12 October 2020
EMA/CHMP/537222/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 12-15 October 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

12 October 2020, 09:00 – 19:30, virtual meeting/ room 1C

13 October 2020, 08:30 – 19:30, virtual meeting/ room 1C

14 October 2020, 08:30 – 19:30, virtual meeting/ room 1C

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 12-15 October 2020. See October 2020 CHMP minutes (to be published post November 2020 CHMP meeting).

The members are informed that due to a vacant CHMP co-opted member position the total number of members eligible to vote is reduced to 31 and the majority is set at 16.

1.2. Adoption of agenda

CHMP agenda for 12-15 October 2020.

1.3. Adoption of the minutes

CHMP minutes for 20-23 July 2020 adopted via written procedure on 07.10.2020.

CHMP minutes for 14-17 September 2020.

ORGAM minutes for 5 October 2020.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

Karyopharm Europe GmbH; treatment of patients with Relapsed Refractory Multiple Myeloma (RRMM).

Scope: Possible oral explanation

Action: Oral explanation to be held on Tuesday, 13 October 2020 at 11:00

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

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

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

Bristol-Myers Squibb Pharma EEIG

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

Scope: "Extension of indication to include treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) after prior fluoropyrimidine- and platinum-based chemotherapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 16.0 of the RMP has also been submitted."

List of experts for the SAG Oncology meeting held on 07.10.2020 adopted via written procedure on 07 October 2020

SAG report

Possible oral explanation

Action: Oral explanation to be held on Wednesday, 14 October 2020 at 16:00

Request for Supplementary Information adopted on 23.07.2020, 30.04.2020.

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. budesonide / glycopyrronium / formoterol fumarate dihydrate - EMEA/H/C/004983

as a maintenance treatment in adult patients with moderate to very severe chronic obstructive pulmonary disease (COPD).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.01.2020. List of Questions adopted on 26.04.2019.

3.1.2. fenfluramine - Orphan - EMEA/H/C/003933

Zogenix ROI Limited; treatment of seizures associated with Dravet syndrome in children aged 2 years to 17 years and adults.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020, 26.03.2020. List of Questions adopted on 27.06.2019.

3.1.3. 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

Kite Pharma EU B.V.; treatment of adult patients with relapsed or refractory Mantle Cell Lymphoma (MCL).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.09.2020. List of Questions adopted on 20.05.2020.

3.1.4. lenalidomide - EMEA/H/C/005306

treatment of multiple myeloma.

Scope: Opinion

Action: For adoption

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

3.1.5. inclisiran - EMEA/H/C/005333

treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2020. List of Questions adopted on 28.05.2020.

3.1.6. autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene - Orphan - ATMP - EMEA/H/C/005321

Orchard Therapeutics (Netherlands) BV; treatment of Metachromatic Leukodystrophy (MLD).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.09.2020. List of Questions adopted on 20.03.2020.

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

Alnylam Netherlands B.V.; treatment of Primary Hyperoxaluria type 1 (PH1).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.09.2020. List of Questions adopted on 21.07.2020.

3.1.8. arachis hypogaea allergens / arachis hypogaea allergens - EMEA/H/C/004917

immunotherapy (OIT) for patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2020, 25.06.2020. List of Questions adopted on 14.11.2019.

3.1.9. rilpivirine - EMEA/H/C/005060

treatment of Human Immunodeficiency Virus type 1 (HIV-1).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2020. List of Questions adopted on 12.12.2019.

3.1.10. ivosidenib - Orphan - EMEA/H/C/005056

Agios Netherlands B.V.; treatment of adult patients (≥ 18 years old) with relapsed or refractory acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020, 27.02.2020. List of Questions adopted on 29.05.2019.

3.1.11. cabotegravir - EMEA/H/C/004976

treatment of Human Immunodeficiency Virus type 1 (HIV-1).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.07.2020. List of Questions adopted on 12.12.2019.

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

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

treatment of metastatic prostate cancer.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

3.2.2. 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 outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.3. remimazolam - EMEA/H/C/005246

indicated for procedural sedation.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

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

treatment of asthma.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.5. ioflupane (^{123}I) - EMEA/H/C/005135

indicated for detecting loss of functional dopaminergic neuron terminals in the striatum.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2019.

3.2.6. risperidone - EMEA/H/C/005406

treatment of schizophrenia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.7. hepatitis b surface antigen - EMEA/H/C/005063

prevention of hepatitis B virus infection.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2019.

3.2.8. 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 outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.9. azathioprine - EMEA/H/C/005055

indicated for the prophylaxis of transplant rejection, and an immunosuppressant antimetabolite and 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: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

3.2.10. insulin aspart - EMEA/H/C/004965

treatment of diabetes mellitus.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.11. lenalidomide - EMEA/H/C/005348

treatment of multiple myeloma.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.12. lenalidomide - EMEA/H/C/005734

treatment of multiple myeloma and Follicular lymphoma.

Scope: List of outstanding issues

Action: For adoption

3.2.13. lenalidomide - EMEA/H/C/005729

treatment of multiple myeloma, myelodysplastic syndromes and follicular lymphoma.

Scope: List of outstanding issues

Action: For adoption

3.2.14. moxetumomab pasudotox - Orphan - EMEA/H/C/005322

AstraZeneca AB; relapsed or refractory Hairy Cell Leukaemia (HCL) after receiving at least two prior systemic therapies.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

3.2.15. ofatumumab - EMEA/H/C/005410

treatment of relapsing forms of multiple sclerosis.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.16. 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 outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

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

treatment of early breast cancer, metastatic breast cancer.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.18. fostemsavir - EMEA/H/C/005011

indicated, in combination with other antiretrovirals, for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen due to resistance, intolerance or safety considerations.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.04.2020.

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

treatment of asthma.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.20. 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 outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

3.2.21. potassium - Orphan - EMEA/H/C/005407

Advicenne S.A.; treatment of distal Renal Tubular Acidosis (dRTA) in patients aged 6 months and older.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2020.

3.2.22. sunitinib - EMEA/H/C/005419

treatment of Gastrointestinal Stromal Tumour (GIST) and Metastatic Renal Cell Carcinoma (MRCC) and pancreatic Neuro-Endocrine Tumours (pNET).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2020.

3.2.23. tucatinib - EMEA/H/C/005263

treatment of metastatic breast cancer or brain metastases.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

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

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

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

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

3.3.3. eflornithine / sulindac - Orphan - EMEA/H/C/005043

Cancer Prevention Pharma (Ireland) Limited; treatment of adults patients with Familial Adenomatous Polyposis (FAP).

Scope: List of questions

Action: For adoption

3.3.4. setmelanotide - Orphan - EMEA/H/C/005089

Accelerated assessment

TMC Pharma (EU) Limited; treatment of obesity and the control of hunger associated with deficiencies in the leptin-melanocortin pathway.

Scope: List of questions

Action: For adoption

3.3.5. vericiguat - EMEA/H/C/005319

treatment of symptomatic chronic heart failure.

Scope: List of questions

Action: For adoption

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

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

treatment of metastatic castration resistant prostate cancer.

Scope: Letter from the applicant requesting an extension of clock-stop to respond to the list of questions adopted in July 2020 – adopted via written procedure on 08 October 2020.

Action: For information

List of Questions adopted on 23.07.2020.

3.4.2. duvelisib - Orphan - EMEA/H/C/005381

Verastem Europe GmbH; treatment of adult patients with relapsed or refractory Chronic Lymphocytic Leukaemia (CLL) or Small Lymphocytic Lymphoma (SLL) and relapsed or refractory Follicular Lymphoma (FL).

Scope: Letter from the applicant dated 28 September 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in September 2020.

Action: For adoption

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

3.4.3. dasatinib - EMEA/H/C/005446

treatment of leukaemia.

Scope: Letter from the applicant dated 07 October 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in June 2020.

Action: For adoption

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

3.4.4. dasatinib - EMEA/H/C/005317

treatment of leukaemia.

Scope: Letter from the applicant dated 07 October 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in June 2020.

Action: For adoption

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

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

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

Scope: Letter from the applicant dated 24 September 2020 requesting an extension of clock-stop to respond to the list of questions adopted in July 2020 – adopted via written procedure on 29.09.2020.

Action: For information

List of questions adopted on 23.07.2020.

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

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

Scope: Draft list of experts for the ad-hoc expert meeting

Action: For adoption

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

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

3.5.1. Gamifant - emapalumab - Orphan - EMEA/H/C/004386

Swedish Orphan Biovitrum AB; treatment of paediatric patients with primary Haemophagocytic Lymphohistiocytosis (HLH).

Scope: Draft list of experts for the ad-hoc expert meeting

Action: For adoption

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

Opinion adopted on 23.07.2020. List of Outstanding Issues adopted on 25.06.2020,

27.06.2019. List of Questions adopted on 13.12.2018.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

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

Mylan S.A.S

Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga

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

Action: For adoption

List of Questions adopted on 23.07.2020.

4.1.2. Plegridy - peginterferon beta-1a - EMEA/H/C/002827/X/0056

Biogen Netherlands B.V.

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new route of administration (intramuscular use) for the 125 µg solution for injection."

Action: For adoption

List of Outstanding Issues adopted on 17.09.2020. List of Questions adopted on 25.06.2020.

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

Boehringer Ingelheim International GmbH

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

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

solution (6.25 mg/ml)), grouped with:
-A type II variation (C.I.6.a) - Extension of indication to include new indication for Pradaxa 75 mg, 110 mg, 150 mg capsules based on the paediatric trials 1160.106 and 1160.108. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.7, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet and labelling are updated in accordance. In addition, the marketing authorisation holder took the opportunity to update the list of local representatives in the package leaflet. The RMP version 37.0 has also been submitted.
-Type IB (B.I.b.1.c)
-Type IA (B.I.b.1.b)
-Type IB (B.I.b.1.d)
-Type IA (B.I.b.2.a)
-Type IA (B.I.b.1.d)
-Type IA (B.I.d.1.a.1)
-Type IA (B.II.d.1.a)
-Type IB (B.II.d.1.d)
-Type IA (B.II.d.2.a)
-Type IA (B.II.c.1.c)"

Action: For adoption

List of Outstanding Issues adopted on 23.07.2020. List of Questions adopted on 27.02.2020.

4.1.4. 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 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

List of Questions adopted on 28.05.2020.

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

4.2.1. 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

List of Questions adopted on 28.05.2020.

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. Buvidal - buprenorphine - EMEA/H/C/004651/X/0008/G

Camurus AB

Rapporteur: Peter Kiely, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Line extension to add a new strength of 160 mg for prolonged-release solution for injection pharmaceutical form. In addition took the marketing authorisation holder the opportunity to align the product information to the latest QRD template and to implement new text regarding the content of ethanol in accordance with the EMA document "Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use" (EMA/CHMP/43486/2018) in the package leaflet. Variations included: A.4 ; A.5.b"

Action: For adoption

4.3.2. Xeljanz - tofacitinib - EMEA/H/C/004214/X/0024/G

Pfizer Europe MA EEIG

Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (oral solution, 1mg/ml) grouped with a type II variation (C.I.6.a) to add a new indication (treatment of active polyarticular course Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older). The RMP (version 12.1) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the product information with the latest QRD template."

Action: For adoption

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

No items

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

No items

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

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

5.1.1. Benlysta - belimumab - EMEA/H/C/002015/II/0080

GlaxoSmithKline (Ireland) Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of lupus nephritis for belimumab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 38 of the RMP has also been submitted."

Action: For adoption

5.1.2. BiResp Spiromax - budesonide / formoterol - EMEA/H/C/003890/II/0033/G

Teva Pharma B.V.

Rapporteur: John Joseph Borg, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Hans Christian Siersted

Scope: "- Type II variation – C.I.6.a. - Extension of indication to include adolescents (12 years and older) for the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) is appropriate: in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β2 adrenoceptor agonists; or in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists. The proposed extension to the indication is based upon data from the literature. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC have been updated and the package leaflet has been updated accordingly. In addition, the marketing authorisation holder took the opportunity to make an administrative update to the Greek, Islandic, Irish and Maltese local representatives phone numbers in the package leaflet. Furthermore, the product information is brought in line with the latest QRD template version 10.1. An updated RMP version 3.0 was submitted

as part of the application.
- Type IB variation - C.I.z other – update of sections 4.2, 5.1 and 5.2 of the SmPC to update the information on paediatric data and section 4.4 of the SmPC to remove the warning regarding the risk of growth retardation in children and the guidance on how to address this risk as agreed during the assessment of the duplicate Budesonide/Formoterol Teva Pharma B.V. (EMEA/H/C/004882), which was approved in January 2020."

Action: For adoption

5.1.3. Blincyto - blinatumomab - Orphan - EMEA/H/C/003731/II/0030

Amgen Europe B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Eva Jirsová

Scope: "To modify the approved therapeutic indication to include the treatment of Philadelphia chromosome positive CD19 positive B-cell precursor Acute Lymphoblastic Leukaemia (ALL) in adult and paediatric patients with relapsed or refractory ALL and adult patients in first or second complete remission with Minimal Residual Disease (MRD) greater than or equal to 0.1%. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and the package leaflet are updated accordingly. The updated RMP version 10.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 14.11.2019.

5.1.4. DuoResp Spiromax - budesonide / formoterol - EMEA/H/C/002348/II/0033/G

Teva Pharma B.V.

Rapporteur: John Joseph Borg, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Hans Christian Siersted

Scope: "- Type II variation – C.I.6.a. - Extension of indication to include adolescents (12 years and older) for the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) is appropriate: in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β2 adrenoceptor agonists; or in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists. The proposed extension to the indication is based upon data from the literature. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC have been updated and the package leaflet has been updated accordingly. In addition, the marketing authorisation holder took the opportunity to make an administrative update to the Greek, Islandic, Irish and Maltese local representatives phone numbers in the package leaflet. Furthermore, the product information is brought in line with the latest QRD template version 10.1.
An updated RMP version 3.0 was submitted as part of the application.
- Type IB variation - C.I.z other – updates of sections 4.2, 5.1 and 5.2 of the SmPC to update the information on paediatric data and section 4.4 of the SmPC to remove the warning regarding the risk of growth retardation in children and the guidance on how to address this risk as agreed during the assessment of the duplicate Budesonide/Formoterol Teva Pharma B.V. (EMEA/H/C/004882), which was approved in January 2020."

Action: For adoption

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

sanofi-aventis groupe

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

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

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 30.04.2020.

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

GW Pharma (International) B.V.

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

Scope: "Extension of indication for use as adjunctive therapy of seizures associated with Tuberous Sclerosis Complex (TSC) for patients 1 year of age and older. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet is updated accordingly. The updated RMP version 1.1 has been submitted.
The marketing authorisation holder also took the opportunity to correct typographic errors and implement editorial updates as well as implement the updated ethanol statement in compliance with the EC Guideline on Excipient." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020.

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

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

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

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020.

5.1.8. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0091

Merck Sharp & Dohme B.V.

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

Scope: "C.I.6 - Extension of indication to include first-line treatment of unresectable or Metastatic Microsatellite Instability-High (MSI H) or Mismatch Repair Deficient (dMMR) colorectal cancer in adults for Keytruda based on the results from KEYNOTE-177 (an international, randomised, open-label phase 3 trial of pembrolizumab versus chemotherapy in MSI-H or dMMR Stage IV Colorectal Carcinoma). As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. In addition, a minor correction has been made in section 4.4, "Immune related endocrinopathies" subsection. Version 29.1 of the RMP has also been submitted."

Action: For adoption

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

Bristol-Myers Squibb Pharma EEIG

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

Scope: "Extension of indication to include treatment of adult patients with unresectable advanced, recurrent or metastatic Oesophageal Squamous Cell Carcinoma (OSCC) after prior fluoropyrimidine- and platinum-based chemotherapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 16.0 of the RMP has also been submitted."

Draft list of experts for the SAG Oncology meeting held on 07.10.2020 adopted via written procedure on 07 October 2020

SAG report

Possible oral explanation

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 30.04.2020.

See 2.3

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

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of hospital-acquired pneumonia (HAP) including Ventilator-Associated Pneumonia (VAP), with or without concurrent bacteraemia in adults for Recarbrio. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The package leaflet is updated in accordance. Furthermore, the marketing authorisation holder made editorial corrections and brought the product information in line with the latest QRD template version 10.1. Version 1.1 of the

RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020.

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

Novo Nordisk A/S

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

Scope: "Extension of indication to include treatment as an adjunct to a healthy nutrition and physical activity counselling for weight management in adolescent patients from the age of 12 years and above with body weight above 60 kg and obesity (BMI corresponding to ≥30 kg/m^2 for adults), based on study NN8022-4180 that evaluated the efficacy of liraglutide 3.0 mg in adolescents aged 12 to less than 18 years with obesity. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are being updated and the package leaflet is updated in accordance. The application relates to paediatric studies submitted according to Article 46 of the paediatric regulation. The application included an updated RMP version 32.0."

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020.

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

Addmedica S.A.S.

Rapporteur: Karin Janssen van Doorn

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

Action: For adoption

5.1.13. Spravato - esketamine - EMEA/H/C/004535/II/0001/G

Janssen-Cilag International N.V.

Rapporteur: Martina Weise, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kirsti Villikka

Scope: "- C.I.6(a): Extension of indication to include a new indication for Spravato for the rapid reduction of depressive symptoms in adult patients with a moderate to severe depressive episode of MDD who have current suicidal ideation with intent.
As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 the SmPC are updated. The RMP version 2.1 has also been submitted.
- B.II.e.5.a.2: Addition of a new pack size corresponding to 4 weeks of treatment in the new indication. The package leaflet and labelling are updated in accordance. In addition, the

marketing authorisation holder took the opportunity to clarify the wording in Annex II.D."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

5.1.14. Tremfya - guselkumab - EMEA/H/C/004271/II/0017

Janssen-Cilag International N.V.

Rapporteur: Agnes Gyurasics, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Addition of a new indication for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior Disease-Modifying Antirheumatic Drug (DMARD) therapy. Consequently sections 4.1, 4.2 4.5 , 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated accordingly. Additionally minor QRD changes are introduced in annex II."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 30.01.2020.

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

AbbVie Deutschland GmbH & Co. KG

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

Scope: "Extension of indication for Venclyxto (venetoclax) in combination with Hypomethylating Agents (HMAs) or Low Dose Cytarabine (LDAC) for the treatment of adult patients with newly-diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy. As a consequence, sections 4.2, 4.3, 4.4, 4.5, 4.7, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and RMP version 6.1 are also updated accordingly." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.16. WS1737 Edistride - dapagliflozin - EMEA/H/C/004161/WS1737/0034 Forxiga - dapagliflozin - EMEA/H/C/002322/WS1737/0053

AstraZeneca AB

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

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC for Edistride and Forxiga to add a new indication for the treatment of symptomatic heart failure with reduced ejection fraction in adults. The package leaflet and labelling are updated in accordance. The RMP version 18 has also been submitted. Furthermore, the product information is brought in line with the latest QRD template version 10.1, as well as editorial change (addition of SI unit for blood glucose)." 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 17.09.2020, 25.06.2020, 27.02.2020.

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

UCB Pharma S.A.

Lead Rapporteur: Filip Josephson, Lead Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Ulla Wändel Liminga

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

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 30.04.2020.

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

No items

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

No items

6. Ancillary medicinal substances in medical devices

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

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. adrenalin - H0005584

adrenalin should be used for the emergency treatment of allergic reactions, including anaphylaxis.

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

Action: For adoption

8.1.2. finerenone - H0005200

finerenone is indicated for the treatment of patients with kidney disease and type 2 diabetes to reduce the risk of cardiovascular mortality and morbidity and to reduce the rate of progression of renal disease.

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

Action: For adoption

8.1.3. voxelotor - H0004869

treatment of haemolytic anaemia associated with sickle cell disease in adults and paediatric patient 12 years and older.

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

Action: For adoption

8.2. Priority Medicines (PRIME)

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

8.2.1. List of applications received

Action: For information

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

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

ratiopharm GmbH

Rapporteur: Christophe Focke, PRAC Rapporteur: Laurence de Fays

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

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 26.03.2020.

9.1.2. Forxiga/Edistride (dapagliflozin) – EMEA/H/C/002322 / EMEA/H/C/004161/WS1844

Astra Zeneca AB

Rapporteur: Kristina Dunder

Scope: MAH's intention to re-classify the imposed cat 1 PASS in the T1DM indication

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020.

9.1.3. Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0011

Portola Netherlands B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: "C.I.4 Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on use of heparin after administration of andexanet based on spontaneous reports, medical literature, reports, clinical trials and in vitro data. The package leaflet is updated accordingly. Additional editorial changes were proposed in Annex I and IIIB."

DHPC and communication plan

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020.

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

Roche Registration GmbH

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

Scope: Renewals of conditional marketing authorisations

Action: For adoption

Request for Supplementary Information adopted on 17.09.2020.

9.1.5. 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)."

Action: For adoption

Request for Supplementary Information adopted on 17.09.2020, 28.05.2020, 30.01.2020, 19.09.2019.

9.1.6. WS1820 Iscover-EMEA/H/C/000175/WS1820/0142, Plavix-EMEA/H/C/000174/WS1820/0140

sanofi-aventis groupe

Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: "Update of section 4.2 of the SmPC in order to add 600 mg as an alternative loading dose to the existing 300 mg to be used at initiation of treatment in the indication 'Secondary prevention of atherothrombotic events in adult patients suffering from acute coronary syndrome'. This update is based on a bibliographic review of published studies. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted."

Action: For discussion

Request for Supplementary Information adopted on 25.06.2020.

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

10.6.1. Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group - EMEA/H/A-31/1471

MAHs: various

Overall Rapporteur: Martina Weise, Co-Rapporteurs:
Candesartan: Kristina Dunder, Irbesartan: Concepcion Prieto Yerro, Losartan: Johann Lodewijk Hillege, Olmesartan: Milena Stain, Valsartan: Armando Genazzani

Scope: Revision of the opinion adopted in January 2019 following a request from the European Commission, draft timetable for adoption via written procedure

Action: For information

10.6.2. Esmya (CAP); NAP - Ulipristal acetate - EMEA/H/A-31/1496

MAH(s): Gedeon Richter Plc.; various

Referral PRAC Rapporteur: Annika Folin, Referral PRAC Co-Rapporteur: Menno van der Elst, CHMP Rapporteurs (Esmya): Kristina Dunder, CHMP Co-Rapporteur (Esmya): Paula Boudewina van Hennik

Scope: CHMP Opinion

Action: For adoption

Review of the benefit-risk balance following notification by the European Commission of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data; PRAC recommendation.

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

October 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

14.1.1. Update on CHMP Co-opted Members

Call for nomination of CHMP co-opted member in light of the end of the mandate of Jan Mueller-Berghaus as co-opted member on 13 November 2020.

Agreed areas of expertise: Quality, safety and efficacy of biological medicinal products, including advanced therapies and with specific emphasis on vaccines.

Nominations should be sent to the CHMP secretariat.

Discussion of area of expertise in light of Koenraad Norga's resignation as CHMP co-opted member as of 31 September 2020.

Proposals should be sent to the CHMP secretariat.

Action: For information

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 27-30 September 2020

Action: For information

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

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at October 2020 PDCO

Action: For information

Report from the PDCO meeting held on 12-15 October 2020

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP October 2020 meeting to CHMP for adoption:

- 27 reports on products in scientific advice and protocol assistance
- 9 reports on products in pre-authorisation procedures
- 2 reports on products in plasma master file

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 15-16 September 2020

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 28 September - 1 October 2020. Table of conclusions

Action: For information

Scientific advice letters: Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

14.3.4. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab
SWP position on the issue related to the MeNP limit in Rifampcin

Action: For adoption

CMDh question to SWP - "Diethanolamine" and "coconut oil diethanolamine condensate" excipients

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

15.1.2. Clarification on authorised indication of melanoma products

CHMP letter to third party on clarification regarding the authorised indication of melanoma products

Action: For discussion

15.1.3. BNT162b2 – Covid-19 mRNA vaccine - H0005735

BNT162b2 is indicated for prophylactic vaccination against Severe Acute Respiratory Syndrome (SARS)-CoV-2.

Scope: Start of rolling review, draft timetable

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)*

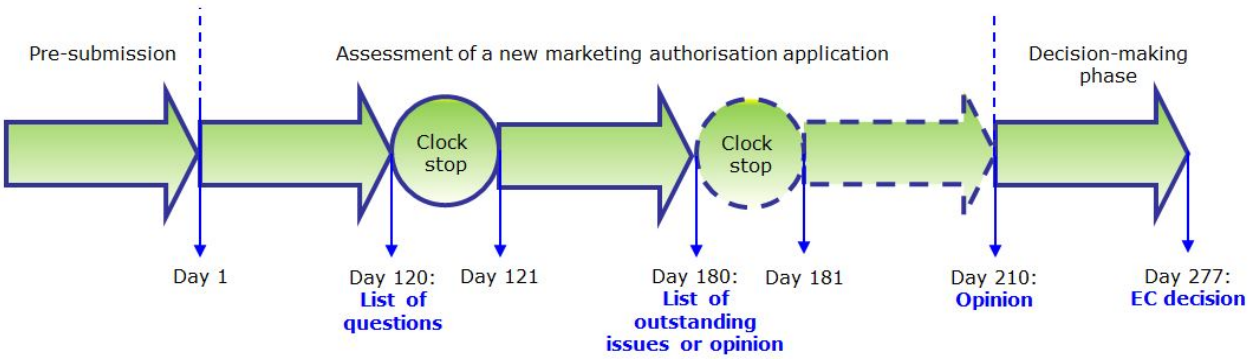
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

12 October 2020
EMA/CHMP/537175/2020

Annex to 12-15 October 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
October 2020: **For adoption**

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

Final Outcome of Rapporteurship allocation for
October 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

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

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Alprolix - eftrenonacog alfa -

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

Coagadex - human coagulation factor X - EMEA/H/C/003855/R/0031, Orphan
BPL Bioproducts Laboratory GmbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst

Descovy - emtricitabine / tenofovir alafenamide - EMEA/H/C/004094/R/0051
Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Ana Sofia Diniz Martins

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

Jevtana - cabazitaxel - EMEA/H/C/002018/R/0042
sanofi-aventis groupe, Rapporteur: Alexandre Moreau, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Tiphaine Vaillant
Request for Supplementary Information adopted on 23.07.2020.

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

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

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

Wakix - pitolisant - EMEA/H/C/002616/R/0024, Orphan

Bioprojet Pharma, Rapporteur: Alexandre Moreau, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka	

B.2.3. Renewals of Conditional Marketing Authorisations

Caprelsa - vandetanib - EMEA/H/C/002315/R/0046 Genzyme Europe BV, Rapporteur: Alexandre Moreau, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Tiphaine Vaillant	
CRYSVITA - burosumab - EMEA/H/C/004275/R/0019, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Brigitte Keller-Stanislawski	
Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0032, Orphan, ATMP Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Paolo Gasparini, CHMP coordinators: Jan Mueller-Berghaus and Armando Genazzani, PRAC Rapporteur: Rhea Fitzgerald	
Polivy - polatuzumab vedotin - EMEA/H/C/004870/R/0003, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 17.09.2020.	See agenda 9.1

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 28 September 2020 – 01 October 2020 PRAC:

Signal of post-partum haemorrhage

BRINTELLIX - vortioxetine; amitriptyline; bupropion; citalopram; escitalopram; fluoxetine; mirtazapine; paroxetine; sertraline; trazodone; venlafaxine

Rapporteurs: various

Brintellix:
Rapporteur: Karin Janssen van Doorn
Co-Rapporteur: Martina Weise

PRAC recommendation on a variation / Monitor in PSUR

Action: For adoption

Signal of Sjögren's Syndrome

KEYTRUDA – pembrolizumab

Rapporteur: Armando Genazzani

Co-Rapporteur: Jan Mueller-Berghaus

PRAC recommendation on a variation

Action: For adoption

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

EMEA/H/C/PSUSA/00001393/202002
(fingolimod)
CAPS:
Gilenya (EMEA/H/C/002202) (fingolimod), Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Period Covered From: 01/03/2019 To: 28/02/2020"

EMEA/H/C/PSUSA/00010073/202003
(bosutinib)
CAPS:
Bosulif (EMEA/H/C/002373) (bosutinib), Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Period Covered From: 04/03/2019 To: 03/03/2020"

EMEA/H/C/PSUSA/00010368/202003
(oritavancin)
CAPS:
Orbactiv (EMEA/H/C/003785) (oritavancin), Menarini International Operations Luxembourg S.A., Rapporteur: Janet Koenig, PRAC

Rapporteur: Adam Przybylkowski, "Period Covered From: 20/03/2019 To: 19/03/2020"	

B.4. EPARs / WPARs

EXPAREL liposomal - bupivacaine - EMEA/H/C/004586 PACIRA IRELAND LIMITED, indicated for prolonged acute pain management and reduction in need for opioids in adults compared to immediate-release bupivacaine., Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
MenQuadfi - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/005084, Article 28 Sanofi Pasteur, immunization against Neisseria meningitidis serogroups A, C, W-135 and Y, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Nyvepria - pegfilgrastim - EMEA/H/C/005085 Pfizer Europe MA EEIG, treatment of neutropenia, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Obiltoxaximab SFL - obiltoxaximab - EMEA/H/C/005169, Orphan SFL Pharmaceuticals Deutschland GmbH, treatment of inhalational anthrax due to Bacillus anthracis, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
PHELINUN - melphalan - EMEA/H/C/005173 ADIENNE S.r.l., High-dose used alone or in combination with other cytotoxic drugs and/or total body irradiation is indicated in the treatment of: - multiple myeloma, - malignant lymphoma (Hodgkin, non-Hodgkin lymphoma), - acute lymphoblastic and myeloblastic leukemia, - childhood neuroblastoma, - ovarian adenocarcinoma, - mammary adenocarcinoma. In combination with other cytotoxic drugs and/or total body irradiation, in adult and paediatric population, is indicated as	For information only. Comments can be sent to the PL in case necessary.

conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (HSCT) in haematological diseases., Hybrid application (Article 10(3) of Directive No 2001/83/EC)	
Rivaroxaban Accord - rivaroxaban - EMEA/H/C/005279 Accord Healthcare S.L.U., prevention of atherothrombotic events, Generic, Generic of Xarelto, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Supemtek - influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159 Sanofi Pasteur, prevention of influenza disease, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0015/G Baxalta Innovations GmbH, Rapporteur: Andrea Laslop Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bemfola - follitropin alfa - EMEA/H/C/002615/II/0027 Gedeon Richter Plc., Rapporteur: Paula Boudewina van Hennik Request for Supplementary Information adopted on 17.09.2020.	
Bexsero - meningococcal group b vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0094 GSK Vaccines S.r.l, Rapporteur: Kristina Dunder	
Caprelsa - vandetanib - EMEA/H/C/002315/II/0044/G Genzyme Europe BV, Rapporteur: Alexandre Moreau Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 11.06.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Desloratadine ratiopharm - desloratadine - EMEA/H/C/002404/II/0025/G ratiopharm GmbH, Generic, Generic of Aerius, Rapporteur: Christophe Focke	
Dupixent - dupilumab - EMEA/H/C/004390/II/0031/G sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 16.07.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Evenity - romosozumab - EMEA/H/C/004465/II/0005 UCB Pharma S.A., Rapporteur: Kristina Dunder	
Flixabi - infliximab - EMEA/H/C/004020/II/0062 Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 24.09.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0017 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz	
Herzuma - trastuzumab - EMEA/H/C/002575/II/0032/G Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0119/G 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 Request for Supplementary Information adopted on 16.07.2020.	
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0049 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 01.10.2020. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 23.07.2020.	
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0055 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus	
Lucentis - ranibizumab - EMEA/H/C/000715/II/0088 Novartis Europharm Limited, Rapporteur: Kristina Dunder	
Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0047 GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 24.09.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0050/G, Orphan MediWound Germany GmbH, Rapporteur: Janet Koenig	
Nulojix - belatacept - EMEA/H/C/002098/II/0069 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson Opinion adopted on 24.09.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nulojix - belatacept - EMEA/H/C/002098/II/0071 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson	
Orencia - abatacept - EMEA/H/C/000701/II/0137/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Orencia - abatacept - EMEA/H/C/000701/II/0140/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Pemetrexed Hospira - pemetrexed -	Positive Opinion adopted by consensus on

EMEA/H/C/003970/II/0024 Pfizer Europe MA EEIG, Generic, Generic of Alimta, Rapporteur: Alar Irs Opinion adopted on 24.09.2020.	24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0002/G, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 10.09.2020.	
Posaconazole Accord - posaconazole - EMEA/H/C/005005/II/0002 Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Kolbeinn Gudmundsson Request for Supplementary Information adopted on 03.09.2020.	
Praluent - alirocumab - EMEA/H/C/003882/II/0058/G sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege	
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0163 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Reblozyl - luspatercept - EMEA/H/C/004444/II/0001/G, Orphan Celgene Europe BV, Rapporteur: Milena Stain	
Riluzole Zentiva - riluzole - EMEA/H/C/002622/II/0027 Zentiva, k.s., Rapporteur: Kirstine Moll Harboe Request for Supplementary Information adopted on 24.09.2020.	Request for supplementary information adopted with a specific timetable.
Ritonavir Mylan - ritonavir - EMEA/H/C/004549/II/0007/G Mylan S.A.S, Generic, Generic of Norvir, Rapporteur: John Joseph Borg Request for Supplementary Information adopted on 01.10.2020, 16.07.2020, 17.04.2020.	Request for supplementary information adopted with a specific timetable.
Rixubis - nonacog gamma - EMEA/H/C/003771/II/0035/G Baxalta Innovations GmbH, Rapporteur: Andrea Laslop	
Ruconest - conestat alfa -	Positive Opinion adopted by consensus on

EMEA/H/C/001223/II/0056 Pharming Group N.V, Rapporteur: Andrea Laslop Opinion adopted on 01.10.2020.	01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Simulect - basiliximab - EMEA/H/C/000207/II/0107 Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus	
Skyrizi - risankizumab - EMEA/H/C/004759/II/0010/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Kiely Request for Supplementary Information adopted on 23.07.2020.	
Trecondi - treosulfan - EMEA/H/C/004751/II/0004/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Verzenios - abemaciclib - EMEA/H/C/004302/II/0012/G Eli Lilly Nederland B.V., Rapporteur: Filip Josephson	
VITRAKVI - larotrectinib - EMEA/H/C/004919/II/0010/G Bayer AG, Rapporteur: Filip Josephson	
Xenical - orlistat - EMEA/H/C/000154/II/0083 CHEPLAPHARM Arzneimittel GmbH, Rapporteur: Jean-Michel Race	
Yervoy - ipilimumab - EMEA/H/C/002213/II/0083/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik	
Zavicefta - ceftazidime / avibactam - EMEA/H/C/004027/II/0023/G Pfizer Ireland Pharmaceuticals, Rapporteur: Bjorg Bolstad Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
WS1863/G **Incruse Ellipta-EMEA/H/C/002809/ WS1863/0030/G** **Rolufta Ellipta-EMEA/H/C/004654/**	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

WS1863/0015/G GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 24.09.2020.	recommendation.
WS1904/G **Hexacima-EMEA/H/C/002702/WS1904/0105/G** **Hexaxim-EMEA/H/W/002495/WS1904/0110/G** **Hexyon-EMEA/H/C/002796/WS1904/0109/G** Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus	

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

AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0029 sanofi-aventis groupe, Rapporteur: Martina Weise, "To update section 4.4 of the SmPC to add information on cases of drug-induced liver injury (DILI) observed in the post-marketing setting and section 4.8 of the SmPC to add the adverse event DILI under the frequency unknown. The package leaflet is updated accordingly." Request for Supplementary Information adopted on 24.09.2020, 14.05.2020.	Request for supplementary information adopted with a specific timetable.
AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0032 sanofi-aventis groupe, Rapporteur: Martina Weise, "C.I.4. Update of section 4.4 of the SmPC in order to update information on the liver monitoring schedule and the use of concomitant potentially hepatotoxic drugs based on evidence from diverse clinical and post-marketing sources including results from three studies, namely TENERE/EFC10891 (Phase 3 multi-center, randomized, double-blind, open-label (for IFN β -1a), parallel-group study), Teri-PRO/LPS13567 study (Phase 4, multicenter, prospective, single-arm, open-label study) and TERIKIDS/EFC11759 (Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with 10 to 17 years of age) together with post-marketing data including real-world data from two European National Disease registries and one US-based	Request for supplementary information adopted with a specific timetable.

database of electronic health records and post-marketing experience included in the Sanofi Global pharmacovigilance database." Request for Supplementary Information adopted on 24.09.2020.	
Busilvex - busulfan - EMEA/H/C/000472/II/0031 Pierre Fabre Medicament, Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.5 of the SmPC regarding the interaction with deferasirox and iron chelating agents. The patient leaflet is updated accordingly. Update of the SmPC section 5.2 with minor changes in the paediatric population PK parameters. In addition, the MAH took the opportunity to clarify statement on incompatibilities in sections 6.2 and 6.6 and to expand the incompatibility of the polycarbonates syringes with Busilvex to the incompatibility of any infusion components containing polycarbonate with Busilvex. This change has been reflected on the subsection "Instructions for use" of the section 2 "recommendations for safe handling" in the preparation guide of the Package Leaflet. In addition, QRD-related changes have been implemented in annex II." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 25.06.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cresemba - isavuconazole - EMEA/H/C/002734/II/0031, Orphan Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.2 of SmPC to clarify the instructions on the start of therapy, according to current treatment guidelines for aspergillus and mucor diseases. Additionally, correction of an oversight is carried out in SmPC section 4.8 and PL section 4 of Cresemba 100mg capsules, to reinstate "odema peripheral" as "uncommon" adverse event, which was unintentionally omitted from the PI at the time of the initial MAA. Re-instatement of text about the potential interaction between isavuconazole and protease inhibitors other than indinavir and lopinavir/ritonavir, wrongly deleted from the interactions table in SmPC section 4.5 and PL section 2 as part of a previous procedure, is also carried out."	

DaTSCAN - ioflupane (123I) - EMEA/H/C/000266/II/0059

GE Healthcare B.V., Rapporteur: Alexandre Moreau, "C.I.4, Update of sections 4.2 and 5.1 of the SmPC in order to describe the possibility of quantitative reading in line with current scientific knowledge."
Request for Supplementary Information adopted on 16.07.2020.

Enbrel - etanercept - EMEA/H/C/000262/II/0234

Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.1 of the SmPC in order to update the efficacy and safety information based on the final results from study (B1801381); this is a multicenter open-label study which evaluated withdrawal and retreatment of etanercept in subjects with non-radiographic axial spondyloarthritis who achieved an adequate response following 24 weeks of treatment. In addition, the MAH took the opportunity to make some editorial changes and bring the PI in line with the latest QRD template version 10.1."

Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0007/G

Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, "C.I.4: To update section 5.1 of the SmPC with the description and final results from study V920-018; this is a phase 3 open-label trial conducted in Guinea to evaluate the safety and immunogenicity of Ervebo in vaccinated frontline workers 18 years of age and older that was implemented as Part B of the Phase 3 ring vaccination study V920-010. With this submission, REC 20 is fulfilled.
C.I.4: To update section 5.1 of the SmPC based on the result of the final study reports on the Correlate of Protection. With this submission, REC 16 is fulfilled.
C.I.4: To update section 5.1 of the SmPC, based on results from the integrated summary of immunogenicity (ISI). With this submission, RECs 15 and 22 are fulfilled.
C.I.13 - Submission of Non-Human Primates (NHP) Correlate of Protection analysis report (non-clinical report) . Analysis is based upon previous submitted NHP studies which are already part of the dossier.

The MAH takes the opportunity to implement changes in the Package Leaflet following the assessment of the User Acceptance Test, procedure EMEA/H/C/004554/REC/011. With the implementation of these changes to the PL, the MAH fulfils REC011. In addition, a minor editorial change has been included in section 4.4 of the SmPC and section 2 of the patient leaflet."	
Eylea - aflibercept - EMEA/H/C/002392/II/0064 Bayer AG, Rapporteur: Alexandre Moreau, "C.1.4 to update section 5.1 of the SmPC based on the ALTAIR Study with additional long-term efficacy information on patients with wet AMD."	
Eylea - aflibercept - EMEA/H/C/002392/II/0065 Bayer AG, Rapporteur: Alexandre Moreau, "C.I.4, Update of section 4.2 to modify the posology in wet AMD and of 5.1 to reflect the underlying data."	
Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0003 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, "Update of section 5.1 of the SmPC in order to introduce effectiveness information of Fluad (trivalent formulation) in the product information of Fluad Tetra based on the results from three retrospective observational studies "CORE 17-18 and 18-19", "HEOR 17-18" and "HEOR 18-19") and a randomised clinical trial "LTCF 16-17"."	
Jevtana - cabazitaxel - EMEA/H/C/002018/II/0043/G sanofi-aventis groupe, Rapporteur: Alexandre Moreau, "Update of sections 4.8 and 5.1 of the SmPC with new clinical data from CARD study - a randomized, multicenter, Phase 4 study comparing cabazitaxel at 25 mg/m^2 every 3 weeks in combination with prednisone versus alternate AR-targeted agent (abiraterone or enzalutamide) for the treatment of mCRPC patients previously treated with docetaxel and who failed a prior AR-targeted agent. Section 4.4 of the SmPC is also updated in accordance with the updated annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal	

products for human use' (SANTE-2017-11668) regarding ethanol used as an excipient. The Package Leaflet is updated accordingly."

Lyumjev - insulin lispro - EMEA/H/C/005037/II/0005

Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-Ikola, "Update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study I8B-MC-ITSA (submitted in accordance with Article 46 of regulation (EC) No 1901/2006). This study was conducted to evaluate the pharmacokinetics and glucodynamics of Lyumjev compared to Humalog in children, adolescents, and adults with Type 1 Diabetes Mellitus."

Nerlynx - neratinib - EMEA/H/C/004030/II/0015

Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC in order to include final OS results from study 3144A2-3004-WW, a randomised, double-blind, placebo-controlled trial of neratinib after trastuzumab in women with early-stage HER-2/neu overexpressed/amplified breast cancer." Request for Supplementary Information adopted on 03.09.2020.

NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0049, Orphan

MediWound Germany GmbH, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC based on interim results from study MW2010-03-02 (DETECT) listed as an obligation in the Annex II; this is a multicenter, multinational, randomized, controlled, assessor blinded, three-arm study performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to Gel Vehicle and compared to Standard of Care. The submitted Clinical Study Report includes data of Acute Phase and 12M Follow Up Period. The MAH also took the opportunity to submit integrated pooled analyses of efficacy and safety data obtained from phase 2 and phase 3 clinical studies to provide a comprehensive assessment of the safety and efficacy of NexoBrid. The Package Leaflet is updated accordingly."

Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0011 Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "C.I.4 Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on use of heparin after administration of andexanet based on spontaneous reports, medical literature reports, clinical trials and In vitro data. The Package Leaflet is updated accordingly. Additional editorial changes were proposed in Annex I and IIIB." Request for Supplementary Information adopted on 25.06.2020.	See agenda 9.1
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." Request for Supplementary Information adopted on 16.07.2020.	
Prolia - denosumab - EMEA/H/C/001120/II/0085/G Amgen Europe B.V., Rapporteur: Kristina Dunder, "Updates to SmPC section 4.8 adding the adverse reactions "hypersensitivity vasculitis" with a frequency category of very rare and "drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome" with a frequency category of not known, and section 4.4 to introduce QRD traceability statement. The package leaflet has been updated accordingly." Opinion adopted on 24.09.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ranexa - ranolazine - EMEA/H/C/000805/II/0063 Menarini International Operations Luxembourg	

S.A., Rapporteur: Kristina Dunder, "C.I.4 Update of section 4.8 of the SmPC in order to add "myoclonus" to the list of adverse drug reactions (ADRs) with frequency "rare" based on post-marketing data and update to section 4.9 based on review of the data regarding events of overdose. The Package Leaflet was updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.1, to correct linguistic mistakes in the SmPC and in some national translations of the Product Information."	
Rekovelle - follitropin delta - EMEA/H/C/003994/II/0023 Ferring Pharmaceuticals A/S, Rapporteur: Jean-Michel Race, "Update of section 5.1 of the SmPC in order to add information on dose equivalence factor to follitropin alfa based on clinical data from literature. The MAH took the opportunity to amend section 4.4. of the SmPC with traceability information and to bring the PI in line with the latest QRD template version 10.1."	
Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0036 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "Submission of the final report from study Zoster-056, in order to fulfil the post-authorisation measure MEA/FSR 006. This is a cross-vaccination study in subjects who previously received placebo in studies Zoster-006 and Zoster-022." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
Strensiq - asfotase alfa - EMEA/H/C/003794/II/0047, Orphan Alexion Europe SAS, Rapporteur: Armando Genazzani, "Update of section 5.1. of the SmPC in order to remove the Paediatric Investigation Plan (PIP) compliance statement as per Article 28(3) of Regulation (EC) No 1901/2006 and to request the 2-year extension of the market exclusivity of Strensiq as per Article 37 of Regulation (EC) No 1901/2006, following submission of the results and reports of all the PIP measures, including results of the Extrapolation Study AXN100107PIP	

("Extrapolation of Efficacy to Asfotase Alfa Treatment in Paediatric Patients Ages 6 months to <3 years with Juvenile-Onset Hypophosphatasia")"

Taltz - ixekizumab - EMEA/H/C/003943/II/0038/G

Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder, "Clinical studies in adult plaque psoriasis:
Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long-term data in the treatment of psoriasis: RHAZ, RHBA, RHBC (3 studies of the "UNCOVER" series) were the pivotal registration studies, with response data up to 60 weeks already included in the SmPC. The current update relates to the extension data available, covering a total of 5 years.
Section 5.1 of the SmPC has also been updated with information from study RHCR (known as "IXORA-R") which is a 24-week head-to-head comparison of Taltz vs guselkumab.
Clinical studies in adult psoriatic arthritis:
Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long-term data in the treatment of psoriatic arthritis: RHAP and RHBE (also known as SPIRIT-P1 and P2) were pivotal registration studies, with response data at 24 weeks and up to 52 weeks (SPIRIT-P1) already included in the SmPC. The current update relates to extension data available covering a total of 3 years. Section 5.1 of the SmPC has also been updated with longer-term data from study RHCF ("SPIRIT-H2H" Taltz vs adalimumab). Response data of up to 24 weeks are already in the SmPC and the addition of 52 week data are being proposed."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0030

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC to reflect the outcome of anti-drug antibody (ADA) analyses conducted across studies POPLAR, OAK, IMpower 150, IMpower 130, IMPower 131, IMpower 132, IMvigor 211, IMmotion 151, IMpower 133 and IMpassion 130, further to the CHMP recommendation."
Request for Supplementary Information adopted on 23.04.2020, 05.12.2019.

Tivicay - dolutegravir -

EMEA/H/C/002753/II/0064 ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 5.1 in order to add long-term efficacy and safety data, following the week 96 results from studies 204861 (GEMINI-1) and 205543 (GEMINI-2), listed as specific category 3 studies in the RMP. These are two identical pivotal ongoing, randomized, double-blind, parallel group, 148-week, phase III studies to evaluate the efficacy, safety and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment naïve patients. In addition, the MAH took the opportunity to introduce minor editorial changes throughout the Product Information."	
Veltassa - patiromer - EMEA/H/C/004180/II/0018 Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Jayne Crowe, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from Study RLY5016-207; this is a randomised, double-blind, placebo-controlled, parallel group study of patiromer to enable concomitant spironolactone treatment in patients with resistant hypertension and CKD." Request for Supplementary Information adopted on 18.06.2020.	
Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0023 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC based on interim analysis data at Week 24 from study GS-US-320-4035 .This is a Phase 2, open-label study evaluating the efficacy and safety of tenofovir alafenamide (TAF) in virologically suppressed chronic hepatitis B subjects with renal and/or hepatic impairment who switch from tenofovir disoproxil fumarate and/or other oral antiviral agents to TAF 25 mg once daily. Supportive safety and pharmacokinetic data are also provided from Study GS-US-292-1825 (phase 3b trial in which Elvitegravir/ cobicistat/emtricitabine/tenofovir alafenamide an fixed-dose TAF containing combination indicated for the treatment of HIV-1 infection, was evaluated in HIV-1 infected subjects with end stage renal disease). Study GS-US-320-4035 is included in the RMP version	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

4.2 under additional PhV activities."
Opinion adopted on 24.09.2020.
Request for Supplementary Information adopted on 23.07.2020, 07.05.2020, 06.02.2020.

Votrient - pazopanib - EMEA/H/C/001141/II/0059
Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, "To update sections 4.2, 4.8 and 5.1 of the SmPC to update the safety information based on results from studies 2012-001306-20 (ADVL0815 / PZP114411) and study 2013-003595-12 (ADVL1322 / VEG116731 / PZP034X2203) listed in the agreed PIP; these are a phase 1 clinical trial of single-agent pazopanib in children with a relapsed or refractory solid (including CNS) tumour, and a therapeutic-exploratory (phase 2) clinical trials of single-agent pazopanib in children (including adolescents) and young adults with a refractory tumour."

VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0048, Orphan
Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC to include information on 1 additional patient with IgG anti-velaglucerase antibodies with neutralizing activity reported during extension Study HGT-GCB-044, and to include vomiting as an infusion-related reaction that has been reported in post-marketing experience. Further, the MAH is updating the instructions in sections 4.2 and 6.6 of the SmPC to state that a 0.2 µm filter and a 0.22 µm filter are both considered acceptable when administering the product. In addition, the MAH took the opportunity to implement some minor editorial changes in SmPC section 5.1 and a clarification that paediatric patients included in the studies were 4 years of age and older. The Package Leaflet is updated accordingly."

XOSPATA - gilteritinib - EMEA/H/C/004752/II/0001, Orphan
Astellas Pharma Europe B.V., Rapporteur: Bjorg Bolstad, "Submission of a pooled analysis report from studies 2215-CL-0101 (Phase 1/2), 2215-CL-0102 (Phase 1), 2215-CL-0301, 2215-CL-9100 (phase 3) listed as "Other forms of routine pharmacovigilance activities in section III.1 of the RMP". This is a pooled analysis to

characterise gilteritinib-related differentiation syndrome, specifically incidence, observed signs and symptoms, duration, and response to intervention based on patient-level data from on-going trials in patients with acute myeloid leukemia."

WS1822
Relvar Ellipta-EMEA/H/C/002673/ WS1822/0045
Revinty Ellipta-EMEA/H/C/002745/ WS1822/0043
GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.1 of the Relvar/Revinty SmPC to include safety information based on results from Therapeutic Index study 203162. This study compared the therapeutic index of fluticasone furoate (FF) and other inhaled corticosteroid (ICS) agents using the efficacy marker of adenosine5'-monophosphate (AMP) challenge and the systemic exposure marker of cortisol suppression. The results provide new information that will help prescribers to understand the relative potency for efficacy and systemic activity of the ICS component of Relvar/Revinty, fluticasone furoate (FF), compared to other ICS drug molecules.
In addition, GSK has taken the opportunity to add text related to SUMMIT data to section 5.1 of the high strength label (184/22 mcg) for Relvar/Revinty Ellipta. The text was agreed in procedure EMEA/H/C/XXXX/WS/0992 finalised on 21st April 2017, however the change was mistakenly not implemented to the SmPC during this procedure.
Additionally minor corrections are introduced in the PL."
Request for Supplementary Information adopted on 25.06.2020.

WS1886/G
Aprovel-EMEA/H/C/000141/WS1886/ 0181/G
CoAprovel-EMEA/H/C/000222/WS1886/ 0199/G
Karvea-EMEA/H/C/000142/WS1886/ 0183/G
Karvezide-EMEA/H/C/000221/WS1886/ 0199/G
sanofi-aventis groupe, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Group of variations

consisting of: C.I.4 - Update of sections 4.4 and 4.8 of the SmPC to add information on hypoglycemia based on a review of available data including the MAH pharmacovigilance data base and a literature review. The Package leaflet is updated accordingly. C.I.4 - Update of sections 4.4 and 4.5 of the SmPC to add information on a drug -drug interaction with irbesartan and repaglinide based on a review of the available data including the MAH database and a literature review. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to implement the updated annex to the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use' to update the excipient sodium.”	
WS1898 **Efficib-EMEA/H/C/000896/WS1898/0095** **Janumet-EMEA/H/C/000861/WS1898/0095** **Ristfor-EMEA/H/C/001235/WS1898/0082** **Velmetia-EMEA/H/C/000862/WS1898/0098** Merck Sharp & Dohme B.V., Lead Rapporteur: Johann Lodewijk Hillege, “Update of the SmPC sections 4.2, 4.8, 5.1 and 5.2, to include data from the pooled analysis of paediatric studies P170 (sitagliptin/metformin) and P289 (sitagliptin/metformin extended release). The package leaflet is revised accordingly, and update of the product information is performed to comply with QRD Version 10.1.” Opinion adopted on 24.09.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.3. CHMP-PRAC assessed procedures

Desloratadine ratiopharm - desloratadine - EMEA/H/C/002404/II/0023/G ratiopharm GmbH, Generic, Generic of Aerius, Rapporteur: Christophe Focke, PRAC Rapporteur: Laurence de Fays, “C.I.5.b - Change in the legal status of desloratadine ratiopharm from ‘medicinal product subject to medical prescription’ to ‘medicinal product not subject to medical prescription’ in view of the safety profile of desloratadine ratiopharm and the post-marketing experience already available	See agenda 9.1

with other medicinal products containing similar long acting histamine antagonists. The RMP version 1.0 has also been submitted. In addition, the MAH also took the opportunity to bring the PI in line with the latest QRD template (version 10.1), to update the list of local representatives in the package leaflet and to make editorial changes. C.I.6.b - To delete the therapeutic indication in adolescents aged 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria. Section 4.1 of the SmPC and section 1 of the PL are updated accordingly." Request for Supplementary Information adopted on 23.07.2020, 26.03.2020.	
Erleada - apalutamide - EMEA/H/C/004452/II/0008 Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Tiphaine Vaillant, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study ARN-509-003 (SPARTAN) listed as a PAES in Annex II; this is a multicenter, randomised, double-blind, placebo-controlled, phase III study of ARN-509 in men with non-metastatic (M0) castration-resistant prostate cancer; the package leaflet and Annex II are updated accordingly. The RMP version 3.1 has also been submitted. In addition the MAH took the opportunity to update the list of local representatives in the Package leaflet." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
Imfinzi - durvalumab - EMEA/H/C/004771/II/0023 AstraZeneca AB, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: David Olsen, "Update of sections 4.2 and 5.1 of the SmPC in order to introduce a new posology regimen of 1500 mg every 4 weeks (Q4W) for the approved indication of the treatment of patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum based chemoradiation therapy. The RMP version 4.1 has also been submitted."	

Kanuma - sebelipase alfa - EMEA/H/C/004004/II/0026/G, Orphan Alexion Europe SAS, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Ulla Wändel Liminga, "Grouping consisting of the following variations: - Update of sections 4.2, 4.4, 4.8 and 5.1 of the Summary of Product Characteristics (SmPC) in order to update the clinical information based on the pooled safety and efficacy analysis of already submitted studies (Studies LAL-CL04, LAL-CL03, LAL-CL06, LAL-CL08 and LAL-CL02) and updated population PK analyses in children and adults. The Package Leaflet has been amended accordingly. The ATC code has been added to the SmPC. The RMP version 4 has also been submitted. Annex II is also updated to remove the obligation related to the provision of study LAL-CL08. - Submission of the final report from study LAL-EA01 An open-label study with sebelipase alfa (1 mg/kg every other week for up to 78 weeks or until drug commercialization) in United States (US) patients who did not otherwise qualify for an active sebelipase alfa trial (expanded access protocol)" Request for Supplementary Information adopted on 23.07.2020, 26.03.2020.	
Myalepta - metreleptin - EMEA/H/C/004218/II/0012, Orphan Amryt Pharmaceuticals DAC, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.4 of the SmPC in order to add a new warning on the risk of autoimmune disease following exposure to metreleptin; the Package Leaflet and the key elements to be included in the Guide/training material for healthcare professionals are updated accordingly. The RMP version 2.0 has also been submitted." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NUBEQA - darolutamide - EMEA/H/C/004790/II/0002 Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser, "Update of section 5.1 of the SmPC in order to update efficacy information based on the final CSR from study 17772 (ARAMIS) listed as a PAES in the Annex	Positive Opinion adopted by consensus on 08.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

II; this is a multinational, randomised, double-blind, placebo-controlled, phase III efficacy and safety study of darolutamide in men with high-risk non-metastatic castration-resistant prostate cancer; the Annex II is updated accordingly. The RMP version 1.1 is accepted." Opinion adopted on 08.10.2020. Request for Supplementary Information adopted on 03.09.2020.	
Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0020 Roche Registration GmbH, Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Submission of the final report for study 17-1133 listed as a Category 3 study in the RMP (MEA 006). This is a study to assess the effects of ocrelizumab on embryo-fetal and pre- and postnatal development in cynomolgus monkeys. The RMP ver. 5.0 has also been submitted." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
OFEV - nintedanib - EMEA/H/C/003821/II/0038 Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of sections 4.5, 4.6 and 5.2 of the SmPC in order to add drug-drug interaction information with the oral contraceptive Microgynon, a combination of ethynilestradiol and levonorgestrel based on final) based on final results from clinical study №1199-0340. This was a phase I, open-label, 2-period cross-over, fixed-sequence design trial, investigated the effect of multiple oral doses of nintedanib on the single dose kinetics of a combination of ethinylestradiol and levonorgestrel (Microgynon). The Package Leaflet is updated accordingly. The RMP version 10 has also been submitted." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
Oncaspar - pegaspargase - EMEA/H/C/003789/II/0036/G Les Laboratoires Servier, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Annika Folin, "Group of 2 Type II variations to submit the study results of Study 12-266 A(12) an open label single arm phase II trial evaluating the efficacy	Request for supplementary information adopted with a specific timetable.

and toxicity of treatment regimens including Oncaspar in adults (aged 18-60) with newly diagnosed Philadelphia chromosome-negative acute lymphoblastic leukaemia and Study CAALL-F01 a prospective multicentre cohort study evaluating Oncaspar used in the first-line treatment of children and adolescents with ALL along with multi-agent chemotherapy. Consequently Annex II is proposed to be updated to remove both PAES. Additionally, update of the product information to remove the need for additional monitoring and to implement editorial changes. The RMP (version 4.1) is updated accordingly." Request for Supplementary Information adopted on 01.10.2020.	
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; 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 Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to align the SmPC (sections 4.1, 4.2, 4.3, 4.4, 4.5 and 4.8) with the EU Core SmPC for IVIG, to update the local representative for Bulgaria and Slovenia in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
SCENESSE - afamelanotide -	Positive Opinion adopted by consensus on

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 revised RMP version 9.0 (in line with rev 2 of the template) is acceptable. In addition, the MAH took the opportunity to introduce minor editorial changes in section 2 of the SmPC and Annex IIIA." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 14.05.2020.	01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Stelara - ustekinumab - EMEA/H/C/000958/II/0081/G Janssen-Cilag International NV, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.2 of Stelara SmPC solution for injection presentations in order to change posology recommendations for patients with ulcerative colitis, and 5.1 of Stelara SmPC to update efficacy information based on 2-year results from study 3001 listed as a category 3 study in the RMP; this is a Phase 3, randomized, double blind, placebo controlled, parallel-group, multicenter protocol to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis. Update of section 5.1 of the SmPC in order to update efficacy information based on 5-year results from study 3003 listed as a category 3 study in the RMP; this is a Phase 3, randomized, double blind, placebo controlled, parallel-group, multicenter trial to evaluate the safety and efficacy of ustekinumab maintenance therapy in adult patients with moderately to severely active Crohn's disease. The RMP version 18.1 has also been submitted."	
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	See agenda 9.1

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 17.09.2020, 28.05.2020, 30.01.2020, 19.09.2019.	
Tevagrastim - filgrastim - EMEA/H/C/000827/II/0077 TEVA GmbH, Duplicate, Duplicate of Biograstim (SRD), Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Submission of a variation to update the RMP to remove the additional pharmacovigilance activity "Cooperation with SCNIR (Severe Chronic Neutropenia International Registry) and analysis of corresponding Ratiograstim/Tevagrastim-SCNIR data"." Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 ." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Vizimpro - dacomitinib - EMEA/H/C/004779/II/0003/G Pfizer Europe MA EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2 and 5.2 of the SmPC in order to revise the dosing recommendation for patients with hepatic impairment and include relevant pharmacokinetics data based on results of Study A7471058, evaluating the effect of severe hepatic impairment on the plasma PK, safety and tolerability after a single dose of dacomitinib. As a consequence, the MAH is proposing to remove the missing information "Safety in Patient with Severe Hepatic Impairment" from the list of safety concerns in the RMP. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1. The MAH has also taken the opportunity to update the EU RMP to include PASS Study A7471064 "Single Arm Study to Evaluate the Safety of Dacomitinib for the First-Line Treatment of Participants in India with Metastatic NSCLC with Epidermal Growth Factor Receptor (EGFR)-Activating Mutations" as a "Category 3 required additional pharmacovigilance activity". A revised RMP v1.1 (clean and tracked) has been submitted."	
WS1792/G **Hexacima-EMEA/H/C/002702/WS1792/0099/G** **Hexaxim-EMEA/H/W/002495/WS1792/0104/G** **Hexyon-EMEA/H/C/002796/WS1792/0103/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus, Lead PRAC Rapporteur: Brigitte Keller-Stanislawski, "C.I.4 (type II) - Update of sections 4.4 and 5.1 of the SmPC in order to revise the warning regarding preterm infants and to add new information on immunogenicity in preterm infants and in infants born from women vaccinated during pregnancy, based on the final results from study A3L00053-EXT; this is an observational cohort study conducted with DTaP-IPV-HB-PRP~T vaccine, aimed to describe the concentrations of IgG against the different antigens. The RMP version 12.0 has been submitted an updated accordingly, following	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

revision 2 with consequential update to the safety concerns. C.I.z (type IB) - Update of sections 2 and 4.4 of the SmPC in order to add a warning for excipients with known effect: phenylalanine, potassium and sodium, according to the European guideline "Excipients in the labelling and package leaflet of medicinal products for human use SANTE-2017-11668". The package leaflet is updated accordingly. In addition, the MAH/SOH took the opportunity to introduce editorial changes in sections 4.2, 4.4, 4.5 and 4.8 of the SmPC and to update the list of local representatives in the Package Leaflet." Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 11.06.2020.	
WS1820 **Iscover-EMEA/H/C/000175/WS1820/0142** **Plavix-EMEA/H/C/000174/WS1820/0140** sanofi-aventis groupe, Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of section 4.2 of the SmPC in order to add 600 mg as an alternative loading dose to the existing 300 mg to be used at initiation of treatment in the indication "Secondary prevention of atherothrombotic events in adult patients suffering from acute coronary syndrome ". This update is based on a bibliographic review of published studies. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted." Request for Supplementary Information adopted on 25.06.2020.	See agenda 9.1
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	See agenda 9.1

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" Request for Supplementary Information adopted on 23.07.2020.	
WS1850 **Anoro Ellipta-EMEA/H/C/002751/ WS1850/0030** **Laventair Ellipta-EMEA/H/C/003754/ WS1850/0033** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Peter Kiely, Lead PRAC Rapporteur: Ilaria Baldelli, "To update the RMP with the completion of study WWE117397 "A Post-authorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting." As part of the assessment of EMEA/H/C/WS1761 the MAH was requested to update the RMP. In addition, the MAH has amendment the RMP with the study 201038 "A Post authorisation Safety Observational Cohort Study to quantify the incidence of selected cardiovascular and cerebrovascular events in COPD patients using inhaled UMEC/VI combination or inhaled UMEC versus Tiotropium" as approved during procedure EMEA/H/C/PSA/S/0032.3." Request for Supplementary Information adopted on 23.07.2020.	

B.5.4. PRAC assessed procedures

PRAC Led **Aclasta - zoledronic acid - EMEA/H/C/000595/II/0076** Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Provision of an updated RMP version 13.0.	Request for supplementary information adopted with a specific timetable.

Proposed changes: 1. Alignment with requirements of GVP Module V Rev.2 with consequential removal/ reclassification of a number of important potential risks; 2. Consequential removal of education material for renal risk (renal dysfunction and use in patients with severe renal impairment); 3. Removal of 'post-dose symptoms' from the list of important identified risks (following the assessment of LEG 037 & variation II/74/G); 4. Update of the targeted questionnaire related to the ONJ risk (following the assessment of LEG 035); 5. Inclusion of the completed 5-year registry study ZOL446H2422 (following the assessment of variation II-69 & MEA 017.1). The additional risk minimisation measures in the Annex II of the product information are proposed to be updated accordingly." Request for Supplementary Information adopted on 01.10.2020.	
PRAC Led **Circadin - melatonin - EMEA/H/C/000695/II/0061** RAD Neurim Pharmaceuticals EEC SARL, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Risk Management Plan update to remove the following risks from the list of potential risks: "Drug interaction with levothyroxine" "Panic Attacks", "Potential interaction with warfarin", "Sperm motility decreased/Spermatozoa morphology abnormal" and "Withdrawal"." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **EMEND - aprepitant - EMEA/H/C/000527/II/0063** Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Filip Josephson, "update of the RMP to version 5.1 to remove all the safety concerns (important identified risks, important potential risks and missing information) and information related to both 40 mg and 165 mg capsules strengths and the Postoperative Nausea and Vomiting indication (PONV), as well as to update data in the post-authorisation exposure (Part II:	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Module SV) and epidemiology (Part II: Module SI) sections." Opinion adopted on 01.10.2020.	
PRAC Led **Esbriet - pirfenidone - EMEA/H/C/002154/II/0066/G, Orphan** Roche Registration GmbH, Rapporteur: Peter Kiely, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on drug-induced liver injury (DILI) subsequent to the latest PSUSA (EMEA/H/C/PSUSA/00002435/201902) and post-authorisation measure (EMEA/H/C/2154/LEG/015). The annex II and package leaflet (PL) are updated accordingly. The RMP version 10.2 has also been updated. In addition, the MAH took the opportunity to add in the PL information about sodium content in line with excipients guideline (EMA/CHMP/302620/2017) and to correct formatting, punctuation and spelling mistakes in the product information. Update of sections 4.4 and 4.8 of the SmPC in order to add a warning on hyponatraemia and to add hyponatraemia with a frequency 'uncommon' to the list adverse reactions subsequent to the latest PSUSA (EMEA/H/C/PSUSA/00002435/201902) and post-authorisation measure (EMEA/H/C/2154/LEG/015). The PL is updated accordingly." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 11.06.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Imbruvica - ibrutinib - EMEA/H/C/003791/II/0061, Orphan** Janssen-Cilag International NV, PRAC Rapporteur: Nikica Mirošević Skvrce, PRAC-CHMP liaison: Selma Arapovic Dzakula, "Update of the RMP introducing changes to safety concerns following the assessment of the renewal R/0049. The MAH is taking this opportunity to include additional changes related to two post-authorisation measures; postponement of the completion date of cat3 study PCI-32765MCL3002 of ibrutinib in combination with BR versus BR alone and removal of Study 54179060CLL1017 on DDI as	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

assessed in II/0058." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 11.06.2020.	
PRAC Led **Ivemend - fosaprepitant - EMEA/H/C/000743/II/0043** Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Filip Josephson, "update of the RMP for Ivemend to version 5.1 to remove all the safety concerns (important identified risks, important potential risks and missing information), as well as to update data in the post-authorisation exposure (Part II: Module SV) and epidemiology (Part II: Module SI) sections." Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Keppra - levetiracetam - EMEA/H/C/000277/II/0189** UCB Pharma S.A., Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Laurence de Fays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report of the PASS EUPAS26595 'Comparing the incidence of acute renal failure in patients with epilepsy exposed to levetiracetam versus other antiepileptics drugs'." Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0044/G** Orexigen Therapeutics Ireland Limited, Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of product information resulting from PRAC Assessment Report request in PSUSA/00010366/201909: - Introduction of a warning concerning the interaction between Naltrexone/Bupropion and Digoxin in SmPC section 4.5 and related PL section. - Update of SmPC section 4.8 and related PL section on drug-induced lupus erythematosus with Naltrexone/Bupropion and its individual substances."	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 01.10.2020.	
PRAC Led **NovoEight - turoctocog alfa - EMEA/H/C/002719/II/0035** Novo Nordisk A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC to include the results of the completed study PASS Guardian 5 NN70083553. The RMP has been updated accordingly." Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Ratiograstim - filgrastim - EMEA/H/C/000825/II/0069** ratiopharm GmbH, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 10.0 in order to remove the additional pharmacovigilance activity "Cooperation with SCNIR (Severe Chronic Neutropenia International Registry) and analysis of corresponding Ratiograstim/Tevagrastim-SCNIR data"." Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Tecentriq - atezolizumab - EMEA/H/C/004143/II/0048** Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the results of study WO41486 evaluating the effectiveness of the HCP brochure designed to mitigate important immune-related risks in patients receiving atezolizumab in the European Union. As a consequence, the MAH is updating section 4.4 of the SmPC, Annex II.D and the RMP. In addition the MAH is proposing a delay in the due date for the submission of the CSR for IMvigor210 ." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.
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 -	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Results of a DUS and changes to RMP." Opinion adopted on 01.10.2020. Request for Supplementary Information adopted on 14.05.2020.	
PRAC Led **Xarelto - rivaroxaban - EMEA/H/C/000944/II/0080** Bayer AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from a Survey on Prescribers' Guide/Patient Alert listed as a category 3 study in the RMP." Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1919 Lyrica-EMEA/H/C/000546/WS1919/0109 Pregabalin Pfizer-EMEA/H/C/003880/ WS1919/0038** Upjohn EESV, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update to the Risk Management Plan to include results of recently completed PASS studies." Request for Supplementary Information adopted on 01.10.2020.	Request for supplementary information adopted with a specific timetable.

B.5.5. CHMP-CAT assessed procedures

Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0026/G, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP coordinator: Ingrid Wang	
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0027, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP coordinator: Ingrid Wang,	
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0003/G, Orphan, ATMP AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP coordinator: Johann Lodewijk Hillege Opinion adopted on 09.10.2020. Request for Supplementary Information adopted	

on 11.09.2020.	
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0006, Orphan, ATMP AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP coordinator: Johann Lodewijk Hillege Request for Supplementary Information adopted on 09.10.2020.	Request for supplementary information adopted with a specific timetable.

B.5.6. CHMP-PRAC-CAT assessed procedures

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0028, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark, "To update SmPC sections; 4.4 on CRS grading and neurologic adverse reactions; 4.8 on safety profile summary; 5.1 on follow-up analysis; to update the safety information based on updates from study KTE-C19-101, entitled "A Phase 1/2 Multicenter Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1)", the pivotal study for Yescarta. The updates include the Phase 2 safety management ZUMA-1 Cohort 4, which was intended to assess the impact of earlier interventions (tocilizumab and/or corticosteroids, in addition to prophylactic levetiracetam) on the rate and severity of CRS and neurologic events; and data from a 36-month analysis from ZUMA-1 Cohorts 1 and 2. The updated RMP version 3.1 has also been submitted."	

B.5.7. PRAC assessed ATMP procedures

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

WS1855/G **Bretaris Genuair-EMEA/H/C/002706/ WS1855/0044/G** **Eklira Genuair-EMEA/H/C/002211/ WS1855/0044/G** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 23.07.2020.	
WS1856/G **Brimica Genuair-EMEA/H/C/003969/ WS1856/0030/G** **Duaklir Genuair-EMEA/H/C/003745/ WS1856/0030/G** AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra Opinion adopted on 24.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 24.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1896 **Keppra-EMEA/H/C/000277/WS1896/0190** UCB Pharma S.A., Lead Rapporteur: Karin Janssen van Doorn, "To update section 4.4, Special warnings and precautions for use, to add a warning "Electrocardiogram QT interval prolongation" and section 4.8 of the SmPC, Undesirable effects to add ADR "Electrocardiogram QT prolonged" following outcome of LEG 088.2. Section 2 and 4 of the Package Leaflet were updated accordingly."	
WS1901 **Actraphane-EMEA/H/C/000427/WS1901/ 0086** **Actrapid-EMEA/H/C/000424/WS1901/ 0079** **Fiasp-EMEA/H/C/004046/WS1901/0024** **Insulatard-EMEA/H/C/000441/WS1901/ 0084** **Levemir-EMEA/H/C/000528/WS1901/ 0100** **Mixtard-EMEA/H/C/000428/WS1901/ 0087** **NovoMix-EMEA/H/C/000308/WS1901/ 0106** **NovoRapid-EMEA/H/C/000258/WS1901/ 0136** **Protaphane-EMEA/H/C/000442/WS1901/ 0083** **Ryzodeg-EMEA/H/C/002499/WS1901/ 0041** **Tresiba-EMEA/H/C/002498/WS1901/0048** **Xultophy-EMEA/H/C/002647/WS1901/ 0038** Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe, "To implement the risk of	

cutaneous amyloidosis in sections 4.4 and 4.8 of the SmPC following a PRAC signal assessment (EPITT no. 19499). Sections 2 and 4 of the PL are updated accordingly and also changed to highlight to patients that the precautions they need to take (such as rotating the injection site) are important not only to help preventing cutaneous amyloidosis but also to help preventing lipodystrophy. Additionally, the annexes have been brought in line with the current QRD template (version 10.1)."	
WS1907/G **Galvus-EMEA/H/C/000771/WS1907/0065/G** **Jalra-EMEA/H/C/001048/WS1907/0067/G** **Xiliarx-EMEA/H/C/001051/WS1907/0065/G** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder Opinion adopted on 01.10.2020.	Positive Opinion adopted by consensus on 01.10.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1910/G **Filgrastim Hexal-EMEA/H/C/000918/WS1910/0058/G** **Zarzio-EMEA/H/C/000917/WS1910/0059/G** Sandoz GmbH, Lead Rapporteur Johann Lodewijk Hillege	
WS1916 **Cegfila-EMEA/H/C/005312/WS1916/0005** **Pelmeg-EMEA/H/C/004700/WS1916/0009** Mundipharma Corporation (Ireland) Limited, Lead Rapporteur: Karin Janssen van Doorn	
WS1925 **Filgrastim Hexal-EMEA/H/C/000918/WS1925/0057** **Zarzio-EMEA/H/C/000917/WS1925/0058** Sandoz GmbH, Lead Rapporteur: Johann Lodewijk Hillege	

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

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

Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0042	Request by the applicant for an extension of the clock stop to respond to the RSI adopted on 23.07.2020.

Orexigen Therapeutics Ireland Limited,
Rapporteur: Kirstine Moll Harboe
Request for Supplementary Information adopted
on 23.07.2020.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

abrocitinib - EMEA/H/C/005452
Indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

avalglucosidase alfa - EMEA/H/C/005501, Orphan
Genzyme Europe BV, for long-term enzyme replacement therapy for the treatment of patients with Pompe disease.

ranibizumab - EMEA/H/C/005545
treatment of neovascular age-related macular degeneration (AMD)

adalimumab - EMEA/H/C/005548
treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis, paediatric uveitis

teriparatide - EMEA/H/C/004932
Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture

pegcetacoplan - EMEA/H/C/005553, Orphan
Apellis Ireland Limited, paroxysmal nocturnal haemoglobinuria (PNH)

ripretinib - EMEA/H/C/005614, Orphan
Deciphera Pharmaceuticals (Netherlands) B.V.,
Treatment of patients with advanced gastrointestinal stromal tumour (GIST)

rivaroxaban - EMEA/H/C/005600
Prevention of venous thromboembolism in adult patients undergoing elective hip or knee replacement surgery and treatment of deep vein thrombosis and pulmonary embolism as well as prevention of recurrent DVT and PE in adults.

Treatment of deep vein thrombosis and pulmonary embolism, and prevention of recurrent DVT and PE in adults. Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors. Treatment of deep vein thrombosis and pulmonary embolism and prevention of recurrent DVT and PE in adults. Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors. Treatment of deep vein thrombosis and pulmonary embolism and prevention of recurrent DVT and PE in adults. Prevention of venous thromboembolism in adult patients undergoing elective hip or knee replacement surgery. Treatment of deep vein thrombosis and pulmonary embolism and prevention of recurrent DVT and PE in adults.	
autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogeneic glioma tumor cell lysates, inactivated - EMEA/H/C/003693, Orphan, ATMP Epitopoietic Research Corporation-Belgium (E.R.C.), treatment of glioma	
elivaldogene autotemcel - EMEA/H/C/003690, Orphan, ATMP bluebird bio (Netherlands) B.V, treatment of ABCD1 genetic mutation and cerebral adrenoleukodystrophy	**Accelerated review**

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

Akynzeo - fosnetupitant / netupitant / palonosetron - EMEA/H/C/003728/X/0031 Helsinn Birex Pharmaceuticals Limited, Rapporteur: Peter Kiely, PRAC Rapporteur: Ilaria Baldelli, "Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion)."	
Noxafil - posaconazole - EMEA/H/C/000610/X/0063/G Merck Sharp & Dohme B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, "Extension application to introduce a new pharmaceutical form (gastro-resistant powder and solvent for oral suspension),	

grouped with a type II variation (C.I.6.a) to extend the approved indications for Noxafil to the paediatric population. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC, as well as the package leaflet, are updated. The RMP (version 17.1) is updated in accordance."

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

bevacizumab - EMEA/H/C/005327

Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.
List of Questions adopted on 23.07.2020.

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

Chiesi Farmaceutici S.p.A., Rapporteur: Janet Koenig, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Jan Neuhauser, "Extension application to add a new pharmaceutical form (inhalation powder) associated with new strength (88µg / 5µg / 9µg).
The RMP (version 6.2) is updated in accordance."
List of Questions adopted on 23.07.2020.

Xerava - eravacycline - EMEA/H/C/004237/X/0009

Tetraphase Pharmaceuticals Ireland Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "Extension application to add a new strength of 100 mg for eravacycline powder for concentrate for solution for infusion.
The RMP (version 3.0) is updated in accordance.
Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template."
List of Questions adopted on 17.09.2020.

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

Bosulif - bosutinib -
EMEA/H/C/002373/R/0045
Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Martin Huber

Cometriq - cabozantinib -
EMEA/H/C/002640/R/0042, Orphan
Ipsen Pharma, Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Menno van der Elst

Ondexxya - andexanet alfa -
EMEA/H/C/004108/R/0015
Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst

WAYLIVRA - volanesorsen -
EMEA/H/C/004538/R/0009, Orphan
Akcea Therapeutics Ireland Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber

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

AMGEVITA - adalimumab -
EMEA/H/C/004212/II/0023
Amgen Europe B.V., Rapporteur: Kristina Dunder

Beromun - tasonermin -
EMEA/H/C/000206/II/0050
Belpharma s.a., Rapporteur: Sinan B. Sarac

Cerezyme - imiglucerase -
EMEA/H/C/000157/II/0118
Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege

Cinqaero - reslizumab -
EMEA/H/C/003912/II/0037/G
Teva B.V., Rapporteur: Johann Lodewijk Hillege

Cinryze - C1 esterase inhibitor (human) -
EMEA/H/C/001207/II/0082/G
Shire Services BVBA, Rapporteur: Jan Mueller-Berghaus

Hulio - adalimumab -
EMEA/H/C/004429/II/0021
Mylan S.A.S, Rapporteur: Christophe Focke

Kentera - oxybutynin -
EMEA/H/C/000532/II/0059
Teva B.V., Rapporteur: Karin Janssen van Doorn

Kyprolis - carfilzomib -
EMEA/H/C/003790/II/0050/G, Orphan
Amgen Europe B.V., Rapporteur: Blanca Garcia-Ochoa

Lonquex - lipegfilgrastim -
EMEA/H/C/002556/II/0060
Teva B.V., Rapporteur: Outi Mäki-Ikola

Lyumjev - insulin lispro -
EMEA/H/C/005037/II/0006/G
Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-Ikola

M-M-RVAXPRO - measles, mumps and rubella vaccine (live) -
EMEA/H/C/000604/II/0103
MSD Vaccins, Rapporteur: Jan Mueller-Berghaus

Palynziq - pegvaliase -
EMEA/H/C/004744/II/0014, Orphan
BioMarin International Limited, Rapporteur: Johann Lodewijk Hillege

Privigen - human normal immunoglobulin -
EMEA/H/C/000831/II/0169
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

ProQuad - measles, mumps, rubella and varicella vaccine (live) -
EMEA/H/C/000622/II/0143
MSD Vaccins, Rapporteur: Jan Mueller-Berghaus

Reblozyl - luspatercept -
EMEA/H/C/004444/II/0002/G, Orphan
Celgene Europe BV, Rapporteur: Milena Stain

Thyrogen - thyrotropin alfa -

EMEA/H/C/000220/II/0106
Genzyme Europe BV, Rapporteur: Peter Kiely

Voncento - human coagulation factor viii / human von willebrand factor - EMEA/H/C/002493/II/0045
CSL Behring GmbH, Rapporteur: Paula Boudewina van Hennik

Xolair - omalizumab - EMEA/H/C/000606/II/0105/G
Novartis Europharm Limited, Rapporteur: Kristina Dunder

Yervoy - ipilimumab - EMEA/H/C/002213/II/0086
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik

WS1906/G
Hexacima-EMEA/H/C/002702/WS1906/0108/G
Hexaxim-EMEA/H/W/002495/WS1906/0113/G
Hexyon-EMEA/H/C/002796/WS1906/0112/G
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS1914/G
Mircera-EMEA/H/C/000739/WS1914/0080/G
NeoRecormon-EMEA/H/C/000116/WS1914/0109/G
Roche Registration GmbH, Lead Rapporteur: Martina Weise

WS1924
HyQvia-EMEA/H/C/002491/WS1924/0064
Kiovig-EMEA/H/C/000628/WS1924/0105
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

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

AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0033
sanofi-aventis groupe, Rapporteur: Martina Weise, "To update sections 4.4 and 4.8 of the SmPC regarding skin reactions in particular to drug reaction with eosinophilia and systemic symptoms (DRESS) and to update the frequency of severe skin reactions from "Not

known" to "Uncommon", following a review of the Sanofi global PV database. The Package Leaflet section 4 is updated as to add fever."

Darzalex - daratumumab - EMEA/H/C/004077/II/0041, Orphan

Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "C.I.4
Update of section 4.8 of the SmPC in order to include CMV infections as a new adverse drug reaction (ADR) with frequency common following a comprehensive, cross-program evaluation of all potential cases of treatment-emergent cytomegalovirus (CMV) infections with use of daratumumab. The Package Leaflet is updated accordingly. Several minor linguistic improvements are also proposed."

Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0013

Sanofi Pasteur, Rapporteur: Christophe Focke, "To update sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen from 3 doses to 2 doses for individuals from 9 years of age based on interim results from study CYD65 listed as a category 3 study in the RMP; this is a Phase II, observer-blind, placebo-controlled trial in order to assess Immunogenicity and Safety of Tetravalent Dengue Vaccine Given in 1-, 2-, or 3-Dose Schedules Followed by a Single Booster; section 3 of the Package Leaflet is updated accordingly"

Foclivia - influenza virus surface antigens (inactivated) of strain A/Vietnam/1194/2004 (H5N1) - EMEA/H/C/001208/II/0058

Seqirus S.r.l, Rapporteur: Armando Genazzani, "Update of sections 2, 4.2-4.8, 5.1, 6.4 and 6.5 of the SmPC based on data obtained from two clinical trials (V87_25 and V87_26) already assessed and approved for Aflunov, the corresponding H5N1 Zoonotic Influenza Vaccine (procedure EMEA/H/C/002094/II/0044/G approved in June 2019) in order to align both products. In addition, the MAH took the opportunity to also add in section 5.1 data from study V87P2 and study V87P11 (A/Turkey/turkey/1/2005) already evaluated for the RMP of both products and included in the label of Aflunov for further alignment; the

Package Leaflet and Labelling are updated accordingly. Finally, the Marketing authorisation holder (MAH) make additional changes based on the most recent EU Guidelines and some additional minor editorial corrections. The requested variation proposed amendments to the Summary of Product Characteristics, Labelling and Package Leaflet."	
Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/II/0070/G Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, "- C.I.4 (Type II): Update of section 4.5 of the SmPC to include data on the drug-drug interaction between Genvoya 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 Genvoya and medicinal products or oral supplements containing polyvalent cations, based on a MAH cumulative safety review. The Package Leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to correct the amount of lactose stated in section 2 of the SmPC and make minor editorial changes throughout the PI."	
Imfinzi - durvalumab - EMEA/H/C/004771/II/0024 AstraZeneca AB, Rapporteur: Sinan B. Sarac, "Update of sections 4.4 and 4.8 of the SmPC in order to add immune thrombocytopenia to the list of adverse drug reactions (ADRs) with frequency (rare) following the MAH internal review; the Package Leaflet (PL) is updated accordingly. The MAH took the opportunity to correct information in the PL and to make editorial changes to the names of the manufacturer in Annex II."	
Invanz - ertapenem - EMEA/H/C/000389/II/0062 Merck Sharp & Dohme B.V., Rapporteur: Fátima Ventura, "Update of section 4.8 of the SmPC in order to add 'hypersensitivity vasculitis' to the	

list of adverse drug reactions (ADRs) with frequency 'Not known', based on post-marketing reports; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, 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 bring the PI in line with the latest QRD template version 10.1. The MAH also updated the Package leaflet to add the missing adverse event "injection site induration" with frequency 'Rare'."	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0094 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "Update of sections 4.4 and 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-361 listed as a PAES in the Annex II; this is a Phase III Randomised, Controlled Clinical Trial of Pembrolizumab with or without Platinum-based Combination Chemotherapy versus Chemotherapy in Subjects with Advanced or Metastatic Urothelial Carcinoma; Annex IID is updated accordingly."	
Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/II/0037 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, "Submission of the final clinical study report from study B16-439 (Phase 3b, a Multi-Center, Randomized, Open-Label, Pragmatic Study of Glecaprevir/Pibrentasvir (G/P) +/- Ribavirin for GT1 Subjects with Chronic Hepatitis C Previously Treated with an NS5A Inhibitor + Sofosbuvir Therapy)."	
Mekinist - trametinib - EMEA/H/C/002643/II/0041 Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.5, 4.6 and 5.2 of the SmPC in order to add drug-drug interaction information with hormonal contraceptives and to updated relevant part of the SmPC regarding this interaction; the Package Leaflet is updated accordingly.	

Furthermore the MAH took the occasion to include the information regarding the sodium content in the products in line with relevant guidelines and to bring the PI in line with the latest QRD template version 10.1. In addition, the MAH took the opportunity to introduce some editorial changes in the PI and to update the list of local representatives for The Netherlands in the Package Leaflet."	
NINLARO - ixazomib - EMEA/H/C/003844/II/0025, Orphan Takeda Pharma A/S, Rapporteur: Armando Genazzani, "Update of the SmPC section 4.9 with additional information on Ninlaro overdose. The Package leaflet is updated accordingly."	
Palynziq - pegvaliase - EMEA/H/C/004744/II/0015, Orphan BioMarin International Limited, Rapporteur: Johann Lodewijk Hillege, "Submission of the final report from the non-clinical study BMN-165-18-080 listed as a category 3 study in the RMP."	
Perjeta - pertuzumab - EMEA/H/C/002547/II/0053 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Submission of the final report from study MO27775 (PERTAIN). This is a randomized, two-arm, open-label, multicenter Phase II trial assessing the efficacy and safety of pertuzumab given in combination with trastuzumab plus an aromatase inhibitor in first line patients with HER2-positive and hormone receptor-positive advanced (metastatic or locally advanced) breast cancer."	
Qutenza - capsaicin - EMEA/H/C/000909/II/0051/G Grunenthal GmbH, Rapporteur: Bruno Sepodes, "Update of section 4.2 and 4.4 to delete the explicit reference to pre treatments used in clinical trials and to opioids. Update of section 4.4 of the SmPC to include more detail on unintended exposure to capsaicin."	
Remsima - infliximab - EMEA/H/C/002576/II/0095 Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Addition of a new posology for the rheumatoid arthritis indication that does not	

include IV induction doses."

Rubraca - rucaparib - EMEA/H/C/004272/II/0024/G
Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, "Submission of the final reports from four non-clinical studies (Report 181000, OPT-2018-074, 8388100 and CLO-P8799)."

Stelara - ustekinumab - EMEA/H/C/000958/II/0083
Janssen-Cilag International NV, Rapporteur: Jayne Crowe, "Update of section 4.8 of the SmPC in order to add hypersensitivity vasculitis to the list of adverse drug reactions (ADRs) with frequency rare based on cumulative review from the literature and post-marketing reporting; the Package Leaflet is updated accordingly."

Stivarga - regorafenib - EMEA/H/C/002573/II/0031
Bayer AG, Rapporteur: Paula Boudewina van Hennik, "Submission of final study report for Study 15982, a randomized, double blind, placebo-controlled, multicenter Phase 3 study that investigated regorafenib in subjects with hepatocellular carcinoma (HCC) after progression on sorafenib treatment."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0050
Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 5.1 of the SmPC in order to reflect efficacy results based on the final OS analysis from study WO29522 (IMpassion130) comparing atezolizumab in combination with nab-paclitaxel with placebo with nab-paclitaxel for patients with previously untreated metastatic triple-negative breast cancer."

Veklury - remdesivir - EMEA/H/C/005622/II/0012
Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Submission of the final D28 mortality data by ordinal scale categories of study COUS-540-5776 (NIAID-ACTT1), listed as a Specific Obligation in the Annex II of the Product Information, in order to confirm the efficacy and safety of remdesivir in patients on Invasive Mechanical Ventilation and Extracorporeal Membrane Oxygenation (IMV/ECMO). In

addition, the MAH discuss the potential imbalance in the use of corticosteroids and effect modification in Study CO-US-540-5776. As a consequence, Annex II is updated accordingly."

Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0014, Orphan

Jazz Pharmaceuticals Ireland Limited, Rapporteur: Outi Mäki-Ikola, "Update of section 5.1 of the SmPC to reflect the 5-years overall survival data from the Follow-Up Phase of the Phase 3 Study CPX310-301. Additionally, the MAH has introduced minor editorial changes in the PI."

Xtandi - enzalutamide - EMEA/H/C/002639/II/0050

Astellas Pharma Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC in order to add severe skin reactions to the list of adverse drug reactions (ADRs) with frequency not known based on a safety review; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor corrections in the SmPC."

Zerbaxa - ceftolozane / tazobactam - EMEA/H/C/003772/II/0032

Merck Sharp & Dohme B.V., Rapporteur: Bjorg Bolstad, "Update of section 5.1 of the SmPC for Zerbaxa to implement the EUCAST MIC breakpoints of ceftolozanetazobactam for Enterobacterales according to the EUCAST Clinical breakpoints table v. 10.0, valid from January 2020.
In addition, the MAH took the opportunity to update the List of Local representatives in the Package leaflet."

WS1877
Invega-EMEA/H/C/000746/WS1877/0068
Paliperidone Janssen-Cilag International-EMEA/H/C/005486/WS1877/0001
Trevicta-EMEA/H/C/004066/WS1877/0026
Xeplion-EMEA/H/C/002105/WS1877/0051

Janssen-Cilag International NV, Lead Rapporteur: Kristina Dunder, "to add a new post-marketing adverse drug reaction (ADR) "

Stevens-Johnson syndrome/toxic epidermal necrolysis" to section 4.8 (Undesirable effects) of the Summary of Product Characteristics (SmPC) for 4 centrally authorised medicinal products (Invega/Xeplion/Trevicta/Paliperidone Janssen-Cilag International) and 2 medicinal products authorised via MRP (Risperdal Oral and Risperdal Consta). Section 4 of the Package Leaflet (PL) for each medicinal product is also amended accordingly."	
WS1917 **Kivexa-EMEA/H/C/000581/WS1917/0087** **Triumeq-EMEA/H/C/002754/WS1917/0085** **Trizivir-EMEA/H/C/000338/WS1917/0119** **Ziagen-EMEA/H/C/000252/WS1917/0114** ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, "Update of sections 4.4 of the SmPC (for Ziagen, Kivexa, Trizivir and Triumeq) and 5.2 (for Triumeq only) to add new information about the drug-drug interactions between abacavir and riociguat. The Package Leaflet is updated accordingly. Furthermore, the MAH took the opportunity to introduce an excipient update for Ziagen, Kivexa and Trizivir in line with the SmPC guideline, a syringe instruction update in the Package Leaflet of Ziagen and a revised statement in section 6.6 of the SmPC for Triumeq in line with the QRD template. Moreover, minor editorial updates have been introduced throughout the Product Information of all four products."	
WS1922 **Lixiana-EMEA/H/C/002629/WS1922/0028** **Roteas-EMEA/H/C/004339/WS1922/0016** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.2 and 5.2 of the SmPC, based on data from the bioavailability study DU176b-A-U166, in order to add information about the bioavailability of edoxaban crushed tablet administered by nasogastric tube or in apple puree and ingested versus the current tablet formulation in healthy subjects. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to correct typos in Lithuanian, Slovakian and Portuguese versions of the SmPC, Labelling and Package Leaflet."	

B.6.10. CHMP-PRAC assessed procedures

Lynparza - olaparib - EMEA/H/C/003726/II/0042

AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Amelia Cupelli, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to add Myelodysplastic syndrome (MDS)/Acute myeloid leukaemia (AML) to the list of adverse drug reactions with the frequency uncommon, modify the existing warning on MDS/AML and update efficacy information based on final results from study SOLO-2 listed as a PAES in the Annex II; this is a phase III randomised, double blind, placebo controlled, multicentre study of olaparib maintenance monotherapy in platinum sensitive relapsed BRCA mutated ovarian cancer patients who are in complete or partial response following platinum based chemotherapy; the Package Leaflet and Annex II are updated accordingly. The RMP version 21 has also been submitted."

Lyxumia - lixisenatide - EMEA/H/C/002445/II/0030

sanofi-aventis groupe, Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin, "Submission of the final report from study TDR14311 listed as a category 3 study in the RMP, and submitted in accordance with article 46. This is a randomized, double-blind, placebo-controlled, dose escalation, study on safety, pharmacokinetics and pharmacodynamics of lixisenatide in paediatric patients with Type 2 diabetes mellitus not adequately controlled with metformin and/or basal insulin. The RMP version 6.0 has also been submitted."

Natpar - parathyroid hormone - EMEA/H/C/003861/II/0026, Orphan

Shire Pharmaceuticals Ireland Limited, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final results of study PAR-C10-008; a long-term open-label study investigating the safety and tolerability of a rhPTH[1-84] for the treatment of adults with hypoparathyroidism – a clinical extension study (RACE). Update of SmPC section 5.1 to reflect 72 month data from the study. Update of the RMP (version 3.0) with the completed study results, to remove this study as an additional pharmacovigilance activity and

to align with the GVP module V Rev 2."

Rubraca - rucaparib - EMEA/H/C/004272/II/0023

Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin, "Update of sections 4.5, 4.6 and 5.2 of the SmPC to add drug-drug interaction (DDI) information with rosuvastatin and oral contraceptives based on the results of study CO-338-095 listed as a category 3 study in the RMP; Study CO-338-095 is a phase 1, open-label, DDI study to determine the effect of rucaparib on the pharmacokinetics of oral rosuvastatin (Arm A) and oral contraceptives (ethinylestradiol and levonorgestrel - Arm B) in patients with advanced solid tumors. The RMP version 4.1 has also been submitted."

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0037

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, "To update sections 4.4 and 5.1 of the SmPC following the final results from study ZOSTER-064, listed as a category 3 study in the RMP; this is an observational study to assess frailty and other prognostic factors for development of herpes zoster in adult subjects who participated in studies ZOSTER-006 and ZOSTER-022 and the HZ efficacy, immunogenicity and safety of Shingrix by frailty status, in order to fulfil the post-authorisation measure MEA/FSR 012. The updated RMP version 4.1 has also been submitted.
The MAH takes the opportunity to implement some editorial changes in sections 4.4 and 5.1. and correction of the abbreviation CHO cells from Chinese Hamster Ovarian cells to Chinese Hamster Ovary cells in the Annex A."

Xeljanz - tofacitinib - EMEA/H/C/004214/II/0027

Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan, "Update of sections 4.1, 4.2, 4.4 , 4.8, 5.1 and 5.2 of Xeljanz 11 mg prolonged-release tablets SmPC in order to include the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior

disease modifying antirheumatic drug therapy; as an alternative to the immediate release film-coated tablets; Section 4.2 of Xeljanz film-coated tablets is also updated to include switching with the prolonged-release tablet in the treatment of PsA. The Package Leaflet is updated accordingly. The RMP version 13.1 has also been submitted."

Zykadia - ceritinib - EMEA/H/C/003819/II/0034

Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to reflect the results of study CLDK378A2112 as recommended by the CHMP. The study assesses the steady-state PK of 450 mg or 600 mg ceritinib taken daily with a low-fat meal as compared with that of 750 mg ceritinib taken daily in the fasted state in patients with metastatic ALK-positive NSCLC. The Package Leaflet is updated accordingly. The RMP version 16 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1. Other editorial changes include the addition of the Sodium content in the SmPCs and PLs and the removal of the black triangle."

B.6.11. PRAC assessed procedures

PRAC Led

Brineura - cerliponase alfa - EMEA/H/C/004065/II/0027, Orphan

BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "An update to the RMP, to change the final date for the completion of the Post-authorisation efficacy study 190-203."

PRAC Led

Neuraceq - florbetaben (18F) - EMEA/H/C/002553/II/0033

Life Radiopharma Berlin GmbH, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "C.I.13: Submission of the final report from study PASS2 listed as a category 3 study in the RMP. This is a cross-sectional safety

study. The RMP version 5.9 has also been submitted."

PRAC Led

Ontruzant - trastuzumab - EMEA/H/C/004323/II/0026

Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the RMP version 4.0 in order to propose the early termination of long-term observational follow up study for cardiac safety (SB3-G31-BC-E)."

PRAC Led

Pioglitazone Accord - pioglitazone - EMEA/H/C/002277/II/0020

Accord Healthcare S.L.U., Generic, Generic of Actos, Rapporteur: Peter Kiely, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "Update of the Risk Management Plan (RMP) for the removal of safety concerns and additional risk minimisation measures (ARRM) as per summary of RMP of Glidipion (pioglitazone; published on 20-Jul-2020), and content adapted to the new GVP Module V (Rev.2)."

PRAC Led

Piqray - alpelisib - EMEA/H/C/004804/II/0001

Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 2.0 in order to replace the category 3 studies CBYL719C2402 and CBYL719A0IC02 with a new non interventional safety study (CBYL719C2404). Additionally, a separated Health Care Professional Survey (CBYL719A0IC02) is proposed as part of the pharmacovigilance plan."

PRAC Led

Stelara - ustekinumab - EMEA/H/C/000958/II/0082

Janssen-Cilag International NV, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "To submit the final safety registry report of CNTO1275PSO4005 "Nordic Database Initiative for Exposure to Ustekinumab: a Review and Analysis of Adverse Events from the Swedish

and Danish National Registry Systems" listed as a category 3 in the RMP. An updated RMP version (18.2) has also been submitted."

PRAC Led

VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0049, Orphan

Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of final physician data study results for PASS study "Evaluation of the Effectiveness of Risk Minimisation Measures: A Survey among Health Care Professionals and Patient/Caregivers to Assess their Knowledge and Attitudes on Prescribing and Home Administration Conditions of Velaglucerase Alpha (VPRIV) in 6 European Countries" (EUPASS 14255)"

PRAC Led

Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0055

Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, PRAC Rapporteur: Maia Uusküla, PRAC-CHMP liaison: Alar Irs, "Update of sections 4.4 and 5.2 of the SmPC in order to include information on the use of ceftaroline in patients with cystic fibrosis, based on a pooled population pharmacokinetic (Pop PK) analysis that included data from cystic fibrosis patients treated with ceftaroline fosamil. This submission fulfils the post-authorisation measure LEG 016.1. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial changes."

PRAC Led

WS1944

Izba-EMEA/H/C/002738/WS1944/0014

Travatan-EMEA/H/C/000390/WS1944/0064

Novartis Europharm Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Eva A. Segovia, "To submit and updated RMP for Travatan and Izba with the following proposed changes:
The following risks are proposed for removal in this RMP update:
important identified risks
- Macular oedema
- Hyperpigmentation

- Hypertrichoses - Iris and uveal inflammations - Cardiac and vascular disorders - Respiratory disorders - Hypersensitivity reactions important potential risks: - Melanoma - Corneal damage due to use of preserved eye drops - Use during pregnancy and lactation removal of the following missing information topics: - Long-term safety in the paediatric population - Potential interactions In addition, the format of the Risk management plan has been aligned with GVP Module V Revision 2 requirements (EMA 2017). The changes made to the RMP were performed following the PRAC recommendation dated 31-Oct-2019 for the recent PSUR with PSUR number PSUSA/003011/201902.”	

B.6.12. CHMP-CAT assessed procedures

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0008, Orphan, ATMP AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinator: Johann Lodewijk Hillege, “Update of SmPC for sections 4.4 (Special warnings and precautions for use), 4.8 (Undesirable Effects) and corresponding sections in the Package Leaflet to add a new safety signal of 'Thrombotic microangiopathy'.”	
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0009/G, Orphan, ATMP AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinator: Johann Lodewijk Hillege	
Zynteglo - betibeglogene autotemcel - EMEA/H/C/003691/II/0017, Orphan, ATMP bluebird bio (Netherlands) B.V, Rapporteur: Carla Herberts, CHMP Coordinator: Paula	

Boudewina van Hennik

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

WS1854
Renvela-EMEA/H/C/000993/
WS1854/0053
Sevelamer carbonate Winthrop-
EMEA/H/C/003971/WS1854/0026
Genzyme Europe BV, Lead Rapporteur: Karin Janssen van Doorn, "To update section 2 of the SmPC, labelling and section 2 of the PL for the Powder for oral suspension presentations for Renvela and Sevelamer carbonate Winthrop with regards to clarify the exact quantity and threshold of propylene glycol per product following the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668).
The MAH took the opportunity to include an update about the local representatives in the Pl for Italy, Malta, The Netherlands and Slovakia."

WS1878
Ambirix-EMEA/H/C/000426/WS1878/
0110
Fendrix-EMEA/H/C/000550/WS1878/
0073
Infanrix hexa-EMEA/H/C/000296/
WS1878/0284
Twinrix Adult-EMEA/H/C/000112/
WS1878/0145
Twinrix Paediatric-EMEA/H/C/000129/
WS1878/0146
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1895/G
Lixiana-EMEA/H/C/002629/WS1895/
0029/G
Roteas-EMEA/H/C/004339/WS1895/
0017/G
Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro

WS1905
Infanrix hexa-EMEA/H/C/000296/
WS1905/0283
GlaxoSmithkline Biologicals SA, Lead
Rapporteur: Christophe Focke

WS1912
Ambirix-EMEA/H/C/000426/WS1912/
0111
Infanrix hexa-EMEA/H/C/000296/
WS1912/0285
Rotarix-EMEA/H/C/000639/WS1912/0117
Twinrix Adult-EMEA/H/C/000112/
WS1912/0146
Twinrix Paediatric-EMEA/H/C/000129/
WS1912/0147
GlaxoSmithkline Biologicals SA, Lead
Rapporteur: Christophe Focke

WS1958/G
Aflunov-EMEA/H/C/002094/WS1958/
0063/G
Foclivia-EMEA/H/C/001208/WS1958/
0059/G
Seqirus S.r.l, Lead Rapporteur: Armando
Genazzani

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

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 12-15 October 2020 CHMP plenary:

G.3.2. List of procedures starting in October 2020 for November 2020 CHMP adoption of outcomes

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