24 September 2020
EMA/CHMP/475571/2020
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Final Minutes for the meeting on 22-25 June 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Disclaimers

Some of the information contained in the minutes 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, the minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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

The participants had no objection to hold the meeting remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See June 2020 CHMP minutes for the list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session held 22 – 25 June 2020.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 17 or more members were present remotely). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 22-25 June 2020.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 25-28 May 2020.

The CHMP adopted the minutes.

ORGAM minutes for 15 June 2020.

The Minutes of the June 2020 CHMP ORGAM meeting held on 15 June 2020, together with all decisions taken at that meeting, were adopted.

Extraordinary CHMP meeting on remdesivir, 19 June 2020.

The minutes of the extraordinary meeting were adopted by written procedure on 25.06.2020 after the Plenary.

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

Participation of patient representatives.

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

An oral explanation was held on Monday, 22 June 2020. The presentation by the applicant focused on the clinical data in support of the Article 58 application and the possibility to conduct a PAES.

See 3.2

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.

An oral explanation was held on Wednesday, 24 June 2020. The presentation by the applicant focused on the clinical efficacy data in support of the marketing authorisation application.

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.

The CHMP agreed that no oral explanation was needed this time.

See 3.2

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

Hansa Biopharma AB; Idefirix 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 Wednesday, 24 June 2020 at 09:00

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

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

The CHMP agreed that no oral explanation was needed this time.

See 3.1

2.1.5. Kaftrio - 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

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

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

An oral explanation was held on Tuesday, 23 June 2020. The presentation by the applicant focused on the clinical efficacy data in support of the marketing authorisation application.

See 3.1

2.1.6. Veklury - remdesivir - EMEA/H/C/005622

Gilead Sciences Ireland UC; 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

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

The CHMP agreed that no oral explanation was needed this time.

See 3.1

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. Aybintio - bevacizumab - EMEA/H/C/005106

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

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The CHMP noted the letter of recommendation dated 24.06.2020.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.2. Gencebok - caffeine citrate - EMEA/H/C/005435

Gennisium Pharma; treatment of primary apnoea.

Scope: Opinion

Action: For adoption

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

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

3.1.3. Idefirix - imlifidase - Orphan - EMEA/H/C/004849

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

Scope: Opinion

Action: For adoption

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

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

See 2.1

The CHMP agreed that no oral explanation was needed this time.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that imlifidase is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The CHMP noted the letter of recommendation dated 24.06.2020.

The summary of opinion was circulated for information.

3.1.4. Kaftrio - 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

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

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

28.01.2020.

An oral explanation was held on Tuesday, 23 June 2020. The presentation by the applicant focused on the clinical efficacy data in support of the marketing authorisation application.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that elexacaftor / tezacaftor / ivacaftor is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 24.06.2020.

The summary of opinion was circulated for information.

The CHMP adopted the similarity report.

3.1.5. Livogiva - teriparatide - EMEA/H/C/005087

Theramex Ireland Limited; treatment of osteoporosis.

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 24.06.2020.

The summary of opinion was circulated for information.

3.1.6. Methylthioninium chloride Cosmo - methylthioninium chloride - EMEA/H/C/002776

Cosmo Technologies Ltd; 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

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

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 23.06.2020.

The summary of opinion was circulated for information.

3.1.7. Qutavina - teriparatide - EMEA/H/C/005388

EuroGenerics Holdings B.V.; treatment of osteoporosis.

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC), Duplicate of Livogiva

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 24.06.2020.

The summary of opinion was circulated for information.

3.1.8. Turalio - 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

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

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.

The CHMP was reminded of previous discussions.

The CHMP adopted a negative opinion by majority (25 negative out of 30 votes), recommending the refusal of the granting of the marketing authorisation. The CHMP adopted the assessment report.

The Norwegian Member was in agreement with the CHMP recommendation, and the Icelandic Member was against.

The divergent position (Elita Poplavska, Sinan B. Sarac, Sol Ruiz, Simona Stankeviciute, John Joseph Borg, Kolbeinn Gudmundsson) was appended to the opinion.

The refusal question and answer document was circulated for information.

3.1.9. Veklury - remdesivir - EMEA/H/C/005622

Gilead Sciences Ireland UC; treatment of coronavirus disease 2019 (COVID-19).

Scope: Opinion

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

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that remdesivir is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The CHMP noted the letter of recommendation dated 23.06.2020.

The summary of opinion was circulated for information.

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 regimen 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 30.04.2020. List of Questions adopted on

14.11.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

The CHMP adopted the draft list of experts to the SAG anti-infectives.

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

Accelerated assessment

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.04.2020.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.3. 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

Participation of patient representatives.

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

An oral explanation was held on Monday, 22 June 2020. The presentation by the applicant focused on the clinical data in support of the Article 58 application and the possibility to conduct a PAES.

The Committee adopted a 4th list of outstanding issues with a specific timetable.

3.2.4. dasatinib - EMEA/H/C/005446

treatment of leukaemia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP agreed to consult the PKWP and adopted a list of questions to this group.

3.2.5. dasatinib - EMEA/H/C/005317

treatment of leukaemia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2019.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP agreed to consult the PKWP and adopted a list of questions to this group.

3.2.6. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.7. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

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

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

Scope: List of outstanding issues

Action: For adoption

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

The Committee was reminded of the status of this application and its remaining outstanding issues.

See 2.1

The CHMP agreed that no oral explanation was needed this time.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

3.2.9. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.10. pegfilgrastim - EMEA/H/C/005085

treatment of neutropenia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2020.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.11. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.12. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.13. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

oral contraceptive.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

oral contraception.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.7. sildenafil - EMEA/H/C/005439

treatment of erectile dysfunction.

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of outstanding issues adopted in May 2020.

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.

The CHMP noted the update on the procedure.

3.4.3. hepatitis B surface antigen - EMEA/H/C/005063

Prevention of hepatitis B virus infection

Scope: Request for an extension to the clock stop to respond to the list of questions adopted in July 2019.

Action: For information

List of Questions adopted on 25.07.2019.

The CHMP noted the extension of clock stop as adopted by CHMP on 11 June 2020.

3.4.4. 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.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of questions adopted in April 2020.

3.4.5. 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.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of questions adopted in May 2020.

3.4.6. 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.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of outstanding issues adopted in May 2020.

3.4.7. trastuzumab - EMEA/H/C/005066

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

Scope: Letter from the applicant dated 24.06.2020 requesting an extension of clock-stop to respond to the list of questions adopted in September 2019.

Action: For adoption

List of Questions adopted on 19.09.2019.

The CHMP agreed to the applicant for an extension of clock-stop to respond to the list of questions adopted in September 2019.

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

Advicenne S.A.; treatment of distal renal tubular acidosis (dRTA) in patients aged 6 months and older.

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

Action: For adoption

List of Questions adopted on 26.03.2020.

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the list of questions adopted in March 2020.

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

No items

3.6. Initial applications in the decision-making phase

3.6.1. 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.

The CHMP adopted a revised assessment report by consensus.

The CHMP adopted a revised similarity assessment report.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Sondelbay - teriparatide - EMEA/H/C/005233

Accord Healthcare S.L.U.; treatment of osteoporosis.

Scope: Withdrawal of initial marketing authorisation application

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The CHMP noted the withdrawal of the marketing authorisation application.

3.7.2. Xiidra - lifitegrast - EMEA/H/C/004653

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

Scope: Withdrawal of initial marketing authorisation application

Action: For information

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

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

The CHMP noted the withdrawal of the marketing authorisation application.

3.7.3. Zemdri - plazomicin - EMEA/H/C/004457

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

Scope: Withdrawal of initial marketing authorisation application

Action: For information

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

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

The CHMP noted the withdrawal of the marketing authorisation application.

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

Extension application to introduce a new strength (200/50 mg film-coated tablets). The new presentation is indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients aged 6 years and older and weighing at least 17 kg. The extension application is grouped with a type II variation (C.I.6.a) to include paediatric use in patients aged 6 years

and older and weighing at least 17 kg. Sections 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 6.0) is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial updates throughout the Product Information."

Action: For adoption

List of Questions adopted on 27.02.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

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.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The CHMP adopted the similarity assessment report.

4.1.3. 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 local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template (v. 10.1), to remove the black triangle and to introduce editorial changes"

Action: For adoption

List of Questions adopted on 26.03.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

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.

The Committee discussed the issues identified in this application, relating to some quality

and clinical aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

4.2.2. 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.

The Committee discussed the issues identified in this application, concerning some quality aspects and the RMP.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

4.2.3. 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.

The Committee discussed the issues identified in this application, concerning some quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

4.2.4. 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.

The Committee discussed the issues identified in this application, relating to some quality and clinical aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

4.2.5. 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.

The Committee discussed the issues identified in this application, mainly concerning the request for 1 year of market protection.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

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

The Committee discussed the issues identified in this application, concerning the bioequivalence.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application, mainly concerning the efficacy data in line with the relevant guidelines and the wording of the indication.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application, mainly concerning the administration device.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application, mainly concerning the efficacy data in line with the relevant guidelines and the wording of the indication.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

The Committee discussed the issues identified in this application, mainly concerning the efficacy data in line with the relevant guidelines and the wording of the indication.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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.

The Committee discussed the issues identified in this application, concerning the clinical data and whether it was sufficient to support the extensions of indications in the target population.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. 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 Netherlands in the Package Leaflet. The RMP was updated to version 6.1.
Furthermore, the Annex II is brought in line with the latest QRD template version 10.1."

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020, 27.02.2020.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

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.

The Committee discussed the issues identified in this application, concerning some clarifications on clinical and pharmacology aspects.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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.

The Committee discussed the issues identified in this application, concerning some aspects on the similarity report.

The Committee adopted a 3rd request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, mainly concerning the efficacy data in young children.

The Committee adopted a request for supplementary information with a specific timetable.

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.

The Committee discussed the issues identified in this application, concerning some clinical efficacy aspects.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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.

The Committee discussed the issues identified in this application, concerning some clinical efficacy aspects with regard to different subgroups.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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.

The Committee discussed the issues identified in this application, concerning some clinical efficacy aspects with regard to different subgroups.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, mainly concerning the efficacy data for the new indication.

The Committee adopted a request for supplementary information with a specific timetable.

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.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

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

The Committee discussed the issues identified in this application, mainly concerning the efficacy data in different subgroups and some clarification of the study conduct.

The Committee adopted a request for supplementary information with a specific timetable.

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.

The Committee discussed the issues identified in this application, concerning some clinical aspects and some clarification of the study conduct.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

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. 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.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

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.

The Committee discussed the issues identified in this application, concerning some safety aspects and the request for 1 year of market protection.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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 Opdivo 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

The Committee discussed the issues identified in this application, mainly concerning the wording of the indication and some clarification of the study conduct.

The Committee adopted a request for supplementary information with a specific timetable.

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

No items

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

No items

6. Ancillary medicinal substances in medical devices

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

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. avalglucosidase alfa - H0005501

treatment of Pompe disease.

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

Action: For adoption

The CHMP did not agree to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

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

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

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

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 2 recommendations for eligibility to PRIME: 2 were denied.

The individual outcomes are listed in PRIME Monthly Report on EMA website.

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

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the Request for Supplementary Information adopted on 28.05.2020.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

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

The Committee discussed the issues identified in this application, mainly concerning the bibliographic review and some statistical analysis.

The Committee adopted a request for supplementary information with a specific timetable.

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

ViiV Healthcare B.V.

Lead Rapporteur: Filip Josephson

Scope: Update of section 4.6 of the SmPC in order to update the safety information

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

CHMP request for PRAC advice

Action: For adoption

Follow-up from February 2020 CHMP.

Following the assessment of further data from the Tsepamo study the CHMP adopted an updated request for PRAC advice.

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

Astra Zeneca AB

Scope: Update on the procedure.

Action: For information

The CHMP noted the update.

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

The CHMP adopted a list of questions to the SWP and noted the report on Wednesday.

The CHMP adopted an opinion by consensus recommending companies to take measures to mitigate the presence of nitrosamines in human medicines as much as possible and to ensure levels of these impurities do not exceed strict limits.

Companies will be required to have appropriate control strategies to prevent or limit the presence of these impurities and, where necessary, improve their manufacturing processes.

Companies will also have to evaluate the risk of nitrosamines being present in medicines and carry out appropriate tests if a risk is identified.

Nitrosamines are classified as probable human carcinogens (substances that could cause cancer). The limits for nitrosamines in medicines have been set using internationally agreed standards (ICH M7(R1)) based on lifetime exposure. Patient should generally not be exposed to a lifetime risk of cancer exceeding 1 in 100,000 from nitrosamines in their medicines.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The CHMP noted the EMA communication.

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.

The CHMP adopted an opinion by consensus, recommending that the application does not satisfy the criteria for authorisation. Therefore, the CHMP recommends that the marketing authorisations for the medicinal products concerned should be refused.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The CHMP noted the EMA communication.

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: List of outstanding issues

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.

The CHMP adopted a list of outstanding issues with a specific timetable.

Submission of responses: 01.07.2020

Re-start of the procedure: 06.07.2020

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 10.07.2020

Comments: 15.07.2020

Rapporteur/co-rapporteur joint updated assessment report(s) circulated to CHMP: 17.07.2020

Oral Explanation 21.07.2020

CHMP opinion: July 2020 CHMP

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

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.

The CHMP appointed Jan Mueller-Berghaus as Rapporteur and Sol Ruiz as Co-Rapporteur

The CHMP adopted the specific timetable.

Notification: 29.05.2020

Start of procedure at CHMP: June 2020 CHMP

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 10.07.2020

Comments: 15.07.2020

Updated Rapporteur / co-rapporteur assessment reports circulated to CHMP: 17.07.2020

CHMP list of questions/Opinion: July 2020 CHMP

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

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

MAHs: various

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

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

Scope: Re-examination draft timetable

Action: For information

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

The CHMP noted the request for re-examination by one MAH with a draft re-examination timetable. Re-examination Rapporteurs will be appointed at the July 2020 CHMP.

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

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. 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

The CHMP noted the seating plan.

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

The CHMP noted the Summary of recommendations and advice.

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

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at June 2020 PDCO

Action: For information

The CHMP noted the 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

The CHMP adopted the BWP reports.

14.3.2. Biostatistics Working Party (BSWP)

Chair: Kit Roes, 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

The CHMP elected Christian B. (Kit) Roes (NL) as new chair of the BSWP.

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

The CHMP noted the report.

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

The CHMP noted the information.

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

The CHMP noted the update.

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 22-25 June 2020 CHMP meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Milena Stain	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Bart Van der Schueren	Alternate	Belgium	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No interests declared	
Ondřej Slanař	Member	Czech Republic	No interests declared	
Tomas Radimersky	Alternate	Czech Republic	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Kirstine Moll Harboe	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Tuomo Lapveteläinen	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Eleftheria Nikolaidi	Alternate	Greece	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Melinda Sobor	Member	Hungary	No restrictions applicable to this meeting	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Kolbeinn Gudmundsson	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Peter Kiely	Alternate	Ireland	No interests declared	
Daniela Melchiorri	Member	Italy	No restrictions applicable to this meeting	
Giuseppa Pistritto	Alternate	Italy	No interests declared	
Elita Poplavska	Alternate	Latvia	No interests declared	
Simona Stankeviciute	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No restrictions applicable to this meeting	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
Koenraad Norga	Co-opted member	Belgium	No participation in final deliberations and voting on:	belantamab mafodotin - Orphan - EMEA/H/C/004935 dostarlimab - EMEA/H/C/005204 Elebrato Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004781/X/0014/G Temybric Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/005254/X/0004/G Trelegy Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004363/X/0012/G Varilrix - EMEA/H/A-30/1499
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czech Republic	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Danica Juricic Nahal	Expert - via telephone*	Croatia	No interests declared	
Eskild Colding-Jorgensen	Expert - via telephone*	Denmark	No restrictions applicable to this meeting	
Balazs Varsanyi	Expert - via telephone*	Hungary	No part in discussions, final deliberations and voting on:	abicipar pegol - EMEA/H/C/005103
Caoimhin Concannon	Expert - via telephone*	Ireland	No interests declared	
Jeanette McCallion	Expert - via telephone*	Ireland	No interests declared	
Rosemary Maher	Expert - via telephone*	Ireland	No restrictions applicable to this meeting	
Ingrid Schellens	Expert - via telephone*	Netherlands	No interests declared	
Jacqueline van Kuijk	Expert - via telephone*	Netherlands	No interests declared	
Laurens de Leur	Expert - via telephone*	Netherlands	No interests declared	
Luz Veth	Expert - via telephone*	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Eva Malikova	Expert - via telephone*	Slovakia	No interests declared	
Jana Klimasová	Expert - via telephone*	Slovakia	No interests declared	
Jana Schweigertová	Expert - via telephone*	Slovakia	No interests declared	
Olga Kholmanskikh	Expert - via Adobe*	Belgium	No interests declared	
Aaron Sosa	Expert - via Adobe*	Denmark	No restrictions applicable to this meeting	
Elisabeth Penninga	Expert - via Adobe*	Denmark	No interests declared	
Mette Linnert Jensen	Expert - via Adobe*	Denmark	No interests declared	
Mogens Westergaard	Expert - via Adobe*	Denmark	No interests declared	
Johanna Lahteenvuo	Expert - via Adobe*	Finland	No interests declared	
Karri Penttila	Expert - via Adobe*	Finland	No interests declared	
Isabel Araujo-Fernandez	Expert - via Adobe*	France	No restrictions applicable to this meeting	
Pierre Demolis	Expert - via Adobe*	France	No interests declared	
Andreas Brandt	Expert - via Adobe*	Germany	No interests declared	
Anna Stubbe	Expert - via Adobe*	Germany	No restrictions applicable to this meeting	
Armin Koch	Expert - via Adobe*	Germany	No restrictions applicable to this meeting	
Bettina Buecker	Expert - via Adobe*	Germany	No interests declared	
Birgit Ahrens	Expert - via Adobe*	Germany	No interests declared	
Christoph Unkrig	Expert - via Adobe*	Germany	No interests declared	
Clemens Mittmann	Expert - via Adobe*	Germany	No interests declared	
Ellen Pantke	Expert - via Adobe*	Germany	No restrictions applicable to this meeting	
Martin Huber	Expert - via Adobe*	Germany	No interests declared	
Nicole Bick	Expert - via Adobe*	Germany	No interests declared	
Regine Lehnert	Expert - via Adobe*	Germany	No interests declared	
Roland Froetschl	Expert - via Adobe*	Germany	No interests declared	
Stephanie Buchholz	Expert - via Adobe*	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Susanna Hausmann	Expert - via Adobe*	Germany	No interests declared	
Susanne Kaul	Expert - via Adobe*	Germany	No interests declared	
Adrianus Hans van Gompel	Expert - via Adobe*	Netherlands	No interests declared	
Alida Spruijt	Expert - via Adobe*	Netherlands	No interests declared	
Berendina Maria van den Hoorn	Expert - via Adobe*	Netherlands	No interests declared	
Erik Hergarden	Expert - via Adobe*	Netherlands	No interests declared	
Hanneke van der Woude	Expert - via Adobe*	Netherlands	No interests declared	
Helene Blok	Expert - via Adobe*	Netherlands	No interests declared	
Ingrid Evers-van Gogh	Expert - via Adobe*	Netherlands	No restrictions applicable to this meeting	
Johannes Theodorus Span	Expert - via Adobe*	Netherlands	No interests declared	
Joost Romme	Expert - via Adobe*	Netherlands	No interests declared	
Leon van Aerts	Expert - via Adobe*	Netherlands	No interests declared	
Lies van Vlijmen	Expert - via Adobe*	Netherlands	No interests declared	
Loes den Otter	Expert - via Adobe*	Netherlands	No interests declared	
Miki Hew	Expert - via Adobe*	Netherlands	No interests declared	
Nienke Rodenhuis	Expert - via Adobe*	Netherlands	No interests declared	
Peter Caspers	Expert - via Adobe*	Netherlands	No interests declared	
Quirine Fillekes	Expert - via Adobe*	Netherlands	No interests declared	
Wouter Iwema Bakker	Expert - via Adobe*	Netherlands	No interests declared	
Anja Schiel	Expert - via Adobe*	Norway	No interests declared	
Erlend Egeland	Expert - via Adobe*	Norway	No interests declared	
Maria Almlof	Expert - via Adobe*	Norway	No interests declared	
Mats Okvist	Expert - via Adobe*	Norway	No restrictions applicable to this meeting	
Augustin Portela	Expert - via Adobe*	Spain	No interests declared	
Meeting run with the help of EMA staff				

*Experts were only evaluated against the product(s) they have been invited to talk about.

17. 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)*

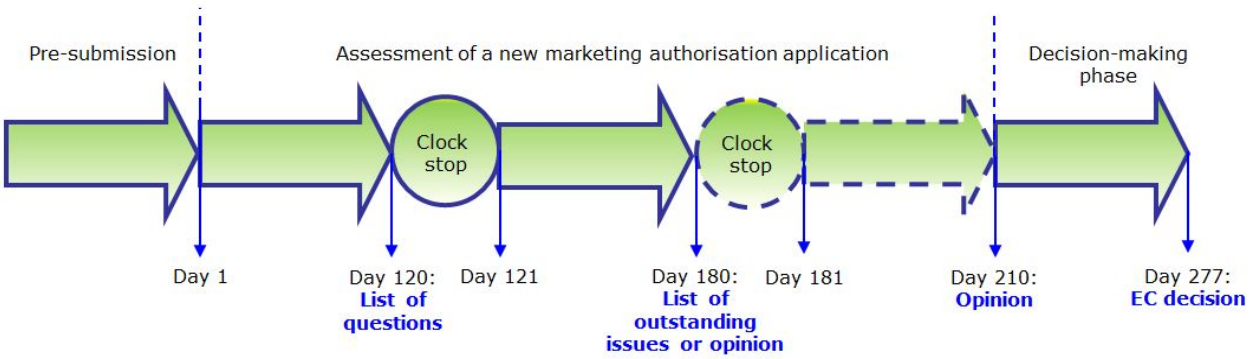
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

24 September 2020
EMA/CHMP/477914/2020

Annex to 22-25 June 2020 CHMP Minutes

Pre-submission and post-authorisations issues

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A. PRE SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for June 2020: **For adoption**	Adopted.

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

Obizur - susoctocog alfa - EMEA/H/C/002792/R/0033 Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 28.05.2020.	The CHMP agreed to the request from the applicant dated 15.06.2020 for an extension to the clock-stop to respond to the request for supplementary information.

B.1.1. Annual re-assessment for products authorised under exceptional circumstances

Evoltra - clofarabine - EMEA/H/C/000613/S/0068 Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Firdapse - amifampridine - EMEA/H/C/001032/S/0066 SERB SA, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga Request for Supplementary Information adopted on 25.06.2020.	Request for Supplementary Information adopted with a specific timetable.

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.	The CHMP agreed to the 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	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
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.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

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	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Benepali - etanercept - EMEA/H/C/004007/R/0053 Samsung Bioepis NL B.V., Rapporteur: Andrea Laslop, Co-Rapporteur: Outi Mäki-Ikola, PRAC	Request for Supplementary Information adopted with a specific timetable.

Rapporteur: Eva A. Segovia Request for Supplementary Information adopted on 25.06.2020.	
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.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
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.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Edistride - dapagliflozin - EMEA/H/C/004161/R/0038 AstraZeneca AB, Rapporteur: Kristina Dunder, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 25.06.2020, 28.05.2020.	Request for Supplementary Information adopted with a specific timetable.
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	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Pemetrexed Hospira - pemetrexed - EMEA/H/C/003970/R/0022 Pfizer Europe MA EEIG, Generic, Generic of Alimta, Rapporteur: Alar Irs, PRAC Rapporteur: Adrien Inoubli	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.

	The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
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.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
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.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
RAVICTI - glycerol phenylbutyrate - EMEA/H/C/003822/R/0034, Orphan Immedica Pharma AB, Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Ilaria Baldelli Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Spectrila - asparaginase - EMEA/H/C/002661/R/0018 medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Andrea Laslop, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 25.06.2020.	Request for Supplementary Information adopted with a specific timetable.

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	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can

Request for Supplementary Information adopted on 28.05.2020.	be granted. The Marketing Authorisation remains conditional. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

PSUR procedures **PRAC recommendation for variation of the terms of the MA adopted at the PRAC meeting held in June 2020 meeting:**	
EMEA/H/C/PSUSA/00001069/201910 (artenimol / piperaquine tetraphosphate) CAPS: **Eurartesim** (EMEA/H/C/001199) (piperaquine tetraphosphate / artenimol), Alfasigma S.p.A., Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Period Covered From: 28/04/2018 To: 27/10/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.1 and 4.4 of the SmPC to reflect the risk of resistance development in P. falciparum against artemisinins and/or piperaquine and a add a warning on geographical drug resistance. Additionally, the drug-drug interaction between efavirenz and artenimol / piperaquine tetraphosphate has been added to section 4.5 of the SmPC. In Section 4.5, some drugs listed were withdrawn in the EU (such as amprenavir, nelfinavir and nefazodone) and have been consequently replaced with darunavir and lopinavir. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
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"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4. of the SmPC to add a warning on the use of the vaccine in children who have been in utero exposed to immunosuppressive treatment. The Package

	leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010301/201911 (ibrutinib) CAPS: **Imbruvica** (EMEA/H/C/003791) (ibrutinib), Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Nikica Mirošević Skvrce, "Period Covered From: 12/11/2018 To: 12/11/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning on splenic rupture following discontinuation of ibrutinib treatment. Update of section 4.4 and 4.8 of the SmPC to add the adverse reaction cardiac failure and a warning regarding cardiac failure. Update of section 4.8 of the SmPC to add the adverse reaction neutrophilic dermatoses. Update of section 4.4 of the SmPC to add a warning regarding Haemophagocytic Lymphohistiocytosis (HLH). The package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
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"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning on thrombotic microangiopathy and update of section 4.8 of the SmPC to add the adverse reaction thrombotic microangiopathy with a frequency rare. Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010575/201911 (tenofovir alafenamide) CAPS: **Vemlidy** (EMEA/H/C/004169) (tenofovir alafenamide), Gilead Sciences Ireland UC,	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the

Rapporteur: Janet Koenig, PRAC Rapporteur: Ilaria Baldelli, "Period Covered From: 10/11/2018 To: 09/11/2019"	terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of the section 4.4 Special warnings and precautions for use of the SmPC, and corresponding section in the PL, are warranted to integrate the existing warning on Nephrotoxicity. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
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"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add recommendations concerning bladder voiding instructions prior to administration of fluciclovine (18F). The package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010644/201911 (atezolizumab) CAPS: **Tecentriq** (EMEA/H/C/004143) (atezolizumab), Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Period Covered From: 17/11/2018 To: 17/11/2019"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change(s): The PRAC concluded that the product information of atezolizumab should be amended to include uveitis and psoriasis as adverse drug reactions for atezolizumab. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010699/201911 (erenumab) CAPS: **Aimovig** (EMEA/H/C/004447) (erenumab), Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, "Period Covered From: 17/05/2019 To:	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s),

16/11/2019”	concerning the following change(s): Update of section 4.4 of the SmPC to add information on the characteristics of constipation. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

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 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)	For information only. Comments can be sent to the PL in case necessary.
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.
Isturisa – osilodrostat - EMEA/H/C/004821 Recordati Rare Diseases; indicated for the treatment of endogenous Cushing’s syndrome in adults. 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.
Corrected EPAR	
MVABEA - ebola vaccine (rdna, replication-incompetent) - EMEA/H/C/005343 Janssen-Cilag International N.V., is indicated for active immunization for prevention of disease	For information only. Comments can be sent to the PL in case necessary.

caused by Ebola virus, New active substance (Article 8(3) of Directive No 2001/83/EC)	
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 No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Sondelbay - teriparatide - EMEA/H/C/005233 Accord Healthcare S.L.U., treatment of osteoporosis, Similar biological application (Article 10(4) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
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.
Xiidra - lifitegrast - EMEA/H/C/004653 Novartis Europharm Limited, treatment of moderate to severe dry eye disease in adults for whom prior artificial tears has not been sufficient, New active substance (Article 8(3) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
ZABDENO - ebola vaccine (rdna, replication-incompetent) -	For information only. Comments can be sent to

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)	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 Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bemfola - follitropin alfa - EMEA/H/C/002615/II/0025/G Gedeon Richter Plc., Rapporteur: Paula Boudewina van Hennik Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
BeneFIX - nonacog alfa - EMEA/H/C/000139/II/0161/G Pfizer Europe MA EEIG, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 17.04.2020, 20.02.2020, 05.12.2019.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Besremi - ropeginterferon alfa-2b - EMEA/H/C/004128/II/0006/G AOP Orphan Pharmaceuticals AG, Rapporteur: Janet Koenig Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Buvidal - buprenorphine - EMEA/H/C/004651/II/0007/G Camurus AB, Rapporteur: Peter Kiely Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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 Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fulphila - pegfilgrastim - EMEA/H/C/004915/II/0005/G Mylan S.A.S, Rapporteur: Martina Weise Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 28.11.2019.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 Request for Supplementary Information adopted on 25.06.2020.	Request for Supplementary Information adopted with a specific timetable.
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 Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0157/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 18.06.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0160 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 18.06.2020.	Request for Supplementary Information adopted with a specific timetable.
Puregon - follitropin beta - EMEA/H/C/000086/II/0106/G Merck Sharp & Dohme B.V., Rapporteur: Peter Kiely	Positive Opinion adopted by consensus on 05.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 05.06.2020. Request for Supplementary Information adopted on 02.04.2020.	
Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0040 CSL Behring GmbH, Rapporteur: Kristina Dunder Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ruxience - rituximab - EMEA/H/C/004696/II/0001 Pfizer Europe MA EEIG, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0030 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
TAKHZYRO - lanadelumab - EMEA/H/C/004806/II/0014/G, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Kristina Dunder Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Victoza - liraglutide - EMEA/H/C/001026/II/0057 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 25.06.2020.	Request for supplementary information adopted with a specific timetable.
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 Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1784/G **Hexacima-EMEA/H/C/002702/WS1784/ 0096/G** **Hexaxim-EMEA/H/W/002495/WS1784/ 0101/G**	Request for Supplementary Information adopted with a specific timetable.

Hexyon-EMEA/H/C/002796/WS1784/0100/G Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted 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 Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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

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." Request for Supplementary Information adopted on 11.06.2020.	Request for Supplementary Information adopted with a specific timetable.
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." Request for Supplementary Information adopted on 25.06.2020.	Request for Supplementary Information adopted with a specific timetable.
Brintellix - vortioxetine - EMEA/H/C/002717/II/0025 H. Lundbeck A/S, Rapporteur: Bart Van der Schueren, "Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC to reflect the outcomes of the paediatric clinical study 12710A (a paediatric efficacy and safety study in adolescent MDD patients) and the study 12708A (paediatric pharmacokinetics and tolerability study in children and adolescent patients with DSM-IV diagnosis of depressive and anxiety disorder). In addition, the MAH took the opportunity to propose minor amendments to the labelling and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 25.06.2020, 17.04.2020.	Request for Supplementary Information adopted with a specific timetable.
Busilvex - busulfan - EMEA/H/C/000472/II/0031 Pierre Fabre Medicament, Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.5 of the SmPC regarding the interaction with deferasirox and iron chelating agents. The patient leaflet is updated accordingly. Update of section 5. with minor changes in the paediatric population PK parameters. In addition, the MAH took the opportunity to clarify statement on incompatibilities in sections 6.2 and 6.6 and to expand the incompatibility of	Request for supplementary information adopted with a specific timetable.

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." Request for Supplementary Information adopted on 25.06.2020.	
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 on 05.06.2020, 17.04.2020.	Request for Supplementary Information adopted with a specific timetable.
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 25.06.2020, 26.03.2020, 14.11.2019.	Request for Supplementary Information adopted with a specific timetable.
LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0007	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP

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 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.	Members were in agreement with the CHMP recommendation.
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	Request for Supplementary Information adopted with a specific timetable.

version 10.1." Request for Supplementary Information adopted on 25.06.2020.	
Nerlynx - neratinib - EMEA/H/C/004030/II/0011/G Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to update the pharmacokinetics properties of neratinib and amend drug-drug interaction (DDI) information with CYP3A4/P-gp inducers and inhibitors based on two ADME studies (PUMA-NER-0105 and PUMA-NER-0102), a PBPK model report and in vitro studies; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor corrections to the PI and to bring the PI in line with the latest QRD template version 10 and SmPC Guideline. 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." Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 28.05.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 25.06.2020, 26.03.2020.	Request for Supplementary Information adopted with a specific timetable.
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0011 Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "C.I.4 Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on use of heparin after administration of andexanet based on spontaneous reports, medical literature reports, clinical trials and in vitro data. The Package Leaflet is updated accordingly. Additional editorial changes were proposed in Annex I and IIIB." Request for Supplementary Information adopted on 25.06.2020.	Request for Supplementary Information adopted with a specific timetable.

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-authorisation 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" Opinion adopted on 18.06.2020.	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
TAGRISSO - osimertinib - EMEA/H/C/004124/II/0036 AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, "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." Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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	Request for Supplementary Information adopted with a specific timetable.

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.	
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")." Opinion adopted on 25.06.2020.	See agenda 9.1 Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Veltassa - patiromer - EMEA/H/C/004180/II/0018 Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Jayne Crowe, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from Study RLY5016-207; this is a randomised, double-blind, placebo-controlled, parallel group study of patiromer to enable concomitant spironolactone treatment in patients with resistant hypertension and CKD." Request for Supplementary Information adopted on 18.06.2020.	Request for Supplementary Information adopted with a specific timetable.
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." Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

P450 (CYP) enzymes. The Package Leaflet is updated accordingly." Opinion adopted on 25.06.2020. 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 - 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.	Request for Supplementary Information adopted 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." Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1790 OPDIVO-EMEA/H/C/003985/WS1790/0082 Yervoy-EMEA/H/C/002213/WS1790/0078 Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Blanca Garcia-Ochoa, "Update of	Request for supplementary information adopted with a specific timetable.

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.	
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 4.4 and 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 and editorial changes." Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1814 **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.	Request for Supplementary Information adopted 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 of section 5.1 of the Relvar/Revinty SmPC to include safety information based on results from Therapeutic Index study 203162. This study compared the therapeutic index of	Request for Supplementary Information adopted with a specific timetable.

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), 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.	Request for Supplementary Information adopted with a specific timetable.
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; 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 Annex	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

II and the Package Leaflet are updated accordingly. The RMP was updated to version 37. In addition, the Marketing authorisation holder took the opportunity to make minor editorial changes to the Annex II and the label." Opinion adopted on 25.06.2020. 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)." Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Darzalex - daratumumab - EMEA/H/C/004077/II/0039, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

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 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.	recommendation.
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." Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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." Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 26.03.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/II/0049 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.8 of the SmPC with the safety data and section 5.1 with the (secondary) efficacy data from the Phase 3, open-label, rollover study for Study 109 and Study 011 Part B designed to evaluate the long-term safety and tolerability of Orkambi treatment for 96 weeks in patients with cystic fibrosis, 6 years of age and older, homozygous for F508del. The MAH also took the opportunity to include minor changes to section 4.5 of the Granules SmPC and sections 4.8 and 5.2 of the Tablets and Granules SmPC which were considered acceptable by CHMP. In addition, the RMP version 8.0 is acceptable." Opinion adopted on 09.07.2020. Request for Supplementary Information adopted on 11.06.2020, 30.01.2020, 31.10.2019, 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	Request for Supplementary Information adopted with a specific timetable.

(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 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." Opinion adopted on 25.06.2020. Request for Supplementary Information adopted on 14.05.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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." Opinion adopted on 25.06.2020. 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	Request for Supplementary Information adopted with a specific timetable.

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.	
WS1820 **Iscover-EMEA/H/C/000175/WS1820/0142** **Plavix-EMEA/H/C/000174/WS1820/0140** sanofi-aventis groupe, Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of section 4.2 of the SmPC in order to add 600 mg as an alternative loading dose to the existing 300 mg to be used at initiation of treatment in the indication "Secondary prevention of atherothrombotic events in adult patients suffering from acute coronary syndrome ". This update is based on a bibliographic review of published studies. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted." Request for Supplementary Information adopted on 25.06.2020.	See agenda 9.1 Request for Supplementary Information adopted with a specific timetable.
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." Request for Supplementary Information adopted	Request for Supplementary Information adopted with a specific timetable.

on 25.06.2020.	

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 **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.	Positive Opinion adopted by consensus on 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	Request for Supplementary Information adopted with a specific timetable.

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.	
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 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.	Request for Supplementary Information adopted with a specific timetable.
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	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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.	
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 category 3 study PCI-32765MCL3002 of ibrutinib in 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.	Request for Supplementary Information adopted with a specific timetable.
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	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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.	
PRAC Led **Xeljanz - tofacitinib - EMEA/H/C/004214/II/0023** Pfizer Europe MA EEIG, Rapporteur: Daniela 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.	Request for Supplementary Information adopted with a specific timetable.
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**	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

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 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.	recommendation.
PRAC Led **Zytiga - abiraterone acetate - EMEA/H/C/002321/II/0061** Janssen-Cilag International NV, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Blanca Garcia-Ochoa, "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** 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	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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 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**	Positive Opinion adopted by consensus on 11.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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.	

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 Opinion adopted on 25.06.2020, 19.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 Opinion adopted on 25.06.2020, 19.06.2020. Request for Supplementary Information adopted on 24.04.2020, 21.02.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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	Positive Opinion adopted by consensus on 18.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

guidance on sodium as well as aligning with the current QRD template. Furthermore the MAH has made minor administrative updates to the annexes." Opinion adopted on 18.06.2020.	
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 Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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 the opportunity to correct the Danish translation of pharmaceutical form for 'Olanzapine Glenmark Europe Orodispersible tablets' in this variation application." Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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, Opinion adopted on 25.06.2020.	Positive Opinion adopted by consensus on 25.06.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

zanubrutinib - EMEA/H/C/004978, Orphan BeiGene Ireland Ltd, Treatment of Waldenström's macroglobulinaemia (WM)	
trastuzumab - EMEA/H/C/005124to treat unresectable or metastatic HER2-positive breast cancer	**Accelerated review**
eflornithine / sulindac - EMEA/H/C/005043, Orphan Cancer Prevention Pharma (Ireland) Limited, treatment of adults patients with familial adenomatous polyposis (FAP)	
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

Buvidal - buprenorphine - EMEA/H/C/004651/X/0008/G Camurus AB, Rapporteur: Peter Kiely, PRAC Rapporteur: Tiphaine Vaillant"Line extension to add a new strength of 160 mg for prolonged-release solution for injection pharmaceutical form. In addition the MAH took the opportunity to align the PI to the latest QRD template and to implement new text regarding the content of ethanol in accordance with the EMA document "Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use" (EMA/CHMP/43486/2018) in the Package Leaflet. Variations included: A.4 - A.5.b -	
Xeljanz - tofacitinib - EMEA/H/C/004214/X/0024/G Pfizer Europe MA EEIG, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Liana Gross-	

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

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

Amlodipine-Valsartan Mylan - amlodipine / valsartan - EMEA/H/C/004037/R/0008
Mylan S.A.S, Generic, Generic of Exforge, Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Anette Kirstine Stark

Feraccru - ferric maltol - EMEA/H/C/002733/R/0027
Norgine B.V., Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Janet Koenig (DE) (MNAT with DE-BfArM for Clinical Pharmacology, DE-BfArM for Quality, DE-BfArM for Clinical Efficacy, DE-BfArM for Coordination, DE-BfArM for Clinical Safety, PT for Non-Clinical), PRAC Rapporteur: Adam Przybylkowski

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

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

Bavencio - avelumab - EMEA/H/C/004338/II/0018
Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted, "Extension of indication to include new indication for Bavencio in the treatment as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy; as a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 of the RMP has also been submitted. The MAH took also the occasion to include some editorial changes in the PI."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

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."

Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0110

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jean-Michel Dogné, "Extension of indication to include the prevention of head and neck cancers causally related to certain oncogenic human papillomavirus types for Cervarix; as a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 23.0 of the RMP has also been submitted to mainly reflect the updated indication.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

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, Rapporteur: Kristina Dunder, 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."

Vaxchora - cholera vaccine, oral, live -

EMEA/H/C/003876/II/0003/G
Emergent Netherlands B.V., Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Jean-Michel Dogné, "C.I.6.a (type II): Extension of the indication for the active immunisation against disease caused by Vibrio cholerae serogroup O1, from the currently approved age range "adults and children aged 6 years and older" to "adults and children aged 2 years and older" for Vaxchora. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. C.I.4 (type II): to update section 5.1 of the SmPC to include long-term immunogenicity data supporting Vaxchora effectiveness at generating a protective immune response that persists for 2 years following vaccination; based on the final results from study PXVX-VC-200-006, a randomized, double-blind, placebo-controlled trial aimed to assess the safety and immunogenicity of Vaxchora in children 2 to <18 years of age.
In addition, the MAH took the opportunity to include editorial changes in the SmPC and Annex II."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

WS1882
HyQvia-EMEA/H/C/002491/WS1882/0060
Kiovig-EMEA/H/C/000628/WS1882/0102
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

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

WS1825 **Segluromet-EMEA/H/C/004314/WS1825/0011** **Steglatro-EMEA/H/C/004315/WS1825/0012** **Steglujan-EMEA/H/C/004313/WS1825/0014**	Merck Sharp & Dohme B.V., Lead Rapporteur: Kristina Dunder, "To update section 4.4 of the SmPC and section 2 of the Package Leaflet to comply with the revised Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use" for sodium."
WS1829 **Aldurazyme-EMEA/H/C/000477/WS1829/0076** **Evoltra-EMEA/H/C/000613/WS1829/0070** **Fasturtec-EMEA/H/C/000331/WS1829/0059** **Rilutek-EMEA/H/C/000109/WS1829/0064** **Zaltrap-EMEA/H/C/002532/WS1829/0057**	sanofi-aventis groupe, Lead Rapporteur: Filip Josephson, "To update the product information with respect to the excipient sodium in accordance with the updated annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668). The product information was also brought in line with the latest QRD template. Finally, the MAH took the opportunity to implement an update of the phone number for

the local representative for Italy for 3 ZALTRAP, EVOLTRA and FASTURTEC.”

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations

E.1.3. Initial PMF Certification

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

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

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

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

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

G. ANNEX G

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

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

G.2. Ongoing procedures

G.3. PRIME

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

G.3.1. List of procedures concluding at 22-25 June 2020 CHMP plenary:

Oncology		
1.	(SME); Treatment of relapse/refractory multiple myeloma in patients having received four prior treatment regimens or more	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Immunology-Rheumatology-Transplantation		
2.	(SME); Treatment of Systemic Sclerosis	The CHMP denied eligibility to PRIME and adopted the critical summary report.

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