19 June 2020
EMA/CHMP/333600/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 22-25 June 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

22 June 2020, 09:00 – 19:30, room 0A/ virtual meeting

23 June 2020, 08:30 – 19:30, room 0A/ virtual meeting

24 June 2020, 08:30 – 19:30, room 0A/ virtual meeting

25 June 2020, 08:30 – 16:00, room 0A/ virtual meeting

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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 22-25 June 2020. See June 2020 CHMP minutes (to be published post July 2020 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 22-25 June 2020.

1.3. Adoption of the minutes

CHMP minutes for 25-28 May 2020.

ORGAM minutes for 15 June 2020.

Extraordinary CHMP meeting on remdesivir, 19 June 2020.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on Monday, 22 June 2020 at 14:00

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

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

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

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday, 24 June 2020 at 11:00

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

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

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

Scope: Possible oral explanation

Action: Oral explanation to be held on Tuesday, 23 June 2020 at 11:00

List of Outstanding Issues adopted on 27.06.2019. List of Questions adopted on 13.12.2018.

2.1.4. imlifidase - Orphan - EMEA/H/C/004849

Hansa Biopharma AB; is indicated for desensitization treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor.

Scope: Possible oral explanation/ Opinion

Action: Oral explanation to be held on Tuesday, 24 June 2020 at 09:00

List of Outstanding Issues adopted on 30.04.2020, 27.02.2020. List of Questions adopted on 27.06.2019.

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

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

Scope: Oral explanation/Opinion

Action: Oral explanation to be held on Tuesday, 23 June 2020 at 09:00

List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 28.01.2020.

2.1.6. remdesivir - EMEA/H/C/005622

treatment of coronavirus disease 2019 (COVID-19).

Scope: Possible oral explanation/Opinion

Action: Oral explanation to be held on Tuesday, 23 June 2020 at 14:00

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. bevacizumab - EMEA/H/C/005106

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.05.2020, 26.03.2020. List of Questions adopted on 14.11.2019.

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

Accelerated assessment

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

Scope: Opinion

Action: For adoption

List of Questions adopted on 28.04.2020.

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

treatment of primary apnoea.

Scope: Opinion

Action: For adoption

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

3.1.4. teriparatide - EMEA/H/C/005087

treatment of osteoporosis.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.05.2020, 27.02.2020. List of Questions adopted on 19.09.2019.

3.1.5. methylthioninium chloride - EMEA/H/C/002776

is indicated as an aid for the enhanced visualization and detection of colorectal lesions in adult patients undergoing screening / surveillance colonoscopy for colorectal cancer.

Scope: Opinion

Action: For adoption

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

3.1.6. teriparatide - EMEA/H/C/005388

treatment of osteoporosis.

Scope: Opinion

Action: For adoption

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

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

Daiichi Sankyo Europe GmbH; treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT), also referred to as giant cell tumour of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS).

Scope: Opinion

Action: For adoption

Oral explanation was held on 26.05.2020. List of Outstanding Issues adopted on 26.03.2020, 12.12.2019. List of Questions adopted on 25.07.2019.

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

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

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

Scope: List of outstanding issues,

Draft list of experts for the SAG on Anti-Infectives meeting

Action: For adoption

List of Outstanding Issues adopted on 28.05.2020, 30.04.2020. List of Questions adopted on 14.11.2019.

3.2.2. dasatinib - EMEA/H/C/005446

treatment of leukaemia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2019.

3.2.3. dasatinib - EMEA/H/C/005317

treatment of leukaemia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2019.

3.2.4. bupivacaine - EMEA/H/C/004586

Indicated for prolonged acute pain management and reduction in need for opioids in adults compared to immediate-release bupivacaine.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2019.

3.2.5. 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: List of outstanding issues

Action: For adoption

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

3.2.6. lenalidomide - EMEA/H/C/005306

treatment of multiple myeloma.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

3.2.7. pegfilgrastim - EMEA/H/C/005085

treatment of neutropenia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2019.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

3.2.10. 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: List of outstanding issues

Action: For adoption

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

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

3.3.1. dostarlimab - EMEA/H/C/005204

Accelerated assessment

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

Scope: List of questions

Action: For adoption

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

oral contraceptive.

Scope: List of questions

Action: For adoption

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

oral contraception.

Scope: List of questions

Action: For adoption

3.3.4. pitolisant - EMEA/H/C/005117

Treatment of Excessive Daytime Sleepiness (EDS) in patients with Obstructive Sleep Apnoea (OSA).

Scope: List of questions

Action: For adoption

3.3.5. sodium thiosulfate - PUMA - EMEA/H/C/005130

for the prevention of ototoxicity induced by cisplatin (CIS) chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumours.

Scope: List of questions

Action: For adoption

3.3.6. tirbanibulin mesilate - EMEA/H/C/005183

topical field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis.

Scope: List of questions

Action: For adoption

3.3.7. sildenafil - EMEA/H/C/005439

treatment of erectile dysfunction.

Scope: List of questions

Action: For adoption

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

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

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

Scope: Letter from the applicant dated 5 June 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in May 2020.

Action: For adoption

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

3.4.2. 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: Update on procedure

Action: For information

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

3.4.3. 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: Letter from the applicant dated 11 June 2020 requesting an extension of clock-stop to respond to the list of questions adopted in April 2020.

Action: For adoption

List of Questions adopted on 30.04.2020.

3.4.4. ofatumumab - EMEA/H/C/005410

treatment of relapsing forms of multiple sclerosis.

Scope: Letter from the applicant dated 12 June 2020 requesting an extension of clock-stop to respond to the list of questions adopted in May 2020.

Action: For adoption

List of Questions adopted on 28.05.2020.

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

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

Scope: Letter from the applicant dated 8 June 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in May 2020

Action: For adoption

List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 19.09.2019.

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

No items

3.6. Initial applications in the decision-making phase

3.6.1. Pretomanid FGK - pretomanid - Orphan - EMEA/H/C/005167

FGK Representative Service GmbH; treatment of tuberculosis.

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

Action: For adoption

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

Opinion adopted on 26.03.2020. List of Outstanding Issues adopted on 30.01.2020. List of Questions adopted on 25.07.2019.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. lifitegrast - EMEA/H/C/004653

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

Scope: Withdrawals of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 26.03.2020, 12.12.2019. List of Questions adopted on 26.04.2019.

3.7.2. plazomicin - EMEA/H/C/004457

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

Scope: Withdrawals of initial marketing authorisation application

Action: For information

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

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

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

4.1.1. Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210/X/0043/G

Gilead Sciences Ireland UC

Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new strength (200/50 mg film-coated tablets). The new formulation is indicated for the treatment of chronic hepatitis C (CHC) in patients aged 6 years and older.
The extension application is grouped with a type II variation (C.I.6.a) to include paediatric use in patients aged 6 to < 18 years who weigh greater than or equal to 35 kg to the existing presentation (400/100 mg film-coated tablets).
Sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated to support the extended indication.
The RMP (version 5.1) is updated in accordance."

Action: For adoption

List of Questions adopted on 27.02.2020.

4.1.2. Idelvion - albutrepenonacog alfa - Orphan - EMEA/H/C/003955/X/0035

CSL Behring GmbH

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

Scope: "Extension application to add a new strength of 3500 IU (700 IU/ml) for albutrepenonacog alfa powder and solvent for solution for injection. The RMP version 3.1 was updated in accordance.
In addition, the applicant took the opportunity to update sections with editorial changes and align the dossier."

Action: For adoption

List of Questions adopted on 30.01.2020.

4.1.3. Pemetrexed Accord - pemetrexed - EMEA/H/C/004072/X/0010

Accord Healthcare S.L.U.

Rapporteur: John Joseph Borg, PRAC Rapporteur: Adrien Inoubli

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

Action: For adoption

List of Questions adopted on 30.01.2020.

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

Pfizer Europe MA EEIG

Rapporteur: Alar Irs

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

Action: For adoption

List of Questions adopted on 27.02.2020.

4.1.5. Praluent - alirocumab - EMEA/H/C/003882/X/0054/G

sanofi-aventis groupe

Rapporteur: Johann Lodewijk Hillege

Scope: "Grouping of:

• Extension application to introduce a new strength of 300 mg solution for injection in pre-filled pen

• B.II.b.3.z

• B.II.d.2.a

• B.II.e.5.a.1

• B.II.e.5.a.1

• B.II.e.5.a.1

• B.II.e.5.a.1

• B.II.e.5.a.1

• B.II.e.6.b

• B.IV.1.c

Update of sections 1, 2, 4.2, 6.3, 6.5 and 8 of the SmPC; the Labelling and Package Leaflet are updated accordingly.
In addition, the applicant has taken the opportunity to update the contact details of the Maltese local representative in the Package Leaflet, to bring the PI in line with the latest QRD template (v. 10.1) and to introduce editorial changes"

Action: For adoption

List of Questions adopted on 26.03.2020.

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. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/X/0083/G

Vertex Pharmaceuticals (Ireland) Limited

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

Scope: "Extension application to add a new strength of 75 mg film-coated tablets of ivacaftor to enable administration to patients aged 6 to less than 11 years
C.II.6.a - To update sections 4.1, 4.2 and 6.5 of the SmPC, and sections 1 and 2 of the PL for the 150 mg film-coated tablet presentations to extend the indication for use in children aged 6 to less than 11 years old in combination with tezacaftor/ivacaftor and to bring it in line with the new dosage form (75 mg film-coated tablets of ivacaftor).
The RMP (version 8.6) is updated in accordance.
In addition, the MAH took the opportunity to implement minor updates in the Product Information."

Action: For adoption

List of Questions adopted on 26.03.2020.

4.2.2. Symkevi - tezacaftor / ivacaftor - Orphan - EMEA/H/C/004682/X/0015/G

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to add a new strength of 50/75 mg film-coated tablets of tezacaftor/ivacaftor to enable administration to patients aged 6 to less than 11 years.
C.II.6.a - To update sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.1 of the SmPC, and sections 2, 3 and 6 of the PL for the 100/150 mg film-coated tablet presentations to extend the indication for use in children aged 6 to less than 11 years old in combination with ivacaftor and to bring it in line with the new dosage form (50/75 mg film-coated tablets tezacaftor/ivacaftor).
The RMP (version 2.1) is updated in accordance.
In addition, the MAH took the opportunity to implement minor updates and formatting changes in the Product Information."

Action: For adoption

List of Questions adopted on 26.03.2020.

4.2.3. Velphoro - iron - EMEA/H/C/002705/X/0020/G

Vifor Fresenius Medical Care Renal Pharma France

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Simona Stankeviciute, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to add a new pharmaceutical form with a new strength - powder for oral suspension 125 mg, and extension of indication to add indication to use Velphoro for the control of serum phosphorus levels in paediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate <30 mL/min/1.73 m^2) or with CKD on dialysis, based on the results from an open-label, randomised, active-controlled, parallel group, multicentre, phase 3 study investigating the safety and efficacy of Velphoro and calcium acetate in paediatric and adolescent CKD patients with hyperphosphataemia (Study PA-CL-PED-01). As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance.
In addition, the MAH took the opportunity to update the list of local representatives in the

Package Leaflet. The RMP version 7.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

List of Questions adopted on 30.01.2020.

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. Diacomit - stiripentol - EMEA/H/C/000664/X/0032

BIOCODEX

Rapporteur: Alar Irs, PRAC Rapporteur: Maia Uusküla

Scope: "Extension application to add a new strength of 100 mg capsules.
The RMP (version 2.0) is updated in accordance."

Action: For adoption

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

GlaxoSmithKline Trading Services Limited

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

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

Action: For adoption

4.3.3. 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

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

GlaxoSmithKline Trading Services Limited

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

Scope: "Extension application to introduce a new strength (184mcg/55mcg/22mcg)

grouped with a type II variation (C.I.6.a) to add a new indication (asthma). Whilst the new indication is applicable also to the existing presentations (EU/1/19/13781237/001-3), the new strength is indicated only for the treatment of asthma. The RMP (version 2.2) is updated in accordance."

Action: For adoption

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

GlaxoSmithKline Trading Services Limited

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

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

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

Amgen Europe B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Daniela Melchiorri, 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 PL are updated accordingly. The updated RMP version 10.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2019.

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

Novartis Europharm Limited

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

Scope: "Extension of indication to include the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy for Cosentyx; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. Section 6.6 of the SmPC for the solution for injection is also updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 6.0 has also been submitted.
Furthermore, the Annex II is brought in line with the latest QRD template version 11.0."

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020, 27.02.2020.

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

Kyowa Kirin Holdings B.V.

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

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

Action: For adoption

Request for Supplementary Information adopted on 30.01.2020.

5.1.4. Deltyba - delamanid - Orphan - EMEA/H/C/002552/II/0040

Otsuka Novel Products GmbH

Rapporteur: Koenraad Norga, PRAC Rapporteur: Laurence de Fays

Scope: "Extension of indication to include adolescents and children above 6 years with a body weight of at least 30 kg. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC and corresponding, relevant sections of the PL are updated accordingly. The updated RMP version 3.2 has also been submitted. Furthermore, the PI is being brought in line with the latest QRD template."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 27.02.2020.

5.1.5. Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0013

Seqirus Netherlands B.V.

Rapporteur: Sol Ruiz, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication of prophylaxis of influenza, from the currently approved age range "adults and children from 9 years of age" to "adults and children from 2 years of age" for Flucelvax Tetra; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted."

Action: For adoption

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

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

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

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

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020.

5.1.7. Lynparza - olaparib - EMEA/H/C/003726/II/0035

AstraZeneca AB

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

Scope: "Extension of indication to include the use of Lynparza tablets in combination with bevacizumab for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy with bevacizumab. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of

the SmPC are updated. The PL is updated accordingly. In addition, sections 4.4 and 4.8 of the SmPC for Lynparza hard capsules are revised based on updated safety data analysis. Furthermore, the PI is brought in line with the latest QRD template version 10.1. The RMP version 19 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020.

5.1.8. Lynparza - olaparib - EMEA/H/C/003726/II/0036

AstraZeneca AB

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

Scope: "Extension of indication to include the use of Lynparza tablets as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and homologous recombination repair gene mutations (germline and/or somatic) who have progressed following a prior new hormonal agent. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The PL is updated accordingly. In addition, sections 4.4 and 4.8 of the SmPC for Lynparza hard capsules are revised based on updated safety data analysis. The RMP version 20 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 26.03.2020.

5.1.9. Quofenix - delafloxacin - EMEA/H/C/004860/II/0003

A. Menarini Industrie Farmaceutiche Riunite s.r.l.

Rapporteur: Janet Koenig, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Željana Margan Koletić

Scope: "Extension of indication to include treatment of Community Acquired Pneumonia (CAP) for Quofenix 450 mg tablets and 300 mg powder for concentrate for solution for infusion; 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 2.0 of the RMP has also been submitted."

Action: For adoption

5.1.10. Remsima - infliximab - EMEA/H/C/002576/II/0082

Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to add Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis to the Remsima SC pharmaceutical form to be in line with the IV formulation."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

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

Roche Registration GmbH

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

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

Action: For adoption

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

Janssen-Cilag International N.V.

Rapporteur: Melinda Sobor, 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 30.01.2020.

5.1.13. Xolair - omalizumab - EMEA/H/C/000606/II/0101

Novartis Europharm Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin

Scope: "Extension of indication to include treatment of nasal polyps in adult patients with inadequate response to intranasal corticosteroids for Xolair; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes in section 4.2 of the SmPC and in the PL and to update the phone number of the NL local representative. The RMP version 16.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

5.1.14. Zavicefta - ceftazidime / avibactam - EMEA/H/C/004027/II/0019

Pfizer Ireland Pharmaceuticals

Rapporteur: Bjorg Bolstad, Co-Rapporteur: Simona Stankeviciute

Scope: "Extension of indication to include bacteraemia (in association with, or suspected to be associated with, the currently approved indications for complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI) and hospital-acquired pneumonia, including ventilator-associated pneumonia (HAP/VAP)) for Zavicefta; as a consequence, sections 4.1 and 4.2 of the SmPC are updated in order to add this indication and the posology. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2020.

5.1.15. 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 PI 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 27.02.2020.

5.1.16. WS1783
Opdivo - nivolumab - EMEA/H/C/003985/WS1783/0081
Yervoy - ipilimumab - EMEA/H/C/002213/WS1783/0077

Bristol-Myers Squibb Pharma EEIG

Lead Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include first-line treatment of metastatic non small cell lung cancer in adults with no EGFR or ALK positive tumour mutations for combination of Odpivo and Yervoy; 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 17.0 of the RMP for Opdivo and version 27.0 for Yervoy have also been submitted."

Action: For adoption

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

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

AstraZeneca AB

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

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

Request by the applicant for an extension of clock-stop to respond to the Request for Supplementary Information adopted on 28.05.2020

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020, 14.11.2019.

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

No items

6. Ancillary medicinal substances in medical devices

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

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issues

8.1.1. avalglucosidase alfa - H0005501

treatment of Pompe disease.

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

Action: For adoption

8.1.2. evinacumab - H0005449

is indicated as an adjunct to other lipid-lowering therapies in adults and adolescents aged 12 years and older with homozygous familial hypercholesterolaemia (HoFH).

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. Caprelsa - vandetanib - EMEA/H/C/002315/II/0043

Genzyme Europe BV

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli

Scope: "C.I.4 Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on interim results from study D4200C00104, listed as a specific obligation in the Annex II. This is an observational study (including a retrospective arm to evaluate the Benefit/Risk of vandetanib (Caprelsa) 300 mg in RET mutation negative and RET mutation positive patients with symptomatic, aggressive, sporadic, unresectable, locally advanced/metastatic thyroid cancer (MTC)), to confirm the efficacy and safety of Caprelsa in RET-negative patients with the aim to fulfil SOB001 and convert Caprelsa from conditional to normal Marketing Authorisation. In addition, the MAH takes to opportunity to rectify the Dutch translation of the Caprelsa Product Information.",

Letter from the applicant dated 02 June 2020 requesting an extension of clock-stop to respond to the Request for Supplementary Information adopted on 28.05.2020.

Action: For adoption

9.1.2. Translarna - ataluren - EMEA/H/C/002720/II/0058, Orphan

PTC Therapeutics International Limited

Rapporteur: Johann Lodewijk Hillege

Scope: "C.I.z Safety Efficacy and Pharmacovigilance - Other changes. Update of section 4.1 and 5.1 solely based on the interpretation of the recently published "Guide for Assessors of Centralised Applications on the wording of the therapeutic indication" (EMA/CHMP/483022/2019) ("EMA Assessor Guide")."

Action: For adoption

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

MAH: Sanofi-aventis groupe

Rapporteur: Bruno Sepodes, Co-Rapporteur: Christophe Focke, 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 adoption

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

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

MAHs: various

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

Scope: Opinion

Action: For adoption

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

No items

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

10.4.1. Budesonide SUN – budesonide – EMEA/H/A-29(4)/1492

MAH: Sun Pharmaceutical Industries Europe B.V.

Re-examination Rapporteur: Kristina Dunder, Re-examination Co-Rapporteur: Janet Koenig

Initial Rapporteur: Johann Lodewijk Hillege, Initial Co-Rapporteur: Giuseppa Pistritto

Scope: Opinion

Action: For adoption

The applicant has submitted an Art. 10(3) application for Budesonide SUN nebuliser suspension and associated names. Concerns regarding the demonstration of bioequivalence have been raised by IT and UK who were of the view that the data presented (comparative in vitro data of the product before nebulisation, including Particle Size Distribution (PSD) of

the active substance) are not sufficient to demonstrate bioequivalence. The procedure was initiated because of disagreements regarding which in-vitro data are considered pivotal.

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

MAH: Fresenius Kabi Deutschland GmbH

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

Scope: Opinion

Action: For adoption

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

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

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

MAHs: GlaxoSmithKline Biologicals

Referral Rapporteur: TBC, Referral Co-Rapporteurs: TBC

Scope: Start of procedure, Timetable, Appointment of Rapporteurs

Action: For adoption

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

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

June 2020 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

13.2. Innovation Task Force briefing meetings

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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Seating plan for CHMP under German EU Presidency, 1 July – 31 December 2020

CHMP Seating Plan 1 July – 31 December 2020, under German EU presidency

Action: For information

14.2. Coordination with EMA Scientific Committees

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

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 08-11 June 2020

Action: For information

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

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at June 2020 PDCO

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

BWP Reports June 2020 meeting to CHMP:

- 19 reports on products in scientific advice and protocol assistance
- 11 reports on products in pre-authorisation procedures
- 3 reports on products in plasma master file

Action: For adoption

14.3.2. Biostatistics Working Party (BSWP)

Chair: TBC, Vice-Chair: Joerg Zinserling

Election of new BSWP chair. Anja Schiel's first 3-year term expired in December 2019.

Nomination(s) received

Action: For election

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 08-11 June 2020. Table of conclusions

Action: For information

Scientific advice letters

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

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. Update of the Business Pipeline report for the human scientific committees

Q2/2020 initial marketing authorisation application submissions with eligibility request to central procedure

Action: For information

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

16. Explanatory notes

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

Oral explanations *(section 2)*

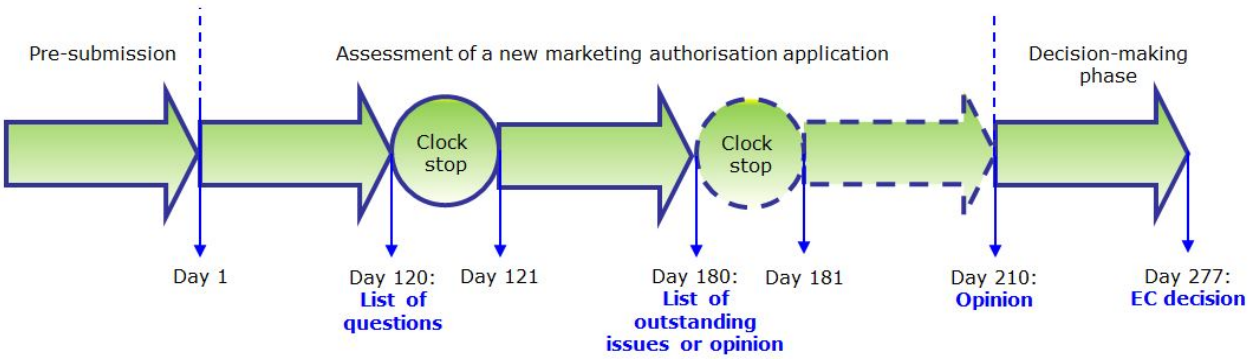
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2020
EMA/CHMP/330901/2020

Annex to 22-25 June 2020 CHMP Agenda

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A. PRE SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for June 2020: **For adoption**

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

Final Outcome of Rapporteurship allocation for June 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

Evoltra - clofarabine - EMEA/H/C/000613/S/0068 Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli	
Firdapse - amifampridine - EMEA/H/C/001032/S/0066 SERB SA, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga	
Kolbam - cholic acid - EMEA/H/C/002081/S/0031, Orphan Retrophin Europe Ltd, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Agni Kapou Request for Supplementary Information adopted on 26.03.2020.	Request from the applicant dated 29.05.2020 for an extension to the clock-stop to respond to the Request for Supplementary Information.
Lamzede - velmanase alfa - EMEA/H/C/003922/S/0011, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jan Neuhauser	
Obizur - susoctocog alfa -	

EMEA/H/C/002792/S/0028
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski
Request for Supplementary Information adopted on 30.04.2020, 27.02.2020.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Armisarte - pemetrexed -
EMEA/H/C/004109/R/0022
Actavis Group PTC ehf, Rapporteur: Alar Irs, PRAC Rapporteur: Adrien Inoubli

Benepali - etanercept -
EMEA/H/C/004007/R/0053
Samsung Bioepis NL B.V., Rapporteur: Andrea Laslop, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Eva A. Segovia

Duloxetine Zentiva - duloxetine -
EMEA/H/C/003935/R/0009
Zentiva k.s., Generic, Generic of Cymbalta, Yentreve, Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon
Request for Supplementary Information adopted on 26.03.2020.

Ebymect - dapagliflozin / metformin -
EMEA/H/C/004162/R/0046
AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Menno van der Elst
Request for Supplementary Information adopted on 28.05.2020.

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

ELOCTA - efmoroctocog alfa -
EMEA/H/C/003964/R/0036
Swedish Orphan Biovitrum AB (publ), Rapporteur: Jan Mueller-Berghaus, Co-

Rapporteur: Sol Ruiz, PRAC Rapporteur: Sonja Hrabcik

Pemetrexed Hospira - pemetrexed - EMEA/H/C/003970/R/0022
Pfizer Europe MA EEIG, Generic, Generic of Alimta, Rapporteur: Alar Irs, PRAC Rapporteur: Adrien Inoubli

Pemetrexed medac - pemetrexed - EMEA/H/C/003905/R/0008
medac Gesellschaft fur klinische Spezialpraparate mbH, Generic, Generic of Alimta, Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Adrien Inoubli
Request for Supplementary Information adopted on 30.04.2020.

Pemetrexed Sandoz - pemetrexed - EMEA/H/C/004011/R/0008
Sandoz GmbH, Generic, Generic of Alimta, Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Adrien Inoubli
Request for Supplementary Information adopted on 30.04.2020.

RAVICTI - glycerol phenylbutyrate - EMEA/H/C/003822/R/0034, Orphan
lmmedica Pharma AB, Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Ilaria Baldelli
Request for Supplementary Information adopted on 30.04.2020.

Spectrila - asparaginase - EMEA/H/C/002661/R/0018
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Jan Neuhauser

B.2.3. Renewals of Conditional Marketing Authorisations

VITRAKVI - larotrectinib - EMEA/H/C/004919/R/0006
Bayer AG, Rapporteur: Filip Josephson, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rugile Pilviniene
Request for Supplementary Information adopted on 28.05.2020.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its June 2020 meeting:
EMEA/H/C/PSUSA/00002666/201911 (rotavirus vaccine pentavalent (live, oral)) CAPS: **RotaTeq** (EMEA/H/C/000669) (rotavirus vaccine (live, oral)), MSD Vaccins, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Period Covered From: 28/11/2018 To: 27/11/2019"
EMEA/H/C/PSUSA/00010535/201911 (ixazomib) CAPS: **NINLARO** (EMEA/H/C/003844) (ixazomib), Takeda Pharma A/S, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Annika Folin, "Period Covered From: 18/11/2018 To: 18/11/2019"
EMEA/H/C/PSUSA/00010575/201911 (tenofovir alafenamide) CAPS: **Vemlidy** (EMEA/H/C/004169) (tenofovir alafenamide), Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Ilaria Baldelli, "Period Covered From: 10/11/2018 To: 09/11/2019"
EMEA/H/C/PSUSA/00010594/201911 (fluciclovine (18F)) CAPS: **Axumin** (EMEA/H/C/004197) (fluciclovine (18F)), Blue Earth Diagnostics Ireland Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Rugile Pilviniene, "Period Covered From: 26/05/2019 To: 26/11/2019"

B.4. EPARs / WPARs

Apixaban Accord - apixaban - EMEA/H/C/005358 Accord Healthcare S.L.U., prevention of venous thromboembolic events (VTE), Generic, Generic of Eliquis, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Erlotinib Accord - erlotinib - EMEA/H/C/005071	For information only. Comments can be sent to the PL in case necessary.

Accord Healthcare S.L.U., treatment of lung and pancreatic cancers, Generic, Generic of Tarceva, Generic application (Article 10(1) of Directive No 2001/83/EC)	
Hepcludex - bulevirtide - EMEA/H/C/004854, Orphan MYR GmbH, indicated for the treatment of chronic hepatitis delta virus (HDV) infection in adult patients with compensated liver 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.
Hopveus - sodium oxybate - EMEA/H/C/004962 D&A PHARMA; medium to long-term maintenance of alcohol abstinence and treatment of mild to moderate alcohol withdrawal syndrome.	For information only. Comments can be sent to the PL in case necessary.
MVABEA - ebola vaccine (rdna, replication-incompetent) - EMEA/H/C/005343 Janssen-Cilag International N.V., is indicated for active immunization for prevention of disease caused by Ebola virus, 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.
Piqray - alpelisib - EMEA/H/C/004804 Novartis Europharm Limited, treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor2 (HER2)-negative, advanced breast cancer with a PIK3CA mutation in combination with fulvestrant after disease progression following an endocrine-based regimen., 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.
Pretomanid FGK - pretomanid - EMEA/H/C/005167, Orphan FGK Representative Service GmbH, treatment of tuberculosis, 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.
Rozlytrek - entrectinib - EMEA/H/C/004936 Roche Registration GmbH, treatment of adult and paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive locally advanced or metastatic solid tumours and treatment of patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC)., New active substance (Article 8(3) of Directive	For information only. Comments can be sent to the PL in case necessary.

No 2001/83/EC)	
Xenleta - lefamulin - EMEA/H/C/005048 Nabriva Therapeutics Ireland DAC, treatment of community-acquired pneumonia (CAP), 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.
ZABDENO - ebola vaccine (rdna, replication-incompetent) - EMEA/H/C/005337 Janssen-Cilag International N.V., is indicated for active immunization for prevention of disease caused by Ebola virus (Zaire ebolavirus species), 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.
Zercepac - trastuzumab - EMEA/H/C/005209 Accord Healthcare S.L.U., treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC), Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0033 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus
Bemfola - follitropin alfa - EMEA/H/C/002615/II/0025/G Gedeon Richter Plc., Rapporteur: Paula Boudewina van Hennik
BeneFIX - nonacog alfa - EMEA/H/C/000139/II/0161/G Pfizer Europe MA EEIG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 17.04.2020, 20.02.2020, 05.12.2019.
Besremi - ropeginterferon alfa-2b - EMEA/H/C/004128/II/0006/G AOP Orphan Pharmaceuticals AG, Rapporteur: Janet Koenig

Buvidal - buprenorphine - EMEA/H/C/004651/II/0007/G Camurus AB, Rapporteur: Peter Kiely	
Caprelsa - vandetanib - EMEA/H/C/002315/II/0044/G Genzyme Europe BV, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
Cegfila - pegfilgrastim - EMEA/H/C/005312/II/0004/G Mundipharma Corporation (Ireland) Limited, Rapporteur: Koenraad Norga Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
Emgality - galcanezumab - EMEA/H/C/004648/II/0013 Eli Lilly Nederland B.V., Rapporteur: Daniela Melchiorri	
Emtricitabine/Tenofovir disoproxil Mylan - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050/II/0013/G Mylan S.A.S, Generic, Generic of Truvada, Rapporteur: Simona Stankeviciute	
Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0014 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz	
Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0101 AstraZeneca AB, Rapporteur: Christophe Focke	
Fulphila - pegfilgrastim - EMEA/H/C/004915/II/0005/G Mylan S.A.S, Rapporteur: Martina Weise Request for Supplementary Information adopted on 28.11.2019.	
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0038, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 05.06.2020.	Positive Opinion adopted by consensus on 05.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Inhixa - enoxaparin sodium - EMEA/H/C/004264/II/0064 Techdow Pharma Netherlands B.V., Duplicate, Duplicate of Thorinane, Rapporteur: Andrea	

Laslop	
Mepsevii - vestronidase alfa - EMEA/H/C/004438/II/0013/G, Orphan Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 05.06.2020, 17.04.2020.	Request for supplementary information adopted with a specific timetable.
Mircera - methoxy polyethylene glycol-epoetin beta - EMEA/H/C/000739/II/0078/G Roche Registration GmbH, Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 05.06.2020.	Positive Opinion adopted by consensus on 05.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NeoRecormon - epoetin beta - EMEA/H/C/000116/II/0105/G Roche Registration GmbH, Rapporteur: Martina Weise	
Orencia - abatacept - EMEA/H/C/000701/II/0139 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 11.06.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Praluent - alirocumab - EMEA/H/C/003882/II/0056/G sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 05.06.2020.	Positive Opinion adopted by consensus on 05.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0186/G Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder	
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0157/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 17.04.2020.	
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0160 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
Puregon - follitropin beta - EMEA/H/C/000086/II/0106/G Merck Sharp & Dohme B.V., Rapporteur: Peter	Positive Opinion adopted by consensus on 05.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Kiely Opinion adopted on 05.06.2020. Request for Supplementary Information adopted on 02.04.2020.	recommendation.
Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0040 CSL Behring GmbH, Rapporteur: Kristina Dunder	
Ruxience - rituximab - EMEA/H/C/004696/II/0001 Pfizer Europe MA EEIG, Rapporteur: Paula Boudewina van Hennik	
Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0030 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke	
TAKHZYRO - lanadelumab - EMEA/H/C/004806/II/0014/G, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder	
Victoza - liraglutide - EMEA/H/C/001026/II/0057 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege	
WS1736/G **Elebrato Ellipta-EMEA/H/C/004781/ WS1736/0015/G** **Temybric Ellipta-EMEA/H/C/005254/ WS1736/0003/G** **Trelegy Ellipta-EMEA/H/C/004363/ WS1736/0013/G** GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Peter Kiely Request for Supplementary Information adopted on 17.04.2020.	
WS1784/G **Hexacima-EMEA/H/C/002702/WS1784/ 0096/G** **Hexaxim-EMEA/H/W/002495/WS1784/ 0101/G** **Hexyon-EMEA/H/C/002796/WS1784/ 0100/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 05.06.2020.	
WS1797/G **Hexacima-EMEA/H/C/002702/WS1797/0100/G** **Hexaxim-EMEA/H/W/002495/WS1797/0105/G** **Hexyon-EMEA/H/C/002796/WS1797/0104/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 05.06.2020.	Request for supplementary information adopted with a specific timetable.
WS1799/G **Luveris-EMEA/H/C/000292/WS1799/0085/G** **Pergoveris-EMEA/H/C/000714/WS1799/0067/G** Merck Europe B.V., Lead Rapporteur: Kirstine Moll Harboe	
WS1819/G **Lantus-EMEA/H/C/000284/WS1819/0119/G** **Suliqua-EMEA/H/C/004243/WS1819/0014/G** **Toujeo-EMEA/H/C/000309/WS1819/0112/G** Sanofi-Aventis Deutschland GmbH, Lead Rapporteur: Kristina Dunder Opinion adopted on 05.06.2020.	Positive Opinion adopted by consensus on 05.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1821/G **Hexacima-EMEA/H/C/002702/WS1821/0101/G** **Hexaxim-EMEA/H/W/002495/WS1821/0106/G** **Hexyon-EMEA/H/C/002796/WS1821/0105/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	

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

AJOVY - fremanezumab - EMEA/H/C/004833/II/0008/G TEVA GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of SmPC to include data from Study TV48125-CNS-30068 (FOCUS) - A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study with an Open-Label Period to Evaluate the Efficacy and Safety	

of Fremanezumab for the Prophylactic Treatment of Migraine in Patients with Inadequate Response to Prior Preventive Treatments.”	
Atripla - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/000797/II/0143/G Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, “Grouped variation: - C.I.3.z (Type IB): Update of sections 4.4, 4.5 and 4.8 of the SmPC regarding the drug-drug interaction with didanosine and of section 4.8 of the SmPC regarding lactic acidosis, as agreed by the PRAC in the Viread procedure EMEA/H/C/PSUSA/00002892/201903, - C.I.3.z (Type IB): Update of section 4.5 of the SmPC to update the wording of the interaction between efavirenz and etonogestrel implants, as agreed by the PRAC in the Sustiva procedure EMEA/H/C/PSUSA/00001200/201804, - C.I.4 (Type II): Update of section 4.5 of the SmPC to state that co-administration of glecaprevir/pibrentasvir with Atripla is not recommended; the Package Leaflet is updated accordingly. In addition, the drugs boceprevir, nelfinavir and simeprevir, which have been withdrawn from the European Market, were removed from the PI. The MAH also took the opportunity to make editorial corrections and 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. Furthermore, the PI is brought in line with the latest QRD template version 10.1.” Opinion adopted on 11.06.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/II/0029 Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, “Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to update the efficacy and safety data in haemodialysis patients population based on week 48 interim results from study GS-US-292-182, “A Phase 3b Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of E/C/F/TAF Fixed Dose Combination (FDC) in	

HIV-1 Infected Subjects on Chronic Hemodialysis". The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor linguistic amendments and editorial changes to the product information."	
Busilvex - busulfan - EMEA/H/C/000472/II/0031 Pierre Fabre Medicament, Rapporteur: Maria Concepcion Prieto Yerro, "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 section 5. with minor changes in the pediatric 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."	
Erleada - apalutamide - EMEA/H/C/004452/II/0006 Janssen-Cilag International N.V., Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC to add interstitial lung disease to the list of adverse drug reactions (ADRs) with frequency unknown based on a safety review; the Package Leaflet is updated accordingly. The MAH also took the opportunity to update the PI in line with the QRD template 10.1." Request for Supplementary Information adopted on 05.06.2020.	Request for supplementary information adopted with a specific timetable.
Gliolan - 5-aminolevulinic acid - EMEA/H/C/000744/II/0018/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Bruno Sepodes, "To update section 4.4 of the SmPC to add a warning (false positive and false negative fluorescence) following an analysis of the MAHs safety database. To update section 4.2 of the SmPC to exclude re-administration if surgery is delayed by less than 12 hours."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 05.06.2020, 17.04.2020.	
Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0016 ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update the safety information regarding the occurrence of neural tube defects with the DTG-containing regimens based on interim analysis from Tsepamo study. This is a birth outcomes surveillance study being conducted in Botswana that was designed to evaluate adverse birth outcomes by HIV status and antiretroviral regimen, and to determine if there is an increased risk of neural tube defects among infants exposed to efavirenz at conception. This surveillance system captures all antiretroviral exposure including dolutegavir. The SmPC is updated accordingly. The RMP is not submitted." Request for Supplementary Information adopted on 26.03.2020, 12.12.2019, 14.11.2019.	
Kisqali - ribociclib - EMEA/H/C/004213/II/0018 Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of section 5.2 of the SmPC to include updated information about the use of Kisqali in patients with mild or moderate renal impairment based on the results of Study CLEE011A2116 Part II and additional data from breast cancer patients with mild or moderate renal impairment." Request for Supplementary Information adopted on 26.03.2020, 14.11.2019.	
LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0007 Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Sinan B. Sarac, Co-Rapporteur: Tuomo Lapveteläinen, "Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning and add new ADRs with frequency uncommon, regarding new safety information in the post marketing setting on the terms "Transplant rejection", "Graft Versus Host Disease (GVHD)" and "Myositis". The MAH took the opportunity to provide minor corrections to the efficacy data in the SmPC from study R2810-ONC-1540 (primary analysis for group 2 and 3 dated 09 Jul 2019), based on	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

errors that were revealed in two patient's data following the completion of the MA. The Package Leaflet is updated accordingly. The MAH also took the opportunity to introduce editorial changes in the PI." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted on 30.04.2020.	
Mepsevii - vestronidase alfa - EMEA/H/C/004438/II/0014, Orphan Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.8 and 5.1 of the SmPC following the assessment of final results from study UX003-CL202, a multicenter, multinational, open-label treatment, extension of study UX003-CL301 in subjects with MPS VII, previously submitted under Article 46 of Regulation (EC) No 1901/2006; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the Product Information." Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0081 Genzyme Europe BV, Rapporteur: Alexandre Moreau, "Update of section 5.1 of the SmPC on long term efficacy of alglucosidase alfa on survival and other clinical outcome based on the review of published scientific literature. In addition, the MAH took the opportunity to update the Product Information to mention the change on contact details of local representatives for Italy and Malta and to add traceability statement as per QRD template version 10.1."	
Nerlynx - neratinib - EMEA/H/C/004030/II/0011/G Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update the pharmacokinetics properties of neratinib and amend drug-drug interaction (DDI) information with CYP3A4/P-gp inducers and inhibitors based on two ADME studies (PUMA-NER-0105 and PUMA-NER-0102), a PBPK model report and in vitro studies; the Package Leaflet is updated	

accordingly. In addition, the MAH took the opportunity to make minor corrections to the PI and to bring the PI in line with the latest QRD template version 10. Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update DDI information with H2-receptor antagonists and add DDI information with loperamide based on two DDI studies (PUMA-NER-0104, PUMA-NER-0103); the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 28.05.2020.	
Obizur - susoctocog alfa - EMEA/H/C/002792/II/0030 Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, "Update of sections 4.4 and 4.8 of the SmPC to add information on anamnesic reaction and to list it with the frequency unknown." Request for Supplementary Information adopted on 26.03.2020.	
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."	
Ozempic - semaglutide - EMEA/H/C/004174/II/0014 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 5.1 of the SmPC in order to include information on the use of semaglutide once weekly in combination with a SGLT-2 inhibitor, based on the final results from the SUSTAIN 9 study (study NN9535-4269); this is a 30-week, randomised, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of semaglutide as add-on to treatment with an SGLT-2 inhibitor ± metformin or sulphonylurea (SU) in subjects with T2DM; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 05.06.2020.	Request for supplementary information adopted with a specific timetable.

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0028 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "Submission of the final report from study Zoster-060, to fulfil post-authorization measure MEA 011.1, listed as a category 3 study in the RMP for Shingrix. The study was conducted to generate data on long-term immunogenicity in adults 50 years of age and above"	
TAGRISSO - osimertinib - EMEA/H/C/004124/II/0036 AstraZeneca AB, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.1 of the SmPC in order to update the information regarding overall survival (OS) based on the final results from study D5160C00003 (AURA3); this is a randomized study of osimertinib versus platinum-based doublet chemotherapy for patients with locally advanced or metastatic non-small cell lung cancer whose disease has progressed with previous EGFR TKI. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1."	
Talzenna - talazoparib - EMEA/H/C/004674/II/0004 Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to include the final OS results from Study 673-301 (C3441009, EMBRACA), a phase 3, open-label, randomised, multicenter study of talazoparib vs chemotherapy in patients with germline BRCA mutated HER-2 negative locally advanced or metastatic breast cancer." Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
Translarna - ataluren - EMEA/H/C/002720/II/0058, Orphan PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, "C.I.z Safety Efficacy and Pharmacovigilance - Other changes. Update of sections 4.1 and 5.1 solely based on the interpretation of the recently published "Guide for Assessors of Centralised Applications on the wording of the therapeutic indication" (EMA/CHMP/483022/2019) ("EMA Assessor Guide")."	See agenda 9.1

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."	
Viekirax - ombitasvir / paritaprevir / ritonavir - EMEA/H/C/003839/II/0057 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Update of section 4.5 of the SmPC in order to add information on drug-drug interaction with fostamatinib. The Package Leaflet is updated accordingly."	
VITRAKVI - larotrectinib - EMEA/H/C/004919/II/0001 Bayer AG, Rapporteur: Filip Josephson, "Update of section 4.5 of the SmPC in order to remove the warning related to drug-drug interactions between larotrectinib and CYP2 substrates based on the results of study PH-40955 investigating the inductive potential of larotrectinib on the expression of cytochrome P450 (CYP) enzymes. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 30.04.2020, 13.02.2020.	
Xagrid - anagrelide - EMEA/H/C/000480/II/0089 Shire Pharmaceuticals Ireland Limited, Rapporteur: Alexandre Moreau, "C.I.4, Update of sections 4.5. and 5.2 of the SmPC in order to add drug-drug interaction information with omeprazole, and update pharmacokinetics, based on final results from clinical study SPD-422-113 a Drug-Drug interaction (DDI) study with Xagrid (anagrelide hydrochloride) assessing the effect of multiple doses omeprazole on anagrelide and 3-OH anagrelide exposure; The study was agreed as a commitment in variation EMEA/H/C/000480/II/0075" Request for Supplementary Information adopted on 05.06.2020.	Request for supplementary information adopted with a specific timetable.
Zejula - niraparib -	Request for supplementary information adopted

EMEA/H/C/004249/II/0020, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Bjorg Bolstad, "Update of section 4.8 of the SmPC in order to add hypersensitivity, psychiatric disorders and non-infectious pneumonitis to the list of adverse drug reactions (ADRs) with the frequency unknown based on safety evaluations; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 11.06.2020.	with a specific timetable.
Zejula - niraparib - EMEA/H/C/004249/II/0021, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Bjorg Bolstad, "Update of section 4.5 of the SmPC in order to add pharmacokinetic interaction information based non-clinical drug-drug interaction (DDI) studies. In addition, the MAH took the opportunity to update section 5.3 of the SmPC in line with the SmPC guideline."	
WS1790 **OPDIVO-EMEA/H/C/003985/WS1790/0082** **Yervoy-EMEA/H/C/002213/WS1790/0078** Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.8 and 5.1 of the SmPC in order to include at least 5 years (60 months) of follow-up for all subjects from study CA209067. Updated efficacy data provided in this submission include overall survival (OS), progression-free survival (PFS) and objective response rate (ORR)." Request for Supplementary Information adopted on 05.06.2020.	Request for supplementary information adopted with a specific timetable.
WS1807 **Glyxambi-EMEA/H/C/003833/WS1807/0028** **Jardiance-EMEA/H/C/002677/WS1807/0051** **Synjardy-EMEA/H/C/003770/WS1807/0048** Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC, in order to add interaction information on interference with the 1,5-anhydroglucitol assay in line with the Company Core Data Sheet"	
WS1814	Request for supplementary information adopted

Elebrato Ellipta-EMEA/H/C/004781/ WS1814/0017 **Temybric Ellipta-EMEA/H/C/005254/ WS1814/0005** **Trelegy Ellipta-EMEA/H/C/004363/ WS1814/0014** GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Peter Kiely, Lead Co-Rapporteur: Janet Koenig, "Update of section 4.8 to add hypersensitivity reactions including anaphylaxis, angiooedema, urticaria and rash." Request for Supplementary Information adopted on 11.06.2020.	with a specific timetable.
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 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."	

B.5.3. CHMP-PRAC assessed procedures

Alprolix - eftrenonacog alfa - EMEA/H/C/004142/II/0029, Orphan Swedish Orphan Biovitrum AB (publ),	Request for supplementary information adopted with a specific timetable.

Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Submission of a variation to update sections 4.2, 4.8 and 5.1 of the SmPC to add information on Previously Untreated Patients (PUPs) following the completion of the clinical study 998HB303 which was already assessed in EMEA/H/C/004142/P46 006. The PL and RMP have been updated accordingly."
Request for Supplementary Information adopted on 11.06.2020.

Benlysta - belimumab - EMEA/H/C/002015/II/0076

GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information based on the final results from study BEL115467 listed as an imposed PASS in the Annex II; this is a Randomized, Double-Blind, Placebo-Controlled 52-Week Study to Assess Adverse Events of Special Interest in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematosus Receiving Belimumab; the Package Leaflet is updated accordingly.
The RMP version 36 has also been submitted.
The MAH took the opportunity to make the following minor updates to the RMP:
- Updated information on transplant study, updated information on BEL116543, added information on paediatric continuation study in Module SIV.
- Updated exposure information and information for BEL116543 in Module SIV.2.
- Update data on revised rates of pregnancy and lactation in Module SIV.3.
- Correction of an error within Annex 3 and provision of the updated protocol Amendment 7 of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of belimumab plus Standard of Care versus Placebo plus standard of Care in Adult Subjects with Active Lupus Nephritis (BEL114054).
This RMP also includes changes being reviewed in procedure II/0062, related to the use of Benlysta in paediatric patients, and BEL116027, evaluating the safety and efficacy of temporary discontinuation of belimumab.
In addition, the Marketing authorisation holder

took the opportunity make minor editorial changes to the Annex II and the label." Request for Supplementary Information adopted on 27.02.2020.	
Cimzia - certolizumab pegol - EMEA/H/C/001037/II/0087 UCB Pharma S.A., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a change in posology for axial spondyloarthritis (axSpA) and to update the safety and efficacy information based on the results of the study AS0005 (C-OPTIMISE) listed as a category 3 study in the RMP; this is a multicentre, open-label (part A) followed by a randomised, double-blind, parallel-group, placebo-controlled study (part B) to evaluate maintenance of remission in subjects with active axSpA receiving either certolizumab pegol 200 mg q2w or 200 mg q4w as compared to placebo. The package leaflet is updated accordingly. The RMP version 17.0 has also been submitted to reflect the completion of study AS0005 and update to list of safety concerns. In addition, the interim study reports AS0006 and AS0007 have been submitted to include additional pooled safety data in the SmPC. Study AS0006 is a phase 3, multicenter, randomised, placebo-controlled, double-blind study to evaluate efficacy and safety of certolizumab pegol in subjects with active aSpA without x-ray evidence of ankylosing spondylitis and objective signs of inflammation. Study AS0007 is a multicenter, open-label study to assess the effects of certolizumab pegol on the reduction of anterior uveitis flares in aSpA subjects with a history of anterior uveitis (C-view)." Request for Supplementary Information adopted on 30.04.2020.	
Darzalex - daratumumab - EMEA/H/C/004077/II/0039, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "C.I.4 Update of section 5.1 of the SmPC in order to update information regarding immunogenicity following completion of post-authorization commitments regarding re-analysis of all ADA	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

samples taken from previously submitted clinical using the Enhanced DT Method (previously developed as a result of PAM-MEA-005). The Important Potential Risk of immunogenicity is removed from the RMP and version 6.5 is submitted." Opinion adopted on 11.06.2020.	
Jakavi - ruxolitinib - EMEA/H/C/002464/II/0044 Novartis Europharm Limited, Rapporteur: Filip Josephson, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Annika Folin, "Update of the SmPC sections 5.1 and 4.8 with efficacy and safety information to reflect the 5-year follow-up data from the final clinical study report (CSR) RESPONSE study (B2301). This is a post-Authorisation efficacy study to provide long-term efficacy and safety data of ruxolitinib including (late) achievement of response, duration of (various) responses, as well as incidence of Adverse Events (AEs) including haematological transformation and second malignancies. The final analyses presented in the CSR are submitted to fulfil the Post-Authorisation Measure, therefore the Annex II.D of the Product Information is updated accordingly. The changes have been reflected in the RMP version 11 submitted with the procedure II/43." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted on 12.03.2020, 03.10.2019.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kyntheum - brodalumab - EMEA/H/C/003959/II/0014 LEO Pharma A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.4 and 4.8 of the SmPC and relevant sections of the PL to reflect a signal of anaphylactic reaction detected in the post-marketing setting. Minor updates have also been included throughout the product information." Request for Supplementary Information adopted on 30.04.2020.	
NINLARO - ixazomib - EMEA/H/C/003844/II/0019/G, Orphan Takeda Pharma A/S, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Annika Folin, "Group of variations consisting of the:	

C.I.11.b: Submission of the final report from study NSMM-5001 listed as a Specific Obligation in the Annex II of the Product Information. This is a global, prospective, non-interventional, observational study in multiple myeloma patients. The Annex II and the RMP (submitted version 5) are updated accordingly. C.I.11.z: Submission of an updated RMP version 5 in order to extend the due date of the Post-authorisation efficacy study (PAES) C16010 listed in Annex IID. The MAH also took the opportunity to correct a typographical error in Annex II." Request for Supplementary Information adopted on 26.03.2020.	
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/II/0049 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Rhea Fitzgerald, "Updated of section 4.8 of the SmPC with the safety data from the Phase 3, open-label, rollover study for Studies 109 and 011 Part B (Study 011B) designed to evaluate the long-term safety and tolerability of Orkambi treatment for 96 weeks in patients with cystic fibrosis, 6 years of age and older, homozygous for F508del." Request for Supplementary Information adopted on 11.06.2020, 30.01.2020, 31.10.2019, 05.09.2019.	Request for supplementary information adopted with a specific timetable.
Protopic - tacrolimus - EMEA/H/C/000374/II/0083/G LEO Pharma A/S, Rapporteur: Peter Kiely, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC following results from two non-interventional post-authorisation safety studies: JOELLE study (Joint European Longitudinal Lymphoma and skin cancer Evaluation, category 3) and APPLES study (a prospective pediatric longitudinal evaluation to assess the long-term safety of tacrolimus ointment for the treatment of atopic dermatitis, category 3). The Package Leaflet is updated accordingly. The RMP version 15.1. has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 11.06.2020, 16.01.2020.	
Resolor - prucalopride - EMEA/H/C/001012/II/0051 Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of the RMP on the patients' exposure based on post-marketing reports. In addition, the MAH took the opportunity to make minor editorial changes to the SmPC and RMP." Request for Supplementary Information adopted on 14.05.2020.	
Voncento - human coagulation factor VIII / human von willebrand factor - EMEA/H/C/002493/II/0042 CSL Behring GmbH, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst, "Submission of an updated RMP version 7 in order to: - align with the revision of the GVP module V - reflect the completion of the post-marketing study (PMS) in patients with Von Willebrand Disease (VWD) - request a waiver to the post-authorisation safety study (category 3 study) in patients with haemophilia A due to feasibility reasons." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1756 **Lixiana-EMEA/H/C/002629/WS1756/0025** **Roteas-EMEA/H/C/004339/WS1756/0012** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Adrien Inoubli, "Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to update the safety information based on final results from the post-authorisation efficacy study DU176b-C-E314 (Evaluation of Edoxaban in Anticoagulant Naïve Patients with Non-Valvular Atrial Fibrillation [NVAF] and High Creatinine Clearance [protocol MEA004]). This is a study to compare the exposure of edoxaban 75 mg once daily dose to edoxaban 60 mg once daily dose in NVAF anticoagulant-naïve patients with CHADS2 score of ≥2 and CrCL >100 mL/min treated for up to 12 months. The RMP version 9.0 has also been submitted. In addition, the worksharing applicant took the opportunity to	

update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1 and to provide updates due to corrections of typos in several language versions of the Product Information." Request for Supplementary Information adopted on 30.01.2020.	
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 and updated accordingly, following 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 labeling 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 and 4.5 of the SmPC and to update the list of local representatives in the Package Leaflet" Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
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."	
WS1830 **Entresto-EMEA/H/C/004062/WS1830/0032** **Neparvis-EMEA/H/C/004343/WS1830/0029** Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Anette Kirstine Stark, "C.I.13: Submission of the final report from study CLCZ696D2301 (PARAGON HF) listed as a category 3 study in the RMP. The intention of this submission is to fulfil post-authorisation measure (MEA 003) to evaluate cognitive function in this interventional multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to valsartan, on morbidity and mortality in heart failure patients (NYHA Class II-IV) with preserved ejection fraction. The RMP version 2.0 has also been submitted."	

B.5.4. PRAC assessed procedures

PRAC Led **Betmiga - mirabegron - EMEA/H/C/002388/II/0033** Astellas Pharma Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Final study report of the PASS Study 178-CL-114 – An evaluation of Cardiovascular Events in Users of Mirabegron and Other Treatments for Overactive Bladder." Request for Supplementary Information adopted on 11.06.2020, 13.02.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led	Positive Opinion adopted by consensus on

BLINCYTO - blinatumomab - EMEA/H/C/003731/II/0033, Orphan Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Ondřej Slanař, "Submission of an updated RMP version 11 is in line with the guideline on Good Pharmacovigilance Practices (GVP) Module V on RMP. In accordance with the RMP update, the protocol for Category 1 PASS 20150136 has been updated and the enrolment period for the study has been extended by 1 year. The milestones in the RMP were updated accordingly. In addition, the RMP includes a proposed update to the milestone of the Category 3 PASS 20180138. The requested variation proposed amendments to the Risk Management Plan (RMP)." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted on 12.03.2020, 28.11.2019.	11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Erivedge - vismodegib - EMEA/H/C/002602/II/0046** Roche Registration GmbH, Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Update of the Educational Materials provided as part of the Erivedge Pregnancy Prevention Program, following conclusion of PSUSA/00010140/201901. Annex IID is updated accordingly. Additionally, RMP v14.0 is submitted. Furthermore, section 4.4 of the SmPC is updated to remove the warning on cutaneous squamous cell carcinoma. The MAH also took the opportunity to update the Package Leaflet with the recommended wording on sodium content." Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
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 DILI subsequent to EMEA/H/C/PSUSA/00002435/201902 and EMEA/H/C/2154/LEG/015. The Package Leaflet is updated accordingly. The RMP version 10.0	Request for supplementary information adopted with a specific timetable.

has also been submitted. 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 PI. Update of sections 4.4 and 4.8 of the SmPC in order to add a warning on Hyponatraemia and to add Hyponatraemia to the list undesirable effects subsequent to EMEA/H/C/PSUSA/00002435/201902 and EMEA/H/C/2154/LEG/015. The requested group of variations proposed amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP)." Request for Supplementary Information adopted on 11.06.2020.	
PRAC Led **Grastofil - filgrastim - EMEA/H/C/002150/II/0030** Accord Healthcare S.L.U., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Tuomo Lapveteläinen, "Submission of an updated RMP version 6.0 in order to update the safety concerns and section of additional pharmacovigilance activities (removal of SCNIR and EBMT registry) in-line with latest approved Accofil (Filgrastim) RMP v4.0, dated 25-Jun-2019 approved on 03-Oct-2019 with procedure EMEA/H/C/003956/II/0037 as per the transfer of Marketing Authorisation of Grastofil from Apotex Netherland B.V to Accord healthcare S.L.U. Spain, for Grastofil 30 MU/0.5 ml & 48 MU/0.5 ml solution for injection or infusion in pre-filled syringe." Opinion adopted on 11.06.2020.	Positive Opinion adopted by consensus on 11.06.2020. 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	Request for supplementary information adopted with a specific timetable.

combination with BR versus BR alone and removal of Study 54179060CLL1017 on DDI as assessed in II/0058." Request for Supplementary Information adopted on 11.06.2020.	
PRAC Led **Jinarc - tolvaptan - EMEA/H/C/002788/II/0029** Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Daniela Melchiorri, "To update the RMP for Jinarc to version 14.4 to include dehydration and pregnancy prevention programme as requiring additional risk minimisation measures in accordance with Annex II." Request for Supplementary Information adopted on 11.06.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Tasigna - nilotinib - EMEA/H/C/000798/II/0103** Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Sinan B. Sarac, "Update of the RMP version 22.1 following the PRAC request to add 'growth retardation' to the list of important identified risks, and study AMN107A2203 as an additional pharmacovigilance activity for the important identified risk of 'growth retardation' to the pharmacovigilance plan. The MAH took the opportunity to revise the list of safety concerns in the EU RMP, in line with the GVP Module V (rev 2) recommendations and implemented the requested changes from PRAC. In addition, the additional pharmacovigilance activity of 'collection of gene signature data in patients who relapse on TFR compared to patients who relapse on treatment' has been deleted from the EU RMP as previously agreed during the procedure EMEA/H/C/000798/PAM/MEA/051.1. Other updates to reflect current study status are proposed through the RMP." Opinion adopted on 11.06.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Xeljanz - tofacitinib - EMEA/H/C/004214/II/0023** Pfizer Europe MA EEIG, Rapporteur: Daniela	Request for supplementary information adopted with a specific timetable.

Melchiorri, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from Study A3921205 listed as a category 3 study in the RMP. This is an Observational, Post-Authorization Safety Study (PASS) within the Consortium of Rheumatology Researchers of North America (CORRONA) Registry Comparing Rates of Malignancy, Cardiovascular and Serious Infection Outcomes among Patients Treated for Moderately to Severely Active Rheumatoid Arthritis. The RMP version 10.1 has also been submitted." Request for Supplementary Information adopted on 11.06.2020.	
PRAC Led **Xermelo - telotristat ethyl - EMEA/H/C/003937/II/0021, Orphan** Ipsen Pharma, Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of updated RMP version 5.1 in order to update to the GVP module V (rev 2). The commitment to revise the RMP was done during variation procedure EMEA/H/C/003937/II/0015." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted on 12.03.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **XGEVA - denosumab - EMEA/H/C/002173/II/0072/G** Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final reports for the following Category 3 studies within the XGEVA Risk Management Plan (RMP) v35: · Study 20101363 - A non-interventional pharmacovigilance study of osteonecrosis of the jaw and infection leading to hospitalization among patients with cancer treated with XGEVA or zoledronic acid in Sweden, Denmark, and Norway Ongoing. · Study 20170728 - Incidence of new primary malignancies among patients with bone metastases from breast, prostate, or lung cancer treated with XGEVA or intravenous zoledronic acid: a retrospective cohort study. The RMP (v35) has been updated to reflect submission of the study reports. In addition, the	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

format of this RMP has been updated to align with the EMA EU RMP template Rev 2.0.1, which accompanies the EMA Guideline on Good Pharmacovigilance Practices Module V Rev 2." Opinion adopted on 11.06.2020.	
PRAC Led **Zytiga - abiraterone acetate - EMEA/H/C/002321/II/0061** Janssen-Cilag International NV, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "To update the Summary of Product Characteristics sections 4.4 and 4.5 and package leaflet as per the PRAC recommendations published on 10th Feb 2020 to add a new warning on Hypoglycemia, the Package Leaflet is updated accordingly. In addition, some minor updates have also been made to Annex II of the product information." Opinion adopted on 11.06.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1747 Enbrel-EMEA/H/C/000262/WS1747/0231 LIFMIOR-EMEA/H/C/004167/WS1747/ 0025** Pfizer Europe MA EEIG, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of an updated RMP (version 7.4) in line with the latest GVP Module V RMP template (rev. 2) and revision of the list of safety concerns. In addition, the MAH took the opportunity to implement outcomes of previous procedures (type II variation EMEA/H/C/WS/1270 and PSUR EMEA/H/C/PSUSA/001295/201902) to remove or consolidate risks. The MAH is also removing the addendum to RMP version 6.3., making clinical and post-marketing data updates in the RMP and reflecting the completion of post-authorisation studies. Furthermore, the 'patient alert card' is renamed 'patient card' throughout the SmPC, package leaflet and Annex IID and the additional risk minimisation measures are updated in the Annex IID of the product information." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 13.02.2020.	
PRAC Led **WS1755** **Cymbalta-EMEA/H/C/000572/WS1755/0083** **Duloxetine Lilly-EMEA/H/C/004000/WS1755/0020** **Xeristar-EMEA/H/C/000573/WS1755/0086** **Yentreve-EMEA/H/C/000545/WS1755/0068** Eli Lilly Nederland B.V., Duplicate, Duplicate of Ariclaim, Yentreve, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "As agreed in the procedure WS-1527G in order to address the foetal outcomes, submission of the final report from study FIJ-MC-B059 'Observational Study to Assess Fetal Outcomes Following Maternal Exposure to Duloxetine' and the revised final report from Study F1J-MC-B057 'Observational Studies to Assess Maternal and Fetal Outcomes Following Exposure to Duloxetine'." Opinion adopted on 11.06.2020. Request for Supplementary Information adopted on 16.01.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1791** **Glidipion-EMEA/H/C/002558/WS1791/0013** **Pioglitazone Actavis-EMEA/H/C/002324/WS1791/0014** **Pioglitazone Teva-EMEA/H/C/002297/WS1791/0023** **Pioglitazone Teva Pharma-EMEA/H/C/002410/WS1791/0023** Teva B.V., Generic, Generic of Actos, Glustin, Lead Rapporteur: Peter Kiely, Lead PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "Update of all safety concerns of the RMP (i.e. deleting them all from the RMP) in line with the principles of GVP V rev 2 (and in line with the originator RMP). Removal of the aRMMs as per outcome of the last PSUSA of pioglitazone PSUSA/00002417/201807." Opinion adopted on 11.06.2020.	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.5. CHMP-CAT assessed procedures

Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0022/G, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0015, Orphan, ATMP
Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 24.04.2020, 21.02.2020.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

WS1774
Emtriva-EMEA/H/C/000533/WS1774/0132
Truvada-EMEA/H/C/000594/WS1774/0163
Viread-EMEA/H/C/000419/WS1774/0198
Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes, "To align the pregnancy language in the package leaflet with the wording in the SmPC.
In addition, the PI for Truvada and Viread has been updated to comply with the excipients guidance on sodium as well as aligning with the current QRD template. Furthermore, the MAH has made minor administrative updates to the annexes."

WS1824
Fluenz Tetra-EMEA/H/C/002617/WS1824/0100
Pandemic influenza vaccine H5N1 AstraZeneca-EMEA/H/C/003963/WS1824/0034
AstraZeneca AB, Lead Rapporteur: Christophe Focke

WS1831
Olanzapine Glenmark-EMEA/H/C/001085/

WS1831/0033
Olanzapine Glenmark Europe-
EMEA/H/C/001086/WS1831/0030
Olazax-EMEA/H/C/001087/WS1831/0026
Glenmark Arzneimittel GmbH, Generic, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC to add salivary hypersecretion with a frequency of uncommon. The package leaflet is updated accordingly. In addition, the MAH has taken opportunity to correct Danish translation of pharmaceutical form for 'Olanzapine Glenmark Europe Orodispersible tablets' in this variation application."

WS1833/G
Trevicta-EMEA/H/C/004066/WS1833/
0024/G
Xeplion-EMEA/H/C/002105/WS1833/
0049/G
Janssen-Cilag International NV, Lead Rapporteur: Kristina Dunder

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

zanubrutinib - EMEA/H/C/004978, Orphan
BeiGene Ireland Ltd, Treatment of Waldenström's macroglobulinaemia (WM)

vericiguat - EMEA/H/C/005319
treatment of symptomatic chronic heart failure

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

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

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

DECTOVA - zanamivir -
EMEA/H/C/004102/S/0006

GlaxoSmithKline Trading Services Limited, Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Ulla Wändel Liminga

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

Feraccru - ferric maltol - EMEA/H/C/002733/R/0027
Norgine B.V., Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Janet Koenig (DE), PRAC Rapporteur: Adam Przybylkowski

Gilenya - fingolimod - EMEA/H/C/002202/R/0063
Novartis Europharm Limited, Rapporteur: Alexandre Moreau, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Adrien Inoubli

Oncaspar - pegaspargase - EMEA/H/C/003789/R/0034
Les Laboratoires Servier, Rapporteur: Alexandre Moreau, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Annika Folin

Zonisamide Mylan - zonisamide - EMEA/H/C/004127/R/0008
Mylan S.A.S, Generic, Generic of Zonegran, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Rhea Fitzgerald

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

Brilique - ticagrelor - EMEA/H/C/001241/II/0049
AstraZeneca AB, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES), a phase III, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic

stroke or transient ischaemic attack; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13 of the RMP has also been submitted."

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

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

Nplate - romiplostim - EMEA/H/C/000942/II/0077

Amgen Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, "Extension of indication to add the use of romiplostim in adult patients who have had ITP for ≤ 12 months and who have had an insufficient response to corticosteroids or immunoglobulins. Sections 4.1, 4.4., 4.8, 5.1 and 5.2 of the SmPC have been updated. In addition, the MAH has taken the opportunity to implement minor editorial changes in sections 4.2, 4.4, 4.8 and 5.1 of the SmPC. Furthermore, the PI is being brought in line with the latest QRD template (version 10.1).
The PL has been updated accordingly. The updated RMP version 20.0 has also been submitted."

Rinvoq - upadacitinib - EMEA/H/C/004760/II/0004 AbbVie Deutschland GmbH & Co. KG, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Nikica Mirošević Skvrce, "C.I.6 (Extension of indication) Extension of indication to include the treatment of active psoriatic arthritis in adult patients for Rinvoq; 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. Minor updates were made to the Annex II. Version 2.0 of the RMP has also been submitted."	
Rinvoq - upadacitinib - EMEA/H/C/004760/II/0005 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, "C.I.6 (Extension of indication) Extension of indication to include the treatment of active ankylosing spondylitis in adult patient for Rinvoq; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Minor editorial changes to the SmPC and Annex II are also proposed. Version 3.0 of the RMP has also been submitted."	

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

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

B.6.10. CHMP-PRAC assessed procedures

B.6.11. PRAC assessed procedures

B.6.12. CHMP-CAT assessed procedures

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

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMEA CERTIFICATION OF PLASMA MASTER FILES

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

commercially confidential information.

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

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

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

G. ANNEX G

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

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

Qualification of Biomarkers:

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 22-25 June 2020 CHMP plenary:

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

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