26 May 2020
EMA/CHMP/276755/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 25-28 May 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

25 May 2020, 09:00 – 19:30, room 1C/ virtual meeting

26 May 2020, 08:30 – 19:30, room 1C/ virtual meeting

27 May 2020, 08:30 – 19:30, room 1C/ virtual meeting

28 May 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).

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 25-28 May 2020. See May 2020 CHMP minutes (to be published post June 2020 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 25-28 May 2020

1.3. Adoption of the minutes

CHMP minutes for 28-30 April 2020

ORGAM minutes for 18 May 2020

CHMP meeting – Scientific Advice topics held on 4 May 2020

Extraordinary CHMP meeting on remdesivir, 15 May 2020

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. bevacizumab - EMEA/H/C/005106

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: Possible Oral Explanation/List of Outstanding Issues

Action: Possible oral explanation to be held on Monday, 25 May 2020 at 16:00

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 14.11.2019.

2.1.2. bulevirtide - Orphan - EMEA/H/C/004854

MYR GmbH; indicated for the treatment of chronic hepatitis delta virus (HDV) infection in adult patients with compensated liver disease.

Scope: Possible oral explanation/Opinion

Draft list of experts for the ad-hoc expert group meeting scheduled on 20 May 2020 - adopted via written procedure on 20 May 2020

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 09:00

List of Outstanding Issues adopted on 24.03.2020. List of Questions adopted on 28.01.2020.

2.1.3. entrectinib - EMEA/H/C/004936

treatment of adult and paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive locally advanced or metastatic solid tumours and treatment of patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC).

Scope: Possible oral explanation/Opinion

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 15:30

List of Outstanding Issues adopted on 12.12.2019, 17.10.2019. List of Questions adopted on 29.05.2019.

2.1.4. pexidartinib - Orphan - EMEA/H/C/004832

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).

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday, 26 May 2020 at 14:00

List of Outstanding Issues adopted on 26.03.2020, 12.12.2019. List of Questions adopted on 25.07.2019.

2.1.5. lefamulin - EMEA/H/C/005048

treatment of community-acquired pneumonia (CAP).

Scope: Possible oral explanation/Opinion

Action: Possible oral explanation to be held on Wednesday, 27 May 2020 at 11:00

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

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Invokana - canagliflozin - EMEA/H/C/002649/II/0046

Janssen-Cilag International NV

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.1, 4.2, 4.8 and 5.1 of the Summary of Product Characteristics to add a new therapeutic indication for Invokana (canagliflozin) for the treatment of stage 2 or 3 chronic kidney disease and albuminuria, as an adjunct to standard of care, in adults with type 2 diabetes mellitus. The proposed new indication is based upon new clinical efficacy and safety data from the Phase 3 study: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial (CREDENCE) (DNE3001).
The Package Leaflet is updated in accordance. The RMP version 8.1 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.",

Possible oral explanation

Action: Possible oral explanation to be held on Tuesday, 26 May 2020 at 16:00

Request for Supplementary Information adopted on 30.04.2020, 27.02.2020, 14.11.2019.

See 5.1

2.3.2. Lynparza - olaparib - EMEA/H/C/003726/II/0033

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Koenraad Norga, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to support the use of Lynparza tablets (100 mg and 150 mg) for the maintenance treatment of gBRCAm metastatic pancreatic cancer based on the results from the pivotal Phase 3 study, POLO; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.8 for Lynparza hard capsules (50 mg) to revise list of ADR based on the pooled safety data analysis. The RMP version 18 has also been submitted. Furthermore, the PI is brought in line with the latest guideline regarding the sodium content. The MAH also took the occasion to include some minor editorial changes in the PI.",

Possible oral explanation

Action: Possible oral explanation to be held on Monday, 25 May 2020 at 14:00

Request for Supplementary Information adopted on 30.04.2020, 30.01.2020, 17.10.2019.

See 5.1

2.3.3. Xtandi - enzalutamide - EMEA/H/C/002639/II/0047/G

Astellas Pharma Europe B.V.

Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Eva A. Segovia

Scope: "C.1.6: Extension of indication to include the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for Xtandi in combination with androgen deprivation therapy; As a consequence, sections 4.1, 4.7, 4.8, 5.1, 5.3 and 6.6 of the SmPC are updated. Furthermore the MAH took the opportunity to make corrections to section 4.7. The Package Leaflet is updated in accordance. The RMP version 13.0 has also been submitted.
C.1.4: Update of section 5.1 of the SmPC based the 5-year Overall Survival (OS) results obtained from the PREVAIL study (MDV310003), a phase 3 study of enzalutamide in chemotherapy naïve patients with metastatic prostate cancer that progressed on ADT.",

Oral explanation

Action: Oral explanation to be held on Tuesday, 26 May 2020 at 11:00

Request for Supplementary Information adopted on 17.10.2019.

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. apixaban - EMEA/H/C/005358

prevention of venous thromboembolic events (VTE).

Scope: Opinion

Action: For adoption

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

3.1.2. filgotinib - EMEA/H/C/005113

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

Scope: Opinion

Action: For adoption

List of Questions adopted on 12.12.2019.

3.1.3. teriparatide - EMEA/H/C/005087

treatment of osteoporosis.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2020. List of Questions adopted on 19.09.2019.

3.1.4. Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343

indicated for active immunisation for prevention of disease caused by Ebola virus.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2020. List of Questions adopted on 25.02.2020.

3.1.5. alpelisib - EMEA/H/C/004804

treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor2 (HER2)-negative, advanced breast cancer with a PIK3CA mutation in combination with fulvestrant after disease progression following an endocrine-based regimen.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2020, 19.09.2019. List of Questions adopted on 29.05.2019.

3.1.6. teriparatide - EMEA/H/C/005388

treatment of osteoporosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2020. List of Questions adopted on 19.09.2019.

3.1.7. Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337

indicated for active immunisation for prevention of disease caused by Ebola virus (Zaire ebolavirus species).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2020. List of Questions adopted on 25.02.2020.

3.1.8. trastuzumab - EMEA/H/C/005209

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

Scope: Opinion

Action: For adoption

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

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

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2019.

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

treatment of relapsed acute promyelocytic leukaemia (APL).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

3.2.3. 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: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.5. satralizumab - Orphan - EMEA/H/C/004788

Roche Registration GmbH; treatment of adult and adolescent patients from 12 years of age with neuromyelitis optica spectrum disorders (NMOSD).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 10.12.2019.

3.2.6. fampridine - EMEA/H/C/005359

treatment of Multiple Sclerosis.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

3.2.7. elexacaftor / tezacaftor / ivacaftor - Orphan - EMEA/H/C/005269

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.01.2020.

3.2.8. caffeine citrate - EMEA/H/C/005435

treatment of primary apnoea.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.9. rivaroxaban - EMEA/H/C/005279

prevention of atherothrombotic events.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2019.

3.2.10. deferiprone - Orphan - EMEA/H/C/005004

Apotex B.V.; treatment of neurodegeneration with brain iron accumulation.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2019.

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

3.3.1. bevacizumab - EMEA/H/C/005286

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

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

3.3.3. risperidone - EMEA/H/C/005406

treatment of schizophrenia.

Scope: List of questions

Action: For adoption

3.3.4. fedratinib - Orphan - EMEA/H/C/005026

Celgene Europe BV; treatment of primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

Scope: List of questions

Action: For adoption

3.3.5. autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured - Orphan - ATMP - EMEA/H/C/005102

Accelerated assessment

Kite Pharma EU B.V.; treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Scope: List of questions

Action: For information

3.3.6. lenalidomide - EMEA/H/C/005348

treatment of multiple myeloma.

Scope: List of questions

Action: For adoption

3.3.7. inclisiran - EMEA/H/C/005333

treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

Scope: List of questions

Action: For adoption

3.3.8. ofatumumab - EMEA/H/C/005410

treatment of relapsing forms of multiple sclerosis.

Scope: List of questions

Action: For adoption

3.3.9. bevacizumab - EMEA/H/C/005556

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

Scope: List of questions

Action: For adoption

3.3.10. pertuzumab / trastuzumab - EMEA/H/C/005386

treatment of early breast cancer, metastatic breast cancer.

Scope: List of questions

Action: For adoption

3.3.11. selpercatinib - EMEA/H/C/005375

indicated for the treatment of adults with: advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy; advanced RET fusion-positive thyroid cancer who require systemic therapy and who have progressed following prior treatment. As monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.

Scope: List of questions

Action: For adoption

3.3.12. tucatinib - EMEA/H/C/005263

treatment of metastatic breast cancer or brain metastases.

Scope: List of questions

Action: For adoption

3.3.13. eladocagene exuparvovec - Orphan - ATMP - EMEA/H/C/005352

PTC Therapeutics International Limited; treatment of aromatic L-amino aciddecarboxylase (AADC) deficiency.

Scope: List of questions

Action: For information

3.3.14. obeticholic acid - EMEA/H/C/005249

improvement of liver fibrosis and resolution of steatohepatitis in adult patients with significant liver fibrosis due to nonalcoholic steatohepatitis (NASH).

Scope: List of questions

Action: For adoption

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

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

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

Scope: Draft list of experts for the SAG on anti-infectives meeting

Action: For adoption

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

3.4.2. azathioprine - EMEA/H/C/005055

indicated for the prophylaxis of transplant rejection, and an immunosuppressant antimetabolite, indicated in patients who are intolerant to glucocorticosteroids, and chronic inflammatory bowel disease (IBD) (Crohn's disease or ulcerative colitis), relapsing multiple sclerosis, generalised myasthenia gravis.

Scope: Letter from the applicant dated 15 May 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.

3.4.3. idebenone - Orphan - EMEA/H/C/005123

Santhera Pharmaceuticals (Deutschland) GmbH; treatment of respiratory dysfunction in patients with Duchenne muscular dystrophy (DMD) not using glucocorticoids.

Scope: Letter from the applicant dated 13 May 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in April 2020 – adopted via written procedure on 14 May 2020.

Action: For information

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

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

for treatment of asthma.

Scope: Letter from the applicant dated 11 May 2020 requesting an extension of clock-stop to respond to the list of questions adopted in February 2020.

Action: For adoption

List of Questions adopted on 27.02.2020.

3.4.5. lifitegrast - EMEA/H/C/004653

treatment of moderate to severe dry eye disease in adults for whom prior artificial tears has not been sufficient.

Scope: List of experts for the ad-hoc expert meeting

Action: For adoption

List of Outstanding Issues adopted on 12.12.2019. List of Questions adopted on 26.04.2019.

3.4.6. plazomicin - EMEA/H/C/004457

treatment of complicated urinary tract infection (cUTI), including pyelonephritis; treatment of bloodstream infection (BSI); treatment of infections due to Enterobacteriaceae.

Scope: Letter from the applicant dated 15 May 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in November 2019.

Action: For adoption

List of Outstanding Issues adopted on 14.11.2019, 25.07.2019. List of Questions adopted on 28.02.2019.

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. erlotinib - EMEA/H/C/005071

treatment of lung and pancreatic cancers.

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 26.03.2020, 29.05.2019. List of Questions adopted on 13.12.2018.

3.7.2. fingolimod - EMEA/H/C/005282

treatment of multiple sclerosis.

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 27.02.2020. List of Questions adopted on 19.09.2019.

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

No items

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. Cosentyx - secukinumab - EMEA/H/C/003729/X/0059

Novartis Europharm Limited

Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension application to add a new strength of 300 mg (in 2 ml) solution for injection (in pre-filled syringe and pre-filled pen). The RMP (version 7.0) is updated in accordance."

Action: For adoption

4.3.2. Nuceiva - botulinum toxin type A - EMEA/H/C/004587/X/0005

Evolus Pharma Limited

Rapporteur: Peter Kiely, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 50 U for botulinum toxin type A for powder for solution for injection in vial (glass), for intramuscular administration."

Action: For adoption

4.3.3. Tivicay - dolutegravir - EMEA/H/C/002753/X/0058/G

ViiV Healthcare B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: "- Extension application to add a new pharmaceutical form associated with new strength (5 mg dispersible tablet). The new presentation is indicated for the treatment of HIV infected children from 4 weeks of life and weighing at least 3 kilograms.
- Type II variation (C.I.4) to update the currently approved Product Information, Labelling and Package Leaflet for the existing film -coated tablets (10 mg, 25 mg and 50 mg) for children 6 years and older and weighing at least 15 kg. The application comprises PK, safety, and efficacy data from the Phase I/II study (P1093) and PK and safety data from relevant sub-studies nested within the Phase II/III Study ODYSSEY (PENTA 20).
In addition, the applicant took the opportunity to amend section 4.1 of the SmPC, the indication for the approved Tivicay film-coated tablets to clarify that children should be "aged at least 6 years" as the current approved indication is inclusive of those aged 6 years. The RMP (version 16) is updated in accordance."

Action: For adoption

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

No items

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

No items

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

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

5.1.1. Brilique - ticagrelor - EMEA/H/C/001241/II/0047/G

AstraZeneca AB

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

Scope: "Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) and type 2 diabetes mellitus (T2DM) without a history of myocardial infarction who have undergone percutaneous coronary intervention (PCI) based on the final results of study D513BC00001 (THEMIS), a phase III multinational, randomised, double-blind, placebo controlled study to evaluate the effect of ticagrelor twice daily on the incidence of cardiovascular death, myocardial infarction or stroke in patients with T2DM; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated.
Update of section 4.8 of the SmPC regarding new safety information on traumatic haemorrhages based on the final results from study D513BC00001 (THEMIS) and data from the ticagrelor clinical development programme and post-marketing data. The Package Leaflet is updated in accordance. The RMP version 12 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2019.

5.1.2. Cosentyx - secukinumab - EMEA/H/C/003729/II/0057

Novartis Europharm Limited

Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension of indication to include the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years, who are candidates for

systemic therapy for Cosentyx; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. Section 6.6 of the SmPC for the solution for injection is also 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. The RMP version 6.0 has also been submitted. Furthermore, the Annex II is brought in line with the latest QRD template version 11.0."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

5.1.3. Doptelet - avatrombopag - EMEA/H/C/004722/II/0004/G

Dova Pharmaceuticals Ireland Limited

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension of indication to include the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments; consequently, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. Additionally, the SmPC section 5.3 is updated with data from juvenile toxicity studies. Furthermore, an additional pack size has been introduced with subsequent updates of sections 6.5 and 8 of the SmPC. The Package Leaflet and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

5.1.4. 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

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

AstraZeneca AB

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jorge Camarero Jiménez, 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 2.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

5.1.6. Invokana - canagliflozin - EMEA/H/C/002649/II/0046

Janssen-Cilag International NV

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.1 , 4.2, 4.8 and 5.1 of the Summary of Product Characteristics to add a new therapeutic indication for Invokana (canagliflozin) for the treatment of stage 2 or 3 chronic kidney disease and albuminuria, as an adjunct to standard of care, in adults with type 2 diabetes mellitus. The proposed new indication is based upon new clinical efficacy and safety data from the Phase 3 study: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial (CREDENCE) (DNE3001).
The Package Leaflet is updated in accordance. The RMP version 8.1 has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.",

Possible oral explanation

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 27.02.2020, 14.11.2019.

See 2.3

5.1.7. Kyprolis - carfilzomib - Orphan - EMEA/H/C/003790/II/0045

Amgen Europe B.V.

Rapporteur: Jorge Camarero Jiménez, Co-Rapporteur: Alexandre Moreau

Scope: "Extension of existing indication to include combination of Kyprolis with daratumumab and dexamethasone; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

5.1.8. Lynparza - olaparib - EMEA/H/C/003726/II/0033

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Koenraad Norga, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to support the use of Lynparza tablets (100 mg and 150 mg) for the maintenance treatment of gBRCAm metastatic pancreatic cancer based on the results from the pivotal Phase 3 study, POLO; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update section 4.8 for Lynparza hard capsules (50 mg) to revise list of ADR based on the pooled safety data analysis. The RMP version 18 has also been submitted. Furthermore, the PI is brought in line with the latest guideline regarding the sodium content. The MAH also took the occasion to include some minor editorial changes in the PI.",

Possible oral explanation

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 30.01.2020, 17.10.2019.

See 2.3

5.1.9. Ofev - nintedanib - Orphan - EMEA/H/C/003821/II/0027

Boehringer Ingelheim International GmbH

Rapporteur: Peter Kiely, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication to include new indication for Ofev for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype based on the results of pharmacology studies and the double-blind, randomised, placebo-controlled phase III trial (INBUILD). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to reflect the use of Ofev in the new indication. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor formatting changes in the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.1. The RMP version 9.0 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 26.03.2020, 12.12.2019.

5.1.10. 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 26.03.2020.

5.1.11. Orfadin - nitisinone - EMEA/H/C/000555/II/0071

Swedish Orphan Biovitrum International AB

Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adult patients with alkaptonuria (AKU) for Orfadin; as a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1 and 10 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.2 of the RMP has also been submitted accordingly and includes an update in accordance with GVP Module V Revision 2.", Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)

Action: For adoption

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

Novo Nordisk A/S

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Mark Ainsworth, PRAC Rapporteur: Menno van der Elst

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

Action: For adoption

5.1.13. Sivextro - tedizolid phosphate - EMEA/H/C/002846/II/0035

Merck Sharp & Dohme B.V.

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication (treatment of ABSSSI in adults) to include adolescent population from 12 years old and older for Sivextro; as a consequence, sections 4.1, 4.2,

4.8 and 5.2 of the SmPC are updated. Sections 1 and 2 of the Package Leaflet are updated in accordance. The updated RMP version 5.1 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"

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

5.1.14. Taltz - ixekizumab - EMEA/H/C/003943/II/0031

Eli Lilly Nederland B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and adolescents who are candidates for systemic therapy for Taltz; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated with new safety and efficacy information. 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. The RMP version 7.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 30.01.2020.

5.1.15. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0039

Roche Registration GmbH

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

Scope: "Extension of indication to include, in combination with bevacizumab, the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy, based on the results of the pivotal study YO40245 (IMbrave150) as well as data from Arms A and F of the supportive Phase Ib study GO30140. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the Tecentriq 1200 mg concentrate for solution for infusion SmPC are updated. The Package Leaflet is updated in accordance. An updated RMP version 13.0 was provided as part of the application."

Action: For adoption

5.1.16. Trumenba - meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0013

Pfizer Europe MA EEIG

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of indication for Trumenba to include active immunisation of children 1-9 years old. Sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated in parallel based on the results from the two pivotal studies B1971017 and B1971035. The Package Leaflet is

updated in accordance. The RMP version 2.0 has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to submit a corrected version of the final report of study B1971016, which was included in the initial marketing authorisation application."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020, 14.11.2019, 25.07.2019, 28.02.2019.

5.1.17. Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0051

Janssen-Cilag International NV

Rapporteur: Martina Weise, PRAC Rapporteur: Menno van der Elst

Scope: "Update of sections 4.2, 4.8 and 5.1 of the Summary of Product Characteristics based upon new clinical efficacy and safety data from the Phase 3 study: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial (CREDENCE) (DNE3001). The Package Leaflet is updated in accordance. 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 30.04.2020, 27.02.2020, 14.11.2019.

5.1.18. Xtandi - enzalutamide - EMEA/H/C/002639/II/0047/G

Astellas Pharma Europe B.V.

Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Eva A. Segovia

Scope: "C.1.6: Extension of indication to include the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for Xtandi in combination with androgen deprivation therapy; As a consequence, sections 4.1, 4.7, 4.8, 5.1, 5.3 and 6.6 of the SmPC are updated. Furthermore the marketing authorisation holder (MAH) took the opportunity to make corrections to section 4.7. The Package Leaflet is updated in accordance.
The RMP version 13.0 has also been submitted.

C.1.4: Update of section 5.1 of the SmPC based the 5-year Overall Survival (OS) results obtained from the PREVAIL study (MDV310003), a phase 3 study of enzalutamide in chemotherapy naïve patients with metastatic prostate cancer that progressed on ADT.",

Oral explanation

Action: For adoption

Request for Supplementary Information adopted on 17.10.2019.

See 2.3

5.1.19. Xyrem - sodium oxybate - EMEA/H/C/000593/II/0076

UCB Pharma S.A.

Rapporteur: Bruno Sepodes, Co-Rapporteur: Mark Ainsworth, PRAC Rapporteur: Ana Sofia

Diniz Martins

Scope: "Extension of indication to include adolescents and children older than 7 years for Xyrem; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. The updated version (9.0) of the RMP was submitted."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2019, 29.05.2019, 15.11.2018.

5.1.20. Zejula - niraparib - Orphan - EMEA/H/C/004249/II/0019

GlaxoSmithKline (Ireland) Limited

Rapporteur: Bjorg Bolstad, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include the maintenance treatment of adult patients with advanced high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy for Zejula in monotherapy; as a consequence, sections 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The MAH is also taking the opportunity to make minor corrections throughout the PI. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted to add the new indication, bring it in line with the RMP template Rev. 2.0.1 and update due dates for category 3 studies.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

5.2.1. Fycompa - perampanel - EMEA/H/C/002434/II/0047

Eisai GmbH

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ghania Chamouni

Scope: "Extension of indication to include adjunctive treatment in paediatric patients from 2 to 11 years of age in Partial-Onset (focal) Seizures with or without secondary generalisation and Primary Generalised Tonic-Clonic Seizures with idiopathic generalised epilepsy for Fycompa. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 4.3 has also been submitted.",

Letter from the applicant dated 19 May 2020 requesting an extension of clock-stop to respond to the request for supplementary information adopted in April 2020.

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 12.12.2019.

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. IV Zanamivir - zanamivir- EMEA/H/K/002288

GlaxoSmithKline Research & Development Limited; treatment of pandemic A(H1N1)v infection or infection due to seasonal influenza A or B virus.

Compassionate Use Rapporteur: Kristina Dunder, Compassionate Use Co-Rapporteur: Alexandre Moreau

Scope: Termination of the compassionate use programme as of 06 May 2019

Action: For information

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. dengue virus serotype 1* (live, attenuated); *genes of serotype-specific surface proteins engineered into dengue type 2 backbone, dengue virus serotype 2 (live, attenuated),dengue virus serotype 3* (live, attenuated); *genes of serotype-specific surface proteins engineered into dengue type 2 backbone, dengue virus

serotype 4* (live, attenuated); *genes of serotype-specific surface proteins engineered into dengue type 2 backbone - H0005362

active immunisation for the prevention of dengue disease caused by any serotype in individuals 2 to 60 years of age.

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

Action: For adoption

8.1.2. risdiplam - H0005145

treatment of Spinal Muscular Atrophy (therapeutic area – neurology).

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. Bavencio - avelumab - EMEA/H/C/004338/II/0013

Merck Europe B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted

Scope: "Update of section 5.1 of the SmPC in order to update efficacy information following results from study EMR100070-003 Part B listed as a specific obligation in the Annex II; this is a Phase II, open-label, multicenter trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in subjects with Merkel cell carcinoma. With this submission the company is also taking the opportunity to update annex-II proposing deletion of the specific obligation and proposing the switch from conditional to full marketing authorisation. The

package leaflet and the RMP (version 2.1) are updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

9.1.2. Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0116

Genzyme Europe BV

Rapporteur: Johann Lodewijk Hillege

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to change posology recommendations in adults, children and adolescents aged 8 years and older by removing the information on the lower dosing regimens that have been used in clinical studies and update the clinical information based on the review of published scientific literature including 3 observational studies in patients remaining on standard dose of Fabrazyme or switching to low-dose Fabrazyme (0.5 mg/kg every 2 weeks) or to the registered dose of agalsidase alfa (0.2 mg/kg every 2 weeks). In addition, the marketing authorisation holder (MAH) took the opportunity to propose changes in the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products."

Action: For adoption

9.1.3. Prevymis - letermovir - EMEA/H/C/004536/II/0016/G, Orphan

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson

Scope: "C.I.4 (type II) – Update of sections 4.4 and 6.6 of the SmPC to include the recommendation to use an in-line filter at the point of administration for finished product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004). The package leaflet and labelling are updated accordingly.
B.II.d.1.z (type IB) –".

C.1.11.z (type IB) - Change in the due date of the Annex II condition for the medicinal product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004)."

Action: For discussion

Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.

9.1.4. Tecfidera - dimethyl fumarate - EMEA/H/C/002601/II/0063

Biogen Netherlands B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.4 and 4.8 of the SmPC to reflect PML in the setting of mild lymphopenia based on data submitted in the ongoing PSUSA/00010143/201903. The Package Leaflet is updated accordingly. Additionally, the Product Information has been updated in line with QRD template (version 10.1).",

PRAC advice

Action: For discussion

Request for Supplementary Information adopted on 30.01.2020, 19.09.2019.

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: Jorge Camarero Jiménez

Scope: List of outstanding issues

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: Opinion

Action: For adoption

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

No items

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

No items

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

No items

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

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

MAH: various

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

Scope: List of outstanding issues

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

10.7. 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

May 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

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

No items

14.2. Coordination with EMA Scientific Committees

Note: Reports of EMA Scientific Committees are available in the MMD folder of the respective Committee.

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 11-14 May 2020

Action: For information

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

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at May 2020 PDCO

Action: For information

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

14.3.1. Ad-hoc Influenza Working Group

Scope: Amended May 2020 - EU Strain selection for the Influenza Vaccines for the Season 2020/2021: Report from the Ad Hoc Influenza working group to the BWP adopted via written procedure on 08 May 2020.

Action: For information

Scope: Amended May 2020 - EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2020/2021 adopted via written procedure on 08 May 2020.

Action: For information

14.3.2. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP May 2020 meeting to CHMP for adoption:

- 10 reports on products in scientific advice and protocol assistance
- 14 reports on products in pre-authorisation procedures
- 4 reports on products in plasma master file

Action: For adoption

14.3.3. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 23 April 2020.

Action: For adoption

14.3.4. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 11–14 May 2020, Table of conclusions

Action: For information

Call for interest for nomination of a replacement SAWP member and his/her alternate.

The required area of expertise is oncology and anti-infectives. The letters of candidacy together with the CV of both member and alternate, as per the SAWP Rules of Procedure, should be sent directly to the SAWP Secretariat

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)*

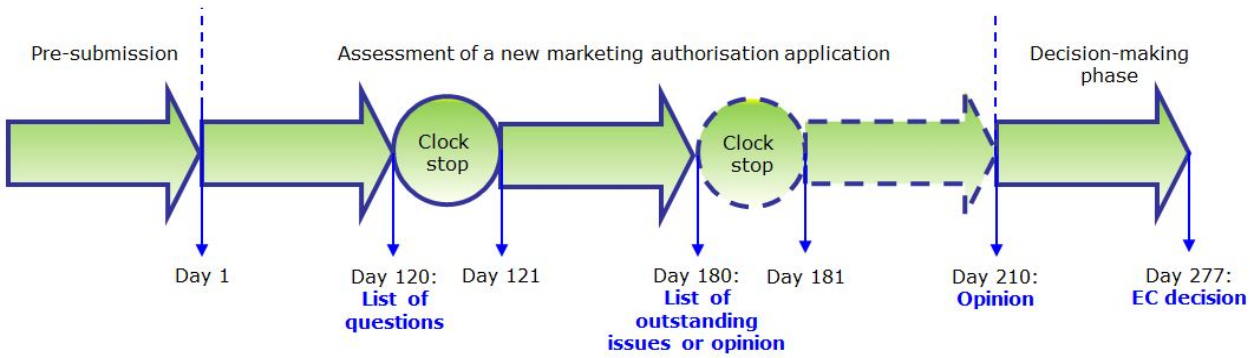
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

27 May 2020
EMA/CHMP/278644/2020

Annex to 25-28 May 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
May 2020: **For adoption**

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

Final Outcome of Rapporteurship allocation for
May 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

Orphacol - cholic acid -
EMEA/H/C/001250/S/0033, Orphan
Laboratoires CTRS, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Sofia Trantza
Request for Supplementary Information adopted on 30.04.2020, 27.02.2020.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Nucala - mepolizumab -
EMEA/H/C/003860/R/0031
GlaxoSmithKline Trading Services Limited, Rapporteur: Peter Kiely, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Brigitte Keller-Stanislawski
Request for Supplementary Information adopted on 30.04.2020.

Omidria - phenylephrine / ketorolac -
EMEA/H/C/003702/R/0015
Omeros Ireland Limited, Rapporteur: Jayne Crowe, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Jan Neuhauser
Request for Supplementary Information adopted on 30.04.2020.

Raxone - idebenone -
EMEA/H/C/003834/R/0020, Orphan
Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: John Joseph Borg, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Amelia Cupelli
Request for Supplementary Information adopted on 26.03.2020.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Aripiprazole Accord - aripiprazole -
EMEA/H/C/004021/R/0019
Accord Healthcare S.L.U., Generic, Generic of Abilify, Rapporteur: John Joseph Borg, PRAC Rapporteur: Ana Sofia Diniz Martins

Briviact - brivaracetam -
EMEA/H/C/003898/R/0025
UCB Pharma S.A., Rapporteur: Filip Josephson, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Adam Przybylkowski

CIAMBRA - pemetrexed -
EMEA/H/C/003788/R/0006
Menarini International Operations Luxembourg S.A., Generic, Generic of Alimta, Rapporteur: Natalja Karpova, PRAC Rapporteur: Adrien Inoubli

Cinacalcet Mylan - cinacalcet -
EMEA/H/C/004014/R/0011
Mylan S.A.S, Generic, Generic of Mimpara, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ulla Wändel Liminga

Cresemba - isavuconazole -
EMEA/H/C/002734/R/0027, Orphan
Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski
Request for Supplementary Information adopted on 26.03.2020.

Ebymect - dapagliflozin / metformin -

EMEA/H/C/004162/R/0046
AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Menno van der Elst

Edistride - dapagliflozin - EMEA/H/C/004161/R/0038
AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Annika Folin

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

Imlygic - talimogene laherparepvec - EMEA/H/C/002771/R/0039, ATMP
Amgen Europe B.V., Rapporteur: Olli Tenhunen, Co-Rapporteur: Rune Kjeken, CHMP Coordinators: Tuomo Lapveteläinen and Ingrid Wang, PRAC Rapporteur: Brigitte Keller-Stanislawski

Obizur - susoctocog alfa - EMEA/H/C/002792/R/0033
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Brigitte Keller-Stanislawski

Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/R/0056
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Praxbind - idarucizumab - EMEA/H/C/003986/R/0019
Boehringer Ingelheim International GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Mark Ainsworth, PRAC Rapporteur: Menno van der Elst

Votubia - everolimus - EMEA/H/C/002311/R/0065, Orphan
Novartis Europharm Limited, Rapporteur: Janet Koenig, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber
Request for Supplementary Information adopted on 30.04.2020.

VPRIV - velaglucerase alfa -

EMEA/H/C/001249/R/0045, Orphan
Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber
Request for Supplementary Information adopted on 26.03.2020.

B.2.3. Renewals of Conditional Marketing Authorisations

Bavencio - avelumab - EMEA/H/C/004338/R/0017
Merck Europe B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Hans Christian Siersted

Translarna - ataluren - EMEA/H/C/002720/R/0057, Orphan
PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Liana Gross-Martirosyan
Request for Supplementary Information adopted on 30.04.2020.

VITRAKVI - larotrectinib - EMEA/H/C/004919/R/0006
Bayer AG, Rapporteur: Filip Josephson, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rugile Pilviniene

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 11-14 May 2020:

Signal of erroneous assay results for levels of anti-factor Xa activity with use of andexanet alfa:

ONDEXXYA - andexanet alfa

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Maria Concepcion Prieto Yerro

PRAC recommendation on a DHPC

Action: For adoption

Signal of diverticulitis:

OLUMIANT – baricitinib

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

PRAC recommendation on a variation

Action: For adoption

Signal of drug-drug interaction with serotonergic drugs leading to serotonin syndrome:

BUVIDAL, SIXMO, SUBOXONE, ZUBSOLV, CYMBALTA, DULOXETINE LILLY, DULOXETINE MYLAN, DULOXETINE ZENTIVA, XERISTAR, YENTREVE, SANCUSO, ALOXI, PALONOSETRON ACCORD, AKYNZEO - buprenorphine, buprenorphine, naloxone, Selective serotonin reuptake inhibitors (SSRIs), Tricyclic antidepressants (TCAs), Other psychiatric medicines, Serotonin receptor agonists, Antiemetics, Other serotonergic drugs

Rapporteur: various, Co-Rapporteur: various

PRAC recommendation on a variation

Action: For adoption

Signal on new information on the known risk of breast cancer:

DUAVIVE - hormone replacement therapy (HRT)

Rapporteur: Martina Weise, Co-Rapporteur: Mark Ainsworth

PRAC recommendation on a variation

Action: For adoption

PSUR procedures

PRAC recommendation for variation of the terms of the MA adopted at the PRAC meeting held on 11-14 May 2020:

EMEA/H/C/PSUSA/00000939/201910 (deferasirox)
CAPS:
EXJADE (EMEA/H/C/000670) (deferasirox), Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "Period Covered From: 01/11/2018 To: 31/10/2019"

EMEA/H/C/PSUSA/00002014/201910
(methotrexate)
CAPS:
Jylamvo (EMEA/H/C/003756) (methotrexate), Therakind (Europe) Limited, Rapporteur: Bruno Sepodes
Nordimet (EMEA/H/C/003983) (methotrexate), Nordic Group B.V., Rapporteur: Bruno Sepodes
NAPS:
NAPs – EU
PRAC Rapporteur: Martin Huber
"Period Covered From: 31/10/2018 To: 31/10/2019"

EMEA/H/C/PSUSA/00002321/201910
(pazopanib)
CAPS:
Votrient (EMEA/H/C/001141) (pazopanib), Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Period Covered From: 19/10/2018 To: 18/10/2019"

EMEA/H/C/PSUSA/00010118/201909
(midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures))
CAPS:
BUCCOLAM (EMEA/H/C/002267) (midazolam), Shire Services BVBA, Rapporteur: Johann Lodewijk Hillege
NAPS:
NAP - EU
PRAC Rapporteur: Liana Gross-Martirosyan, "Period Covered From: 06/04/2017 To: 08/09/2019"

EMEA/H/C/PSUSA/00010318/201910
(nintedanib (oncology indications))
CAPS:
Vargatef (EMEA/H/C/002569) (nintedanib), Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Agni Kapou, "Period Covered From: 15/10/2018 To: 15/10/2019"

EMEA/H/C/PSUSA/00010534/201910
(irinotecan (liposomal formulations))
CAPS:
Onivyde pegylated liposomal (EMEA/H/C/004125) (irinotecan hydrochloride trihydrate), Les Laboratoires Servier, Rapporteur: Filip Josephson, PRAC Rapporteur: David Olsen, "Period Covered From: 23/04/2019

To: 22/10/2019”	
EMEA/H/C/PSUSA/00010723/201910 (durvalumab) CAPS: **Imfinzi** (EMEA/H/C/004771) (durvalumab), AstraZeneca AB, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: David Olsen, “Period Covered From: 01/05/2019 To: 31/10/2019”	

B.4. EPARs / WPARs

Fingolimod Mylan - fingolimod - EMEA/H/C/005282 Mylan Ireland Limited, treatment of multiple sclerosis, Generic, Generic of Gilenya, Generic application (Article 10(1) of Directive No 2001/83/EC) **WPAR**	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

Adcetris - brentuximab vedotin - EMEA/H/C/002455/II/0075/G, Orphan Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik	
Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0029/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 19.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Emtricitabine/Tenofovir disoproxil Zentiva - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137/II/0015 Zentiva k.s., Generic, Generic of Truvada, Rapporteur: Alar Irs	
Entyvio - vedolizumab - EMEA/H/C/002782/II/0049 Takeda Pharma A/S, Rapporteur: Daniela Melchiorri	
Grastofil - filgrastim - EMEA/H/C/002150/II/0029	

Accord Healthcare S.L.U., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka	
Grastofil - filgrastim - EMEA/H/C/002150/II/0031/G Accord Healthcare S.L.U., Rapporteur: Outi Mäki-Ikola	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0112/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0037, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 02.04.2020, 30.01.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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.	Request for supplementary information adopted with a specific timetable.
Kevzara - sarilumab - EMEA/H/C/004254/II/0022/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Mekinist - trametinib - EMEA/H/C/002643/II/0038/G Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. 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/0098 Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Ogivri - trastuzumab - EMEA/H/C/004916/II/0016 Mylan S.A.S, Rapporteur: Koenraad Norga	

Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0010/G Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 17.04.2020.	
Ozempic - semaglutide - EMEA/H/C/004174/II/0011 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 13.02.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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.	Request for supplementary information adopted with a specific timetable.
Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0185/G Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0159 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
RoActemra - tocilizumab - EMEA/H/C/000955/II/0096 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Soliris - eculizumab - EMEA/H/C/000791/II/0112, Orphan Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez	
TAKHZYRO - lanadelumab - EMEA/H/C/004806/II/0012/G, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder Opinion adopted on 07.05.2020. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 12.03.2020.	
Ultomiris - ravulizumab - EMEA/H/C/004954/II/0005 Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez	
XGEVA - denosumab - EMEA/H/C/002173/II/0071/G Amgen Europe B.V., Rapporteur: Kristina Dunder Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Zevalin - ibritumomab tiuxetan - EMEA/H/C/000547/II/0051/G Ceft Biopharma s.r.o., Rapporteur: Sinan B. Sarac	
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	

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

Abilify Maintena - aripiprazole - EMEA/H/C/002755/II/0035 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of the PI to add an alternate initiation regimen" Request for Supplementary Information adopted on 26.03.2020.	
AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0029 sanofi-aventis groupe, Rapporteur: Martina Weise, "To update section 4.4 of the SmPC to add information on cases of drug-induced liver injury (DILI) observed in the postmarketing setting and section 4.8 of the SmPC to add the adverse event DILI under the frequency unknown. The package leaflet is updated accordingly." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Benlysta - belimumab - EMEA/H/C/002015/II/0077 GlaxoSmithKline (Ireland) Limited, Rapporteur:	

Kristina Dunder, "Update of section 4.2 of the SmPC in order to update the information on elderly patients based on the interim results from study BEL116559 listed as a category 3 study in the RMP; this is a meta-analysis to assess efficacy and safety in elderly subjects treated in selected belimumab studies." Request for Supplementary Information adopted on 26.03.2020.	
BLINCYTO - blinatumomab - EMEA/H/C/003731/II/0036, Orphan Amgen Europe B.V., Rapporteur: Alexandre Moreau, "C.I.13: Submission of the final report from study MT103-211 classified as Category 3 Post-Authorization Safety Study (PASS) in the Risk Management Plan (RMP). This is an interventional clinical study (Open-label, Multicenter, Phase 2) to Evaluate Efficacy and Safety of the Bi-specific T cell Engager (BiTE) Antibody Blinatumomab in Adult Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (ALL). The objective of this PASS was to evaluate central nervous system (CNS) symptoms and explore predictive factors for CNS events associated with blinatumomab, based on an additional evaluation cohort that had been opened to help better understand CNS symptoms with blinatumomab."	
Caelyx pegylated liposomal - doxorubicin - EMEA/H/C/000089/II/0094 Janssen-Cilag International NV, Rapporteur: Ondřej Slanař, "Update of sections 4.2 and 4.8 of the SmPC in line with the SmPC guideline. In addition, the MAH took the opportunity to update the PI in line with the QRD template version 10.1 and with the EDQM standard terms. Furthermore, the list of local representatives in the Package Leaflet is updated." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
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 postmarketing cases associated with the use of daptomycin. Wording has been added to the Product information with regard to the contents of sodium, implementing the guideline for excipients in the labelling and package leaflet of medicinal products for human use. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce QRD-related, spelling, formatting and spacing corrections."	
Darzalex - daratumumab - EMEA/H/C/004077/II/0038, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to: -add sepsis to the list of adverse drug reactions (ADRs) with frequency common -add new data on infections and special populations following a review of relevant safety information from the daratumumab clinical program resulting in an updated Company Core Data Sheet (CCDS) based on results from a Phase 3, randomized, controlled study comparing daratumumab in combination with carfilzomib (twice weekly) and dexamethasone (DKd) with carfilzomib (twice weekly) plus dexamethasone (Kd) in subjects with relapsed/refractory multiple myeloma (study 20160275 - CANDOR) The MAH also proposes the following minor corrections. - In section 4.8 of the SPC, the ADR frequencies for Neutropenia and Back-pain were corrected. - The Package Leaflet and labelling is updated accordingly" Request for Supplementary Information adopted on 07.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Dupixent - dupilumab - EMEA/H/C/004390/II/0030** sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Update of section 4.8 of the SmPC to include arthralgia as	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

a new Adverse Drug Reaction (ADR) with a frequency not known. This is based on safety review of post-marketing data and PRAC recommendation adopted in the last PSUR assessment dated April 2020. The package leaflet is updated accordingly. The requested variation proposed amendments to the Summary of Product Characteristics and Package Leaflet." Opinion adopted on 14.05.2020.	
Dynastat - parecoxib - EMEA/H/C/000381/II/0077 Pfizer Europe MA EEIG, Duplicate, Duplicate of Xapit (SRD), Rapporteur: Jayne Crowe, "SmPC sections 4.3 and 4.4 are updated to include Drug Reaction with Eosinophilia and Systemic Symptoms syndrome (DRESS syndrome)." Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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"	
Elaprase - idursulfase - EMEA/H/C/000700/II/0086 Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.9 of the SmPC in order to include a warning on the risk of anaphylactoid reaction following overdose with Elaprase."	
EVRA - ethinylestradiol / norelgestromin - EMEA/H/C/000410/II/0046/G Janssen-Cilag International NV, Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.5 and 4.8 of the SmPC in order to add drug-drug interaction information on use with cobicistat and to add anaphylactic reaction to the list of adverse drug reactions (ADRs) with frequency rare, following the update of the company's core data sheet (CCDS) due to new data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted	

on 26.03.2020.	
Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0116 Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 5.1 of the SmPC in order to change posology recommendations in adults, children and adolescents aged 8 years and older by removing the information on the lower dosing regimens that have been used in clinical studies and update the clinical information based on the review of published scientific literature including 3 observational studies in patients remaining on standard dose of Fabrazyme or switching to low-dose Fabrazyme (0.5 mg/kg every 2 weeks) or to the registered dose of agalsidase alfa (0.2 mg/kg every 2 weeks). In addition, the MAH took the opportunity to propose changes in the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products."	See agenda 9.1
Fotivda - tivozanib - EMEA/H/C/004131/II/0012 EUSA Pharma (Netherlands) B.V., Rapporteur: Bruno Sepodes, "Submission of AV-951-15-303 (TIVO-3) study (Phase 3 randomized, controlled, multi-centre, open-label study to compare tivozanib versus sorafenib in RCC patients who have failed 2 or 3 prior systemic regimens) in order to present the second interim OS analysis and to fulfil PAM LEG-003 procedure."	
Galafold - migalastat - EMEA/H/C/004059/II/0025, Orphan Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, "Update to the Galafold Summary of Product Characteristics (SmPC), section 5.1 Pharmacodynamic Properties to add 1017 new amenable mutations in Table 2: Galafold (migalastat) amenability table and delete the entire Table 3: Mutations not amenable to Galafold (migalastat). In addition, the MAH took the opportunity to update contact details of the MAH and Belgium local representatives and the Labelling (outer packaging), section 5. Method and Route(s) of administration as well as Package Leaflet, section 3. How to take Galafold	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

in order to improve the instructions for opening and removal of the capsules out of the packaging. Editorial linguistic changes are made in Czech, Dutch, Finnish, Greek, Polish, Icelandic, Italian and Swedish languages." Opinion adopted on 14.05.2020.	
Glivec - imatinib - EMEA/H/C/000406/II/0117 Novartis Europharm Limited, Rapporteur: Jorge Camarero Jiménez, "Update of section 4.6 of the SmPC to include that women of childbearing potential must be advised to use effective contraception for at least 15 days after stopping treatment with imatinib, based on a company review of the company Core Data Sheet. The PL has been updated accordingly." Request for Supplementary Information adopted on 26.03.2020, 30.01.2020, 10.10.2019.	
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0034, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, "Submission of a variation to update the dosing regimen as follows: -21-day prophylaxis regimen with rIX-FP at a dose of 100 IU/kg body weight for patients ≥ 12 years who are well controlled on a 14-day prophylaxis regimen. -10- or 14-day prophylaxis regimen with rIX-FP at a dose of 75 IU/kg body weight for patients < 12 years who are well controlled on a 7-day prophylaxis regimen. This submission also updates the existing population PK model with additional intravenous and subcutaneous (SC) data from the PTPs in the PTP arm of study CSL654_3003 and re-evaluates the covariates that are possible determinants of PK variability." Request for Supplementary Information adopted on 26.03.2020, 14.11.2019.	
Kalydeco - ivacaftor - EMEA/H/C/002494/II/0084, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.1 of the SmPC in order to include the information based on results from study VX14-661-110, which is a Phase 3, multicenter, open label, rollover study for Studies 103, 106, 107, 108, 109, 111, 112, and 114 designed to evaluate the long-term safety	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

and tolerability of TEZ/IVA treatment in combination with ivacaftor for 96 weeks in cystic fibrosis (CF) subjects 12 years and older, homozygous or heterozygous for the F508del CFTR mutation." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
Nerlynx - neratinib - EMEA/H/C/004030/II/0011/G Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update the pharmacokinetics properties of neratinib and amend drug-drug interaction (DDI) information with CYP3A4/P-gp inducers and inhibitors based on two ADME studies (PUMA-NER-0105 and PUMA-NER-0102), a PBPK model report and in vitro studies; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor corrections to the PI and to bring the PI in line with the latest QRD template version 10. Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update DDI information with H2-receptor antagonists and add DDI information with loperamide based on two DDI studies (PUMA-NER-0104, PUMA-NER-0103); the Package Leaflet is updated accordingly."	
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0003 Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from Population PK and PK/PD Modelling Report (POR-PKPD-ADEX-321) listed as a category 2 study in the RMP/Specific Obligation 004 in Annex II." Request for Supplementary Information adopted on 12.12.2019.	
Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0123 Boehringer Ingelheim International GmbH, Rapporteur: Mark Ainsworth, "Update of section 4.8 of the SmPC in order to update the safety information regarding neutropenia and agranulocytosis following update to the Pradaxa Company Core Data Sheet. The Package Leaflet are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

opportunity to make Minor Linguistic Changes to the several language versions of the Product Information." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
PREVYMIS - letermovir - EMEA/H/C/004536/II/0016/G, Orphan Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, "C.I.4 (type II) – Update of sections 4.4 and 6.6 of the SmPC to include the recommendation to use an in-line filter at the point of administration for finished product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004). The package leaflet and labelling are updated accordingly. B.II.d.1.z (type IB) – C.1.11.z (type IB) - Change in the due date of the Annex II condition for the medicinal product Prevymis 240 mg and 480 mg concentrate for solution for infusion (EU/1/17/1245/003-004) ." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019.	See agenda 9.1
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.	Request for supplementary information adopted with a specific timetable.
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.”	
Rubraca - rucaparib - EMEA/H/C/004272/II/0019/G Clovis Oncology Ireland Limited, Rapporteur: Jorge Camarero Jiménez, “Submission of the final report from study CO-338-017 (ARIEL2), a Phase 2, open-label study evaluating the efficacy and safety of rucaparib in patients with relapsed high-grade serous or endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer. Submission of the final report from study CO-338-010 (Study 10), a Phase 1/2, open-label study evaluating the safety, PK and efficacy of rucaparib in patients with relapsed platinum-sensitive high grade ovarian cancer.”	
Signifor - pasireotide - EMEA/H/C/002052/II/0046, Orphan Novartis Europharm Limited, Rapporteur: Kristina Dunder, “Update of sections 4.4 of the SmPC in order to add new warnings on cholangitis and ketoacidosis and 4.8 to add diabetic ketoacidosis to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly.” Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Soliris - eculizumab - EMEA/H/C/000791/II/0113, Orphan Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez, “Submission of a variation to update section 4.2 of the SmPC to include home-infusion as an alternative infusion setting for Soliris for all the approved indications (paroxysmal nocturnal hemoglobinuria, atypical	

hemolytic uremic syndrome, refractory generalized myasthenia gravis and neuromyelitis optica spectrum disorder). The PL has been updated accordingly."	
Stribild - elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil - EMEA/H/C/002574/II/0111/G Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, "Grouped application: - C.I.4 (Type II): Update of section 4.5 of the SmPC to include data on the drug-drug interaction between Stribild and the thienopyridine anti-platelet drugs clopidogrel and prasugrel, based on a MAH cumulative safety review. The Package Leaflet is updated accordingly. - C.I.4 (Type II): Update of section 4.5 of the SmPC to include data on the drug-drug interaction between Stribild and medicinal products or oral supplements containing polyvalent cations, based on a MAH cumulative safety review. The Package Leaflet is updated accordingly. - C.I.3.z (Type IBz): Update of sections 4.5 and 4.8 of the SmPC to implement information related to the interaction with didanosine, and section 4.8 of the SmPC to implement new wording regarding lactic acidosis, in line with the PRAC recommendation from EMEA/H/C/PSUSA/00002892/201903. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to correct the amount of lactose stated in section 2 of the SmPC, update section 4.5 of the SmPC in line with the clinical study report for Study GS-US-216-0125, 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 sodium content and make minor editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.1." Opinion adopted on 14.05.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tegsedi - inotersen - EMEA/H/C/004782/II/0011, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, "Update of SmPC section 5.3 to	

reflect the results of rat carcinogenicity study."	
Tygacil - tigecycline - EMEA/H/C/000644/II/0110 Pfizer Europe MA EEIG, Rapporteur: Jorge Camarero Jiménez, "Update of sections 4.4 and 4.8 of the SmPC in order to add a recommendation regarding monitoring of coagulation parameters prior to and during tigecycline treatment based on post-marketing data and to update the frequency of the existing adverse drug reaction hypofibrinogenaemia from 'Not known' to 'Rare'. 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 sodium content and to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tysabri - natalizumab - EMEA/H/C/000603/II/0117 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "C.I.4 Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on an updated PK analysis from 11 studies (both IV and SC administration) and data with serial PK sampling as measured by an industry standard assay."	
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	Request for supplementary information adopted with a specific timetable.

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 of 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.	Request for supplementary information adopted with a specific timetable.
Xermelo - telotristat ethyl - EMEA/H/C/003937/II/0014, Orphan	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP

Ipsen Pharma, Rapporteur: Martina Weise, "To update sections 4.2 and 5.2 of the SmPC following final results from study LX1606-111; this is a Phase 1, open-label, parallel-group study to evaluate the single-dose pharmacokinetics of Telotristat Ethyl in Male and Female Subjects with Severe Hepatic Impairment and Matched Subjects with Normal Function; the Package Leaflet is updated accordingly. Additionally, the MAH took the opportunity to include minor editorial updates to the PL." Opinion adopted on 07.05.2020. Request for Supplementary Information adopted on 16.01.2020, 14.11.2019, 19.09.2019, 11.07.2019.	Members were in agreement with the CHMP recommendation.
WS1779 **Thymanax-EMEA/H/C/000916/WS1779/0044** **Valdoxan-EMEA/H/C/000915/WS1779/0046** Les Laboratoires Servier, Lead Rapporteur: Bjorg Bolstad, "Update of section 4.8 of the SmPC to add 'Myalgia' with a frequency 'uncommon' following routine pharmacovigilance review. The Package Leaflet section 4 is updated accordingly. In addition, the WorkShare Applicant takes the opportunity to bring the Product Information of Valdoxan and Thymanax in line with the latest QRD template version 10.1." Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1798 **Lyrica-EMEA/H/C/000546/WS1798/0104** **Pregabalin Pfizer-EMEA/H/C/003880/WS1798/0033** Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.8 and 5.1 of the SmPC to reflect data from study A0081106 "A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age With Partial Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age With Primary Generalized Tonic-Clonic Seizures"". Request for Supplementary Information adopted on 07.05.2020.	Request for supplementary information adopted with a specific timetable.

B.5.3. CHMP-PRAC assessed procedures

Bavencio - avelumab - EMEA/H/C/004338/II/0013 Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted, "Update of section 5.1 of the SmPC in order to update efficacy information following results from study EMR100070-003 Part B listed as a specific obligation in the Annex II; this is a Phase II, open-label, multicenter trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in subjects with Merkel cell carcinoma. With this submission the company is also taking the opportunity to update annex-II proposing deletion of the specific obligation and proposing the switch from conditional to full marketing authorisation. The package leaflet and the RMP (version 2.1) are updated accordingly." Request for Supplementary Information adopted on 27.02.2020.	See agenda 9.1
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 Request for Supplementary Information adopted on 26.03.2020.	
Caprelsa - vandetanib - EMEA/H/C/002315/II/0043 Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "C.I.4 Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on interim results from study D4200C00104, listed as a specific obligation in the Annex II. This is an observational study (including a retrospective arm to evaluate the Benefit/Risk of vandetanib (Caprelsa) 300 mg in RET mutation negative and RET mutation positive patients with symptomatic, aggressive, sporadic, unresectable, locally advanced/metastatic thyroid cancer (MTC)), to confirm the efficacy and safety of Caprelsa in RET-negative patients with the aim to fulfil SOB001 and convert Caprelsa from conditional to normal Marketing Authorization. In addition the MAH takes to opportunity to rectify the Dutch translation of the Caprelsa	

Product Information.”	
Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0106 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Jean-Michel Dogné, “Update of sections 4.4 and 5.1 of the SmPC based on final results from study HPV-019 listed as a category 3 study in the RMP (in fulfilment of MEA080); this is a safety and immunogenicity study of Cervarix in HIV-positive female subjects aged 15-25 years as compared to HPV-4, which was already submitted in P46-95. In addition, the Marketing authorisation holder (MAH) took the opportunity to reflect an update in section 4.2 of the SmPC to indicate that limited clinical data is now available in 4-6 years old children based on study HPV-073 following assessment in P46-90; this is a safety and immunogenicity study of Cervarix in girls aged 4-6 years, as an alternative to the current adolescent HPV vaccination schedule. The RMP version 21 has also been submitted to reflect the availability of the final results of the HPV-019 and HPV-073 studies, and the use of Cervarix in HIV-infected subjects or subjects with known immune deficiencies has been removed as missing information. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1.” Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cyramza - ramucirumab - EMEA/H/C/002829/II/0038 Eli Lilly Nederland B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add posterior reversible encephalopathy syndrome (PRES) and dysphonia as a warning and as undesirable effect, respectively. The Labelling and Package Leaflet are updated accordingly. The RMP version 9.3 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template.”	

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: Adrien Inoubli, "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." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Kisqali - ribociclib - EMEA/H/C/004213/II/0021 Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted, "Update of sections 4.2 and 4.4 of the SmPC in order to add a warning on ILD/pneumonitis and related dose modification recommendations. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted." Request for Supplementary Information adopted on 27.02.2020.	
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0047, Orphan MediWound Germany GmbH, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the final report from study MW2013-06-01, listed as a category 3 study in the RMP. This is an international, observational retrospective, data-collection study assessing efficacy of applied risk-minimisation measures in burn patients treated with NexoBrid. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to revise the RMP in line with the new RMP template (GVP Rev. 2) and to change the due date for the following category 3 studies: MW2013-06-01 and MW2010-03-02 (DETECT)" Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
ProQuad - measles, mumps, rubella and varicella vaccine (live) -	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP

EMEA/H/C/000622/II/0139 MSD Vaccins, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "To update sections 4.4 and 4.8 of the SmPC to update the safety information and further characterise the risk of secondary transmission following MAH evaluation of new significant Pharmacovigilance data. The Package Leaflet is updated accordingly. The RMP has been updated to version 7.1 to reflect those changes and with the consequential revisions: the important potential risk of "potential secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible high-risk individuals leading to severe clinical consequences" is renamed to "secondary transmission of Oka/Merck varicella vaccine virus strain in susceptible individuals leading to disseminated disease" and is reclassified to important identified risk. The MAH takes the opportunity to implement some changes in section 6.5 of the SmPC with information on the glass type for the immediate container following the "Excipients in the labelling and package leaflet of medicinal products for human use guideline" and the "Guideline on quality aspects included in the product information for vaccines for human use". Annex A has been updated with the same information. In addition, the MAH implements QRD v10.1 taking into account the 'Compilation of QRD decisions on stylistic matters in product information' (EMA/25090/2002 rev.19. The MAH also takes the chance to align some wordings across other MMRV vaccines owned by the MAH, in particular section 6.6 'Special precautions for disposal and other handling'." Opinion adopted on 14.05.2020.	Members were in agreement with the CHMP recommendation.
Resolor - prucalopride - EMEA/H/C/001012/II/0051 Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.4 'Special warnings and precautions for use' of the Summary of Product Characteristics (SmPC) with text relating to suicidal ideation and behaviour and to add 'suicidal ideation and behaviour' to the list of safety concerns as an important potential risk in the EU Risk	Request for supplementary information adopted with a specific timetable.

Management Plan (RMP vs 16.0) based on post-marketing reports. The package leaflet is proposed to be updated accordingly. The MAH has also taken to opportunity to make editorial changes to RMP and SmPC." Request for Supplementary Information adopted on 14.05.2020.	
SCENESSE - afamelanotide - EMEA/H/C/002548/II/0033, Orphan Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.8 of the SmPC to revise the frequencies of adverse drug reactions (ADRs) based on safety reports and to add new ADRs based on post-marketing spontaneous reports as requested during Scenesse Renewal procedure (EMEA/H/C/002548/R/0026); the Package Leaflet is updated accordingly. The RMP version 9.0 (in line with rev 2 of the template) has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes in section 2 of the SmPC and Annex IIIA." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
Symkevi - tezacaftor / ivacaftor - EMEA/H/C/004682/II/0016, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.8 and 5.1 of the SmPC in order to update the information based on final results from study VX14-661-110 listed as a category 3 study in the RMP; this is a Phase 3, multicenter, open label, rollover study for Studies 103, 106, 107, 108, 109, 111, 112, and 114 designed to evaluate the long-term safety and tolerability of TEZ/IVA treatment for 96 weeks in cystic fibrosis (CF) subjects 12 years and older, homozygous or heterozygous for the F508del CFTR mutation. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.1. The RMP version 2.2 has also been submitted." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 13.02.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Talzenna - talazoparib - EMEA/H/C/004674/II/0001 Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of sections 4.2 and 5.2 of the SmPC in order to change posology recommendations in patients with severe renal impairment and update pharmacokinetic information based on the results from PK study MDV3800-01 (C3441001) listed as a category 3 study in the RMP. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to make minor changes through the product information and to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 26.03.2020.	
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0063 Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Update of sections 4.4 and 4.8 of the SmPC to reflect PML in the setting of mild lymphopenia based on data submitted in the ongoing PSUSA/00010143/201903. The Package Leaflet is updated accordingly. Additionally, the Product Information has been updated in line with QRD template (version 10.1)." Request for Supplementary Information adopted on 30.01.2020, 19.09.2019.	See agenda 9.1
Tremfya - guselkumab - EMEA/H/C/004271/II/0020 Janssen-Cilag International N.V., Rapporteur: Melinda Sobor, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.4 and 4.8 of the SmPC to include anaphylaxis as an adverse drug reaction (ADR) with a frequency uncommon. Additionally, the ADR "injection site erythema" is amended to reflect injection site reactions in more general terms. The package leaflet is updated accordingly. Furthermore, the RMP is updated to version 5.3." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Trumenba - meningococcal group B vaccine (recombinant, adsorbed) -	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP

EMEA/H/C/004051/II/0023 Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the SmPC in order to update the safety and immunogenicity information based on final results from study B1971033 listed as a category 3 study in the RMP (MEA007); this is a duration of immunity study to assess persistence of hSBA response for up to 48 months after completion of vaccination with Trumenba and the immunogenicity, safety, and tolerability of a booster dose of Trumenba. The RMP version 3.0 has also been submitted, including changes related to this variation, changes agreed during another ongoing variation (II-13) and editorial changes. In addition, the Marketing authorisation holder (MAH) took the opportunity to include editorial changes in Annex II, in the labelling and in the Package Leaflet." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Members were in agreement with the CHMP recommendation.
Velphoro - iron - EMEA/H/C/002705/II/0021 Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 5.1 of the SmPC in order to add information related to the results of the VERIFIE study. This was a non-interventional voluntary PASS trial, which aimed to investigate the short and long-term real-life safety, effectiveness, and adherence of Velphoro in patients with hyperphosphataemia undergoing haemodialysis or peritoneal dialysis. It was listed as an additional pharmacovigilance activity (EMEA/H/C/002705/MEA/002), a category 3 study in the RMP. Furthermore, minor editorial wording changes in section 4.2 to provide consistent information between the SmPC and that already existing in the Labelling and PL were introduced. The RMP version 8.0 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." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 12.03.2020.	

B.5.4. PRAC assessed procedures

PRAC Led **Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/II/0024** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of the Risk Management Plan (RMP) to V3.0, to include amended study milestones and to revise the RMP document format in line with latest Good Pharmacovigilance Practices Guidance Module V, revision 2 guidelines, as requested during the assessment of the renewal." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Flixabi - infliximab - EMEA/H/C/004020/II/0052** Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of the RMP to replace the prospective observational cohort study of Flixabi in patients with Crohn's disease (CD) (SB2-G42-CD), with real-world data from PERFUSE, CREDIT and CEDUR studies." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Kineret - anakinra - EMEA/H/C/000363/II/0073** Swedish Orphan Biovitrum AB (publ), Rapporteur: Mark Ainsworth, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of the final report from study (Sobi.ANAKIN-302) listed as a category 3 study in the RMP and in accordance with Article 46 of Regulation (EC) No 1901/2006. This is a non-interventional, post-authorisation safety study to evaluate long-term safety of anakinra (Kineret) in patients with systemic juvenile idiopathic arthritis. The RMP version 5.3 has also been updated to reflect the completion of the study."	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
PRAC Led **Moventig - naloxegol - EMEA/H/C/002810/II/0029/G** Kyowa Kirin Holdings B.V., Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "Submission of an updated RMP version 6 in order to update the list of safety concerns" Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Naglazyme - galsulfase - EMEA/H/C/000640/II/0081** BioMarin International Limited, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Fátima Ventura, "Submission of an updated RMP version 6.0 in order to update the safety specification plan based on a review of the preclinical, clinical, post-marketing and literature data. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the Naglazyme RMP to the latest EU RMP template." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Replagal - agalsidase alfa - EMEA/H/C/000369/II/0106** Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update of section 4.8 of the Summary of Product Characteristics (SmPC) in order to update the list of adverse drug reactions (ADRs) information based on the final results from study HGT-REP-081 " a Multicenter Open-label Treatment Protocol to Observe the Safety of Replagal (agalsidase alfa) Enzyme Replacement Therapy in Canadian Patients with Fabry Disease". In addition, the MAH took the opportunity to introduce editorial and QRD changes in sections throughout the Product Information according to the QRD templates and current guidelines, including new	Request for supplementary information adopted with a specific timetable.

warnings related to sodium excipient and traceability of biological medicinal products. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 14.05.2020.	
PRAC Led **Retacrit - epoetin zeta - EMEA/H/C/000872/II/0094** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Pfizer's biosimilar epoetin zeta list of safety concerns has been aligned to the Innovator's Eprex (reference product, INN epoetin alfa)." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 13.02.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Spectrila - asparaginase - EMEA/H/C/002661/II/0017** medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Andrea Laslop, "Update of the Risk Management Plan (version 12) for Spectrila in accordance with GVP Module V Rev 2 including the implementation of the new RMP template and the new definition of safety concerns. The QPPV and the Milestones / Timelines for the clinical study MC-Spectrila.1/ALL were updated in accordance to the newly applied DLP for this Risk Management Plan." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Tybost - cobicistat - EMEA/H/C/002572/II/0054** Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new contraindication regarding drug-drug interactions between cobicistat - containing products and thienopyridines. The proposed addition is based on a cumulative safety review conducted by MAH and related to the Pharmacovigilance Risk Assessment	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Committee recommendation dated June 2019 with regards to the interaction of clopidogrel with boosted antiviral HIV therapy leading to insufficient inhibition of platelet aggregation. In addition, the MAH took also the opportunity to amend of the amount of sunset yellow FCF aluminium lake (E110) per tablet in section 2 of the SmPC following the suggestion done by EMA Labelling group during the renewal application (EMEA/H/C/002572/R/0041). Moreover, the sodium excipient wording is added in accordance with the "Excipients in the labelling and package leaflet of medicinal products for human use"(SANTE-2017-11668). Finally, some minor linguistic amendments are also implemented. The Package Leaflet is updated accordingly." Opinion adopted on 14.05.2020.	
PRAC Led **Xadago - safinamide - EMEA/H/C/002396/II/0035** Zambon S.p.A., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "C.I.13 - Results of a DUS and changes to RMP." Request for Supplementary Information adopted on 14.05.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS1742** **Ebymect-EMEA/H/C/004162/WS1742/0043** **Edistride-EMEA/H/C/004161/WS1742/0037** **Forxiga-EMEA/H/C/002322/WS1742/0056** **Xigduo-EMEA/H/C/002672/WS1742/0054** AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final results of a Post-Authorization Safety Study (listed as a category 3 study in the RMPs): meta-analysis across studies D1690C00018, D1690C00019 and D1693C00001 (DECLARE), for analysis of lower limb amputation and relevant preceding adverse events. These three studies include T2DM patients with established CVD or with CVD risk factors treated with dapagliflozin or placebo in clinical trial settings. The updated dapagliflozin RMP version 19.3 and	Positive Opinion adopted by consensus on 14.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

dapagliflozin/metformin fixed dose combination (FDC) RMP version 12.3 were agreed during the procedure." Opinion adopted on 14.05.2020. Request for Supplementary Information adopted on 12.03.2020.	
PRAC Led **WS1760** **Lixiana-EMEA/H/C/002629/WS1760/0024** **Roteas-EMEA/H/C/004339/WS1760/0011** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final study report from study ETNA-DUS: a retrospective drug utilisation chart review study listed as a category 3 study in the RMP. The Edoxaban Treatment in Routine Clinical Practice Drug Utilisation Study (ETNA-DUS) was designed to gain insight on how edoxaban is used in real practice. The ETNA-DUS intends to help identify prescription patterns and the effectiveness of the educational programs" Request for Supplementary Information adopted on 14.05.2020, 16.01.2020.	Request for supplementary information adopted with a specific timetable.

B.5.5. CHMP-CAT assessed procedures

Alofisel - darvadstrocel - EMEA/H/C/004258/II/0016/G, Orphan, ATMP Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder	
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0021/G, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang	
Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0015, ATMP CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder , "Update of sections 4.8 and 5.1 of the SmPC following the 48-month follow up data for trial cod 16 HS 13, a study assessing the long-term efficacy and safety of Spherox." Request for Supplementary Information adopted	

on 24.04.2020.

B.5.6. CHMP-PRAC-CAT assessed procedures

Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - EMEA/H/C/003854/II/0026, Orphan, ATMP

Orchard Therapeutics (Netherlands) BV, Rapporteur: Sol Ruiz, CHMP Coordinator: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst, "Submission of an updated RMP version 2.0 in order to introduce changes to the design of the post-authorisation study STRIM-002 to reflect a change in the proposed RIS analysis methodology from SLiM-PCR to S-EPTS/LM-PCR and shifting the timelines."

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0021, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark, "Submission of a variation to allow clinicians to administer Yescarta to seriously ill patients with relapsed/refractory Non-Hodgkin lymphoma while having on site an adequate supply of tocilizumab (i.e. to ensure that 1 dose of tocilizumab per patient is available at the treating centres to manage CRS, in addition, treatment centres should have access to an additional dose within 8 hours of each previous dose). The PL and RMP have been updated accordingly."

B.5.7. PRAC assessed ATMP procedures

PRAC Led

Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0016, ATMP

CO.DON AG, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of the RMP to bring it in line with GVP Module V Rev. 2 template.
The educational materials described in Annex II

have been updated accordingly.”	

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

WS1745 **Biktarvy-EMEA/H/C/004449/WS1745/0028** **Descovy-EMEA/H/C/004094/WS1745/0046** **Vemlidy-EMEA/H/C/004169/WS1745/0025** Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes, “To update section 2 of the Product Information Annexes (PIs) of the medicinal products concerned, to align the pregnancy language between the summary of product characteristics (SmPC) and the patient information leaflet (PIL). In addition, the MAH has taken this opportunity to: · Introduce an update to the sodium wording in section 6 of the PIL for Descovy, Biktarvy and Vemlidy. This update is in line with the excipient guidance. · Implement minor linguistic amendments (MLAs) for Descovy to the below languages: CS, ES, FI, MT, NL, NO, PT, RO, SV” Request for Supplementary Information adopted on 26.03.2020.	
WS1781/G **Infanrix hexa-EMEA/H/C/000296/WS1781/0272/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 07.05.2020.	Positive Opinion adopted by consensus on 07.05.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1785/G **Infanrix hexa-EMEA/H/C/000296/WS1785/0274/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	
WS1787/G **M-M-RVAXPRO-EMEA/H/C/000604/WS1787/0099/G** **ProQuad-EMEA/H/C/000622/WS1787/0140/G** MSD Vaccins, Lead Rapporteur: Jan Mueller-Berghaus	
WS1788/G	

Ambirix-EMEA/H/C/000426/WS1788/0106/G
Cervarix-EMEA/H/C/000721/WS1788/0108/G
Infanrix hexa-EMEA/H/C/000296/WS1788/0273/G
Twinrix Adult-EMEA/H/C/000112/WS1788/0141/G
Twinrix Paediatric-EMEA/H/C/000129/WS1788/0142/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1801
Imatinib Teva-EMEA/H/C/002585/WS1801/0043
Teva B.V., Generic, Generic of Glivec, Lead Rapporteur: Jorge Camarero Jiménez

WS1803
Efficib-EMEA/H/C/000896/WS1803/0093
Janumet-EMEA/H/C/000861/WS1803/0093
Januvia-EMEA/H/C/000722/WS1803/0070
Ristaben-EMEA/H/C/001234/WS1803/0062
Ristfor-EMEA/H/C/001235/WS1803/0080
TESAVEL-EMEA/H/C/000910/WS1803/0070
Velmetia-EMEA/H/C/000862/WS1803/0096
Xelevia-EMEA/H/C/000762/WS1803/0074
Merck Sharp & Dohme B.V., Lead Rapporteur: Johann Lodewijk Hillege, "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'."

WS1816
Nuwiq-EMEA/H/C/002813/WS1816/0035
Vihuma-EMEA/H/C/004459/WS1816/0017
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS1818
Rasilez-EMEA/H/C/000780/WS1818/0124
Rasilez HCT-EMEA/H/C/000964/WS1818/0094
Noden Pharma DAC, Lead Rapporteur: Daniela

Melchiorri

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

tralokinumab - EMEA/H/C/005255
treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy

roxadustat - EMEA/H/C/004871
treatment of anaemia

pralsetinib - EMEA/H/C/005413
treatment of non-small cell lung cancer (NSCLC)

pegfilgrastim - EMEA/H/C/004780
treatment of neutropenia

tafasitamab - EMEA/H/C/005436, Orphan
Morphosys AG, is indicated in combination with lenalidomide followed by monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from low grade lymphoma, who are not eligible for, or refuse, autologous stem cell transplant (ASCT).

thiotepa - EMEA/H/C/005434
conditioning treatment prior to haematopoietic progenitor cell transplantation (HPCT), treatment of solid tumours

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

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

Pradaxa - dabigatran etexilate - EMEA/H/C/000829/X/0122/G
Boehringer Ingelheim International GmbH, Rapporteur: Mark Ainsworth, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Anette Kirstine Stark, "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)
List of Questions adopted on 27.02.2020.

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

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

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

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

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

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/0015/G
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

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

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/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

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, Duplicate of Remsima, Rapporteur: Outi Mäki-Ikola

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

Lamzede - velmanase alfa - EMEA/H/C/003922/II/0012/G, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege

MabThera - rituximab - EMEA/H/C/000165/II/0173/G
Roche Registration GmbH, Rapporteur: Sinan B. Sarac

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

Ongentys - opicapone - EMEA/H/C/002790/II/0028/G
Bial - Portela & Cª, S.A., Rapporteur: Martina Weise

Orencia - abatacept - EMEA/H/C/000701/II/0140/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola

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: Mark Ainsworth

Perjeta - pertuzumab - EMEA/H/C/002547/II/0049/G
Roche Registration GmbH, Rapporteur: Sinan B. Sarac

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: Mark Ainsworth

Remsima - infliximab - EMEA/H/C/002576/II/0088/G
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola

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
Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege

RoActemra - tocilizumab - EMEA/H/C/000955/II/0096
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus
Opinion adopted on 14.05.2020.

Somavert - pegvisomant - EMEA/H/C/000409/II/0095
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race

Stelara - ustekinumab - EMEA/H/C/000958/II/0080/G
Janssen-Cilag International NV, Rapporteur: Jayne Crowe

Taltz - ixekizumab -

EMEA/H/C/003943/II/0034
Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder

Trecondi - treosulfan - EMEA/H/C/004751/II/0003/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

Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0052/G
Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs

Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0022
Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus

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

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
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

B.6.9. 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, "C.I.4: Update of section 4.5 of the SmPC in order to include a new interaction with Dolutegravir. The Product Leaflet has been updated accordingly."
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 of the SmPC in order to update the safety information and include Rash as Adverse Reaction in adolescents and adults. The Package Leaflet is are updated accordingly."
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"."
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."	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0007, Orphan GW Pharma (International) B.V., Rapporteur: Mark Ainsworth, "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: Mark Ainsworth, "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 section 4.5 and 5.2 of the SmPC to propose an additional statement regarding the stiripentol interaction based on the pharmacological study GWEP1447 (provided in eCTD sequence 018, P46 006). 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."	
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: 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."

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."

Lenvima - lenvatinib - EMEA/H/C/003727/II/0035/G

Eisai GmbH, Rapporteur: Bart Van der Schueren, "-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”	
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).”	
Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0002 FGK Representative Service 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.”	
Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0002 FGK Representative Service 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.”	
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 1199.33 (INPULSIS-ON)”	
OFEV - nintedanib - EMEA/H/C/003821/II/0034, Orphan Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, “Update of section 5.1	

of 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)."	
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: Mark Ainsworth, "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)."	
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."	
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."	
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, "C.I.4: Change in 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 SmPC in order to comply with the current QRD template and provide clarity to instructions contained in the Package leaflet.”	
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 interacion 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.”	
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.6.10. CHMP-PRAC assessed procedures

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 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.”
Lucentis - ranibizumab - EMEA/H/C/000715/II/0085 Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, “Submission of the results of the non-interventional post-approval efficacy and safety study OBTAIN”
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 beeen submitted.”
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."	
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 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. The date provided in the RMP for the submission of the protocols for these 2 studies , as agreed with the Rapporteur."	
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, due by 31/12/2026”

B.6.11. PRAC assessed procedures

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.”
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, “Variation to update the RMP with regards to the measures to evaluate effectiveness of additional risk minimization measures. The RMP update opportunity was used to add the completion date of the interim report for the post approval safety study (PASS) MLN00020401.”
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)."

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)."

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."

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. 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."

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."

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"

PRAC Led

WS1589

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."	
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 remove: 'safety in patients with hepatic or severe renal impairment', 'safety in patients with benign hyperplasia or urinary retention' and 'use in pregnancy or lactation'."	
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 remove: 'safety in patients with hepatic or severe renal impairment', 'safety in patients with benign hyperplasia or urinary retention' and 'use in pregnancy or lactation'."

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."

B.6.12. 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.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

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

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

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

WS1812
Infanrix hexa-
EMEA/H/C/000296/WS1812/0277
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

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

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

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)."	
WS1860 **Aflunov-EMEA/H/C/002094/WS1860/0061** **Foclivia-EMEA/H/C/001208/WS1860/0057** Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri	

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.

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 25-28 May 2020 CHMP plenary:

G.3.2. List of procedures starting in May 2020 for June 2020 CHMP adoption of outcomes

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