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Taltz - ixekizumab - EMEA/H/C/003943/II/0034 Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Trecondi - treosulfan - EMEA/H/C/004751/II/0003/G	

medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura	
Trecondi - treosulfan - EMEA/H/C/004751/II/0004/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura	
Vosevi - sofosbuvir / velpatasvir / voxilaprevir - EMEA/H/C/004350/II/0040/G Gilead Sciences Ireland UC, Rapporteur: Filip Josephson	
Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0012/G, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Tuomo Lapveteläinen Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0052/G Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0022 Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1587/G **Abasaglar-EMEA/H/C/002835/WS1587/0028/G** **Humalog-EMEA/H/C/000088/WS1587/0178/G** Eli Lilly Nederland B.V., Lead Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 30.04.2020, 14.11.2019, 19.09.2019.	
WS1786 **Hexacima-EMEA/H/C/002702/WS1786/0097** **Hexaxim-EMEA/H/W/002495/WS1786/0102** **Hexyon-EMEA/H/C/002796/WS1786/0101** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Berghaus Opinion adopted on 02.07.2020. Request for Supplementary Information adopted on 30.04.2020.	
WS1815/G **Hexacima-EMEA/H/C/002702/WS1815/0102/G** **Hexaxim-EMEA/H/W/002495/WS1815/0107/G** **Hexyon-EMEA/H/C/002796/WS1815/0106/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	
WS1817/G **Infanrix hexa-EMEA/H/C/000296/WS1817/0276/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1823/G **Aflunov-EMEA/H/C/002094/WS1823/0060/G** **Foclivia-EMEA/H/C/001208/WS1823/0055/G** Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1826 **Ambirix-EMEA/H/C/000426/WS1826/0107** **Twinrix Adult-EMEA/H/C/000112/WS1826/0142** **Twinrix Paediatric-EMEA/H/C/000129/WS1826/0143** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	
WS1870/G **Entresto-EMEA/H/C/004062/WS1870/0033/G** **Neparvis-EMEA/H/C/004343/WS1870/0030/G** Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege	
WS1882 **HyQvia-EMEA/H/C/002491/WS1882/0060** **Kiovig-EMEA/H/C/000628/WS1882/0102** Takeda Manufacturing Austria AG, Lead	

Rapporteur: Jan Mueller-Berghaus	
Hexacima-EMEA/H/C/002702/WS1802/0098 **Hexaxim-EMEA/H/W/002495/WS1802/0103** **Hexyon-EMEA/H/C/002796/WS1802/0102** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 28.05.2020.	

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

Aptivus - tipranavir - EMEA/H/C/000631/II/0085 Boehringer Ingelheim International GmbH, Rapporteur: Jean-Michel Race, "Update of section 4.5 of the SmPC in order to include a new interaction with Dolutegravir. The Product Leaflet has been updated accordingly." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0091 GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to update the safety information and include Rash as Adverse Reaction in adolescents and adults. The Package Leaflet is updated accordingly." Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/II/0032 Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update the efficacy and safety data in HIV-1 infected subjects aged ≥ 65 years based on week 48 interim results from study GS-US-380-4449, "A Phase 3b, Multicenter, Open-Label Study to Evaluate Switching from an Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Fixed-Dose Combination Regimen or a Tenofovir Disoproxil Fumarate Containing Regimen to Fixed-Dose Combination of Bictegravir /Emtricitabine/Tenofovir Alafenamide in Elderly, Virologically-Suppressed, HIV-1	

Infected Subjects Aged ≥ 65 Years”.”	
Bosulif - bosutinib - EMEA/H/C/002373/II/0041 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, “Update of section 5.2 of the SmPC in order to update the population PK model and the exposure-response model with additional PK and safety data from the recently completed Phase 2 study (B1871048) following a commitment within variation EMEA/H/C/002373/II/0036. In addition, a pooled safety data analysis has been performed to assess the clinical impact of reduced clearance in Asian population. The MAH takes also the opportunity to make editorial changes on the Package Leaflet.” Request for Supplementary Information adopted on 30.04.2020.	
Cometriq - cabozantinib - EMEA/H/C/002640/II/0036, Orphan Ipsen Pharma, Rapporteur: Paula Boudewina van Hennik, “Submission of PK results from the clinical study ADVL1211 (an open-label trial to evaluate toxicity, tolerability, pharmacokinetics and pharmacodynamics of cabozantinib in children with refractory or relapsed malignant solid tumours (MEA 019)).” Opinion adopted on 02.07.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cubicin - daptomycin - EMEA/H/C/000637/II/0075 Merck Sharp & Dohme B.V., Rapporteur: Bjorg Bolstad, “Update of sections 4.4 and 4.8 of the SmPC in order to include two new terms, tubulointerstitial nephritis (TIN) and drug reaction with eosinophilia and systemic symptoms (DRESS) to the Special warnings and precautions of the SmPC. TIN has also been added to the Adverse events section, based on a review of the cumulative post-marketing cases associated with the use of daptomycin. The Package Leaflet is updated accordingly. In addition, QRD-related, spelling, formatting and spacing corrections were implemented.” Request for Supplementary Information adopted on 28.05.2020.	
Darzalex - daratumumab - EMEA/H/C/004077/II/0038, Orphan	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP

Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to add sepsis with frequency common as an ADR and incidence data on fatal infections and adverse reactions in the elderly patients based on cross-programmatic review of data. The MAH also proposed minor corrections in section 4.8 of the SPC. The Package Leaflet and labelling is updated accordingly. Correction of Annex II which was overlooked during procedure II-018 (approved on 11 July 2019)" Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 07.05.2020.	Members were in agreement with the CHMP recommendation.
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."	
Dovato - dolutegravir / lamivudine - EMEA/H/C/004909/II/0001 ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update the safety information regarding the occurrence of neural tube defects with the DTG-containing regimens based on interim analysis from Tsepamo study. This is a birth outcomes surveillance study being conducted in Botswana that was designed to evaluate adverse birth outcomes by HIV status and antiretroviral regimen, and to determine if there is an increased risk of neural tube defects among infants exposed to efavirenz at conception. This surveillance system captures all antiretroviral exposure including dolutegavir. The SmPC is updated accordingly. The RMP is not submitted." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019, 14.11.2019.	See agenda 9.1
Dupixent - dupilumab - EMEA/H/C/004390/II/0032 sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, "Update of SmPC sections 4.8 and 5.1 based on results of a paediatric study report, LTS12551 to fulfil the article 46 requirement (Regulation EC No 1901/2006).	

The LTS12551 study is an open–label extension study to evaluate the long-term safety and tolerability of dupilumab in patients with asthma."	
Effentora - fentanyl - EMEA/H/C/000833/II/0054/G Teva B.V., Rapporteur: Janet Koenig, "Update of the SmPC in line with the recent PSUSA evaluation outcome and to reflect the updated Company core safety information" Request for Supplementary Information adopted on 28.05.2020.	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0007, Orphan GW Pharma (International) B.V., Rapporteur: Kirstine Moll Harboe, "Update of section 4.2 of the SmPC in order to add information regarding enteral administration using nasogastric and gastrostomy tubes."	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0008/G, Orphan GW Pharma (International) B.V., Rapporteur: Kirstine Moll Harboe, "Update of section 4.5 of the SmPC to reflect the data of the rifampicin drug-drug interaction study GWEP17074. Update of section 4.5 of the SmPC to reflect the data of the CYP1A2 substrate (caffeine) drug-drug interaction study GWCP18056. Update of sections 4.5 and 5.2 of the SmPC to propose an additional statement regarding the stiripentol interaction based on the pharmacological study GWEP1447 . Update of section 5.2 of the SmPC to reflect the data of the pharmacokinetic study GWEP17076, exploring the impact of meal, milk and alcohol on cannabidiol exposure. In addition, the MAH took the opportunity to correct the MAH address in the SmPC."	
Erleada - apalutamide - EMEA/H/C/004452/II/0006 Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.8 of the SmPC to add interstitial lung disease to the list of adverse drug reactions (ADRs) with frequency unknown based on a safety review; the Package Leaflet is updated accordingly. The MAH also took the opportunity to update the PI in line with the QRD template 10.1." Request for Supplementary Information adopted	See agenda 9.1

on 05.06.2020.	
Gliolan - 5-aminolevulinic acid - EMEA/H/C/000744/II/0018/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Bruno Sepodes, "To update section 4.4 of the SmPC to add a warning (false positive and false negative fluorescence) following an analysis of the MAHs safety database. To update section 4.2 of the SmPC to exclude re-administration if surgery is delayed by less than 12 hours." Request for Supplementary Information adopted on 05.06.2020, 17.04.2020.	
Herceptin - trastuzumab - EMEA/H/C/000278/II/0160 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.7 of the SmPC in order to add "dizziness and somnolence" to the recommendations on the effects on the patient's ability to drive and use machines. Update of section 4.8 of the SmPC to remove Herpes zoster, Erysipelas, Cellulitis Common, Sepsis, Thinking abnormal, Ataxia, Paresis, Brain oedema, Pericarditis, Bradycardia and Hepatic failure as adverse drug reactions. An update of the frequencies of adverse reactions is proposed in accordance to a change in the company core datasheet (CDS) for Herceptin: Anaphylactic reaction and Anaphylactic shock is changed to frequency Rare, Wheezing is changed to frequency Uncommon, Pneumonitis is changed to frequency Uncommon and Palpitation is changed to frequency Common. The MAH is taking the opportunity to update section 2 of the Herceptin PL to ensure compliance with the guidance on Excipients in the Labelling and Package Leaflet of medicinal products for Human Use (SANTE 2017-11668). The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 17.04.2020.	
Infanrix hexa - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and Haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/000296/II/0275 GlaxoSmithkline Biologicals SA, Rapporteur:	Request for supplementary information adopted with a specific timetable.

Christophe Focke, "Update of sections 4.8 and 5.1 of the SmPC in relation to the frequency of adverse reactions somnolence and fatigue and to update the safety and immunogenicity information in infants and toddlers born to mothers vaccinated with dTpa during pregnancy; based on data generated from DTPA-048 and DTPA-049; these are phase IV, open-label, non-randomised, multicentre studies aimed to provide immunological responses to Infanrix hexa in terms of seroprotection status for diphtheria (D), tetanus (T), HBs antigen, inactivated poliovirus (IPV) and Haemophilus influenzae type b (Hib) antigens (PRP) and in terms of vaccine or booster responses to the pertussis antigens, 1 month after the last dose of the primary vaccination or the booster dose. The MAH took the opportunity to update the posology information in the package leaflet to align it with the SmPC. 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 09.07.2020.	
Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0016 ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update the safety information regarding the occurrence of neural tube defects with the DTG-containing regimens based on interim analysis from Tsepamo study. This is a birth outcomes surveillance study being conducted in Botswana that was designed to evaluate adverse birth outcomes by HIV status and antiretroviral regimen, and to determine if there is an increased risk of neural tube defects among infants exposed to efavirenz at conception. This surveillance system captures all antiretroviral exposure including dolutegavir. The SmPC is updated accordingly. The RMP is not submitted." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019, 14.11.2019.	See agenda 9.1
Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0027 ViiV Healthcare B.V., Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to	

add new information on resistance in vivo and clinical efficacy, based on final results from studies 201636 (SWORD-1) and 201637 (SWORD-2): Phase III, Randomized, Multicenter, Parallel-Group, Non-Inferiority Studies Evaluating the Efficacy, Safety, and Tolerability of Switching to Dolutegravir plus Rilpivirine from Current INSTI-, NNRTI-, or PI-Based Antiretroviral Regimen in HIV-1-Infected Adults who are Virologically Suppressed."	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0087/G Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from three interventional efficacy studies in non-small cell lung cancer; study KEYNOTE-407 listed as a PAES in the Annex II, study KEYNOTE-189 listed as a category 3 study in the RMP and KEYNOTE-021 (cohort A, C and G1) listed as a category 3 study in the RMP." Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kisplyx - lenvatinib - EMEA/H/C/004224/II/0035 Eisai GmbH, Rapporteur: Christophe Focke, "Submission of the final Clinical Study Report for Study E7080-J081-208 (Study 208), a Phase 2 Study of lenvatinib in Subjects with Advanced Thyroid Cancer."	
Lenvima - lenvatinib - EMEA/H/C/003727/II/0035/G Eisai GmbH, Rapporteur: Christophe Focke, "-Submission of non-clinical final report from study M14014: Antiproliferative Activities of Lenvatinib Mesilate and Sorafenib Tosylate in VEGF-Stimulated Growth of HUVECs (human umbilical vein endothelial cells), relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study M13015: Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in Human Papillary Thyroid Cancer Cell Line K1 Xenografts in Mice, relevant to the license's approved indications of differentiated thyroid	

cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study M13016: Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in Human Follicular Thyroid Cancer Cell Line RO82-W-1 Xenografts in Mice, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study W-20140845: Antiangiogenic Activity of Lenvatinib Mesilate and Sorafenib Tosylate in bFGF-Induced Matrigel Plug Assay in Athymic Mice, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application. -Submission of non-clinical final report from study on the Immuno-modulatory Activity of Lenvatinib Contributes to Antitumor Activity in the Hep1-6 Hepatocellular Carcinoma Model, relevant to the license's approved indications of differentiated thyroid cancer (DTC) and hepatocellular carcinoma (HCC) which were conducted since the approval of the initial Marketing Authorisation Application.”	
Lucentis - ranibizumab - EMEA/H/C/000715/II/0086 Novartis Europharm Limited, Rapporteur: Kristina Dunder, “C.I.11.b - Submission of the results of the second interim analysis (IA2) of the PAES study H2301E1”	
Mepsevii - vestronidase alfa - EMEA/H/C/004438/II/0014, Orphan Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, “Update of sections 4.8 and 5.1 of the SmPC following the assessment of final results from study UX003-CL202, a multicenter, multinational, open-label treatment, extension of study UX003-CL301 in subjects with MPS VII, previously submitted under Article 46 of Regulation (EC) No 1901/2006; the Package Leaflet is updated accordingly.	

In addition, the MAH took the opportunity to implement minor editorial changes in the Product Information." Request for Supplementary Information adopted on 11.06.2020.	
Nerlynx - neratinib - EMEA/H/C/004030/II/0014/G Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Submission of the final reports from a safety pharmacology study evaluating the potential cardiovascular toxicity of M3, a metabolite of neratinib maleate (report 20130869) and from a toxicology study evaluating the potential toxicity of M11, another metabolite of neratinib maleate (Report 20104291)." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0002 Daiichi Sankyo Europe GmbH, Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final report from phase 2 study (1002FDC-058) listed as a category 3 study in the RMP. This is a randomized, double-blind, parallel Group Study to evaluate the efficacy and safety of the FDC (bempedoic acid 180 mg + ezetimibe 10 mg) compared to ezetimibe and placebo in subjects with type 2 diabetes and elevated LDL-Cholesterol." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0002 Daiichi Sankyo Europe GmbH, Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final report from phase 2 study (1002FDC-058) listed as a category 3 study in the RMP. This is a randomized, double-blind, parallel Group Study to evaluate the efficacy and safety of the FDC (bempedoic acid 180 mg + ezetimibe 10 mg) compared to ezetimibe and placebo in subjects with type 2 diabetes and elevated LDL-Cholesterol." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
OFEV - nintedanib - EMEA/H/C/003821/II/0033, Orphan Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, "Update of SmPC sections 4.8 and 5.1 to include additional clinical information from an open-label extension trial	Request for supplementary information adopted with a specific timetable.

1199.33 (INPULSIS-ON)" Request for Supplementary Information adopted on 16.07.2020.	
OFEV - nintedanib - EMEA/H/C/003821/II/0034, Orphan Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, "Update of section 5.1 of the SmPC to include results of a double-blind, randomised, parallel-group trial to evaluate the efficacy and safety of Ofev co-administered with oral sildenafil, compared to treatment with Ofev alone (INSTAGE Trial)." Request for Supplementary Information adopted on 16.07.2020.	Request for supplementary information adopted with a specific timetable.
Ovitrelle - choriogonadotropin alfa - EMEA/H/C/000320/II/0081 Merck Europe B.V., Rapporteur: Paula Boudewina van Hennik, "Changes in sections 4.1, 4.2, 4.4 and 4.6 of the SmPC in order to update the terminology, in 4.3 to amend existing contraindications and in 4.8 to delete certain adverse drug reactions (ADRs) and add gastrointestinal ADRs with frequency common, with the aim to align the Product Information with similar text provided for other gonadotropin products. 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 and performed minor linguistic changes."	
Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0069 Merck Europe B.V., Rapporteur: Kirstine Moll Harboe, "Submission of immunogenicity results on anti-drug antibodies (ADAs) against follicle stimulating hormone (FSH) and luteinizing hormone (LH), which were measured using validated assays in the bioequivalence study designed to compare the bioavailability of the liquid formulation to the previously-approved freeze-dried formulation (study EMR200061-006), as agreed during the assessment of the line extension application EMEA/H/C/714/X/47 (EC Decision received on 8 May 2017)."	
Praxbind - idarucizumab - EMEA/H/C/003986/II/0020 Boehringer Ingelheim International GmbH, Rapporteur: Jan Mueller-Berghaus, "C.I.4	

Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update information on pediatrics based on final results from study 1321.7. This was single dose, open
label, uncontrolled, safety trial of intravenous administration of idarucizumab to paediatric patients enrolled from ongoing phase IIb/III clinical trials with dabigatran etexilate for the treatment and secondary prevention of venous thromboembolism listed as part of PIP (P46)."

Qutenza - capsaicin -
EMEA/H/C/000909/II/0049

Grunenthal GmbH, Rapporteur: Bruno Sepodes, "Update of section 4.8 of the SmPC in order to update the safety information on adverse reactions frequencies based on latest clinical data pooling; the Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version."
Request for Supplementary Information adopted on 14.05.2020, 19.03.2020.

Repatha - evolocumab -
EMEA/H/C/003766/II/0043

Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, "C.I.4,
Update of section 5.1 of the SmPC based on final results from study 20167869 (EVOPACS). It was a randomised, double-blind, placebo-controlled, multicenter study assessing the superiority of evolocumab vs. placebo administered during the acute phase of ACS (within 72 hours)."

Reyataz - atazanavir / atazanavir sulfate -
EMEA/H/C/000494/II/0129/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Grouped application:
- C.I.4 (Type IB) - Update of sections 4.3 and 4.5 of the SmPC to add a new contraindication and a new drug-drug interaction related to co-administration with lomitapide, based on recommendations already approved for lomitapide; the Package Leaflet is updated accordingly.
- C.I.4 (Type II) - Update of section 4.5 of the SmPC to add a new drug-drug interaction related to co-administration with direct oral anticoagulants (DOACs), to align with wording

approved for DOACs; the Package Leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update the PI in line with the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017 Rev.1) regarding sucrose content, remove boceprevir from section 4.5 of the SmPC and section 2 of the PL, bring the PI in line with the latest QRD template version 10.1 and update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 28.05.2020.	
Tafinlar - dabrafenib - EMEA/H/C/002604/II/0045 Novartis Europharm Limited, Rapporteur: Filip Josephson, "Submission of the final report from study DRB436A2107 listed as a category 3 study in the RMP. This is a phase I, open label, multicenter, single dose study to evaluate the pharmacokinetics of dabrafenib in healthy subjects with normal hepatic function and subjects with impaired hepatic function."	
Tafinlar - dabrafenib - EMEA/H/C/002604/II/0046 Novartis Europharm Limited, Rapporteur: Filip Josephson, "Submission of the final report from study DRB436A2106 listed as a category 3 study in the RMP. This is a phase I, open label, multicenter, single dose study to evaluate the pharmacokinetics of dabrafenib in healthy subjects with normal renal function and subjects with impaired renal function."	
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0036 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Submission of the final report from study GO28915 (OAK) listed as a category 3 study in the RMP. This is a Phase III, open-label multicenter, randomized study to investigate the efficacy and safety of atezolizumab (anti−PD-L1 antibody) compared with docetaxel in patients with NSCLC after failure with platinum-containing chemotherapy. In addition, the MAH submitted integrated analyses of the potential relationship of ADA and safety we based on studies IMvigor210, IMvigor211, OAK,	See agenda 9.1

POPLAR, IMpower150, IMpower130, IMpower131, IMpower132, IMpower133 and IMpassion130 as recommended by the CHMP." Request for Supplementary Information adopted on 12.03.2020.	
Tivicay - dolutegravir - EMEA/H/C/002753/II/0052 ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update the safety information regarding the occurrence of neural tube defects with the DTG-containing regimens based on interim analysis from Tsepamo study. This is a birth outcomes surveillance study being conducted in Botswana that was designed to evaluate adverse birth outcomes by HIV status and antiretroviral regimen, and to determine if there is an increased risk of neural tube defects among infants exposed to efavirenz at conception. This surveillance system captures all antiretroviral exposure including dolutegavir. The SmPC is updated accordingly. The RMP is not submitted." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019, 14.11.2019.	See agenda 9.1
Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0069 ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update the safety information regarding the occurrence of neural tube defects with the DTG-containing regimens based on interim analysis from Tsepamo study. This is a birth outcomes surveillance study being conducted in Botswana that was designed to evaluate adverse birth outcomes by HIV status and antiretroviral regimen, and to determine if there is an increased risk of neural tube defects among infants exposed to efavirenz at conception. This surveillance system captures all antiretroviral exposure including dolutegavir. The SmPC is updated accordingly. The RMP is not submitted." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019, 14.11.2019.	See agenda 9.1
Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0023 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of sections 4.4, 4.8, 5.1 and	

5.2 of the SmPC based on interim analysis data at Week 24 from study GS-US-320-4035. This is a Phase 2, open-label study evaluating the efficacy and safety of tenofovir alafenamide (TAF) in virologically suppressed chronic hepatitis B subjects with renal and/or hepatic impairment who switch from tenofovir disoproxil fumarate and/or other oral antiviral agents to TAF 25 mg once daily. Supportive safety and pharmacokinetic data are also provided from study GS-US-292-1825 (phase 3b trial in which Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide an fixed-dose TAF containing combination indicated for the treatment of HIV-1 infection, was evaluated in HIV-1 infected subjects with end stage renal disease). Study GS-US-320-4035 is included in the RMP version 4.2 under additional PhV activities." Request for Supplementary Information adopted on 07.05.2020, 06.02.2020.	
Vfend - voriconazole - EMEA/H/C/000387/II/0137/G Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, "Grouping of two type II variations: -to update section 4.4 of the SmPC in order to add a new warning on adrenal events, along with editorial changes to the paragraph and the abbreviation of severe cutaneous adverse reactions (SCARs), -to update section 4.5 of the SmPC in order to add drug-drug interaction information with naloxegol, ivacaftor and corticosteroids following PRAC request during the assessment of PSUR 18 (for corticosteroids) and the French National Agency for the Safety of Medicines and Health Products (ANSM) update of the French "Medical Interaction Thesaurus" (May 2018), where voriconazole is classified as a strong CYP3A4 inhibitor. In addition the MAH has taken the opportunity to update the information in the SmPC in line with the EU excipient guidance from October 2017 (SANTE-2017-11668) for sodium and cyclodextrin, to introduce a correction to the amount of sodium per vial for the IV presentations in sections 2. QUALITATIVE AND QUANTITATIVE COMPOSITION and 4.4 Special warnings and precautions for use of the SmPC. The Package Leaflet is updated accordingly.	

Following a recent discussion with EMA/EDQM; the MAH is also updating Annex IIIA Outer carton text for both iv presentations 16. INFORMATION IN BRAILLE to include: "Justification for not including Braille accepted." In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 14.05.2020.	
Zejula - niraparib - EMEA/H/C/004249/II/0020, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Bjorg Bolstad, "Update of section 4.8 of the SmPC in order to add hypersensitivity, psychiatric disorders and non-infectious pneumonitis to the list of adverse drug reactions (ADRs) with the frequency unknown based on safety evaluations; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 11.06.2020.	
Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0053 Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, "Update of sections 4.8 and 4.9 of the SmPC in order to add eosinophilic pneumonia and encephalopathy as adverse drug reactions (ADRs), with frequencies 'not known' and 'uncommon' respectively, based on a review of the MAH global safety database and literature. The package leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) clarified in section 4.8 of the SmPC that the ADRs agranulocytosis, neutropenia and eosinophilia have been identified post-marketing. Furthermore, the PI is brought in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
WS1749 AZILECT-EMEA/H/C/000574/WS1749/0084 **Rasagiline ratiopharm-EMEA/H/C/003957/WS1749/0016** Teva B.V., Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the final report from study TV1030-CNS-50024 listed as a category 3 study	Request for supplementary information adopted with a specific timetable.

in the RMP. This is a non-interventional retrospective cohort study which was conducted using the United States Medicare research database to assess the potential risk of melanoma associated with the use of rasagiline mesylate in patients with Parkinson's disease." Request for Supplementary Information adopted on 09.07.2020, 13.02.2020.	
WS1790 **OPDIVO-EMEA/H/C/003985/WS1790/0082** **Yervoy-EMEA/H/C/002213/WS1790/0078** Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.8 and 5.1 of the SmPC in order to include at least 5 years (60 months) of follow-up for all subjects from study CA209067. Updated efficacy data provided in this submission include overall survival (OS), progression-free survival (PFS) and objective response rate (ORR)." Request for Supplementary Information adopted on 05.06.2020.	
WS1842 **Aluvia-EMEA/H/W/000764/WS1842/0113** **Kaletra-EMEA/H/C/000368/WS1842/0185** **Norvir-EMEA/H/C/000127/WS1842/0158** AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to update the safety information for nephrolithiasis as an adverse reaction following an update to the Kaletra and Aluvia (lopinavir/ritonavir) and Norvir (ritonavir) Company Core Data Sheets (CCDS 0220). The Package Leaflet is updated accordingly. In addition, the MAH/SOH takes the opportunity to make additional changes in the PI in order to comply with the current QRD template and provide clarity to instructions contained in the Package Leaflet." Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1845 **Aluvia-EMEA/H/W/000764/WS1845/0114** **Kaletra-EMEA/H/C/000368/WS1845/0186** **Norvir-EMEA/H/C/000127/WS1845/0159** AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Jean-Michel Race, "C.I.4: Change in section 4.5 of the SmPCs to update the safety	

information and include information on the interaction with fostamatinib following an update to the Kaletra and Aluvia (lopinavir/ritonavir) and Norvir (ritonavir) Company Core Data Sheets (CCDS 0419). The Package Leaflets are updated accordingly."	
WS1846 **Vfend-EMEA/H/C/000387/WS1846/0138** Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC in order to include additional text regarding interactions between voriconazole and letermovir & tolvaptan in the interaction table. The Package Leaflet is updated accordingly." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1848 **DuoPlavin-EMEA/H/C/001143/WS1848/0057** **Iscover-EMEA/H/C/000175/WS1848/0143** **Plavix-EMEA/H/C/000174/WS1848/0141** sanofi-aventis groupe, Lead Rapporteur: Bruno Sepodes, "To update sections 4.4 and 4.5 of the SmPC to add drug-drug interaction information for rifampicin and clopidogrel based on a literature review and a review of the MAH pharmacovigilance database. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives and to update the SmPC for the excipient lactose in accordance with the Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use". The MAH also took the opportunity to update the product information regarding the standard term for the all aluminium unit-dose blisters."	

B.5.3. CHMP-PRAC assessed procedures

Bavencio - avelumab - EMEA/H/C/004338/II/0015 Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to change posology recommendations, amend an existing warning and add new ADRs with frequency uncommon regarding myasthenia gravis and myasthenic	

syndrome. The update results from an update of the Company Core Data Sheet (CCDS) based on the review of cases of myasthenia gravis/myasthenic syndrome. The Package Leaflet is updated accordingly. The RMP version 2.2 has also been submitted with the proposal to reclassify "Other immune-related events (myasthenic syndrome)" from an important potential risk to an important identified risk of "Other immune-related events (myasthenia gravis/myasthenic syndrome)"” Request for Supplementary Information adopted on 30.04.2020.	
Bortezomib Fresenius Kabi - bortezomib - EMEA/H/C/005074/II/0001/G Fresenius Kabi Deutschland GmbH, Generic, Generic of VELCADE, Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Amelia Cupelli"B.II.e.5.c - An updated RMP (version 2.0) is provided due to the addition of new presentations. B.II.e.5.a.1 - An updated RMP (version 2.0) is provided due to the addition of new presentations.” Request for Supplementary Information adopted on 28.05.2020, 26.03.2020.	
Desloratadine ratiopharm - desloratadine - EMEA/H/C/002404/II/0023/G ratiopharm GmbH, Generic, Generic of Aerius, Rapporteur: Koenraad Norga, PRAC Rapporteur: Laurence de Fays, "C.I.5.b - Change in the legal status of desloratadine ratiopharm from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' in view of the safety profile of desloratadine ratiopharm and the post-marketing experience already available with other medicinal products containing similar long acting histamine antagonists. The RMP version 1.0 has also been submitted. In addition, the MAH also took the opportunity to bring the PI in line with the latest QRD template (version 10.1), to update the list of local representatives in the package leaflet and to make editorial changes. C.I.6.b - To delete the therapeutic indication in adolescents aged 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria. Section 4.1 of the SmPC and section 1 of the PL are updated	

accordingly." Request for Supplementary Information adopted on 26.03.2020.	
Firmagon - degarelix - EMEA/H/C/000986/II/0037 Ferring Pharmaceuticals A/S, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "C.I.11.b update of Annex II to revise risk minimisation measures based on previous and a newly submitted study. As a consequence, the RMP is updated accordingly. The MAH took the occasion to transfer to GVP V revision 2 of the RMP, to align the PI to QRD template v.10.1 and propose combination of different strengths." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 14.05.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fortacin - lidocaine / prilocaine - EMEA/H/C/002693/II/0030 Recordati Ireland Ltd, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, "Change in the legal status of Fortacin from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' in view of the safety profile of Fortacin, the post-marketing experience already available with other medicinal products containing amide local anaesthetics and in view of making the product more accessible to the target population. Furthermore, the PI is being brought in line with the latest QRD template (version 10.1). The RMP version 3.1 has also been submitted." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.	
Kanuma - sebelipase alfa - EMEA/H/C/004004/II/0026/G, Orphan Alexion Europe SAS, Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, "Grouping consisting of the following variations: - Update of sections 4.2, 4.4, 4.8 and 5.1 of the Summary of Product Characteristics (SmPC) in order to update the clinical information based on the pooled safety and efficacy analysis of already submitted studies (Studies LAL-CL04, LAL-CL03, LAL-CL06, LAL-CL08 and LAL-CL02) and updated population PK analyses in children and adults. The Package Leaflet has been	

amended accordingly. The ATC code has been added to the SmPC. The RMP version 4 has also been submitted. Annex II is also updated to remove the obligation related to the provision of study LAL-CL08. - Submission of the final report from study LAL-EA01 An open-label study with sebelipase alfa (1 mg/kg every other week for up to 78 weeks or until drug commercialization) in United States (US) patients who did not otherwise qualify for an active sebelipase alfa trial (expanded access protocol)" Request for Supplementary Information adopted on 26.03.2020.	
Myalepta - metreleptin - EMEA/H/C/004218/II/0012, Orphan Amryt Pharmaceuticals DAC, Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.4 of the SmPC in order to add a new warning on the risk of autoimmune disease following exposure to metreleptin; the Package Leaflet and the key elements to be included in the Guide/training material for healthcare professionals are updated accordingly. The RMP version 2.0 has also been submitted." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/II/0049 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.8 of the SmPC with the safety data and section 5.1 with the (secondary) efficacy data from the Phase 3, open-label, rollover study for Studies 109 and Study 011 Part B designed to evaluate the long-term safety and tolerability of Orkambi treatment for 96 weeks in patients with cystic fibrosis, 6 years of age and older, homozygous for F508del. The MAH also took the opportunity to include minor changes to section 4.5 of the Granules SmPC and sections 4.8 and 5.2 of the Tablets and Granules SmPC which were considered acceptable by CHMP. In addition, the RMP version 8.0 is acceptable." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 11.06.2020, 30.01.2020, 31.10.2019,	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

05.09.2019.	
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/II/0055 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.8 of the SmPC with safety data in children from the Phase 3, open-label, multicentre rollover study for Study 115 Part B, designed to evaluate long-term safety of Orkambi treatment for 96 weeks in patients with cystic fibrosis, 2 years of age and older, homozygous for F508del. The MAH also took the opportunity to update the SmPC in line with the latest version of the QRD template v10.1. The Package Leaflet is updated accordingly. In addition, the RMP version 8.0 is acceptable." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0161/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "C.I.4: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to amend an existing warning on haemolytic anaemia and to update safety information based on final results from study IgPro10_5003 listed as a category 3 study in the RMP; this is an observational hospital-based cohort study in the US to evaluate Privigen use and haemolytic anaemia in adults and children and the Privigen safety profile in children with CIDP; the Package Leaflet is updated accordingly. C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update to the list of adverse drug reactions based on final results from study IgPro10_3004; this is a Prospective Open-Label Single-Arm Study of the Pharmacokinetics and Safety of Intravenous IgPro10 in Japanese Subjects with Primary Immunodeficiency. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to align the SmPC with the EU Core SmPC for IVIG, to update the local representative for Bulgaria in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 09.07.2020.	
Protopic - tacrolimus - EMEA/H/C/000374/II/0083/G LEO Pharma A/S, Rapporteur: Peter Kiely, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC following results from two non-interventional post-authorisation safety studies: JOELLE study (Joint European Longitudinal Lymphoma and skin cancer Evaluation, category 3) and APPLES study (a prospective paediatric longitudinal evaluation to assess the long-term safety of tacrolimus ointment for the treatment of atopic dermatitis, category 3). The Package Leaflet is updated accordingly. The RMP version 15.1. has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 11.06.2020, 16.01.2020.	
RoActemra - tocilizumab - EMEA/H/C/000955/II/0097 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 4.2 of the SmPC for RoActemra 20 mg/mL concentrate for solution for infusion in order to amend the existing recommendations for monitoring of laboratory abnormalities in systemic juvenile idiopathic arthritis (sJIA) patients based on final results from study WA28029 (ARTHUR) listed as a category 3 study in the RMP; this is a Phase IV study to evaluate decreased dose frequency in sJIA who experience laboratory abnormalities during treatment with tocilizumab. The submission of the final study report for study WA28029 (ARTHUR) fulfils requirements of Article 46 of the paediatric regulation. The RMP version 26.0 has also been submitted. Changes to the RMP reflect the completion of study WA29029 (ARTHUR) and study WA22480 (ARTIS) which was assessed as part of variation EMEA/H/C/000955/II/0094."	
Trumenba - meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0027/G Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel	Request for supplementary information adopted with a specific timetable.

Dogné, "C.I.11.b- To update the RMP for Trumemba to version 4.0 to provide a revised protocol outline for study B1971060 in immunocompromised individuals: Although the study was originally designed to evaluate 3 doses of Trumenba administered on a 0-, 2-, and 6-month schedule, the MAH is now proposing a 2-dose regimen administered on 0- and 6-month schedule. C.I.11.b- To submit the protocol outline for the co-administration study (C3511006). The MAH is proposing that the commitment to conduct a co-administration study with Trumenba may be met by a study of the MAH's candidate pentavalent meningococcal vaccine (which contains Trumenba) co-administered with MMR and PnC vaccines." Request for Supplementary Information adopted on 09.07.2020.	
WS1664 **Keppra-EMEA/H/C/000277/WS1664/0187** UCB Pharma S.A., Lead Rapporteur: Koenraad Norga, Lead PRAC Rapporteur: Laurence de Fays, "Update of section 4.2 of the SmPC to recommend the same dosing for monotherapy and adjunctive therapy based on data from modelling and simulation project. The Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted. The MAH took the opportunity to move Braille to another box section and to review and adapt the German PI according to the current QRD template." Request for Supplementary Information adopted on 30.04.2020.	
WS1844 **Edistride-EMEA/H/C/004161/WS1844/0039** **Forxiga-EMEA/H/C/002322/WS1844/0057** AstraZeneca AB, Lead 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 minimization 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"

B.5.4. PRAC assessed procedures

PRAC Led

Ceplene - histamine dihydrochloride - EMEA/H/C/000796/II/0040

Noventia Pharma Srl, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of an updated RMP version 8.1 in order to include the information about the termination of the non-interventional study (NIS) of category 3 Ceplene-3290 and of the PAES Ceplene Cohort Study 3306.
-RMP has been adapted to the new RMP template (GVP V rev.2, mandatory since 31 March 2018).
-The safety concerns (Part II Modules SVII and SVIII, Part V, Part VI) have been changed. A new important potential risk, named "Drug effect decreased as a consequence of drug interaction", has been added to the list of safety concerns.
-Part III and Part IV have been updated to include information about the termination of the non-interventional study (NIS) of category 3 Ceplene-3290 and of the PAES Ceplene Cohort Study 3306.
-updated information about the other ongoing studies included in the Pharmacovigilance Plan, "Ceplene-3292" and "Ceplene-3298", have been included in Part III and related parts/modules.
-Details about the Marketing Authorization Holder have been updated accordingly upon implementation of transfer from previous Marketing Authorisation Holder, Meda AB, (positive decision received 08 December 2017)"
Request for Supplementary Information adopted on 17.04.2020.

PRAC Led **Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/ II/0025** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final clinical study report (CSR) for the Duavive Non-Interventional EU Drug Utilisation Study (DUS) - Study B2311061. This final CSR relates to the Post-Authorisation Measure MEA 003." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Entyvio - vedolizumab - EMEA/H/C/002782/II/0050** Takeda Pharma A/S, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Update of the RMP with regards to the measures to evaluate effectiveness of additional risk minimization measures (educational material) and addition of the completion date of the interim report for the post approval safety study (PASS) MLN00020401." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Fampyra - fampridine - EMEA/H/C/002097/II/0046** Biogen Netherlands B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update of sections 4.2, 4.3, 4.4, 4.8, 4.9 and 5.2 of the SmPC in order to remove the contraindication for patients with mild renal impairment, add a warning for patients with mild renal impairment, update the frequency of seizure to uncommon, add vertigo with frequency common, add dizziness in section 4.9 to reflect safety information based on from final results of study 218MS401 (LIBERATE) listed as category 3 study in the RMP; study 218MS401 was a Phase IV prospective, noninterventional, multicentre, observational study in MS patients who began Fampyra treatment in the post-marketing setting. The Package Leaflet is updated accordingly. An updated RMP version 13.1 has also been submitted to align with the RMP Rev.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

2 template and to remove all safety concerns; some continue to be monitored in PSUSA safety specifications." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 13.02.2020.	
PRAC Led **Forsteo - teriparatide - EMEA/H/C/000425/II/0054** Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau, "submission of the concluding report of the European Union (EU) component of the post-authorisation safety study (PASS): Study B3D-MC-GHBX(2.1) of Forsteo (teriparatide)." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Lemtrada - alemtuzumab - EMEA/H/C/003718/II/0031** Sanofi Belgium, Duplicate, Duplicate of Lemtrada (WD), Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Kirstine Moll Harboe, "Submission of an update of the RMP (version 7.2) incorporating all amendments and additional activities defined in the Article 20 referral procedure (EMEA/H/A-20/1483/C/3718/0028)." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Lucentis - ranibizumab - EMEA/H/C/000715/II/0085** Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the results of the non-interventional post-approval efficacy and safety study OBTAIN" Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0079** Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau,	Request for supplementary information adopted with a specific timetable.

"Submission of the final report from study ALGMYC07390, Prevalence of immunology testing in patients treated with alglucosidase alfa with significant hypersensitivity/anaphylactic reactions (MEA 053 resulting from variation EMEA/H/C/000636/II/0052) to test the effectiveness of the approved Safety Information Packet (SIP)." Request for Supplementary Information adopted on 09.07.2020, 12.03.2020.	
PRAC Led **Neulasta - pegfilgrastim - EMEA/H/C/000420/II/0113** Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from study 20160176 listed as a category 3 study in the RMP. This is a retrospective cohort study with primary outcome the time from index date to diagnosis of MDS or AML (safety)." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Olumiant - baricitinib - EMEA/H/C/004085/II/0017** Eli Lilly Nederland B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "C.I.13: Submission of the final report from study I4V-MC-B010 "Rheumatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant" listed as a category 3 study in the RMP. This observational study was a multi-national cross-sectional survey. The RMP version 9.2 has also been submitted. In addition to the removal of this study from the RMP, three safety concerns (Use in combination with bDMARDs or with other JAK inhibitors, Use in patients with severe hepatic impairment, Effect on fertility, on pregnancy and the foetus, and use in breastfeeding) previously classified as Missing Information, have been removed from the list of safety concerns as per Procedure EMEA/H/C/004085/II/006." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.

PRAC Led **Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0031** GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, PRAC-CHMP liaison: Andrea Laslop, "C.I.11.b To update the RMP for Shingrix to version 3.0 in order to present the outcome of the MAH assessment with respect to a potential increased risk of exacerbation of pre-existing pIMDs following vaccination with Shingrix. This change has been agreed by CHMP in the outcome of the Scientific Advice The implementation of the change is further substantiated by new additional data on post-hoc analyses and spontaneous reports of potential exacerbations of pIMDS from a worldwide safety database submitted by the MAH." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Siklos - hydroxycarbamide - EMEA/H/C/000689/II/0045** Addmedica S.A.S., Rapporteur: Koenraad Norga, PRAC Rapporteur: Laurence de Fays, PRAC-CHMP liaison: Christophe Focke, "Update of sections 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 and 5.1 of the SmPC as a consequence of the final study results of the non-interventional cohort study ESCORT-HU (European Sickle Cell Disease Cohort – Hydroxyurea) and harmonisation with other HU products. In addition, Annex II is amended to revise the information on the physician information pack and to add that pharmacists should receive targeted communication on the risk of medication error due to the confusion between the two strengths where both are available. The PIL is updated in accordance with the changes to the SmPC. The RMP (v. 20 revision 1) is updated to reflect the finalisation of the ESCORT-HU study and modifications on the risk minimisation measures." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Trulicity - dulaglutide - EMEA/H/C/002825/II/0048**	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "Submission of the final study report from Study B010, investigating the utilisation of dulaglutide in European countries: A cross-sectional, multi-country and multi-source drug utilisation study using electronic health record databases. Study B010 is listed as a category 3 study in the RMP (MEA 001). An updated RMP version 5.2 was agreed during the procedure." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 12.03.2020.	recommendation.
PRAC Led **Trulicity - dulaglutide - EMEA/H/C/002825/II/0051** Eli Lilly Nederland B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "Submission of the final study report for the PASS category 3 dulaglutide drug utilisation study B009: a multi-database collaborative research program of observational studies to monitor the utilisation and safety of dulaglutide in the EU (ref. PAM MEA 002-002.5). An updated RMP version 6.1 was provided as part of the application." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Yervoy - ipilimumab - EMEA/H/C/002213/II/0080** Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 28.0 in order to propose the discontinuation of the Healthcare Professional Adverse Reaction Management Guide as an additional risk minimization measure described in the RMP Annex 6 and in the Product Information Annex II.D. The RMP and the annex II.D are updated accordingly. The MAH also took the occasion to align the PI to the latest QRD version 10.1 and to include standard text on sodium excipient information." Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1589**	Request for supplementary information adopted with a specific timetable.

Incruse Ellipta-EMEA/H/C/002809/ WS1589/0029 **Rolufta Ellipta-EMEA/H/C/004654/ WS1589/0014** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "C.I.11.b. Submission of an updated RMP version 7.1 following completion of a category 3 study (WWE117397) "A Post-authorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting". In addition, updates are included relating to the Category 1 study 201038 "A Post Authorisation Safety Observational Cohort Study to quantify the incidence of selected cardiovascular and cerebrovascular events in COPD patients using inhaled UMEC/VI combination or inhaled UMEC versus Tiotropium" (EMEA/H/C/PSA/S/0032.3). The RMP is also updated to align with the Guidance on the Good Pharmacovigilance Practice (GVP) Module V - Risk management systems Revision 2 guidelines." Request for Supplementary Information adopted on 09.07.2020.	
PRAC Led **WS1761** **Anoro Ellipta-EMEA/H/C/002751/ WS1761/0029** **Incruse Ellipta-EMEA/H/C/002809/ WS1761/0028** **Laventair Ellipta-EMEA/H/C/003754/ WS1761/0032** **Rolufta Ellipta-EMEA/H/C/004654/ WS1761/0013** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "Submission of the final report from study WWE117397 listed as a category 3 study in the RMP. This was a retrospective longitudinal non-interventional observational study of new users of inhaled umeclidinium/vilanterol (UMEC/VI) or new users of inhaled umeclidinium (UMEC) or new users or long-acting bronchodilators (LABD) in the primary care setting."	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 12.03.2020.	
PRAC Led **WS1794** **Brimica Genuair-EMEA/H/C/003969/ WS1794/0029** **Duaklir Genuair-EMEA/H/C/003745/ WS1794/0029** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra, Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from study D6570R00002 listed as a category 3 study in the RMP. This is a descriptive, non-interventional, multinational European cohort study of new users of aclidinium, aclidinium/formoterol, and other selected COPD medications. The RMP version 5.0 has also been submitted. As a consequence, the following safety concerns, listed as missing information in the RMP, are proposed to be removed: 'safety in patients with hepatic or severe renal impairment', 'safety in patients with benign hyperplasia or urinary retention' and 'use in pregnancy or lactation'." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS1795** **Bretaris Genuair-EMEA/H/C/002706/ WS1795/0043** **Eklira Genuair-EMEA/H/C/002211/ WS1795/0043** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra, Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from study D6570R00002 listed as a category 3 study in the RMP. This is a descriptive, non-interventional, multinational European cohort study of new users of aclidinium, aclidinium/formoterol, and other selected COPD medications. The RMP version 5.0 has also been submitted. As a consequence, the following safety concerns, listed as missing information in the RMP, are proposed to be removed: 'safety in patients with hepatic or severe renal impairment', 'safety in patients with benign hyperplasia or urinary retention' and 'use in	Request for supplementary information adopted with a specific timetable.

pregnancy or lactation'." Request for Supplementary Information adopted on 09.07.2020.	
PRAC Led **WS1805** **Advagraf-EMEA/H/C/000712/WS1805/0057** **Modigraf-EMEA/H/C/000954/WS1805/0035** Astellas Pharma Europe B.V., Lead Rapporteur: Jayne Crowe, Lead PRAC Rapporteur: Ronan Grimes, PRAC-CHMP liaison: Jayne Crowe, "Submission of an updated RMP version 3 in order to add a non-interventional post-authorization safety study related to the safety concerns of use during pregnancy and use during lactation. The two important potential risks, 'Exchangeability between the granule and capsule formulations of tacrolimus' for Modigraf and 'If administered accidentally either arterially or perivascularly, the reconstituted solution may cause irritation at the injection site' for Prograf concentrate for solution for infusion, are combined into the important identified risk 'Medication errors'. The RMP is being brought to EU RMP template revision 2." Request for Supplementary Information adopted on 09.07.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS1850** **Anoro Ellipta-EMEA/H/C/002751/WS1850/0030** **Laventair Ellipta-EMEA/H/C/003754/WS1850/0033** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Peter Kiely, Lead PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Daniela Melchiorri, "To update the RMP completion of study WWE117397 "A Post-authorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting." As part of the assessment of EMEA/H/C/WS1761 the MAH was requested to update the RMP. In addition, the MAH has amendment the RMP with the study 201038 "A Post authorisation Safety Observational Cohort Study to quantify the incidence of selected cardiovascular and cerebrovascular events in COPD patients using	

inhaled UMEC/VI combination or inhaled UMEC versus Tiotropium" as approved during procedure EMEA/H/C/PSA/S/0032.3."

B.5.5. CHMP-CAT assessed procedures

Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0025, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

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

WS1796/G **Aflunov-EMEA/H/C/002094/WS1796/0059/G** **Foclivia-EMEA/H/C/001208/WS1796/0054/G** Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri Request for Supplementary Information adopted on 02.07.2020.	Request for supplementary information adopted with a specific timetable.
WS1806 **Juluca-EMEA/H/C/004427/WS1806/0026** **Tivicay-EMEA/H/C/002753/WS1806/0060** **Triumeq-EMEA/H/C/002754/WS1806/0081** ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1809/G **Fluenz Tetra-EMEA/H/C/002617/WS1809/0099/G** **Pandemic influenza vaccine H5N1 AstraZeneca-EMEA/H/C/003963/WS1809/0033/G** AstraZeneca AB, Lead Rapporteur: Christophe Focke Opinion adopted on 09.07.2020.	Positive Opinion adopted by consensus on 09.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1812 **Infanrix hexa-EMEA/H/C/000296/WS1812/0277** GlaxoSmithkline Biologicals SA, Lead	

Rapporteur: Christophe Focke	
WS1816 **Nuwiq-EMEA/H/C/002813/WS1816/0035** **Vihuma-EMEA/H/C/004459/WS1816/0017** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 02.07.2020. Request for Supplementary Information adopted on 28.05.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1825 **Segluromet-EMEA/H/C/004314/WS1825/0011** **Steglatro-EMEA/H/C/004315/WS1825/0012** **Steglujan-EMEA/H/C/004313/WS1825/0014** Merck Sharp & Dohme B.V., Lead Rapporteur: Kristina Dunder, "To update section 4.4 of the SmPC and section 2 of the Package Leaflet 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" for sodium."	
WS1827 **Keppra-EMEA/H/C/000277/WS1827/0188** UCB Pharma S.A., Lead Rapporteur: Koenraad Norga, "To update the PI following outcome of LEG-087. Section 4.4 of the SmPC: Special warnings and precautions for use was updated as follows: - Addition of warning "seizure worsening" Section 4.8 Undesirable effects was updated as follows: - Addition of ADR "seizures aggravated" The PL was also updated accordingly. The requested worksharing procedure proposed amendments to the Summary of Product Characteristics and Package Leaflet."	
WS1829 **Aldurazyme-EMEA/H/C/000477/WS1829/0076** **Evoltra-EMEA/H/C/000613/WS1829/0070** **Fasturtec-EMEA/H/C/000331/WS1829/0059** **Rilutek-EMEA/H/C/000109/WS1829/0064** **Zaltrap-EMEA/H/C/002532/WS1829/0057** sanofi-aventis groupe, Lead Rapporteur: Filip Josephson, "To update the product information	

with respect to the excipient Sodium 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). The Product Information was also brought in line with the latest QRD template. Finally, the MAH took the opportunity to implement an update of the phone number for the local representative for Italy for 3 ZALTRAP, EVOLTRA and FASTURTEC.”	
WS1835 **Glyxambi-EMEA/H/C/003833/WS1835/0030** **Jentadueto-EMEA/H/C/002279/WS1835/0056** **Trajenta-EMEA/H/C/002110/WS1835/0042** Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1839/G **Hexacima-EMEA/H/C/002702/WS1839/0103/G** **Hexaxim-EMEA/H/W/002495/WS1839/0108/G** **Hexyon-EMEA/H/C/002796/WS1839/0107/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	
WS1841 **Ryzodeg-EMEA/H/C/002499/WS1841/0039** **Tresiba-EMEA/H/C/002498/WS1841/0045** **Xultophy-EMEA/H/C/002647/WS1841/0036** Novo Nordisk A/S, Lead Rapporteur: Kristina Dunder Opinion adopted on 02.07.2020.	Positive Opinion adopted by consensus on 02.07.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1843/G **Ebymect-EMEA/H/C/004162/WS1843/0048/G** **Xigduo-EMEA/H/C/002672/WS1843/0058/G** AstraZeneca AB, Lead Rapporteur: Kristina Dunder	
WS1847 **Nuwiq-EMEA/H/C/002813/WS1847/0036**	

Vihuma-EMEA/H/C/004459/WS1847/0018 Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus, "To adapt SmPC, labelling and package leaflet and Annex II according to the currently valid Core SmPC guideline for human plasma derived and recombinant coagulation factor VIII products rev. 3 (EMA/CHMP/BPWP/1619/1999 Rev. 3). Moreover, the MAH took the opportunity to align the PI to QRD template version 10.1. In addition, more minor linguistic amendments like editorial changes in wording, typographical errors or punctuation mistakes were performed. Finally, section 4.4 of the SmPC and the PIL were updated in relation to sodium content following the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668)."	
WS1855/G **Bretaris Genuair-EMEA/H/C/002706/WS1855/0044/G** **Eklira Genuair-EMEA/H/C/002211/WS1855/0044/G** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra	
WS1856/G **Brimica Genuair-EMEA/H/C/003969/WS1856/0030/G** **Duaklir Genuair-EMEA/H/C/003745/WS1856/0030/G** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra	
WS1860 **Aflunov-EMEA/H/C/002094/WS1860/0061** **Foclivia-EMEA/H/C/001208/WS1860/0057** Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri	

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

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0042, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Update of section 4.2 of the SmPC to	The MAH withdrew the procedure on 13.07.2020.

update the posology by expanding the once weekly routine prophylaxis regimen of IDELVION from 35-to 50 IU/kg to 25- to 50 IU/kg."	

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

abiraterone acetate - EMEA/H/C/005649 Treatment of prostate cancer in adult men	
lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731, Orphan, ATMP Celgene Europe BV, treatment of large B-cell lymphoma, diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B)	**Accelerated review**
dabigatran etexilate - EMEA/H/C/005639 prevention of venous thromboembolic events	
imatinib - EMEA/H/C/005595 treatment of Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML), Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), myelodysplastic/myeloproliferative diseases (MDS/MPD), hypereosinophilic syndrome (HES), eosinophilic leukaemia (CEL), Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST), and unresectable dermatofibrosarcoma protuberans (DFSP)	
setmelanotide - EMEA/H/C/005089, Orphan TMC Pharma (EU) Limited, Setmelanotide is indicated for the treatment of obesity and the control of hunger associated with deficiencies in the leptin-melanocortin pathway in patients 6 years of age or older	**Accelerated review**

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

Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0026 Eurocept International B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Extension application to introduce a new pharmaceutical form associated with new strength (350 mg/ml oral solution). The RMP (version 0.1) is updated in accordance."
Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0028 Eurocept International B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 0.1) is updated in accordance."

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

Trimbow - beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium - EMEA/H/C/004257/X/0008/G Chiesi Farmaceutici S.p.A., Rapporteur: Janet Koenig, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Jan Neuhauser, "Extension application to introduce a new strength (172 µg / 5 µg / 9 µg) grouped with a type II variation (C.I.6.a) to add a new indication (asthma). The RMP (version 6.1) is updated in accordance." List of Questions adopted on 26.03.2020. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)
icosapent ethyl - EMEA/H/C/005398 indicated to reduce cardiovascular risk as an adjunct to statin therapy. List of Questions adopted on 26.03.2020.
baloxavir marboxil - EMEA/H/C/004974 Treatment of influenza in patients aged 12 and above, including patients at high risk of developing influenza-related complications and for post-exposure prophylaxis of influenza in individuals aged 12

List of Questions adopted on 26.03.2020.

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

Qarziba - dinutuximab beta -
EMEA/H/C/003918/S/0022, Orphan
EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

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

Alprolix - eftrenonacog alfa -
EMEA/H/C/004142/R/0032, Orphan
Swedish Orphan Biovitrum AB (publ), Rapporteur: Andrea Laslop, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Brigitte Keller-Stanislawski

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

Empliciti - elotuzumab -
EMEA/H/C/003967/R/0024
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Brigitte Keller-Stanislawski

Lonsurf - trifluridine / tipiracil -
EMEA/H/C/003897/R/0020
Les Laboratoires Servier, Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin

Neofordex - dexamethasone -
EMEA/H/C/004071/R/0016
Laboratoires CTRS, Rapporteur: Ondřej Slanař, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Tiphaine Vaillant

OCALIVA - obeticholic acid -
EMEA/H/C/004093/R/0023, Orphan
Intercept Pharma International Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Liana Gross-Martirosyan

Polivy - polatuzumab vedotin -
EMEA/H/C/004870/R/0003, Orphan

Roche Registration GmbH, Rapporteur: Alexandre Moreau, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Annika Folin

Taltz - ixekizumab - EMEA/H/C/003943/R/0039
Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Brigitte Keller-Stanislawski

Uptravi - selexipag - EMEA/H/C/003774/R/0030
Janssen-Cilag International N.V., Rapporteur: Martina Weise, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Adrien Inoubli

Wakix - pitolisant - EMEA/H/C/002616/R/0024, Orphan
Bioprojet Pharma, Rapporteur: Alexandre Moreau, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka

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

Benlysta - belimumab - EMEA/H/C/002015/II/0080
GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "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."

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0091
Merck Sharp & Dohme B.V., Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "C.I.6 -Extension of indication to include first-line treatment of unresectable or metastatic microsatellite instability-high (MSI H) or mismatch repair deficient (dMMR) colorectal cancer in adults for Keytruda based on the results from KEYNOTE-177 (an international, randomised, open-label Phase 3 trial of pembrolizumab versus chemotherapy in MSI-H

or dMMR Stage IV Colorectal Carcinoma). As a consequence, sections 4.1, 4.2, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, a minor correction has been made in section 4.4, "Immune related endocrinopathies" subsection. Version 29.1 of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

AJOVY - fremanezumab - EMEA/H/C/004833/II/0011 TEVA GmbH, Rapporteur: Jan Mueller-Berghaus
Bavencio - avelumab - EMEA/H/C/004338/II/0020/G Merck Europe B.V., Rapporteur: Filip Josephson
CRYSVITA - burosumab - EMEA/H/C/004275/II/0017, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder
Dukoral - cholera vaccine (inactivated, oral) - EMEA/H/C/000476/II/0062/G Valneva Sweden AB, Rapporteur: Kristina Dunder
Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004250/II/0019 Zentiva k.s., Generic, Generic of Atripla, Rapporteur: Tomas Radimersky
Eylea - aflibercept - EMEA/H/C/002392/II/0062/G Bayer AG, Rapporteur: Alexandre Moreau
Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0002 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Gardasil - human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0086 MSD Vaccins, Rapporteur: Kristina Dunder
Herzuma - trastuzumab - EMEA/H/C/002575/II/0031 Celltrion Healthcare Hungary Kft., Rapporteur:

Jan Mueller-Berghaus

Idacio - adalimumab -
EMEA/H/C/004475/II/0006/G
Fresenius Kabi Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege

IDELVION - albutrepenonacog alfa -
EMEA/H/C/003955/II/0044/G, Orphan
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Imraldi - adalimumab -
EMEA/H/C/004279/II/0037/G
Samsung Bioepis NL B.V., Rapporteur: Outi Mäki-Ikola

IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) -
EMEA/H/C/002596/II/0050
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

Invokana - canagliflozin -
EMEA/H/C/002649/II/0052/G
Janssen-Cilag International NV, Rapporteur: Martina Weise

LIBTAYO - cemiplimab -
EMEA/H/C/004844/II/0010/G
Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Sinan B. Sarac

LUTATHERA - lutetium (177Lu) oxodotreotide -
EMEA/H/C/004123/II/0021/G, Orphan
Advanced Accelerator Applications, Rapporteur: Janet Koenig

MabThera - rituximab -
EMEA/H/C/000165/II/0176
Roche Registration GmbH, Rapporteur: Sinan B. Sarac

Nepexto - etanercept -
EMEA/H/C/004711/II/0002
Mylan IRE Healthcare Limited, Rapporteur: Martina Weise

Oncaspar - pegaspargase -
EMEA/H/C/003789/II/0035
Les Laboratoires Servier, Rapporteur: Alexandre Moreau

Ondexxya - andexanet alfa -
EMEA/H/C/004108/II/0012/G

Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus

Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0071
Merck Europe B.V., Rapporteur: Kirstine Moll Harboe

Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0002/G, Orphan
Roche Registration GmbH, Rapporteur: Alexandre Moreau

Posaconazole Accord - posaconazole - EMEA/H/C/005005/II/0002
Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Kolbeinn Gudmundsson

Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0164
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Repatha - evolocumab - EMEA/H/C/003766/II/0044
Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege

Simponi - golimumab - EMEA/H/C/000992/II/0095
Janssen Biologics B.V., Rapporteur: Kristina Dunder

Strensiq - asfotase alfa - EMEA/H/C/003794/II/0046, Orphan
Alexion Europe SAS, Rapporteur: Daniela Melchiorri

Trepulmix - treprostinil sodium - EMEA/H/C/005207/II/0002/G, Orphan
SciPharm Sarl, Rapporteur: Johann Lodewijk Hillege

Trogarzo - ibalizumab - EMEA/H/C/004961/II/0008
Theratechnologies Europe Limited, Rapporteur: Johann Lodewijk Hillege

Yellox - bromfenac - EMEA/H/C/001198/II/0025
Bausch Health Ireland Limited, Rapporteur: Kirstine Moll Harboe

WS1838
Infanrix hexa-EMEA/H/C/000296/ WS1838/0279

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1865
Levemir-EMEA/H/C/000528/WS1865/0099
Ryzodeg-EMEA/H/C/002499/WS1865/0040
Tresiba-EMEA/H/C/002498/WS1865/0046
Xultophy-EMEA/H/C/002647/WS1865/0037
Novo Nordisk A/S, Lead Rapporteur: Kristina Dunder

WS1866
Actraphane-EMEA/H/C/000427/WS1866/0084
Actrapid-EMEA/H/C/000424/WS1866/0077
Insulatard-EMEA/H/C/000441/WS1866/0082
Mixtard-EMEA/H/C/000428/WS1866/0085
Protaphane-EMEA/H/C/000442/WS1866/0081
Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe

WS1884
Nuwiq-EMEA/H/C/002813/WS1884/0037
Vihuma-EMEA/H/C/004459/WS1884/0019
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS1888/G
Blitzima-EMEA/H/C/004723/WS1888/0033/G
Ritemvia-EMEA/H/C/004725/WS1888/0033/G
Truxima-EMEA/H/C/004112/WS1888/0036/G
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

WS1889/G
M-M-RVAXPRO-EMEA/H/C/000604/WS1889/0101/G
ProQuad-EMEA/H/C/000622/WS1889/0141/G
MSD Vaccins, Lead Rapporteur: Jan Mueller-Berghaus

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

Abilify - aripiprazole - EMEA/H/C/000471/II/0136/G Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of the product information and the Company Core Data Sheet (CCDS) due to new safety data. The applicant used the opportunity to revise the wording for "Akathesia" in the package leaflet for a better differentiation between akathisia and restless leg syndrome (adaption to Abilify Maintena)."	
Abilify Maintena - aripiprazole - EMEA/H/C/002755/II/0037 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "to update the product information with "DRESS" as new identified ADR in section 4.8 of the SmPC and subsequently in section 4 of the package leaflet according to the current CCDS version."	
Benlysta - belimumab - EMEA/H/C/002015/II/0081 GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to correct the result for the other efficacy endpoint of time to first severe flare over 52 weeks for the clinical study BEL114055 conducted in paediatric patients. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Constella - linaclotide - EMEA/H/C/002490/II/0049 Allergan Pharmaceuticals International Limited, Rapporteur: Martina Weise, "Update of section 4.6 of the SmPC based on the final results of Lactation study 1915-7/LIN-PK-01 listed as a category 3 study in the RMP; this is an open-label, multiple-dose, milk-only lactation study in lactating women receiving linaclotide therapeutically. The Package Leaflet is updated accordingly."	
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)."

Deltyba - delamanid - EMEA/H/C/002552/II/0045, Orphan

Otsuka Novel Products GmbH, Rapporteur: Koenraad Norga, "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."

ELOCTA - efmoroctocog alfa - EMEA/H/C/003964/II/0039

Swedish Orphan Biovitrum AB (publ), Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.8 and 5.1 of the SmPC to include the 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)."

Erleada - apalutamide - EMEA/H/C/004452/II/0007/G

Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.8 of the SmPC in order to add toxic epidermal necrolysis and decreased appetite to the list of adverse drug reactions (ADRs) with frequency 'not known' and 'very common' respectively based on cumulative safety reviews; the Package Leaflet is updated accordingly."

EXJADE - deferasirox - EMEA/H/C/000670/II/0073

Novartis Europharm Limited, Rapporteur: Alexandre Moreau, "Submission of the final study report from the post-authorisation pharmacovigilance measure in the Annex II and in the RMP, a single-arm interventional Phase

IV, evaluating the safety of paediatric patients with transfusional hemosiderosis treated with deferasirox crushed film-coated tablets. This submission also serves to comply with Article 46 of the Regulation (EC) No 1901/2006 on medicinal products for paediatric use."

Gardasil - human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0087

MSD Vaccins, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update the information of the duration of immunity following a 2-dose schedule of Gardasil based on the results from extension Protocol V501-167; this was a randomized clinical trial that assessed the immunogenicity of a 2 dose schedule of the qHPV in adolescents 9 to 13 years of age compared to a 3-dose schedule in young women 16 to 26 years of age.
In addition, the MAH is taking the opportunity to implement the following guidelines/template in the Product Information: Annex to the European Commission, Volume 2C, Guidelines, Medicinal products for human use, Safety, environment and information, Excipients in the label and package leaflet of medicinal products for human use, Rev 2, Mar 2018; and the Guideline on quality aspects included in the product information for vaccines for human use EMA/CHMP/BWP/133540/2017. Furthermore, the PI is being brought in line with the latest QRD template (version 10.1) and some minor editorial changes regarding the nomenclature for excipients have been implemented."

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."

Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0012
Bayer AG, Rapporteur: Kirstine Moll Harboe, "Update of sections 4.8 and 5.1 of the SmPC to reflect the final study results of the long-term extension study 13024 (PROTECT VIII). This extension study is a category 3 study of the Jivi RMP (MEA-005). The PL is updated to reflect a change in the contact of a local representative."

Lemtrada - alemtuzumab - EMEA/H/C/003718/II/0032
Sanofi Belgium, Duplicate, Duplicate of Lemtrada (WD), Rapporteur: Kirstine Moll Harboe, "to update sections 4.4 and 4.8 of the SmPC to amend the existing warning and adverse drug reactions on Epstein-Barr virus (EBV) infections and EBV associated hepatitis, following safety evaluation report (SER). The package leaflet is updated accordingly."

Luminity - perflutren - EMEA/H/C/000654/II/0033
Lantheus EU Limited, Rapporteur: Peter Kiely, "To update sections 4.4 and 6.1 of the SmPC on the hypersensitivity reactions for patients with a history of allergy to polyethylene glycol (PEG), following a signal identified from a review of the existing and previously submitted safety information. The Package Leaflet is updated in accordance."

MabThera - rituximab - EMEA/H/C/000165/II/0177
Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Submission of the final Clinical Study Report for study WA29330 (Pemphix) in order to fulfil the Post-Authorization Measure in the Annex IID of the MabThera PI following 48 week safety follow up period of the study."

Nerlynx - neratinib - EMEA/H/C/004030/II/0015
Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC in order to include final OS results from study

3144A2-3004-WW, a randomised, double-blind, placebo-controlled trial of neratinib after trastuzumab in women with early-stage HER-2/neu overexpressed/amplified breast cancer."

Nplate - romiplostim - EMEA/H/C/000942/II/0078

Amgen Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.8 and 5.1 of the SmPC to reflect the main results from study 20101221 following the assessment performed under Article 46 of Regulation 1901/2006. Study 20101221 is an open-label trial to evaluate safety in children from 1 year of age to less than 18 years of age with primary ITP regardless of splenectomy status, including a protocol supplement to implement bone marrow evaluations."

Slenyto - melatonin - EMEA/H/C/004425/II/0017

RAD Neurim Pharmaceuticals EEC SARL, Rapporteur: Kristina Dunder, "The update of the 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."

SomaKit TOC - edotreotide - EMEA/H/C/004140/II/0015, Orphan

Advanced Accelerator Applications, Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.4, 4.5 and 4.6 of the SmPC in order to amend an existing warning extending the period during which close contact with infants and pregnant women should be restricted, add information on interactions with glucocorticosteroids and extend the period during which breastfeeding should be interrupted following. The Package Leaflet is updated accordingly. Additionally, the MAH took the opportunity to update the details of local representatives."

Somavert - pegvisomant - EMEA/H/C/000409/II/0097

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.4, 4.6 and 5.3 of the SmPC in order to add a new warning on acromegaly control and adjustment of doses during pregnancy, include information on use during pregnancy and effects on fertility, as well as an update on the effects of the drug product

on the early embryonic development and embryo-foetal development in pregnant rabbits, following international regulatory procedures outcomes and literature review. The MAH took the opportunity to make editorial changes to the Package Leaflet."

Stocrin - efavirenz - EMEA/H/C/000250/II/0123

Merck Sharp & Dohme B.V., Duplicate, Duplicate of Sustiva, Rapporteur: Bruno Sepodes, "Update of sections 4.4 and 4.8 of the SmPC in order to add new warnings regarding late-onset neurotoxicity, including ataxia and encephalopathy, based on reviews of the published literature and MAH safety database; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor editorial amendments."

Sunosi - solriamfetol - EMEA/H/C/004893/II/0004

Jazz Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig, "Submission of the results of the Environmental Risk Assessment Phase II risk assessment of solriamfetol."

TAGRISSO - osimertinib - EMEA/H/C/004124/II/0037

AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.8 of the SmPC in order to add cutaneous vasculitis to the list of adverse drug reactions (ADRs) with frequency "uncommon", based on the review of the available safety data. In addition, the MAH took the opportunity of this variation to introduce minor editorial updates to the SmPC."

Tasigna - nilotinib - EMEA/H/C/000798/II/0106

Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, "Update of section "4.8 Undesirable effects" of the SmPC with 'Facial paralysis' with the frequency unknown. Section "4 possible side effects" of the package leaflet has been updated accordingly.
The QRD template version 10.1 has been implemented as part of this PI update. The Annex III has been updated accordingly.
Editorial changes have been made to the Annex II to follow the new QRD template."

Tecentriq - atezolizumab -

EMEA/H/C/004143/II/0047
Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to add headache, dry skin and blood creatinine increased to the list of adverse drug reactions (ADRs) for atezolizumab given as monotherapy identified in study WO29636. The MAH has taken this opportunity to update the frequencies of existing ADRs in section 4.8 subsections 'Summary of the safety profile' and 'Description of selected adverse reactions' to reflect the updated pool of patients for atezolizumab monotherapy. Other minor corrections and editorial changes are being proposed. The package leaflet is updated accordingly."

Tresiba - insulin degludec - EMEA/H/C/002498/II/0047
Novo Nordisk A/S, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update the description of day-to-day variability in glucose-lowering effect further to assessment of post-authorisation measure LEG013. In addition, the MAH took the opportunity to make editorial corrections in section 5.2 of the SmPC."

Uptravi - selexipag - EMEA/H/C/003774/II/0029
Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC based on interim survival and safety data from study AC-065A303 a long-term single-arm, open-label study to evaluate the safety and tolerability of selexipag / ACT-293987 in patients with Pulmonary Arterial Hypertension. In addition, the MAH took the opportunity to implement minor editorial changes and update the list of local representatives in the Package Leaflet."

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 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."

Xarelto - rivaroxaban - EMEA/H/C/000944/II/0079

Bayer AG, Rapporteur: Kristina Dunder, "Submission of the final report from the CASSINI study, an interventional phase III study comparing 10 mg rivaroxaban to placebo in the prevention of venous thromboembolism in ambulatory cancer patients."

Xeljanz - tofacitinib - EMEA/H/C/004214/II/0025

Pfizer Europe MA EEIG, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Liana Gross-Martirosyan, "To submit the final report from study A3921092, a long term, open-label extension study of tofacitinib for the treatment of adult patients with PsA, listed as a category 3 study in the RMP. An updated RMP version 11.1 has also been submitted. The MAH took also the opportunity to update the milestones for study A3921347 (US UC active surveillance study) in the RMP."

XOSPATA - gilteritinib - EMEA/H/C/004752/II/0003, Orphan

Astellas Pharma Europe B.V., Rapporteur: Bjorg Bolstad, "C.I.4
Update of section 5.2 of the SmPC in order to update information about Transporter drug-drug interactions based on final results from in vitro transporter studies identified as recommendations by CHMP (REC003) during the initial approval. In addition, the MAH took the opportunity to perform minor corrections and editorial changes in the PI."

WS1780
Glyxambi-EMEA/H/C/003833/WS1780/0027
Jardiance-EMEA/H/C/002677/WS1780/0049
Synjardy-EMEA/H/C/003770/WS1780/0046

Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.4. of the SmPC for Jardiance, Synjardi and Glyxambi in the SmPC subsection `Diabetic ketoacidosis' to reflect new data from 2 phase

III interventional studies (EASE-2 1245.69 and EASE-3 1245.72) from the clinical trial program of empagliflozin as an adjunct to insulin in patients with type 1 diabetes."	
WS1883 **Prezista-EMEA/H/C/000707/WS1883/0108** **Rezolsta-EMEA/H/C/002819/WS1883/0038** **Symtuza-EMEA/H/C/004391/WS1883/0025** Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC for Prezista, Rezolsta and Symtuza in order to include information on the interaction with Clopidogrel. The MAH also takes the opportunity to make several editorial changes in the SmPC to include the sodium-free statement in section 4.4 and remove simeprevir, boceprevir and nelfinavir from section 4.5 from the list of interactions, as they are no longer marketed."	
WS1893 **Blitzima-EMEA/H/C/004723/WS1893/0034** **Ritemvia-EMEA/H/C/004725/WS1893/0034** **Truxima-EMEA/H/C/004112/WS1893/0037** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Hans Christian Siersted, "To provide CT-P10 3.4 final CSR along with the updated RMP (version 10.1) in compliance with the post-authorisation measure. CT-P10 3.4 was a Phase 3, randomised, parallel-group, active-controlled, double-blind study to compare efficacy and safety between CT-P10 and Rituxan in patients with LTBFL. Study CTP10 3.4 was designed to demonstrate similarity of efficacy of CT-P10 to Rituxan in patients with LTBFL. The patients were randomised in a 1:1 ratio in a double-blinded fashion."	

B.6.10. CHMP-PRAC assessed procedures

Bosulif - bosutinib - EMEA/H/C/002373/II/0043	

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "C.I.4, Update of section 5.3 of the SmPC in order to update non-clinical information following the final results from the six-month transgenic rasH2 mouse carcinogenicity study, listed as a category 3 in the current approved RMP version 4.5.; The RMP version 5.0 has also been submitted. The MAH took the opportunity to implement changes resulting from the revision of the SmPC guideline on excipients, applied in the SmPC section 4.4 and in the Package Leaflet section 2 ."

NUBEQA - darolutamide - EMEA/H/C/004790/II/0002

Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser, "Update of section 5.1 of the SmPC in order to update efficacy information based on final OS results from study 17772 (ARAMIS) listed as a PAES in the Annex II; this is a multinational, randomised, double-blind, placebo-controlled, phase III efficacy and safety study of darolutamide in men with high-risk non-metastatic castration-resistant prostate cancer; the Annex II is updated accordingly.
The RMP version 1.1 has also been submitted."

Orbactiv - oritavancin - EMEA/H/C/003785/II/0030

Menarini International Operations Luxembourg S.A., Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Submission of the final report from 14-TMC-01, a Surveillance study investigation, listed as a category 3 study in the RMP, part of the global SENTRY Antimicrobial Surveillance Program platform to monitor the activity of oritavancin against Gram-positive clinical isolates collected from Europe and the US.
This application addresses PAM MEA 003.4, presenting the cumulative surveillance data from 2010 to 2019 (including the first 5-year post-approval period).
The RMP version 3.0 has also been submitted."

Rydapt - midostaurin - EMEA/H/C/004095/II/0014, Orphan

Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "C.I.4

Update of sections 4.2, 4.4, and 5.1 of the SmPC in order to change posology recommendations and add Special warnings and precautions for use in Paediatric population following the occurrence of severe dose limiting toxicities (DLTs) in the paediatric study CPKC412A2218 which is currently on clinical hold. The study is part of the agreed PIP (EMEA-000780-PIP01-09-M05) for which a Request for Modification was submitted on 20-Apr-2020 (RSI/Opinion by PDCO expected on 24-Jul-2020). Section 5.1 of the SmPC and the Package Leaflet are updated accordingly. The RMP version 5.0 has also been submitted. In addition Novartis takes this opportunity to introduce minor editorial changes to align the PI to the updated QRD template version 10.1."	
Sivextro - tedizolid phosphate - EMEA/H/C/002846/II/0037 Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Update of section 5.1 of the SmPC in order to update the description of the potential risk of emergence of drug resistance with tedizolid phosphate, based on final results from study Surveillance of Tedizolid Activity and Resistance (STAR) listed as a category 3 study in the RMP; this is a surveillance study established in January 2014 to monitor tedizolid susceptibility activity and emergence of resistance across the US, 11 European Union countries, Russia and Turkey. The RMP version 6.2 has also been submitted."	
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 updates and bring the PI in line with the latest QRD template version 10.1."

B.6.11. PRAC assessed procedures

PRAC Led
Beovu - brolucizumab - EMEA/H/C/004913/II/0002
Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "C.I.4, Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation."

PRAC Led
Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0092
GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "C.I.13: Submission of the final report from study V72_38OB listed as a category 3 study PASS in the RMP. This is an observational study conducted by Public Health England (PHE) to assess Bexsero effectiveness and impact in infants in the UK upon introduction of the vaccine in the infant National Immnunization Program (NIP) administered at 2, 4 and 12 months of age.
An updated RMP version 8.0 has also been submitted. This version includes the changes due to this variation and those due to a separate type II variation submitted in parallel to include the final report of an additional PASS V72_82OB"

PRAC Led
Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0093
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_82OB listed as a category 3 PASS in the RMP. This is an observational study on the safety of Bexsero in pregnant women and their

offspring, the objective of the study was to evaluate pregnancy outcomes among women immunized with the Bexsero vaccine within 30 days prior to the last menstrual period (LMP) or at any time during pregnancy.
An updated RMP version 8.0 has also been submitted. This version includes the changes due to this variation and those due to a separate type II variation submitted in parallel to include the final report of an additional PASS V72_38OB"

PRAC Led
Conbriza - bazedoxifene - EMEA/H/C/000913/II/0052
Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final clinical study report (CSR) for the Conbriza Non-Interventional EU Post Authorisation Safety Study (EU PASS) - Protocol B1781044. This final CSR relates to the Post Approval Measure EMEA/H/C/000913/MEA 012.12."

PRAC Led
DaTSCAN - ioflupane (123I) - EMEA/H/C/000266/II/0060
GE Healthcare B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the first RMP"

PRAC Led
Evoltra - clofarabine - EMEA/H/C/000613/II/0069
Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of the RMP (version 9.0) to reflect updated information regarding the Evoltra European Registry Programme and to remove all safety concerns from the list of important identified and potential risks and
missing information to follow revised guidance in the good pharmacovigilance practice (GVP) Module V Rev.2."

PRAC Led
Iressa - gefitinib - EMEA/H/C/001016/II/0033
AstraZeneca AB, Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Filip Josephson, "Submission of an

updated RMP version 11 in order to provide the RMP in revision 2 as per the revised `Guideline on Good Pharmacovigilance Practices: Module V - Risk management systems (Rev. 2)' together with inclusion of RMP changes as per the commitments indicated in PSUSA procedure (EMEA/H/C/PSUSA/00001518/201807)"

PRAC Led

Obizur - susoctocog alfa - EMEA/H/C/002792/II/0034

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of a final report of the survey among Health Care Professionals to Assess their Knowledge on Dosing and Administration of OBIZUR (Susoctocog alfa) in 6 European Countries."

PRAC Led

Orfadin - nitisinone - EMEA/H/C/000555/II/0074

Swedish Orphan Biovitrum International AB, PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Daniela Melchiorri, "Submission of the final report from study Sobi.NTBC-005 listed as a category 3 study in the RMP. This is a non-interventional Post Authorization Safety Study (PASS) to evaluate long-term safety of Orfadin treatment in hypertyrosinemia type 1 (HT-1) patients in standard clinical care. The RMP version 5.3 has also been submitted."

PRAC Led

XOSPATA - gilteritinib - EMEA/H/C/004752/II/0001, Orphan

Astellas Pharma Europe B.V., Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "C.I.13: Submission of a pooled analysis report from studies 2215-CL-0101 (Phase 1/2), 2215-CL-0102 (Phase 1), 2215-CL-0301, 2215-CL-9100 (phase 3) listed as "Other forms of routine pharmacovigilance activities in section III.1 of the RMP". This is a pooled analysis to characterize gilteritinib-related differentiation syndrome, specifically incidence, observed signs and symptoms, duration, and response to intervention based on patient-level data from on-going trials in patients with acute myeloid leukaemia."

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)."

PRAC Led

WS1849
Thymanax-EMEA/H/C/000916/WS1849/0045
Valdoxan-EMEA/H/C/000915/WS1849/0047

Les Laboratoires Servier, Lead Rapporteur: Bjorg Bolstad, Lead PRAC Rapporteur: Pernille Harg, PRAC-CHMP liaison: Bjorg Bolstad, "Submission of an updated RMP version 23.1 in order to revise the safety concerns, important identified and potential risks in line with the new GVP module V. In addition, the completed studies have been deleted and, as agreed in LEG 031, the frequency of the educational material distribution is updated to once a year."

PRAC Led

WS1861/G
Kisplyx-EMEA/H/C/004224/WS1861/0037/G
Lenvima-EMEA/H/C/003727/WS1861/0037/G

Eisai GmbH, Lead Rapporteur: Christophe Focke, Lead PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final clinical study report (CSR) for study E7080-G000-201 (Study 201) - To evaluate the long-term safety of lenvatinib in Medullary and Iodine-131 Refractory, Unresectable differentiated thyroid carcinoma (DTC), Stratified by Histology (MEA 001 for Lenvima; from initial MAA for Kisplyx). Submission of the final CSR for Study E7080-G000-303 (Study 303) - To evaluate long-term

safety of lenvatinib in patients with RR-DTC (radioiodine refractory differentiated thyroid cancer) in a randomized, double-blind, placebo-controlled Phase 3 study (MEA 004 for Lenvima; MEA 002 for Kisplyx).
Submission of an updated integrated summary of safety (ISS) including data from DTC subjects in Studies 201, 303 and E7080-J081-208 (Study 208) - the latter study was to determine the long-term safety profile of lenvatinib in Japanese patients with advanced thyroid cancer (Kisplyx REC from Study 208 variation (procedure EMEA/H/C/003727/II/0008) for Lenvima).
The RMP version 12 has also been submitted."

PRAC Led
WS1879
Cymbalta-EMEA/H/C/000572/WS1879/0084
Duloxetine Lilly-EMEA/H/C/004000/WS1879/0021
Yentreve-EMEA/H/C/000545/WS1879/0069
Eli Lilly Nederland B.V., Duplicate, Duplicate of Ariclaim, Yentreve, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "This worksharing variation is being submitted to present and discuss the results of Study F1J-MC-B034 Pregnancy Registry to meet the commitment made during the previous procedure No. EMEA/H/C/WS1527/G which received positive CHMP opinion on 25 July 2019.
As a consequence of the submission of the F1J-MC-B034 Study Report, the Risk Management Plan (RMP) for duloxetine has been updated. The RMP for all Lilly duloxetine products are combined. The changes introduced are not specific to one product and are therefore the same for all products."

B.6.12. CHMP-CAT assessed procedures

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0003/G, Orphan, ATMP
AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinator:

Johann Lodewijk Hillege

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

WS1853/G **Ebymect-EMEA/H/C/004162/WS1853/0049/G** **Edistride-EMEA/H/C/004161/WS1853/0040/G** **Forxiga-EMEA/H/C/002322/WS1853/0058/G** **Xigduo-EMEA/H/C/002672/WS1853/0059/G**	AstraZeneca AB, Lead Rapporteur: Kristina Dunder
WS1857 **Adrovance-EMEA/H/C/000759/WS1857/0042** **FOSAVANCE-EMEA/H/C/000619/WS1857/0045** **VANTAVO-EMEA/H/C/001180/WS1857/0032**	Merck Sharp & Dohme B.V., Lead Rapporteur: Andrea Laslop, "To update section 4.4 of the SmPC for excipients lactose and sodium and section 2 of the Package Leaflet for the excipient sodium to comply with the updated Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use" (Revised March 2018) and corresponding Annex (Rev.01, 09Oct2017; Corr.1 19Nov2018). Minor formatting changes and editorial changes to comply with the latest QRD template are also applied in the Product Information. In addition, the MAH took the opportunity to update the list of local representatives as follows: - The Netherlands for the 3 products - Belgium and Portugal for Adrovance and Vantavo - Luxembourg for Adrovance"
WS1859/G **Blitzima-EMEA/H/C/004723/WS1859/**	

0032/G
Ritemvia-EMEA/H/C/004725/WS1859/0032/G
Truxima-EMEA/H/C/004112/WS1859/0035/G

Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, "To update section 4.1 and related SmPC sections, to add the extension of indication to include treatment of paediatric GPA/MPA patients to align the PI with the parent product MabThera which had this indication approved with procedure II-162. The Package Leaflet was updated accordingly.
To update section 4.1 and related SmPC sections, to add the extension of indication to include treatment of paediatric NHL patients to align the PI with the parent product MabThera which had this indication approved with procedure II-168. The Package Leaflet was updated accordingly.
To update section 4.4 and 4.8 of the SmPC to add the Post-authorisation efficacy study (PAES) randomised phase 3 study without new additional clinical data required to align the PI with the parent product Mabthera which had this change approved with procedure II-169."

WS1864/G
Kivexa-EMEA/H/C/000581/WS1864/0086/G
Trizivir-EMEA/H/C/000338/WS1864/0118/G
Ziagen-EMEA/H/C/000252/WS1864/0113/G

ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race

WS1867/G
Rivastigmine 1A Pharma-EMEA/H/C/001181/WS1867/0029/G
Rivastigmine Hexal-EMEA/H/C/001182/WS1867/0030/G
Rivastigmine Sandoz-EMEA/H/C/001183/WS1867/0031/G

Sandoz GmbH, Informed Consent of Exelon, Lead Rapporteur: Alexandre Moreau

WS1873/G
Filgrastim Hexal-EMEA/H/C/000918/WS1873/0056/G
Zarzio-EMEA/H/C/000917/WS1873/0057/G

Sandoz GmbH, Lead Rapporteur: Johann Lodewijk Hillege	
WS1875/G **Rixathon-EMEA/H/C/003903/WS1875/0042/G** **Riximyo-EMEA/H/C/004729/WS1875/0042/G** Sandoz GmbH, Duplicate, Duplicate of Rixathon, Lead Rapporteur: Jan Mueller-Berghaus, "To update section 4.8, 5.1 and 5.2 of the SmPC following safety changes for the parent product Mabthera adopted during procedure II-169. To update sections 1, 2, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 8 of the SmPC following adoption of extension of indication to include the induction of remission in paediatric patients (aged ≥ 2 to <18 years old) with severe, active granulomatosis with polyangiitis (GPA) (Wegener's) and microscopic polyangiitis (MPA) for parent product Mabthera during procedure II-162. The PL was updated accordingly. Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC following adoption of extension of indication to include treatment of paediatric patients (aged ≥6 months to <18 years old) with previously untreated advanced stage diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL) in combination with chemotherapy for parent product MabThera during procedure II-168. The Package Leaflet is updated accordingly. The MAH also took this opportunity to introduce minor editorial changes. Amongst these the MAH included in Annex III of the Product Information the text appearing on the peel-off label recently introduced for both, Rixathon and Riximyo."	
WS1880 **Lixiana-EMEA/H/C/002629/WS1880/0027** **Roteas-EMEA/H/C/004339/WS1880/0015** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro	
WS1885/G **Silodosin Recordati-EMEA/H/C/004964/WS1885/0005/G** **Silodyx-EMEA/H/C/001209/WS1885/0041/G**	

Urorec-EMEA/H/C/001092/WS1885/0044/G
Recordati Ireland Ltd, Generic, Generic of Urorec, Lead Rapporteur: Margareta Bego

WS1894/G
Incresync-EMEA/H/C/002178/WS1894/0032/G
Vipdomet-EMEA/H/C/002654/WS1894/0028/G
Vipidia-EMEA/H/C/002182/WS1894/0023/G
Takeda Pharma A/S, Lead Rapporteur: Johann Lodewijk Hillege

WS1899/G
Elebrato Ellipta-EMEA/H/C/004781/WS1899/0019/G
Temybric Ellipta-EMEA/H/C/005254/WS1899/0007/G
Trelegy Ellipta-EMEA/H/C/004363/WS1899/0016/G
GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Peter Kiely

WS1903
Actraphane-EMEA/H/C/000427/WS1903/0085
Actrapid-EMEA/H/C/000424/WS1903/0078
Insulatard-EMEA/H/C/000441/WS1903/0083
Mixtard-EMEA/H/C/000428/WS1903/0086
Protaphane-EMEA/H/C/000442/WS1903/0082
Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe

WS1909
Humalog-EMEA/H/C/000088/WS1909/0183
Liprolog-EMEA/H/C/000393/WS1909/0143
Eli Lilly Nederland B.V., Lead Rapporteur: Kristina Dunder, "To update sections 4.2, 4.4 and 4.8 of the SmPC and sections 2 and 4 of the PL to implement the signal recommendations on "Signal assessment report on cutaneous amyloidosis with insulin human (regular and NPH), insulin degludec, insulin aspart, insulin lispro, insulin detemir, insulin glargine, insulin glulisine and insulin porcine (class effect of

insulin containing products) "(EPITT no 19499) adopted at the 17/04/2020 PRAC meeting. In addition, the MAH is taking the opportunity to make some corrections to the labelling specifically the pictures in the Liprolog instructions Information For Use and some typographic issues in the Icelandic, Danish and Norway, Patient Information Leaflet and Summary of Product Characteristic."	
Hexacima-EMEA/H/C/002702/WS1872/0104/G **Hexaxim-EMEA/H/W/002495/WS1872/0109/G** **Hexyon-EMEA/H/C/002796/WS1872/0108/G** Sanofi Pasteur, 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):

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

Qualification of Biomarkers:

HTA:

G.2. Ongoing procedures

G.3. PRIME

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

G.3.1. List of procedures concluding at 20-23 July 2020 CHMP plenary:

G.3.2. List of procedures starting in July 2020 for September 2020 CHMP adoption of outcomes

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