13 January 2021
EMA/CHMP/625456/2020 Corr.[1]
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 14-17 September 2020

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Disclaimers

Some of the information contained in these 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, these 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).

[1] Addition of the list of participants

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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 (current) September 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 14-17 September 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 14-17 September 2020.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

ORGAM minutes for 07 September 2020.

CHMP minutes for 20 – 23 July 2020.

CHMP minutes for August 2020 written procedure – adopted via written procedure on 27 August 2020.

The Minutes of the September 2020 CHMP ORGAM meeting held on 07 September 2020, together with all decisions taken at that meeting, were adopted.

The minutes of the July plenary were adopted via written procedure after the plenary.

The CHMP noted the final minutes of the August written procedure.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. 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: Oral explanation, letter from third party

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

Participation of patient representatives.

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

An oral explanation was held on Monday 14 September 2020. The presentation focused on the appropriate patient population and proposal for a controlled access programme.

See 3.2

2.1.2. defatted powder of *Arachis hypogaea L.,* semen (peanuts) - EMEA/H/C/004917

desensitization of children and adolescents to peanut allergy.

Scope: Possible oral explanation/ List of outstanding issues

Action: Oral explanation to be held on Tuesday, 15 September 2020 at 14:00

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

The CHMP agreed that an oral explanation was not needed at this time.

See 3.2

2.1.3. 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: Oral explanation

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

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

An oral explanation was held on Wednesday 16 September 2020. The presentation by the applicant focused on the clinical data in support of the application and in particular the proposed indication.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. 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.",

Oral explanation

Action: Oral explanation to be held on Wednesday, 16 September 2020 at 09:00

Request for Supplementary Information adopted on 25.06.2020, 26.03.2020.

An oral explanation was held on Wednesday 16 September 2020. The presentation by the applicant focused on clinical data in support of the extension of indication.

See 5.1

2.3.2. 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.",

Oral explanation

Action: Oral explanation to be held on Wednesday, 16 September 2020 at 11:00

Request for Supplementary Information adopted on 25.06.2020, 26.03.2020.

An oral explanation was held on Wednesday 16 September 2020. The presentation by the

applicant focused on clinical data in support of the extension of indication.

See 5.1

2.4. Referral procedure oral explanations

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

MAHs: various

Re-examination Rapporteur: John Joseph Borg, Re-examination Co-Rapporteur: Blanka Hirschlerova

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Armando Genazzani

Scope: Oral explanation/Opinion

Action: Oral explanation to be held on Tuesday, 15 September at 11:00

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.

An oral explanation was held on Tuesday 15 September 2020. The presentation by the company focused on NDMA data for a ranitidine product, solution for injection, and proposed actions to further reduce NDMA in the finished product.

See 10.6

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Exparel - bupivacaine - EMEA/H/C/004586

PACIRA IRELAND LIMITED; indicated for prolonged acute pain management and reduction in need for opioids in adults compared to immediate-release bupivacaine.

Scope: Opinion

Action: For adoption

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

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

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 summary of opinion was circulated for information.

3.1.2. MenQuadfi - meningococcal group A, C, W135 and Y conjugate vaccine - Article 28 - EMEA/H/C/005084

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

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.07.2020. 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 CHMP noted the letter of recommendations dated 17 September 2020.

The summary of opinion was circulated for information.

3.1.3. Nyvepria - pegfilgrastim - EMEA/H/C/005085

Pfizer Europe MA EEIG; treatment of neutropenia.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.06.2020. 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 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 recommendations dated 16 September 2020.

The summary of opinion was circulated for information.

3.1.4. Obiltoxaximab SFL - obiltoxaximab - Orphan - EMEA/H/C/005169

SFL Pharmaceuticals Deutschland GmbH; treatment of inhalational anthrax due to bacillus anthracis.

Scope: Opinion

Action: For adoption

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

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

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 under exceptional circumstances by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that obiltoxaximab 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 summary of opinion was circulated for information.

3.1.5. Phelinun - melphalan - EMEA/H/C/005173

ADIENNE S.r.l.; high-dose of Phelinun used alone or in combination with other cytotoxic drugs and/or total body irradiation is indicated in the treatment of: multiple myeloma, malignant lymphoma (Hodgkin, non-Hodgkin lymphoma), acute lymphoblastic and myeloblastic leukaemia, childhood neuroblastoma, ovarian adenocarcinoma, mammary adenocarcinoma.
Phelinun in combination with other cytotoxic drugs and/or total body irradiation, in adult and paediatric population, is indicated as conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (HSCT) in haematological diseases.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.07.2020, 26.03.2020. List of Questions adopted on 25.07.2019.

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 summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.6. Rivaroxaban Accord - rivaroxaban - EMEA/H/C/005279

Accord Healthcare S.L.U.; prevention of atherothrombotic events.

Scope: Opinion

Action: For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Xarelto

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

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 recommendations dated 10 September 2020.

The summary of opinion was circulated for information.

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

Sanofi Pasteur; prevention of influenza disease.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.07.2020. 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.

Furthermore, the CHMP considered that recombinant influenza A/H3N2 virus

haemagglutinin 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 recommendations dated 16 September 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. duvelisib - Orphan - EMEA/H/C/005381

Verastem Europe GmbH; treatment of adult patients with relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) and relapsed or refractory follicular lymphoma (FL).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

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.

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

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

Scope: Oral explanation, letter from third party

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

Participation of patient representatives.

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

See 2.1

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

An oral explanation was held on Monday 14 September 2020. The presentation focused on the appropriate patient population and proposal for a controlled access programme.

The Committee adopted a 3rd list of outstanding issues with a specific timetable.

3.2.3. autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - Orphan - ATMP - EMEA/H/C/005102

Accelerated assessment

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.05.2020.

The CHMP was updated on discussions at the CAT. The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee endorsed the list of outstanding issues with a specific timetable as adopted by the CAT.

3.2.4. lenalidomide - EMEA/H/C/005306

treatment of multiple myeloma.

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. 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 2nd list of outstanding issues with a specific timetable.

3.2.5. inclisiran - EMEA/H/C/005333

treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 28.05.2020.

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.

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

Accelerated assessment

Orchard Therapeutics (Netherlands) BV; treatment of metachromatic leukodystrophy (MLD).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.03.2020.

The CHMP was updated on discussions at the CAT. The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee endorsed the list of outstanding issues with a specific timetable as adopted by the CAT.

3.2.7. glucagon - EMEA/H/C/005391

treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

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.

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

Accelerated assessment

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.07.2020.

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.

3.2.9. defatted powder of *Arachis hypogaea L.,* semen (peanuts) - EMEA/H/C/004917

desensitization of children and adolescents to peanut allergy.

Scope: List of outstanding issues

Action: For adoption

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

The CHMP agreed that an oral explanation was not needed at this time.

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.

3.2.10. pemigatinib - Orphan - EMEA/H/C/005266

Incyte Biosciences Distribution B.V.; treatment of locally advanced or metastatic cholangiocarcinoma.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

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.

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

3.2.11. rilpivirine - EMEA/H/C/005060

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

Scope: List of outstanding issues

List of experts for the SAG HIV viral diseases meeting scheduled on 8 September 2020 (pm) adopted via written procedure on 8 September 2020 (am),

SAG report

Action: For adoption

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

The CHMP noted the SAG report.

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.

3.2.12. netarsudil / latanoprost - EMEA/H/C/005107

reduction of elevated intraocular pressure.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.04.2020.

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.

3.2.13. valoctocogene roxaparvovec - Orphan - ATMP - EMEA/H/C/004749

Accelerated assessment

BioMarin International Limited; treatment of haemophilia A.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.04.2020.

The CHMP was informed about discussions at the CAT. The Committee was reminded of the status of this application and its remaining outstanding issues. The CHMP noted that the CAT did not agree to the request by the applicant for an extension to the clock stop.

CHMP endorsed the list of outstanding issues with a specific timetable, as adopted by CAT.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. 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.

The CHMP agreed to consult an ad-hoc expert group and adopted a list of questions to this group.

3.2.15. icosapent ethyl - EMEA/H/C/005398

indicated to reduce cardiovascular risk as an adjunct to statin therapy.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2020.

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.

3.2.16. cabotegravir - EMEA/H/C/004976

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

Scope: List of outstanding issues

List of experts for the SAG HIV viral diseases meeting scheduled on 8 September 2020

(pm) adopted via written procedure on 8 September 2020 (am),

SAG report

Action: For adoption

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

The CHMP noted the SAG report.

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.

3.2.17. baloxavir marboxil - EMEA/H/C/004974

treatment of influenza in patients aged 12 and above, including patients at high risk of developing influenza-related complications and for post-exposure prophylaxis of influenza in individuals aged 12.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2020.

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.

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

3.3.1. idecabtagene vicleucel - Orphan - ATMP - EMEA/H/C/004662

Accelerated assessment

Celgene Europe BV; treatment of multiple myeloma.

Scope: List of questions

Action: For information

The CHMP was updated on discussions at the CAT. The Committee was reminded of the status of this application and its identified issues.

The Committee endorsed the list of questions as adopted by the CAT.

3.3.2. tralokinumab - EMEA/H/C/005255

treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

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. trastuzumab deruxtecan - EMEA/H/C/005124

Accelerated assessment

treatment for unresectable or metastatic HER2-positive breast cancer.

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. roxadustat - EMEA/H/C/004871

treatment of anaemia.

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. pralsetinib - EMEA/H/C/005413

treatment of non-small cell lung cancer (NSCLC).

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. bevacizumab - EMEA/H/C/005433

indicated in adults for the treatment of neovascular macular degeneration associated with aging and diabetes.

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. azacitidine - EMEA/H/C/004761

treatment for acute myeloid leukaemia.

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.

3.3.8. sitagliptin - EMEA/H/C/005598

treatment of type 2 diabetes mellitus.

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.

3.3.9. pegfilgrastim - EMEA/H/C/004780

treatment of neutropenia.

Scope: List of questions,

Request dated 17.09.2020 for an extension to the clock stop to respond to the 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.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions.

3.3.10. sugammadex - EMEA/H/C/005403

treatment of neuromuscular blockade induced by rocuronium or vecuronium.

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.

3.3.11. tafasitamab - Orphan - EMEA/H/C/005436

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

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.

3.3.12. thiotepa - EMEA/H/C/005434

conditioning treatment prior to haematopoietic progenitor cell transplantation (HPCT), treatment of 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.

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

3.4.1. leuprorelin - EMEA/H/C/005034

indicated for the treatment of hormone dependent advanced prostate cancer.

Scope: Request by the applicant dated 31.08.2020 for an extension to the clock stop to respond to the list of questions adopted in July 2020

Action: For adoption

List of Questions adopted on 23.07.2020.

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

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

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

Scope: Request by the applicant dated 28.08.2020 for an extension to the 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 to the clock stop to respond to the list of questions adopted in May 2020.

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

treatment of patients with diabetes mellitus who require intravenous insulin

Scope: Request by the applicant dated 17.09.2020 for an extension to the clock stop to respond to the list of questions adopted in July 2020

Action: For adoption

List of Questions adopted on 23.07.2020.

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

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

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

Scope: Request by the applicant dated 14.08.2020 for an extension to the clock stop to respond to the list of questions adopted in July 2020,

Draft list of questions to the SAG-Oncology/ad-hoc expert group meeting

Action: For adoption

List of Questions adopted on 23.07.2020.

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

The CHMP adopted the list of questions to the SAG.

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

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

Scope: Request by the applicant dated 14.08.2020 for an extension to the clock stop to respond to the list of questions adopted in July 2020 for adoption via written procedure

Action: For adoption

List of questions adopted on 23.07.2020.

The CHMP noted the request by the applicant which was agreed via written procedure.

3.4.6. pitolisant - EMEA/H/C/005117

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

Scope: Request by the applicant dated 26.08.2020 for an extension to the clock stop to

respond to the list of questions adopted in June 2020

Action: For adoption

List of Questions adopted on 25.06.2020.

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

3.4.7. 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 localised, non-metastatic, solid tumours.

Scope: Request by the applicant dated 03.08.2020 for an extension to the clock stop to respond to the list of questions adopted in June 2020

Action: For adoption

List of Questions adopted on 25.06.2020.

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

3.4.8. ponesimod - EMEA/H/C/005163

treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Scope: Request by the applicant dated 06.08.2020 for an extension to the clock stop to respond to the list of questions adopted in July 2020.

Action: For adoption

List of Questions adopted on 23.07.2020.

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

3.4.9. tanezumab - EMEA/H/C/005189

treatment of moderate to severe chronic pain associated with osteoarthritis (OA) in adult patients for whom treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and/or an opioid is ineffective, not tolerated or inappropriate

Scope: Request by the applicant for an extension to the clockstop to respond to the List of questions adopted in July 2020.

Action: For adoption

List of Questions adopted on 23.07.2020.

The CHMP agreed to the request by the applicant for an extension to the clockstop to respond to the list of questions adopted in July 2020.

3.4.10. sildenafil - EMEA/H/C/005439

treatment of erectile dysfunction.

Scope: Request by the applicant dated 27.08.2020 for an extension to the clock stop to respond to the list of questions adopted in June 2020

Action: For adoption

List of Questions adopted on 25.06.2020.

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

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

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

Scope: Request by the applicant dated 04.09.2020 for an extension to the 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 to the clock stop to respond to the list of questions adopted in May 2020.

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

3.5.1. Elzonris - tagraxofusp - Orphan - EMEA/H/C/005031

Stemline Therapeutics B.V.; treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Scope: Draft timetable

Action: For adoption

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

Opinion adopted on 23.07.2020. List of Outstanding Issues adopted on 26.03.2020, 25.06.2019. List of Questions adopted on 24.04.2019.

The CHMP adopted the draft timetable.

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

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

Scope: Draft timetable, appointment of re-examination rapporteur

Action: For adoption

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

Opinion adopted on 23.07.2020. List of Outstanding Issues adopted on 25.06.2020, 27.06.2019. List of Questions adopted on 13.12.2018.

The CHMP appointed a Re-examination Rapporteur. The Re-examination Co-Rapporteur was already appointed in August.

The CHMP adopted the draft timetable.

3.6. Initial applications in the decision-making phase

3.6.1. Jyseleca - filgotinib - EMEA/H/C/005113

Gilead Sciences Ireland UC; treatment of adult patients with moderately to severely active rheumatoid arthritis.

Scope: Final opinion documents, adopted via written procedure on 02.09.2020

Action: For information

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

Opinion adopted on 23.07.2020. List of Outstanding Issues adopted on 28.05.2020. List of Questions adopted on 12.12.2019.

The CHMP noted the final documents.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Upkanz - deferiprone - Orphan - EMEA/H/C/005004

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

Scope: Withdrawal of initial marketing authorisation application

Action: For information

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 19.09.2019.

The CHMP noted the withdrawal of initial 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. Cosentyx - secukinumab - EMEA/H/C/003729/X/0059

Novartis Europharm Limited

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

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

Action: For adoption

List of Questions adopted on 28.05.2020.

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. 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 Outstanding Issues adopted on 25.06.2020. 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.

The CHMP adopted the similarity Assessment Report.

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

Accord Healthcare S.L.U.

Rapporteur: John Joseph Borg, PRAC Rapporteur: Tiphaine Vaillant

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

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. 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.

4.1.4. 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 package leaflet 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 marketing authorisation holder took the opportunity to implement minor updates and formatting changes in the Product Information."

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. 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.

The CHMP adopted the similarity assessment report.

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

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Ilaria Baldelli

Scope: "Extension application to introduce two new strengths of 3 mg and 4.5 mg solution for injection in pre-filled pen."

Action: For adoption

List of Outstanding Issues adopted on 23.07.2020. 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.

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

Alexion Europe SAS

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

Scope: "Extension application to add a new strength (1100 mg in 11 ml vial, concentration 100 mg/ml) for Ultomiris concentrate for solution for infusion, grouped with a Type II application for a new presentation."

Action: For adoption

List of Outstanding Issues adopted on 23.07.2020. List of Questions 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 CHMP noted the letter of recommendations dated 16.09.2020.

4.1.7. 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 of indication to add an 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 9.0 is also agreed. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

List of Outstanding Issues adopted on 25.06.2020. 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.

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

Biogen Netherlands B.V.

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

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

Action: For adoption

List of Questions adopted on 25.06.2020.

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

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

4.2.2. Sirturo - bedaquiline - Orphan - EMEA/H/C/002614/X/0036/G

Janssen-Cilag International NV

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to add a new strength (20 mg tablets) grouped with a type II

variation (C.I.6) to extend the existing Sirturo indication to include paediatric patients aged from 5 years to less than 18 years of age and weighing more than 15 kg, based on the results of the week 24 analysis of cohort 2 (paediatric subjects aged ≥5 to <12 years) of study TMC207-C211. Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 and the Product Leaflet are updated to support the extended indication. The RMP (version 4.4) is updated in accordance."

Action: For adoption

List of Questions adopted on 30.04.2020.

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

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

4.2.3. Tepadina - thiotepa - EMEA/H/C/001046/X/0036

ADIENNE S.r.l.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (400 mg powder and solvent for solution for infusion)."

Action: For adoption

List of Questions adopted on 26.03.2020.

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.

4.2.4. Trimbow - beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium - EMEA/H/C/004257/X/0008/G

Chiesi Farmaceutici S.p.A.

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

Scope: "Extension application to introduce a new strength (172 µg / 5 µg / 9 µg) grouped with a type II variation (C.I.6.a) to add a new indication (asthma). The RMP (version 6.1) is updated in accordance."

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 as well as the RMP.

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

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

Bayer AG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form, granules for oral suspension, 1 mg/ml.
Extension of indication to include treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years following initiation of standard anticoagulation treatment for Xarelto 15 and 20 mg tablets. As a consequence, sections 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated accordingly.
In addition, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC is updated for all other dose strengths (2.5/10/ and 15/20 mg initiation packs) of Xarelto and corresponding sections of the package leaflet. Section 4.4 has been updated with regards to sodium content according to the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668). The RMP version 12.1 has also been submitted.",

List of experts for the SAG Cardiovascular meeting scheduled on 07 September 2020 adopted via written procedure on 04 September 2020,

SAG Report

Action: For adoption

List of Outstanding Issues adopted on 23.07.2020. List of Questions adopted on 30.04.2020.

The CHMP noted the SAG report.

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

The Committee adopted the CHMP recommendation and scientific discussion together with the 2nd 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. Aubagio - teriflunomide - EMEA/H/C/002514/X/0031/G

sanofi-aventis groupe

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: "Extension of a marketing authorisation for Aubagio to add the new strength, 7 mg film-coated tablet, for use in paediatric patients from 10 years of age and older with relapsing remitting multiple sclerosis (MS).
Type II (C.I.6) - Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS) for Aubagio 14 mg tablet. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet and labelling are updated in accordance.

The marketing authorisation holder is requesting an extension of the market protection of one additional year in line with the guidance on elements required to support the significant clinical benefit in comparison with existing therapies of a new therapeutic indication in order to benefit from an extended (11-year) marketing protection period.
Version 6.0 of the RMP has also been submitted."

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to some clinical issues and the request for an additional 1 year of marketing protection.

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

4.3.2. Bortezomib Accord - bortezomib - EMEA/H/C/003984/X/0023

Accord Healthcare S.L.U.

Rapporteur: Milena Stain, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg/ml solution for injection)."

Action: For adoption

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

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

4.3.3. Fabrazyme - agalsidase beta - EMEA/H/C/000370/X/0118/G

Genzyme Europe BV

Rapporteur: Johann Lodewijk Hillege

Scope: Quality changes

Action: For adoption

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

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

4.3.4. Ferriprox - deferiprone - EMEA/H/C/000236/X/0145

Chiesi Farmaceutici S.p.A.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form (gastro-resistant tablets). The RMP (version 14.0) is updated in accordance."

Action: For adoption

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 questions.

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

4.3.5. Maviret - glecaprevir / pibrentasvir - EMEA/H/C/004430/X/0033/G

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (50/20 mg coated granules in sachet), grouped with a type II extension of indication variation (C.I.6.a) to include the treatment of children from 3 to 12 years of age for the approved Maviret 100 mg/40 mg film-coated tablets; as a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated accordingly. Version 5.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Action: For adoption

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

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

4.3.6. Nitisinone MDK - nitisinone - EMEA/H/C/004281/X/0007

MendeliKABS Europe Limited

Rapporteur: Alar Irs, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension application to add a new strength of 20 mg (hard capsule)."

Action: For adoption

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

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

4.3.7. Volibris - ambrisentan - EMEA/H/C/000839/X/0061/G

GlaxoSmithKline (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension application to introduce a new strength (2.5 mg film-coated tablet), grouped with an extension of indication to include paediatric use (8 to less than 18 years). Version 9.0 of the RMP has been submitted.
Type IA category A.7"

Action: For adoption

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

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

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

Tetraphase Pharmaceuticals Ireland Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 100 mg for eravacycline powder for concentrate for solution for infusion. The RMP (version 3.0) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template."

Action: For adoption

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

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

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

Boehringer Ingelheim International GmbH

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

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

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

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

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

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

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

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

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

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

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

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

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

List of experts for the SAG Cardiovascular meeting scheduled on 07 September 2020 adopted via written procedure on 04 September 2020,

SAG report

Action: For information

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

The CHMP noted the list of experts adopted via written procedure.

The CHMP noted the report from the SAG.

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. Bavencio - avelumab - EMEA/H/C/004338/II/0018

Merck Europe B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Hans Christian Siersted

Scope: "Extension of indication to include a 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 marketing authorisation holder 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)

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to the efficacy data in a sub-population and the request for an additional 1 year of market protection.

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

5.1.2. 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

Scope: "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."

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to some clinical aspects with regard to the appropriate target population.

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

5.1.3. 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

Scope: "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 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."

Action: For adoption

The Committee discussed the issues identified in this application, concerning the clinical data in support of the extension of indication application.

The Committee adopted a request for supplementary information.

The CHMP agreed to the request for an extension to the clock stop 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 25.06.2020, 30.04.2020, 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.

The CHMP adopted the similarity assessment report.

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

Dova Pharmaceuticals Ireland Limited

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

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

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020.

The Committee discussed the issues identified in this application, mainly concerning the dosing scheme.

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

5.1.6. 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 the 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

Request for Supplementary Information adopted on 25.06.2020.

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.

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

Eisai GmbH

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension of indication to include the paediatric patients from 4 to 11 years of age for the adjunctive treatment of partial-onset seizures with or without secondary generalisation and from 7 to 11 years of age for the adjunctive treatment of primary generalised tonic-clonic seizures with idiopathic generalised epilepsy for Fycompa.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 4.5 has also been submitted.
The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP)."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020, 12.12.2019.

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.

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

Vertex Pharmaceuticals (Ireland) Limited

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

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

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020.

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.

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

Merck Sharp & Dohme B.V.

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

Scope: "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."

Action: For adoption

The Committee discussed the issues identified in this application, mainly concerning some clinical aspects and in particular the indication wording.

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

5.1.10. 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."

Oral explanation

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 26.03.2020.

See 2.3

An oral explanation was held on Wednesday, 16 September 2020. The presentation by the applicant focused on clinical data in support of the extension of indication.

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 noted the letter of recommendations dated 17.09.2020.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

5.1.11. 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."

Oral explanation

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020, 26.03.2020.

See 2.3

An oral explanation was held on Wednesday, 16 September 2020. The presentation by the applicant focused on clinical data in support of the extension of indication.

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.

5.1.12. Nordimet - methotrexate - EMEA/H/C/003983/II/0016

Nordic Group B.V.

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include the treatment of mild to moderate Crohn's disease either alone or in combination with corticosteroids in patients refractory or intolerant to thiopurines for Nordimet; as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 5.0 has also been submitted. The marketing authorisation holder took the opportunity to update the RMP with changes related to GVP V version 2 template and the outcome of MTX referral."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

The Committee discussed the issues identified in this application, mainly relating to the clinical data and in particular the wording of the indication.

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

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

Amgen Europe B.V.

Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia

Scope: "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 marketing authorisation holder 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."

Action: For adoption

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

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

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

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include a new indication in the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy for Olumiant; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
The guide for HCPs and the patient alert card in the Annex II were updated to reflect the risk of deep venous thrombosis (DVT) and pulmonary embolism (PE).
Minor editorial changes were brought to the Labelling. Furthermore, the Annex II is brought in line with the latest QRD template version 10.1.
The RMP version 8.1 has also been submitted and adopted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.
The variation leads to amendments to the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet and to the Risk Management Plan (RMP)."

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 28.05.2020, 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.

The summary of opinion was circulated for information.

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

Swedish Orphan Biovitrum International AB

Rapporteur: Armando Genazzani, PRAC Rapporteur: Amelia Cupelli

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

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020.

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.

5.1.16. Rinvoq - upadacitinib - EMEA/H/C/004760/II/0004

AbbVie Deutschland GmbH & Co. KG

Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "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."

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to the clinical data and in particular the wording of the indication.

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

5.1.17. Rinvoq - upadacitinib - EMEA/H/C/004760/II/0005

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "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."

Action: For adoption

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

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

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

Roche Registration GmbH

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

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

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020.

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 noted the letter of recommendation dated 17.09.2020.

The summary of opinion was circulated for information.

5.1.19. Vaxchora - cholera vaccine, oral, live - EMEA/H/C/003876/II/0003/G

Emergent Netherlands B.V.

Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Jean-Michel Dogné

Scope: "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 marketing authorisation holder took the opportunity to include editorial changes in the SmPC and Annex II."

Action: For adoption

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

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

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

UCB Pharma S.A.

Rapporteur: Bruno Sepodes, Co-Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Ana Sofia Diniz Martins

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

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020, 12.12.2019, 29.05.2019, 15.11.2018.

The Committee discussed the issues identified in this application, relating to the RMP.

The Committee adopted a 5th request for supplementary information with a specific timetable.

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

Pfizer Ireland Pharmaceuticals

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

Scope: "Extension of indication to include paediatric patients aged 3 months to less than 18 years for Zavicefta (for the treatment of cIAI and cUTI, HAP/VAP and aerobic Gram-negative infections in patients with limited treatment options), based on data from paediatric studies D4280C00014, C3591004 and C3591005 and the population PK modelling/simulation analyses (CAZ-MS-PED-01 and CAZ-MS-PED-02). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated in order to reflect this additional population, the paediatric posology, paediatric safety information, the description of the clinical trials and handling instructions for paediatric dosing. The Package Leaflet is updated in accordance. A warning was included in section 4.4 of the SmPC, with a cross-reference to section 4.9, to highlight a potential risk of overdosing for the youngest children from 3 months to less than 12 months of age, related to the difficulties to calculate the volume of administration of the dose. In addition, a table with dosing volumes calculated based on different weights was added to section 6.6.

The Marketing authorisation holder (MAH) took the opportunity to correct the sodium content to SmPC sections 2 and 4.4 and PL section 2 and the volumes of distribution of ceftazidime and avibactam in SmPC section 5.2. The RMP version 3.2 has been approved with this variation."

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 26.03.2020, 25.07.2019.

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.

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

GlaxoSmithKline (Ireland) Limited

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

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

Action: For adoption

Request for Supplementary Information adopted on 28.05.2020.

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.

5.1.23. 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 25.06.2020, 27.02.2020.

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

aspects.

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

5.1.24. WS1769
Iscover - clopidogrel - EMEA/H/C/000175/WS1769/0140
Plavix - clopidogrel - EMEA/H/C/000174/WS1769/0138

sanofi-aventis groupe

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

Scope: "Extension of indication to include adult patients with high risk Transient Ischemic Attack (TIA) (ABCD2 score ≥4) or minor Ischemic Stroke (IS) (NIHSS ≤3) within 24 hours of either the TIA or IS event. The new indication is based on the results of two double-blind, randomised, placebo-controlled phase III trials (studies POINT & CHANCE); as a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated, the PL is updated accordingly. Version 1.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.04.2020.

The Committee discussed the issues identified in this application, concerning the wording of some SmPC sections.

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

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

Bristol-Myers Squibb Pharma EEIG

Lead Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include first-line treatment of metastatic non small cell lung cancer in adults with no EGFR or ALK positive tumour mutations for combination of Odpivo and Yervoy; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 17.0 of the RMP for Opdivo and version 27.0 for Yervoy have also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020.

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.

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

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

Pfizer Ireland Pharmaceuticals

Rapporteur: Alar Irs

Scope: "Extension of indication for the treatment of community acquired pneumonia (CAP) to include concurrent bacteraemia due to Streptococcus pneumoniae (SP) for all age groups, based on the results of previously submitted studies: FOCUS 1 (study P903-08) and FOCUS 2 (study P903-09), paediatric CAP study (study P903-31) and relevant post-marketing safety experience with ceftaroline for bacteraemic Streptococcus pneumoniae CAP. As a consequence sections 4.1 and 5.1 of the SmPC are updated accordingly. No RMP has been provided within this application.",

Request by the applicant dated 07.09.2020 for an extension to the clock stop to respond to the request for supplementary information adopted in July 2020

Action: For adoption

Request for Supplementary Information adopted on 23.07.2020, 12.12.2019.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in July 2020.

5.2.2. 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."

Request by the applicant for an extension to the clock stop to respond to the Request for Supplementary Information adopted on 25.06.2020

Action: For adoption

Request for Supplementary Information adopted on 25.06.2020.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Request for Supplementary Information adopted on 25.06.2020

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. dexamethasone phosphate - H0005740

treatment of hospitalised adult patients with COVID19 who are on oxygen therapy, non-invasive or invasive ventilation, or ECMO (Extracorporeal Membrane Oxygenation).

Scope: The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment via written procedure on 28.08.2020

Action: For information

The CHMP noted the accelerated assessment agreed via written procedure.

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

The CHMP noted the information.

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 9 recommendations for eligibility to PRIME: 6 were accepted and 3 were denied.

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Dukoral - cholera vaccine (inactivated, oral) - EMEA/H/C/00476/II/0062/G

Valneva Sweden AB

Rapporteur: Kristina Dunder

Scope: quality changes

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.

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

Genzyme Europe BV

Rapporteur: Johann Lodewijk Hillege

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to change posology recommendations in adults, children and adolescents aged 8 years and older by removing the information on the lower dosing regimens that have been used in clinical studies and update the clinical information based on the review of published scientific literature including two observational studies in patients remaining on standard dose of Fabrazyme or switching to lower dose regimens. In addition, the MAH took the opportunity to propose

changes in the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products."

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. Ocaliva - obeticholic acid - EMEA/H/C/004093/R/0023, Orphan

Intercept Pharma International Limited

Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Renewal of Conditional Marketing Authorisation

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

Biogen Netherlands B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

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

Request for PRAC advice

Action: For adoption

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

The CHMP agreed to request advice from the PRAC.

The Committee adopted an 4th request for supplementary information with a specific timetable.

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. Dexamethasone EMEA/H/A-5(3)/1500

MAHs: various

Referral Rapporteur: Peter Kiely, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Opinion

Action: For adoption

Dexamethasone for the treatment of COVID-19 in hospitalised adult patients. Assessment of the recovery study arm based on preliminary results (Horby et al 2020).

The CHMP adopted an opinion by consensus, recommending the use of dexamethasone 6 mgs IV/PO for up to 10 days in treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) who require supplemental oxygen therapy.

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

The EMA public health communication was circulated for information.

10.2.2. 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: Letter from European Commission

Action: For discussion

The CHMP noted the letter from the EC.

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

No items

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

No items

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

No items

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

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

MAHs: various

Re-examination Rapporteur: John Joseph Borg, Re-examination Co-Rapporteur: Blanka Hirschlerova

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Armando Genazzani

Scope: Oral explanation/Opinion

Oral explanation to be held on Tuesday 15 September at 11:00

Action: For adoption

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.

See 2.4

An oral explanation was held on Tuesday 15 September 2020. The presentation by the company focused on NDMA data for a ranitidine product, solution for injection, and proposed actions to further reduce NDMA in the finished product.

The CHMP agreed by consensus to modify the conditions.

The CHMP adopted an opinion by consensus that the risk-benefit balance of ranitidine containing medicinal products is not favourable. Therefore, the CHMP was of the opinion by consensus that the marketing authorisation(s) for ranitidine containing medicinal products should be suspended.

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

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

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

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

such inspections

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

13.2. Innovation Task Force briefing meetings

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. Strategic Review and Learning Meetings (SRLM)

CHMP SRLM under the German presidency of the European Union (EU) Council – remote meeting, 22 September 2020

Action: For information

The CHMP noted the information.

14.2. Coordination with EMA Scientific Committees

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

14.2.1. Committee on Herbal Medicinal Products (HMPC)

HMPC communication on pyrrolizidine alkaloids

Action: For information

The CHMP noted the information.

14.2.2. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 31 August - 03 September 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 September 2020

Action: For adoption

The CHMP adopted the EURD list.

14.2.3. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2020 PDCO

Action: For information

The CHMP noted the information.

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

14.3.2. Biostatistics Working Party (BSWP)

Chair: Christian B. (Kit) Roes, Vice-Chair: Joerg Zinserling

BSWP response to CMDh question on the chosen statistical approach for data analysis - Cabazitaxel

Action: For adoption

The CHMP adopted the BSWP response to CMDh.

14.3.1. Biologics Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP September 2020 meeting to CHMP for adoption:

- 20 reports on products in scientific advice and protocol assistance
- 15 reports on products in pre-authorisation procedures

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 31 August - 03 September 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

Q3/2020 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 information.

15.1.2. chadox1 ncov-19 - replication-defective adenovirus vector vaccine - H0005675

intramuscular (IM) injection of vaccine for coronavirus disease 2019 (COVID-19).

Scope: Start of rolling review, Draft timetable

Action: For information

The CHMP noted the draft timetable

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 14-17 September 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	
Karin Janssen van Doorn	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Eleftheria Nikolaidi	Alternate	Greece	No interests declared	
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	
Armando Genazzani	Member	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	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No part in discussions, final deliberations and voting	Plegridy - peginterferon beta-1a - EMEA/H/C/002827/X/0056
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Kristina Dunder	Member	Sweden	No interests declared	
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	Volibris - EMEA/H/C/000839/X/0061/G
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	
Esklid Colding-Jørgensen	Expert - via telephone*	Denmark	No restrictions applicable to this meeting	
Anne Kleinau	Expert - via telephone*	Germany	No interests declared	
Hans van Gompel	Expert - via telephone*	Netherlands	No interests declared	
Helga Haugom Olsen	Expert - via telephone*	Norway	No interests declared	
Hilde Røshol	Expert - via telephone*	Norway	No interests declared	
Rune Kjeken	Expert - via telephone*	Norway	No restrictions applicable to this meeting	
Candida Silva	Expert - via telephone*	Portugal	No interests declared	
Mario Miguel Coelho da Rosa	Expert - via telephone*	Portugal	No interests declared	
Andreas Kirisits	Expert - via Adobe*	Austria	No interests declared	
Ilona Reischl	Expert - via Adobe*	Austria	No interests declared	
Thomas Lang	Expert - via Adobe*	Austria	No interests declared	
Didier Hue	Expert - via Adobe*	Belgium	No interests declared	
Ingrid Bourges	Expert - via Adobe*	Belgium	No restrictions applicable to this meeting	
Olga Kholmanskikh	Expert - via Adobe*	Belgium	No interests declared	
Stefan Bonne	Expert - via Adobe*	Belgium	No interests declared	
Violette Dirix	Expert - via Adobe*	Belgium	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Aaron Sosa	Expert - via Adobe*	Denmark	No restrictions applicable to this meeting	
Anne-Marie Dalseg	Expert - via Adobe*	Denmark	No interests declared	
Mette Linnert Jensen	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	
Olli Tenhunen	Expert - via Adobe*	Finland	No interests declared	
Muriel Uzzan	Expert - via Adobe*	France	No interests declared	
Pierre Demolis	Expert - via Adobe*	France	No interests declared	
Tiphaine Vaillant	Expert - via Adobe*	France	No interests declared	
Violaine Closson-Carella	Expert - via Adobe*	France	No interests declared	
Andrea Rohmer	Expert - via Adobe*	Germany	No interests declared	
Benjamin Hofner	Expert - via Adobe*	Germany	No restrictions applicable to this meeting	
Birgit Ahrens	Expert - via Adobe*	Germany	No interests declared	
Christine Greiner	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	
Elmer Schabel	Expert - via Adobe*	Germany	No interests declared	
Gabriele Schloser-Weber	Expert - via Adobe*	Germany	No interests declared	
Lukas Aquirre Davila	Expert - via Adobe*	Germany	No interests declared	
Martin Huber	Expert - via Adobe*	Germany	No interests declared	
Martina Schussler-Lenz	Expert - via Adobe*	Germany	No interests declared	
Ralf Meyer	Expert - via Adobe*	Germany	No interests declared	
Sofia Kapanadze	Expert - via Adobe*	Germany	No restrictions applicable to this meeting	
Susanna Hausmann	Expert - via Adobe*	Germany	No interests declared	
Susanne Kaul	Expert - via Adobe*	Germany	No interests declared	
Tim Niehues	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
Agnieszka Przybyszewska	Expert - via Adobe*	Ireland	No interests declared	
Benita Cullen	Expert - via Adobe*	Ireland	No interests declared	
Geraldine O`Dea	Expert - via Adobe*	Ireland	No interests declared	
Larissa Higgins	Expert - via Adobe*	Ireland	No interests declared	
Sinead Harrington	Expert - via Adobe*	Ireland	No interests declared	
Angelo Molinaro	Expert - via Adobe*	Italy	No interests declared	
Antonella Isgro	Expert - via Adobe*	Italy	No interests declared	
Cristina Migali	Expert - via Adobe*	Italy	No interests declared	
Odoardo Maria Olimipieri	Expert - via Adobe*	Italy	No interests declared	
Svetlana Lorenzano	Expert - via Adobe*	Italy	No restrictions applicable to this meeting	
Liva Jakovele	Expert - via Adobe*	Latvia	No interests declared	
Andre Elferink	Expert - via Adobe*	Netherlands	No interests declared	
Carla Herberts	Expert - via Adobe*	Netherlands	No interests declared	
Erik Hergarden	Expert - via Adobe*	Netherlands	No interests declared	
Esther Broekman	Expert - via Adobe*	Netherlands	No restrictions applicable to this meeting	
Frank Holtkamp	Expert - via Adobe*	Netherlands	No interests declared	
Hester Peltenburg	Expert - via Adobe*	Netherlands	No interests declared	
Ingrid Bijsmans	Expert - via Adobe*	Netherlands	No interests declared	
Ingrid Schellens	Expert - via Adobe*	Netherlands	No interests declared	
Jaap Fransen	Expert - via Adobe*	Netherlands	No interests declared	
Jessica Harskamp	Expert - via Adobe*	Netherlands	No interests declared	
Jessica van Montfoort	Expert - via Adobe*	Netherlands	No interests declared	
Johannes Theodorus Span	Expert - via Adobe*	Netherlands	No interests declared	
Joost Romme	Expert - via Adobe*	Netherlands	No interests declared	
Laura Rodwell	Expert - via Adobe*	Netherlands	No interests declared	
Leon Bongers	Expert - via Adobe*	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lieke Sandberg	Expert - via Adobe*	Netherlands	No interests declared	
Loes den Otter	Expert - via Adobe*	Netherlands	No interests declared	
Louise Claessen	Expert - via Adobe*	Netherlands	No interests declared	
Mark van Bussel	Expert - via Adobe*	Netherlands	No interests declared	
Monique van Raamsdonk	Expert - via Adobe*	Netherlands	No interests declared	
Nancy Postma	Expert - via Adobe*	Netherlands	No interests declared	
Nienke Rodenhuis	Expert - via Adobe*	Netherlands	No interests declared	
Sanna Gevers	Expert - via Adobe*	Netherlands	No interests declared	
Viktoriia Starokozhko	Expert - via Adobe*	Netherlands	No restrictions applicable to this meeting	
Anja Schiel	Expert - via Adobe*	Norway	No interests declared	
Elisabet Storset	Expert - via Adobe*	Norway	No interests declared	
Ingrid Lund	Expert - via Adobe*	Norway	No interests declared	
Nina Malvik	Expert - via Adobe*	Norway	No interests declared	
Mats Welin	Expert - via Adobe*	Sweden	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)*

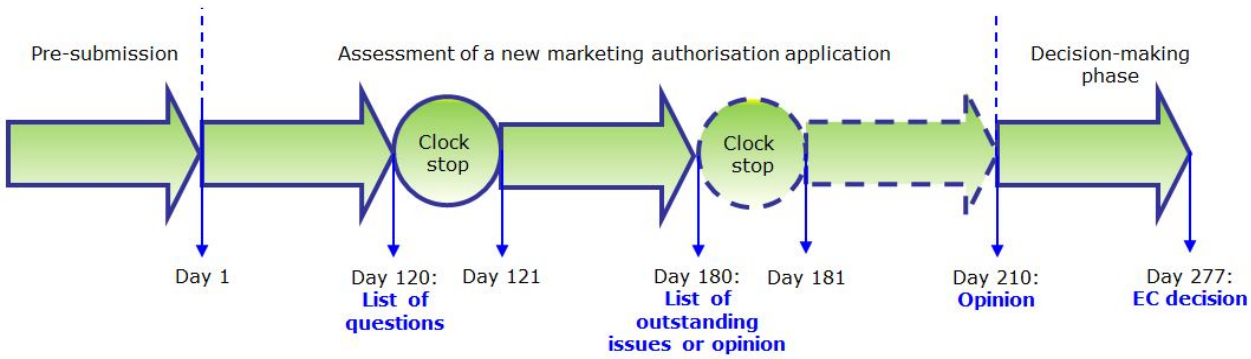
The items listed in this section are those for which marketing authorisation holders or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section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

22 December 2020
EMA/CHMP/629163/2020

Annex to 14-17 September 2020 CHMP Minutes

Pre-submission and post-authorisations issues

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for September 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

B.1.1. Annual reassessment for products authorised under exceptional circumstances

DECTOVA - zanamivir - EMEA/H/C/004102/S/0006 GlaxoSmithKline Trading Services Limited, Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Ulla Wändel Liminga	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.	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

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.	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 an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/R/0056 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Armando Genazzani, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald 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 an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Rasagiline Mylan - rasagiline - EMEA/H/C/004064/R/0006 Mylan S.A.S, Generic, Generic of AZILECT, Rapporteur: Kolbeinn Gudmundsson, PRAC Rapporteur: Ana Sofia Diniz Martins Request for Supplementary Information adopted on 23.07.2020.	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 an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

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 Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Benepali - etanercept - EMEA/H/C/004007/R/0053 Samsung Bioepis NL B.V., Rapporteur: Andrea Laslop, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Eva A. Segovia Request for Supplementary Information adopted on 25.06.2020.	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.
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 Quality, DE-BfArM for Clinical Efficacy, DE-BfArM for Clinical Pharmacology, DE-BfArM for Clinical Safety, DE-BfArM for Coordination, PT for Non-Clinical), PRAC Rapporteur: Adam Przybylkowski	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.
Gilenya - fingolimod - EMEA/H/C/002202/R/0063 Novartis Europharm Limited, Rapporteur: Alexandre Moreau, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Tiphaine Vaillant	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.
Imlygic - talimogene laherparepvec - EMEA/H/C/002771/R/0039, ATMP Amgen Europe B.V., Rapporteur: Olli Tenhunen, Co-Rapporteur: Rune Kjeken, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 20.05.2020.	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.
Lopinavir/Ritonavir Mylan - lopinavir / ritonavir - EMEA/H/C/004025/R/0014 Mylan S.A.S, Generic, Generic of Kaletra, Rapporteur: John Joseph Borg, PRAC Rapporteur: Adrien Inoubli Request for Supplementary Information adopted on 23.07.2020.	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.
Oncaspar - pegaspargase - EMEA/H/C/003789/R/0034 Les Laboratoires Servier, Rapporteur: Alexandre Moreau, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Annika Folin	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.
Zonisamide Mylan - zonisamide - EMEA/H/C/004127/R/0008 Mylan S.A.S, Generic, Generic of Zonegran, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Rhea Fitzgerald	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.

B.2.3. Renewals of Conditional Marketing Authorisations

NINLARO - ixazomib - EMEA/H/C/003844/R/0021, Orphan Takeda Pharma A/S, Rapporteur: Armando Genazzani, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 23.07.2020.	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 be granted. The Marketing Authorisation remains conditional. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
OCALIVA - obeticholic acid - EMEA/H/C/004093/R/0023, Orphan Intercept Pharma International Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Liana Gross-Martirosyan Request for Supplementary Information adopted on 17.09.2020.	See agenda 9.1 Request for supplementary information adopted with a specific timetable.
Polivy - polatuzumab vedotin - EMEA/H/C/004870/R/0003, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection	
PRAC recommendations on signals adopted at the PRAC meeting held on 31 August– 03 September 2020 PRAC:	
Signal of anaphylactic reaction ZYTIGA – abiraterone Rapporteur: Blanca Garcia-Ochoa Co-Rapporteur: Sinan B. Sarac PRAC recommendation on a variation **Action:** For adoption	Adopted.
Signal of heart valve regurgitation, cervical artery dissection, and aortic aneurysm and dissection QUINSAIR, QUOFENIX – fluoroquinolones NAPs Rapporteur: various, Co-Rapporteur: various PRAC recommendation on a variation/DHPC **Action:** For adoption	Adopted.
Signal of neuromyelitis optica spectrum disorder INTRONA, PEGASYS, PEGINTRON, VIRAFERONPEG, ROFERON-A - interferon alfa-2a, Interferon alfa-2b, peginterferon alfa-2a, peginterferon alfa-2b NAPs Rapporteur: various, Co-Rapporteur: various PRAC recommendation on a variation **Action:** For adoption	Adopted.
Signal of Progressive Multifocal Leukoencephalopathy IMNOVID – pomalidomide Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Sinan B. Sarac PRAC recommendation on a variation **Action:** For adoption	Adopted.
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its September 2020 meeting:	
EMEA/H/C/PSUSA/00002162/202001 (nilotinib) CAPS: **Tasigna** (EMEA/H/C/000798) (nilotinib),	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,

Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Period Covered From: 01/02/2019 To: 31/01/2020"	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 4.5 of the SmPC to add a warning on rhabdomyolysis caused by the drug-drug interaction with statins and update of section 4.8 to amend frequencies of the adverse reactions: cardiac failure, pneumonia, and renal failure. 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/00002511/202001 (pregabalin) CAPS: **Lyrica** (EMEA/H/C/000546) (pregabalin), Upjohn EESV, Rapporteur: Johann Lodewijk Hillege **Pregabalin Pfizer** (EMEA/H/C/003880) (pregabalin), Upjohn EESV, Rapporteur: Johann Lodewijk Hillege NAPS: **PREGABALINĂ TERAPIA** - TERAPIA S.A., PRAC Rapporteur: Liana Gross-Martirosyan, "Period Covered From: 01/02/2019 To: 31/01/2020"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC 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 medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.8 of the SmPC to add respiratory depression with frequency of "not known". The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00009263/202001 (pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent) CAPS: **Prevenar 13** (EMEA/H/C/001104) (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)), Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Period Covered From: 10/01/2017 To: 09/01/2020"	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): Update of section 4.8 of the SmPC to add the adverse reaction anaphylaxis with a frequency not known to the group of children > 5 years and adults. The MAH has taken the opportunity to move all events reported in the post-marketing setting (not only anaphylaxis) from an age specific subsection (6 weeks to 5 years) into a subsection addressing all age ranges. The Package leaflet is updated accordingly.

	Furthermore, the MAH took the opportunity to introduce changes to the product information in line with QRD 10.1 template. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010075/202001 (dolutegravir, dolutegravir / abacavir / lamivudine, dolutegravir / lamivudine) CAPS: **Dovato** (EMEA/H/C/004909) (dolutegravir / lamivudine), ViiV Healthcare B.V., Rapporteur: Filip Josephson **Tivicay** (EMEA/H/C/002753) (dolutegravir), ViiV Healthcare B.V., Rapporteur: Filip Josephson **Triumeq** (EMEA/H/C/002754) (dolutegravir / abacavir / lamivudine), ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Period Covered From: 17/07/2019 To: 16/01/2020"	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 4.6 of the SmPC to amend the new data regarding the transfer of DTG into breast milk. The package leaflet is updated accordingly where no wording on this effect yet exists. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010380/202002 (lenvatinib) CAPS: **Kisplyx** (EMEA/H/C/004224) (lenvatinib), Eisai GmbH, Rapporteur: Karin Janssen van Doorn **Lenvima** (EMEA/H/C/003727) (lenvatinib), Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Annika Folin, "Period Covered From: 11/02/2019 To: 11/02/2020"	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 and 4.8 of the SmPC to add the adverse reaction osteonecrosis of the jaw with a frequency uncommon and a warning on the risk of osteonecrosis of the jaw. 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/00010447/202001 (brivaracetam) CAPS: **Briviact** (EMEA/H/C/003898) (brivaracetam), UCB Pharma S.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "Period Covered From: 15/01/2019 To: 14/01/2020"	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 SmPC section 4.5 to reflect data on coadministration with cannabidiol. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010578/202002 (baricitinib) CAPS: **Olumiant** (EMEA/H/C/004085) (baricitinib), Eli Lilly Nederland B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, "Period Covered From: 12/08/2019 To: 12/02/2020"	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, concerning the following change(s): Update of section 4.4 of the SmPC to modify the wording on "Hepatic transaminase elevations" to indicate that this effect is dose-dependent and update of section 4.8 of the SmPC "Hepatic transaminase elevations" accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010609/202001 (sarilumab) CAPS: **Kevzara** (EMEA/H/C/004254) (sarilumab), sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Eva A. Segovia, "Period Covered From: 21/01/2019 To: 21/01/2020"	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): Update of section 4.4 of the SmPC to reflect that gastrointestinal perforation has been reported in association with Kevzara in patients with and without diverticulitis. Update of section 4.8 of the SmPC to add "Gastrointestinal perforation" under the SOC "Gastrointestinal disorders" with a frequency "rare". The package leaflet is being updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010630/202001 (spheroids of human autologous matrix-associated chondrocytes) CAPS: **Spherox** (EMEA/H/C/002736) (spheroids of human autologous matrix-associated chondrocytes), CO.DON AG, Rapporteur: Lisbeth	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),

Barkholt, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Period Covered From: 09/07/2019 To: 09/01/2020"	concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reactions Arthritis infective and Arthrofibrosis related to Spherox, to add Pneumonia, Pulmonary embolism and Haemothorax as surgery-related adverse reactions and to add Cellulitis, Osteomyelitis related to both and update the frequency of a number of the adverse reactions already listed. 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/00010695/202002 (bictegravir / emtricitabine / tenofovir alafenamide) CAPS: **Biktarvy** (EMEA/H/C/004449) (bictegravir / emtricitabine / tenofovir alafenamide), Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Liana Gross-Martirosyan, "07/08/2019 To: 06/02/2020"	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 4.8 of the SmPC to amend the wording of "suicidal behaviour" into "suicidal ideation and suicide attempt" in the light of the causal relationship between bictegravir / emtricitabine / tenofovir alafenamide and suicidal behaviour, with the frequency remaining uncommon. 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/00010715/202002 (patisiran) CAPS: **Onpattro** (EMEA/H/C/004699) (patisiran), Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "Period Covered From: 08/08/2019 To: 08/02/2020"	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 4.8 of the SmPC to amend a warning on Infusion-related reactions. 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/00010742/202001 (voretigene neparvovec) CAPS: **Luxturna** (EMEA/H/C/004451) (voretigene neparvovec), Novartis Europharm Limited, Rapporteur: Sol Ruiz, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Period Covered From: 25/07/2019 To: 23/01/2020"	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 and 4.8 of the SmPC to add the adverse reaction vitreous opacities / visual floaters with a frequency common. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

B.4. EPARs / WPARs

Abicipar Pegol Allergan - abicipar pegol - EMEA/H/C/005103 Allergan Pharmaceuticals, treatment of neovascular (wet) age-related macular degeneration (AMD) 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.
Abilify Mycite- aripiprazole- EMEA/H/C/005062 Otsuka Pharmaceutical Netherlands B.V., treatment of schizophrenia, or of moderate to severe manic episodes in bipolar I disorder with sensor to measure medication adherence, Hybrid application (Article 10(3) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
Adakveo - crizanlizumab - EMEA/H/C/004874 Novartis Europharm Limited; treatment of sickle cell 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.
Arikayce liposomal - amikacin - EMEA/H/C/005264, Orphan Insmed Netherlands B.V., treatment of lung infection as part of combination antibacterial drug regiment in adults, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0014/G Baxalta Innovations GmbH, Rapporteur: Andrea Laslop Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
AJOVY - fremanezumab - EMEA/H/C/004833/II/0011 TEVA GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bavencio - avelumab - EMEA/H/C/004338/II/0020/G Merck Europe B.V., Rapporteur: Filip Josephson Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bemfola - follitropin alfa - EMEA/H/C/002615/II/0027 Gedeon Richter Plc., Rapporteur: Paula Boudewina van Hennik Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Betaferon - interferon beta-1b - EMEA/H/C/000081/II/0129 Bayer AG, Rapporteur: Martina Weise Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Cegfila - pegfilgrastim - EMEA/H/C/005312/II/0004/G Mundipharma Corporation (Ireland) Limited, Duplicate, Duplicate of Pelmeg, Rapporteur: Koenraad Norga Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 11.06.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cinacalcet Mylan - cinacalcet - EMEA/H/C/004014/II/0009 Mylan S.A.S, Generic, Generic of Mimpara, Rapporteur: Tomas Radimersky Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 02.07.2020, 30.04.2020.	
CRYSVITA - burosumab - EMEA/H/C/004275/II/0017, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Daptomycin Hospira - daptomycin - EMEA/H/C/004310/II/0014/G Pfizer Europe MA EEIG, Generic, Generic of Cubicin, Rapporteur: Kolbeinn Gudmundsson Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Dukoral - cholera vaccine (inactivated, oral) - EMEA/H/C/000476/II/0062/G Valneva Sweden AB, Rapporteur: Kristina Dunder, "B.II.b.3.z (type II), B.II.c.1.z) (type IB), A.4 (type IA), A.5.a (type IAin) Opinion adopted on 17.09.2020.	See agenda item 9.1 Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004250/II/0019 Zentiva k.s., Generic, Generic of Atripla, Rapporteur: Tomas Radimersky Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Emtricitabine/Tenofovir disoproxil Zentiva - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137/II/0015 Zentiva k.s., Generic, Generic of Truvada, Rapporteur: Alar Irs Request for Supplementary Information adopted on 03.09.2020, 28.05.2020.	Request for supplementary information adopted with a specific timetable.
Entyvio - vedolizumab - EMEA/H/C/002782/II/0053 Takeda Pharma A/S, Rapporteur: Armando Genazzani Opinion adopted on 04.09.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Extavia - interferon beta-1b - EMEA/H/C/000933/II/0102 Novartis Europharm Limited, Informed Consent of Betaferon, Rapporteur: Martina Weise Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.

Eylea - aflibercept - EMEA/H/C/002392/II/0062/G Bayer AG, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0002 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0004/G Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Gardasil - human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0086 MSD Vaccins, Rapporteur: Kristina Dunder Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Herzuma - trastuzumab - EMEA/H/C/002575/II/0031 Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0116 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 16.07.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0117 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Idacio - adalimumab - EMEA/H/C/004475/II/0006/G Fresenius Kabi Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0044/G, Orphan	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020.	Members were in agreement with the CHMP recommendation.
ILARIS - canakinumab - EMEA/H/C/001109/II/0069/G Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 04.09.2020. Request for Supplementary Information adopted on 02.07.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Imraldi - adalimumab - EMEA/H/C/004279/II/0037/G Samsung Bioepis NL B.V., Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0047/G Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0050 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Invokana - canagliflozin - EMEA/H/C/002649/II/0052/G Janssen-Cilag International NV, Rapporteur: Martina Weise Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0014 Bayer AG, Rapporteur: Kirstine Moll Harboe Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kovaltry - octocog alfa - EMEA/H/C/003825/II/0031 Bayer AG, Rapporteur: Kristina Dunder Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lamzede - velmanase alfa -	Positive Opinion adopted by consensus on

EMEA/H/C/003922/II/0012/G, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020.	03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0010/G Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Sinan B. Sarac Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
LUTATHERA - lutetium (177Lu) oxodotreotide - EMEA/H/C/004123/II/0021/G, Orphan Advanced Accelerator Applications, Rapporteur: Janet Koenig Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
MabThera - rituximab - EMEA/H/C/000165/II/0173/G Roche Registration GmbH, Rapporteur: Sinan B. Sarac Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
MabThera - rituximab - EMEA/H/C/000165/II/0176 Roche Registration GmbH, Rapporteur: Sinan B. Sarac Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Movymia - teriparatide - EMEA/H/C/004368/II/0020 STADA Arzneimittel AG, Duplicate, Duplicate of Terrosa, Rapporteur: Milena Stain, "SmPC section 6.5 was updated. The MAH took the opportunity to amend SmPC section 4.4 to add traceability information and to align the product information to the QRD template version 10.1. Moreover, the applicant fulfils the EMA request dated 12 March 2020 to amend the packaging labelling elements in Annex IIIA. The Package Leaflet introduces amendments to the details of local representatives." Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. 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	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 25.06.2020.	
Nepexto - etanercept - EMEA/H/C/004711/II/0002 Mylan IRE Healthcare Limited, Rapporteur: Martina Weise Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
NovoMix - insulin aspart - EMEA/H/C/000308/II/0105 Novo Nordisk A/S, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Nucala - mepolizumab - EMEA/H/C/003860/II/0033 GlaxoSmithKline Trading Services Limited, Rapporteur: Peter Kiely Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Oncaspar - pegaspargase - EMEA/H/C/003789/II/0035 Les Laboratoires Servier, Rapporteur: Alexandre Moreau Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0012/G Portola Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Pazenir - paclitaxel - EMEA/H/C/004441/II/0007 ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Milena Stain Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 16.07.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Pelmeg - pegfilgrastim - EMEA/H/C/004700/II/0006/G Mundipharma Corporation (Ireland) Limited, Rapporteur: Koenraad Norga Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 30.04.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0068	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP

Merck Europe B.V., Rapporteur: Kirstine Moll Harboe Opinion adopted on 10.09.2020. Request for Supplementary Information adopted on 09.07.2020.	Members were in agreement with the CHMP recommendation.
Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0071 Merck Europe B.V., Rapporteur: Kirstine Moll Harboe Opinion adopted on 04.09.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Perjeta - pertuzumab - EMEA/H/C/002547/II/0049/G Roche Registration GmbH, Rapporteur: Sinan B. Sarac Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0002/G, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Posaconazole Accord - posaconazole - EMEA/H/C/005005/II/0002 Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Kolbeinn Gudmundsson Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0160 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 18.06.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0164 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation
Repatha - evolocumab - EMEA/H/C/003766/II/0044 Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 10.09.2020.	
Rilutek - riluzole - EMEA/H/C/000109/II/0065 Sanofi Mature IP, Rapporteur: Kirstine Moll Harboe Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Sancuso - granisetron - EMEA/H/C/002296/II/0058 Kyowa Kirin Holdings B.V., Rapporteur: Simona Stankeviciute Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Simponi - golimumab - EMEA/H/C/000992/II/0095 Janssen Biologics B.V., Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Strensiq - asfotase alfa - EMEA/H/C/003794/II/0046, Orphan Alexion Europe SAS, Rapporteur: Armando Genazzani Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Terrosa - teriparatide - EMEA/H/C/003916/II/0018 Gedeon Richter Plc., Rapporteur: Milena Stain, "SmPC section 6.5. was updated. The MAH took the opportunity to amend SmPC section 4.4. to add traceability information and to align the product information to the QRD template version 10.1. Moreover, the applicant fulfils the EMA request dated 12 March 2020 to amend the packaging labelling elements in Annex IIIA. Editorial changes introduced in the Package Leaflet." Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Trepulmix - treprostinil sodium - EMEA/H/C/005207/II/0002/G, Orphan SciPharm Sarl, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Trogarzo - ibalizumab - EMEA/H/C/004961/II/0008 Theratechnologies Europe Limited, Rapporteur: Johann Lodewijk Hillege	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Opinion adopted on 03.09.2020.	recommendation.
Victoza - liraglutide - EMEA/H/C/001026/II/0057 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 25.06.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0012/G, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Tuomo Lapveteläinen Opinion adopted on 10.09.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Yellox - bromfenac - EMEA/H/C/001198/II/0025 Bausch Health Ireland Limited, Rapporteur: Kirstine Moll Harboe Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Zevalin - ibritumomab tiuxetan - EMEA/H/C/000547/II/0051/G Ceft Biopharma s.r.o., Rapporteur: Sinan B. Sarac Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 28.05.2020.	Positive Opinion adopted by consensus on 03.09.2020. 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** **Hexyon-EMEA/H/C/002796/WS1784/0100/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 05.06.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1797/G **Hexacima-EMEA/H/C/002702/WS1797/0100/G** **Hexaxim-EMEA/H/W/002495/WS1797/0105/G** **Hexyon-EMEA/H/C/002796/WS1797/**	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

0104/G Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 05.06.2020.	
WS1838 **Infanrix hexa-EMEA/H/C/000296/WS1838/0279** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1865 **Levemir-EMEA/H/C/000528/WS1865/0099** **Ryzodeg-EMEA/H/C/002499/WS1865/0040** **Tresiba-EMEA/H/C/002498/WS1865/0046** **Xultophy-EMEA/H/C/002647/WS1865/0037** Novo Nordisk A/S, Lead Rapporteur: Kristina Dunder Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1866 **Actraphane-EMEA/H/C/000427/WS1866/0084** **Actrapid-EMEA/H/C/000424/WS1866/0077** **Insulatard-EMEA/H/C/000441/WS1866/0082** **Mixtard-EMEA/H/C/000428/WS1866/0085** **Protaphane-EMEA/H/C/000442/WS1866/0081** Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1882 **HyQvia-EMEA/H/C/002491/WS1882/0060** **Kiovig-EMEA/H/C/000628/WS1882/0102** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1884 **Nuwiq-EMEA/H/C/002813/WS1884/0037** **Vihuma-EMEA/H/C/004459/WS1884/**	Request for supplementary information adopted with a specific timetable.

0019 Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 03.09.2020.	
WS1888/G **Blitzima-EMEA/H/C/004723/WS1888/0033/G** **Ritemvia-EMEA/H/C/004725/WS1888/0033/G** **Truxima-EMEA/H/C/004112/WS1888/0036/G** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
WS1889/G **M-M-RVAXPRO-EMEA/H/C/000604/WS1889/0101/G** **ProQuad-EMEA/H/C/000622/WS1889/0141/G** MSD Vaccins, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. 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

Abilify - aripiprazole - EMEA/H/C/000471/II/0136/G Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of the product information and the Company Core Data Sheet (CCDS) due to new safety data. The applicant used the opportunity to revised the wording for "Akathesia" in the package leaflet for a better differentiation between akathisia and restless leg syndrome (adaption to Abilify Maintena)." Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Abilify Maintena - aripiprazole - EMEA/H/C/002755/II/0035 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "update of the PI to add an alternate initiation regimen" Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 28.05.2020, 26.03.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Abilify Maintena - aripiprazole -	Positive Opinion adopted by consensus on

EMEA/H/C/002755/II/0037 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, "to update the product information with "DRESS" as new identified ADR in section 4.8 of the SmPC and subsequently in section 4 of the package leaflet according to the current CCDS version." Opinion adopted on 10.09.2020.	10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
AJOVY - fremanezumab - EMEA/H/C/004833/II/0008/G TEVA GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the 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." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 11.06.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0028 sanofi-aventis groupe, Rapporteur: Martina Weise, "Submission of information in relation to human experience of use of teriflunomide during pregnancy from an analysis of the data recorded in the global safety database and available sources (clinical trial cases, registries and cohort studies, literature and post-marketing pregnancy reports). The MAH updated sections 2 and 4.4 of the SmPC to align with the updated annex of the guideline excipients with regards to sodium. The Labelling and Package Leaflet are updated accordingly." Opinion adopted on 10.09.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
BeneFIX - nonacog alfa - EMEA/H/C/000139/II/0164 Pfizer Europe MA EEIG, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.2 of the SmPC to remove reference to the severity of the disease pertaining to the prophylaxis regimen. In addition, the product information is being brought in line with the most recent QRD	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

template version 10.1 and the MAH has taken the opportunity to include in section 4.4 of the SmPC an update related to the guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' regarding the sodium content." Opinion adopted on 17.09.2020.	
Benlysta - belimumab - EMEA/H/C/002015/II/0081 GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to correct the result for the other efficacy endpoint of time to first severe flare over 52 weeks for the clinical study BEL114055 conducted in paediatric patients. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bevespi Aerosphere - glycopyrronium / formoterol fumarate dihydrate - EMEA/H/C/004245/II/0006 AstraZeneca AB, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add 'Urinary Tract Infection' (UTI) to the list of adverse drug reactions (ADRs) with frequency common, based on final results from study ETHOS (PT010005): A randomized, double-blind, multi-center, parallel-group study to assess the efficacy and safety of PT010 (budesonide/glycopyrronium/formoterol fumarate) relative to PT003 (glycopyrronium/formoterol fumarate, Bevespi Aerosphere) and PT009 (budesonide/formoterol fumarate) on COPD exacerbations over a 52-week treatment period in subjects with moderate to very severe COPD; and study KRONOS (PT010006): A randomized, double-blind, parallel-group, 24-week, chronic-dosing, multi-center study to assess the efficacy and safety of PT010, PT003, and PT009 compared with Symbicort Turbuhaler as an active control in subjects with moderate to very severe COPD. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide -	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP

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." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 25.06.2020.	Members were in agreement with the CHMP recommendation.
Brintellix - vortioxetine - EMEA/H/C/002717/II/0025 H. Lundbeck A/S, Rapporteur: Karin Janssen van Doorn, "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." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 25.06.2020, 17.04.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Caelyx pegylated liposomal - doxorubicin - EMEA/H/C/000089/II/0094 Janssen-Cilag International NV, Rapporteur: Ondřej Slanař, "Update of sections 4.2 and 4.8 of the SmPC in line with the SmPC guideline. In addition, the MAH took the opportunity to update the PI in line with the QRD template version 10.1 and with the EDQM standard terms. Furthermore, the list of local representatives in the Package Leaflet is updated." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 03.09.2020, 14.05.2020.	
Constella - linaclotide - EMEA/H/C/002490/II/0049 Allergan Pharmaceuticals International Limited, Rapporteur: Martina Weise, "Update of section 4.6 of the SmPC based on the final results of Lactation study 1915-7/LIN-PK-01 listed as a category 3 study in the RMP; this is an open-label, multiple-dose, milk-only lactation study in lactating women receiving linaclotide therapeutically. The Package Leaflet is updated accordingly." Opinion adopted on 04.09.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cresemba - isavuconazole - EMEA/H/C/002734/II/0030, Orphan Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.3 of the SmPC to update the description of non-clinical information following REC 002.2, based on final results from study B-7855, a 2-year carcinogenicity studies in mice. In this context, the safety margins described in section 5.3 based on PK data provided with the initial Cresemba MAA have been recalculated, corrected and expressed based on exposure (AUC; including free fraction) rather than based on body surface area (only bound fraction)." Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
CRYSVITA - burosumab - EMEA/H/C/004275/II/0018, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC to include the new ADR 'blood phosphorous increased', which includes the terms blood phosphorus increased and hyperphosphataemia, with a frequency of 'not known' based on post-marketing data. In addition, the MAH took the opportunity to implement some editorial changes in SmPC section 4.8 and to include an age qualifier for the paediatric population (>1 year of age) for clarity. The Package Leaflet has been updated accordingly." Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Deltyba - delamanid - EMEA/H/C/002552/II/0045, Orphan Otsuka Novel Products GmbH, Rapporteur: Koenraad Norga, "Submission of the revised final study report from the Hollow Fiber System	Request for supplementary information adopted with a specific timetable.

- Tuberculosis (HFS-TB) study listed as a Specific Obligation in the Annex II of the Product Information. This is a PK/PD study carried out using the HFS-TB model and designed to obtain the pharmacodynamic target (PDT) of delamanid in the HFS-TB, using Mycobacterium tuberculosis (Mtb) both under log-phase growth conditions and under low pH conditions (pH 5.8). The Annex II is updated accordingly. This submission addresses the post-authorisation measure SOB 009." Request for Supplementary Information adopted on 17.09.2020.	
Dupixent - dupilumab - EMEA/H/C/004390/II/0032 sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, "Update of SmPC sections 4.8 and 5.1 based on results of a paediatric study report, LTS12551 to fulfil the article 46 requirement (Regulation EC No 1901/2006). The LTS12551 study is an open–label extension study to evaluate the long-term safety and tolerability of dupilumab in patients with asthma." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
ELOCTA - efmoroctocog alfa - EMEA/H/C/003964/II/0039 Swedish Orphan Biovitrum AB (publ), Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.8 and 5.1 of the SmPC to include the results of study 997HA306 in previously untreated patients which have previously been assessed as an Article 46 paediatric submission and renewal (EMEA/H/C/003964/R/0036)." Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Erleada - apalutamide - EMEA/H/C/004452/II/0007/G Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.8 of the SmPC in order to add toxic epidermal necrolysis and decreased appetite to the list of adverse drug reactions (ADRs) with frequency 'not known' and 'very common' respectively based on cumulative safety reviews; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 10.09.2020.	
EXJADE - deferasirox - EMEA/H/C/000670/II/0073 Novartis Europharm Limited, Rapporteur: Alexandre Moreau, "Submission of the final study report from the post-authorisation pharmacovigilance measure in the Annex II and in the RMP, a single-arm interventional Phase IV, evaluating the safety of paediatric patients with transfusional hemosiderosis treated with deferasirox crushed film-coated tablets. This submission also serves to comply with Article 46 of the Regulation (EC) No 1901/2006 on medicinal products for paediatric use." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0116 Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 5.1 of the SmPC in order to change posology recommendations in adults, children and adolescents aged 8 years and older by removing the information on the lower dosing regimens that have been used in clinical studies and update the clinical information based on the review of published scientific literature including 3 observational studies in patients remaining on standard dose of Fabrazyme or switching to low-dose Fabrazyme (0.5 mg/kg every 2 weeks) or to the registered dose of agalsidase alfa (0.2 mg/kg every 2 weeks). In addition, the MAH took the opportunity to propose changes in the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 28.05.2020.	See agenda 9.1 Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fotivda - tivozanib - EMEA/H/C/004131/II/0012 EUSA Pharma (Netherlands) B.V., Rapporteur: Bruno Sepodes, "Submission of AV-951-15-303 (TIVO-3) study (Phase 3 randomized, controlled, multi-centre, open-label study to compare tivozanib versus sorafenib in RCC patients who have failed 2 or 3 prior systemic regimens) in order to present the second interim OS analysis and to fulfil PAM LEG-003	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

procedure." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 28.05.2020.	
Gardasil - human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0087 MSD Vaccins, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update the information of the duration of immunity following a 2-dose schedule of Gardasil based on the results from extension Protocol V501-167; this was a randomized clinical trial that assessed the immunogenicity of a 2 dose schedule of the qHPV in adolescents 9 to 13 years of age compared to a 3-dose schedule in young women 16 to 26 years of age. In addition, the MAH is taking the opportunity to implement the following guidelines/template in the Product Information: Annex to the European Commission, Volume 2C, Guidelines, Medicinal products for human use, Safety, environment and information, Excipients in the label and package leaflet of medicinal products for human use, Rev 2, Mar 2018; and the Guideline on quality aspects included in the product information for vaccines for human use EMA/CHMP/BWP/133540/2017. Furthermore, the PI is being brought in line with the latest QRD template (version 10.1) and some minor editorial changes regarding the nomenclature for excipients have been implemented." Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0040 MSD Vaccins, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in relation to the post-marketing safety experience information, currently based on the post-marketing safety experience for the quadrivalent HPV vaccine, based on 4 years of post-marketing experience of the 9vHPV vaccine. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the wording regarding sodium according to the Guideline on quality aspects included in the product information for	Request for supplementary information adopted with a specific timetable.

vaccines for human use EMA/CHMP/BWP/133540/2017 and to implement an editorial change in sections 5.1 and 9 of the SmPC, and the package leaflet." Request for Supplementary Information adopted on 10.09.2020.	
Gliolan - 5-aminolevulinic acid - EMEA/H/C/000744/II/0018/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Bruno Sepodes, "To update section 4.2 of the SmPC to exclude re-administration if surgery is delayed by less than 12 hours. 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." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 16.07.2020, 05.06.2020, 17.04.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Imnovid - pomalidomide - EMEA/H/C/002682/II/0038, Orphan Celgene Europe BV, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC with information from a paediatric study in patients aged 4 to 18 years with recurrent or progressive high-grade glioma, medulloblastoma, ependymoma or diffuse intrinsic pontine glioma (DIPG) with primary location in the CNS." Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Infanrix hexa - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and Haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/000296/II/0275 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "Update of sections 4.8 and 5.1 of the SmPC in relation to the frequency of adverse reactions somnolence and fatigue and to update the safety and immunogenicity information in infants and toddlers born to mothers vaccinated with dTpa during pregnancy; based on data generated from DTPA-048 and DTPA-049; these are phase IV, open-label, non-randomised, multicentre studies aimed to provide immunological responses to Infanrix hexa in terms of seroprotection status	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

for diphtheria (D), tetanus (T), HBs antigen, inactivated poliovirus (IPV) and Haemophilus influenzae type b (Hib) antigens (PRP) and in terms of vaccine or booster responses to the pertussis antigens, 1 month after the last dose of the primary vaccination or the booster dose. The MAH took the opportunity to update the posology information in the package leaflet to align it with the SmPC. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020.	
Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0012 Bayer AG, Rapporteur: Kirstine Moll Harboe, "Update of sections 4.8 and 5.1 of the SmPC to reflect the final study results of the long-term extension study 13024 (PROTECT VIII). This extension study is a category 3 study of the Jivi RMP (MEA-005). The PL is updated to reflect a change in the contact of a local representative." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Juluca - dolutegravir / rilpivirine - EMEA/H/C/004427/II/0027 ViiV Healthcare B.V., Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to add new information on resistance in vivo and clinical efficacy, based on final results from studies 201636 (SWORD-1) and 201637 (SWORD-2): Phase III, Randomized, Multicenter, Parallel-Group, Non-Inferiority Studies Evaluating the Efficacy, Safety, and Tolerability of Switching to Dolutegravir plus Rilpivirine from Current INSTI-, NNRTI-, or PI-Based Antiretroviral Regimen in HIV-1-Infected Adults who are Virologically Suppressed." Request for Supplementary Information adopted on 23.07.2020.	
Kisqali - ribociclib - EMEA/H/C/004213/II/0018 Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC to include updated information about the use of Kisqali in patients with mild, moderate or severe renal impairment	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation

based on the results of Study CLEE011A2116 Part II and additional data from breast cancer patients with mild or moderate renal impairment. The package leaflet is updated accordingly." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 25.06.2020, 26.03.2020, 14.11.2019.	
Lemtrada - alemtuzumab - EMEA/H/C/003718/II/0032 Sanofi Belgium, Duplicate, Duplicate of Lemtrada (WD), Rapporteur: Kirstine Moll Harboe, "to update sections 4.4 and 4.8 of the SmPC to amend the existing warning and adverse drug reactions on Epstein-Barr virus (EBV) infections and EBV associated hepatitis, following safety evaluation report (SER). The package leaflet is updated accordingly." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lorviqua - lorlatinib - EMEA/H/C/004646/II/0008 Pfizer Europe MA EEIG, Rapporteur: Sinan B. Sarac, "Update of sections 4.2, 4.4 and 4.8 to include the new term "Psychotic effects" as an adverse drug reaction (ADR) based on the cumulative review of the data available through Clinical Databases and Safety Database. The package leaflet has been updated accordingly." Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Luminity - perflutren - EMEA/H/C/000654/II/0033 Lantheus EU Limited, Rapporteur: Peter Kiely, "Update of section 4.4 of the SmPC on the hypersensitivity reactions for patients with a history of allergy to polyethylene glycol (PEG), following a signal identified from a review of the existing and previously submitted safety information and of section 6.1 of the SmPC to clarify the abbreviations used in the list of excipients. The Package Leaflet is updated in accordance." Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
MabThera - rituximab - EMEA/H/C/000165/II/0177 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, "Submission of the final Clinical Study Report for study WA29330 (Pemphix) in order	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

to fulfil the Post Authorisation Measure in the Annex IID of the MabThera PI following 48 week safety follow-up period of the study. In addition, the marketing authorisation holder took the opportunity to update the statement on sodium in the package leaflet and to introduce minor editorial corrections in the labelling and package leaflet." Opinion adopted on 03.09.2020.	
Nerlynx - neratinib - EMEA/H/C/004030/II/0015 Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC in order to include final OS results from study 3144A2-3004-WW, a randomised, double-blind, placebo-controlled trial of neratinib after trastuzumab in women with early-stage HER-2/neu overexpressed/amplified breast cancer." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Nplate - romiplostim - EMEA/H/C/000942/II/0078 Amgen Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.8 and 5.1 of the SmPC to reflect the main results from study 20101221 following the assessment performed under Article 46 of Regulation 1901/2006. Study 20101221 is an open-label trial to evaluate safety in children from 1 year of age to less than 18 years of age with primary ITP regardless of splenectomy status, including a protocol supplement to implement bone marrow evaluations." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Obizur - susoctocog alfa - EMEA/H/C/002792/II/0030 Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, "Update of the sections 4.4 and 4.8 of the SmPC to add information on anamnesic reaction and to list it with the frequency unknown." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 25.06.2020, 26.03.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
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	Request for supplementary information adopted with a specific timetable.

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 10.09.2020, 05.06.2020.	
Praxbind - idarucizumab - EMEA/H/C/003986/II/0020 Boehringer Ingelheim International GmbH, Rapporteur: Jan Mueller-Berghaus, "C.I.4 Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update information on paediatrics based on final results from study 1321.7. This was single dose, open label, uncontrolled, safety trial of intravenous administration of idarucizumab to paediatric patients enrolled from ongoing phase IIb/III clinical trials with dabigatran etexilate for the treatment and secondary prevention of venous thromboembolism listed as part of PIP (P46)." Opinion adopted on 17.09.2020. Request for Supplementary Information adopted on 23.07.2020.	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Slenyto - melatonin - EMEA/H/C/004425/II/0017 RAD Neurim Pharmaceuticals EEC SARL, Rapporteur: Kristina Dunder, "The update of the product information to reflect information from children treated with Circadin during the French RTU program and the known safety profile of Circadin authorised for adults." Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
SomaKit TOC - edotreotide - EMEA/H/C/004140/II/0015, Orphan Advanced Accelerator Applications, Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.4, 4.5 and 4.6 of the SmPC in order to amend an existing warning extending the period during which close contact with infants and pregnant women should be restricted, add information on interactions with	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

glucocorticosteroids and extend the period during which breastfeeding should be interrupted. The Package Leaflet is updated accordingly. Additionally, the MAH took the opportunity to update the details of local representatives." Opinion adopted on 03.09.2020.	
Somavert - pegvisomant - EMEA/H/C/000409/II/0097 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.4, 4.6 and 5.3 of the SmPC in order to add a new warning on acromegaly control and adjustment of doses during pregnancy, include information on use during pregnancy and effects on fertility, as well as an update on the effects of the drug product on the early embryonic development and embryo-foetal development in pregnant rabbits, following international regulatory procedures outcomes and literature review. The MAH took the opportunity to make editorial changes to the Package Leaflet." Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Stocrin - efavirenz - EMEA/H/C/000250/II/0123 Merck Sharp & Dohme B.V., Duplicate, Duplicate of Sustiva, Rapporteur: Bruno Sepodes, "Update of sections 4.4 and 4.8 of the SmPC in order to add new warnings regarding late-onset neurotoxicity, including ataxia and encephalopathy, based on reviews of the published literature and MAH safety database; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make minor editorial amendments." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Sunosi - solriamfetol - EMEA/H/C/004893/II/0004 Jazz Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig, "Submission of the results of the Environmental Risk Assessment Phase II risk assessment of solriamfetol." Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
TAGRISSO - osimertinib - EMEA/H/C/004124/II/0037 AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, "Update of section 4.8 of the SmPC in order to add cutaneous vasculitis to the list of	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

adverse drug reactions (ADRs) with frequency "uncommon", based on the review of the available safety data. In addition, the MAH took the opportunity of this variation to introduce minor editorial updates to the SmPC." Opinion adopted on 03.09.2020.	
Talzenna - talazoparib - EMEA/H/C/004674/II/0004 Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to include the final OS results from Study 673-301 (C3441009, EMBRACA), a phase 3, open-label, randomised, multicentre study of talazoparib vs chemotherapy in patients with germline BRCA mutated HER-2 negative locally advanced or metastatic breast cancer. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 11.06.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tasigna - nilotinib - EMEA/H/C/000798/II/0106 Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, "Update of section "4.8 Undesirable effects" of the SmPC with 'Facial paralysis' with the frequency unknown. Section "4 possible side effects" of the package leaflet has been updated accordingly. The QRD template version 10.1 has been implemented as part of this PI update. The Annex III has been updated accordingly. Editorial changes have been made to the Annex II to follow the new QRD template." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0037 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to amend the information regarding immunogenicity further to the assessment of the effect of atezolizumab neutralising antibodies on the pharmacokinetics and efficacy endpoints including OS, PFS and ORR on the NSCLC studies POPLAR, OAK, IMpower 150, IMpower 130, IMPower 131 and IMpower 132 as well as on studies IMvigor 211 (UC), IMmotion 151 (RCC), IMpower 133 (SCLC) and IMpassion 130 (TNBC), as recommended by the CHMP."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 03.09.2020, 12.03.2020.	
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0047 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to add headache, dry skin and blood creatinine increased to the list of adverse drug reactions (ADRs) for atezolizumab given as monotherapy identified in study WO29636. The MAH has taken this opportunity to update the frequencies of existing ADRs in section 4.8 subsections 'Summary of the safety profile' and 'Description of selected adverse reactions' to reflect the updated pool of patients for atezolizumab monotherapy. Other minor corrections and editorial changes are being proposed. The package leaflet is updated accordingly." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tegsedi - inotersen - EMEA/H/C/004782/II/0011, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, "Update of SmPC section 5.3 to reflect the results of rat carcinogenicity study." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 28.05.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tresiba - insulin degludec - EMEA/H/C/002498/II/0047 Novo Nordisk A/S, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update the description of day-to-day variability in glucose-lowering effect further to assessment of post-authorisation measure LEG013. In addition, the MAH took the opportunity to make editorial corrections in section 5.2 of the SmPC ." Request for Supplementary Information adopted on 10.09.2020.	Request for supplementary information adopted with a specific timetable.
Uptravi - selexipag - EMEA/H/C/003774/II/0029 Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC based on interim survival and safety data from study AC-065A303 a long-term single-arm, open-label study to evaluate the safety and tolerability of selexipag / ACT-293987 in patients with Pulmonary Arterial Hypertension.	Request for supplementary information adopted with a specific timetable.

In addition, the MAH took the opportunity to implement minor editorial changes and update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 03.09.2020.	
Vfend - voriconazole - EMEA/H/C/000387/II/0137/G Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, "Grouping of two type II variations: -to update section 4.4 of the SmPC in order to add a new warning on adrenal events, along with editorial changes to the paragraph and the abbreviation of severe cutaneous adverse reactions (SCARs), -to update section 4.5. of the SmPC in order to add drug-drug interaction information with naloxegol, ivacaftor and corticosteroids following PRAC request during the assessment of PSUR 18 (for corticosteroids) and the French National Agency for the Safety of Medicines and Health Products (ANSM) update of the French "Medical Interaction Thesaurus" (May 2018), where voriconazole is classified as a strong CYP3A4 inhibitor. In addition the MAH has taken the opportunity to update the information in the SmPC in line with the EU excipient guidance from October 2017 (SANTE-2017-11668) for sodium and cyclodextrin, to introduce a correction to the amount of sodium per vial for the IV presentations in sections 2. QUALITATIVE AND QUANTITATIVE COMPOSITION and 4.4 Special warnings and precautions for use of the SmPC. The Package Leaflet is updated accordingly. Following a recent discussion with EMA/EDQM; the MAH is also updating Annex IIIA Outer carton text for both iv presentations 16. INFORMATION IN BRAILLE to include: "Justification for not including Braille accepted." In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1." Opinion adopted on 10.09.2020. Request for Supplementary Information adopted on 23.07.2020, 14.05.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Wakix - pitolisant - EMEA/H/C/002616/II/0023/G, Orphan Bioprojet Pharma, Rapporteur: Alexandre	Request for supplementary information adopted with a specific timetable.

Moreau, PRAC Rapporteur: Kirsti Villikka, "Update of the product information based on new clinical data from the open-label, long-term treatment of EDS (with or without cataplexy) in narcolepsy P09-10 HARMONY III study, and the randomised, double-blind, placebo-controlled, drug abuse potential study (P16-02). The proposed update also includes results of a post approval network meta-analysis which compares efficacy and safety of multiple treatments, multi-arm studies, and multi-criteria treatment decisions." Request for Supplementary Information adopted on 03.09.2020.	
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 04.09.2020, 05.06.2020.	Request for supplementary information adopted with a specific timetable.
Xarelto - rivaroxaban - EMEA/H/C/000944/II/0079 Bayer AG, Rapporteur: Kristina Dunder, "Submission of the final report from the CASSINI study, an interventional phase III study comparing 10 mg rivaroxaban to placebo in the prevention of venous thromboembolism in ambulatory cancer patients." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Xeljanz - tofacitinib - EMEA/H/C/004214/II/0025 Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan, "To submit the final report from study A3921092, a long term, open-label extension study of tofacitinib for the treatment of adult patients with psoriatic arthritis (PsA),	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

listed as a category 3 study in the RMP. An updated RMP version 11.1 has also been submitted. The MAH took also the opportunity to update the milestones for study A3921347 (US UC active surveillance study) in the RMP." Opinion adopted on 03.09.2020.	
XOSPATA - gilteritinib - EMEA/H/C/004752/II/0003, Orphan Astellas Pharma Europe B.V., Rapporteur: Bjorg Bolstad, "C.I.4 - Update of section 5.2 of the SmPC in order to update information about Transporter drug-drug interactions based on final results from in vitro transporter studies identified as recommendations by CHMP (REC003) during the initial approval. In addition, the MAH took the opportunity to perform minor corrections and editorial changes in the PI." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0053 Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, "Update of sections 4.2, 4.8 and 4.9 of the SmPC in order to add eosinophilic pneumonia and encephalopathy as adverse drug reactions (ADRs), with frequencies 'not known' and 'uncommon' respectively, based on a review of the MAH global safety database and literature. The package leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) clarified in section 4.8 of the SmPC that the ADRs agranulocytosis, neutropenia and eosinophilia have been identified post-marketing. Furthermore, the PI is brought in line with the latest QRD template version 10.1 and the MAH took the opportunity to make minor editorial changes." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1749 AZILECT-EMEA/H/C/000574/WS1749/0084 **Rasagiline ratiopharm-EMEA/H/C/003957/WS1749/0016** Teva B.V., Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the final report from study	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

TV1030-CNS-50024 listed as a category 3 study in the RMP. This is a non-interventional retrospective cohort study which was conducted using the United States Medicare research database to assess the potential risk of melanoma associated with the use of rasagiline mesylate in patients with Parkinson's disease. Section 4.4. of SmPC was updated to amend the information on risk of melanoma associated with the use of rasagiline. The package leaflet is updated in accordance." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020, 13.02.2020.	
WS1780 **Glyxambi-EMEA/H/C/003833/WS1780/0027** **Jardiance-EMEA/H/C/002677/WS1780/0049** **Synjardy-EMEA/H/C/003770/WS1780/0046** Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.4. of the SmPC for Jardiance, Synjardi and Glyxambi in the SmPC subsection `Diabetic ketoacidosis' to reflect new data from 2 phase III interventional studies (EASE-2 1245.69 and EASE-3 1245.72) from the clinical trial program of empagliflozin as an adjunct to insulin in patients with type 1 diabetes." Opinion adopted on 04.09.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1798 **Lyrica-EMEA/H/C/000546/WS1798/0104** **Pregabalin Pfizer-EMEA/H/C/003880/WS1798/0033** Upjohn EESV, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 and section 5.1 of the SmPC to reflect data from study A0081106 "A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age With Partial Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age With Primary Generalized Tonic-Clonic Seizures"." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 07.05.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1814	Positive Opinion adopted by consensus on

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 of the SmPC to add hypersensitivity reactions including anaphylaxis, angiooedema, urticaria and rash with a frequency estimated as "rare" based on review of the Applicant clinical safety database. The package leaflet is updated accordingly. In addition, minor changes are introduced in line with QRD template and to align the Product information with the approved product information of products containing same active substance of the same Applicant (Relvar/Anoro/Incruse/Revinty)" Opinion adopted on 10.09.2020. Request for Supplementary Information adopted on 11.06.2020.	10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1874/G **Advagraf-EMEA/H/C/000712/WS1874/ 0058/G** **Modigraf-EMEA/H/C/000954/WS1874/ 0036/G** Astellas Pharma Europe B.V., Lead Rapporteur: Jayne Crowe, "C.I.4 - Update of sections 4.4 and 4.5 of the SmPC on the drug-drug interaction with CYP3A4 based on a comprehensive review of available data. Section 4.5 of the SmPC is also updated to include impact of direct acting antiviral therapy. C.I.z - Update of section 4.8 of the SmPC to add posterior reversible encephalopathy syndrome as an adverse reaction. The MAH took also the opportunity to change the SOC for febrile neutropenia from General disorders and administration site conditions to Blood and lymphatic system disorders in section 4.8 of the SmPC and to update the instruction for handling of the product in section 6.6 of the SmPC. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
WS1883 **Prezista-EMEA/H/C/000707/WS1883/ 0108**	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Rezolsta-EMEA/H/C/002819/WS1883/0038 **Symtuza-EMEA/H/C/004391/WS1883/0025** Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC for Prezista, Rezolsta and Symtuza in order to include information on the interaction with Clopidogrel. The MAH also takes the opportunity to make several editorial changes in the SmPC to include the sodium-free statement in section 4.4 and remove simeprevir, boceprevir and nelfinavir from section 4.5 from the list of interactions, as they are no longer marketed." Opinion adopted on 03.09.2020.	recommendation.
WS1893 **Blitzima-EMEA/H/C/004723/WS1893/0034** **Ritemvia-EMEA/H/C/004725/WS1893/0034** **Truxima-EMEA/H/C/004112/WS1893/0037** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Hans Christian Siersted, "To provide CT-P10 3.4 final CSR along with the updated RMP (version 10.1) in compliance with the post-authorisation measure. CT-P10 3.4 was a Phase 3, randomised, parallel-group, active-controlled, double-blind study to compare efficacy and safety between CT-P10 and Rituxan in patients with LTBFL. Study CTP10 3.4 was designed to demonstrate similarity of efficacy of CT-P10 to Rituxan in patients with LTBFL. The patients were randomised in a 1:1 ratio in a double-blinded fashion." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.

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	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 11.06.2020.	
Bosulif - bosutinib - EMEA/H/C/002373/II/0043 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 5.3 of the SmPC in order to update non-clinical information following the final results from the six-month transgenic rasH2 mouse carcinogenicity study, listed as a category 3 in the current approved RMP version 4.5.; The RMP version 5.0 has also been submitted. The MAH took the opportunity to implement changes resulting from the revision of the SmPC guideline on excipients, applied in the SmPC section 4.4 and in the Package Leaflet section 2." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Defitelio - defibrotide - EMEA/H/C/002393/II/0048, Orphan Gentium S.r.l., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update the RMP version 8.0 in line with PRAC recommendations, following approval of PBRER 12 (EMEA/H/C/PSUSA/00010086/201910), to update section SVII 2, Safety Concerns and Reclassification for removal of the Important Potential Risks and Missing Information from the RMP: Injection site reactions/infections, including septicaemia as a serious complication of these reactions/infections; Immunogenicity (generation of anti-nuclear antibodies); Use in patients with grade B-D GvHD; Use in patients with ethnic background other than Caucasian; use in patients >65 years of age and off-label use; the RMP has been also updated with the results of study (DF VOD 2013 03 REG). Furthermore, the Marketing Authorisation Holder took the opportunity to: · Update Sub-section Cardiac Electrophysiology in section 5.1 of Annex I (SmPC) to correct a typographical error; · Introduce other minor editorial and QRD updates throughout Annexes I-III; · Change Annex IIIB in line with the excipients	Positive Opinion adopted by consensus on 17.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

warning for medicinal products containing Sodium." Opinion adopted on 17.09.2020.	
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0047, Orphan MediWound Germany GmbH, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the final study report for study MW2013-06-01, listed as a category 3 study in the RMP. This is an international, observational retrospective, data-collection study assessing efficacy of applied risk-minimisation measures in burn patients treated with NexoBrid. In addition, the MAH took the opportunity to revise the RMP in line with the new RMP template (GVP Rev. 2) and to change the due date for studies MW2013-06-01 and MW2010-03-02 (DETECT). The updated RMP version 7.1 is acceptable." Opinion adopted on 04.09.2020. Request for Supplementary Information adopted on 14.05.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NUBEQA - darolutamide - EMEA/H/C/004790/II/0002 Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser, "Update of section 5.1 of the SmPC in order to update efficacy information based on final OS results from study 17772 (ARAMIS) listed as a PAES in the Annex II; this is a multinational, randomised, double-blind, placebo-controlled, phase III efficacy and safety study of darolutamide in men with high-risk non-metastatic castration-resistant prostate cancer; the Annex II is updated accordingly. The RMP version 1.1 has also been submitted." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
Orbactiv - oritavancin - EMEA/H/C/003785/II/0030 Menarini International Operations Luxembourg S.A., Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Submission of the final report from 14-TMC-01, a Surveillance study investigation, listed as a category 3 study in the RMP, part of the global SENTRY Antimicrobial Surveillance Program platform to monitor the activity of oritavancin against Gram-positive clinical isolates collected from Europe and the US.	Request for supplementary information adopted with a specific timetable.

This application addresses PAM MEA 003.4, presenting the cumulative surveillance data from 2010 to 2019 (including the first 5-year post-approval period). The RMP version 3.0 has also been submitted." Request for Supplementary Information adopted on 03.09.2020.	
Palynziq - pegvaliase - EMEA/H/C/004744/II/0007/G, Orphan BioMarin International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4, 4.8 and 5.1 of the SmPC based on final results from studies 1655-003, a long-term extension of a Phase 2, open-label, dose-finding study and 165-302 a Phase 3, randomised, double-blind, placebo-controlled, four-arm, discontinuation study which are listed in the RMP as category 3 studies. The RMP version 2.0 has also been submitted. In addition, the SmPC was amended with minor editorial changes." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 17.04.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Rubraca - rucaparib - EMEA/H/C/004272/II/0020 Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin, "Update of sections 4.2 and 5.2 of the SmPC in order to update the information on the use of rucaparib in patients with hepatic impairment based on final results from Part I of Study CO-338-078 listed as a category 3 study in the RMP; this is a phase 1, open- label, parallel group study to determine the pharmacokinetics, safety and tolerability of rucaparib in patients with an advanced solid tumour and either moderate hepatic impairment or normal hepatic function; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to make minor corrections in the SmPC, 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 excipient guideline." Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
Rydapt - midostaurin -	Request for supplementary information adopted

EMEA/H/C/004095/II/0014, Orphan Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "C.I.4 - Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to change posology recommendations and add Special warnings and precautions for use in Paediatric population following the occurrence of severe dose limiting toxicities (DLTs) in the paediatric study CPKC412A2218 which is currently on clinical hold. The study is part of the agreed PIP (EMEA-000780-PIP01-09-M05) for which a Request for Modification was submitted on 20-Apr-2020. Section 5.1 of the SmPC and the Package Leaflet are updated accordingly. The RMP version 5.0 has also been submitted. In addition Novartis takes this opportunity to introduce minor editorial changes to align the PI to the updated QRD template version 10.1." Request for Supplementary Information adopted on 17.09.2020.	with a specific timetable.
Sivextro - tedizolid phosphate - EMEA/H/C/002846/II/0037 Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Update of section 5.1 of the SmPC in order to update the description of the potential risk of emergence of drug resistance with tedizolid phosphate, based on final results from study Surveillance of Tedizolid Activity and Resistance (STAR) listed as a category 3 study in the RMP; this is a surveillance study established in January 2014 to monitor tedizolid susceptibility activity and emergence of resistance across the US, 11 European Union countries, Russia and Turkey. The RMP version 6.2 has also been submitted." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0063 Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Update of sections 4.4 and 4.8 of the SmPC to reflect PML in the setting of mild lymphopenia based on data submitted in the ongoing PSUSA/00010143/201903. The Package Leaflet is updated accordingly. Additionally, the Product Information has been updated in line with QRD	See agenda item 9.1 Request for supplementary information adopted with a specific timetable.

template (version 10.1)." Request for Supplementary Information adopted on 17.09.2020, 28.05.2020, 30.01.2020, 19.09.2019.	
Xtandi - enzalutamide - EMEA/H/C/002639/II/0049 Astellas Pharma Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.7, 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information based on final results from study MDV3100-14 (PROSPER) listed as a PAES in the Annex II; this is a phase 3, randomized, double-blind, placebo-controlled, efficacy and safety study of enzalutamide in patients with nonmetastatic castration-resistant prostate cancer; the Package Leaflet and Annex II are updated accordingly. The RMP version 14.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, make few editorial updates and bring the PI in line with the latest QRD template version 10.1." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
WS1664 Keppra-EMEA/H/C/000277/WS1664/0187 UCB Pharma S.A., Lead Rapporteur: Koenraad Norga, Lead PRAC Rapporteur: Laurence de Fays, "Update of section 4.2 of the SmPC to recommend the same dosing for monotherapy and adjunctive therapy based on data from modelling and simulation project. The Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted. The MAH took the opportunity to move Braille to another box section and to review and adapt the German PI according to the current QRD template." Request for Supplementary Information adopted on 17.09.2020, 23.07.2020, 30.04.2020.	Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **Beovu - brolucizumab - EMEA/H/C/004913/II/0002** Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Mueller-Berghaus, "C.I.4, Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation." Opinion adopted on 03.09.2020.	
PRAC Led **Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0092** GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "C.I.13: Submission of the final report from study V72_38OB listed as a category 3 study PASS in the RMP. This is an observational study conducted by Public Health England (PHE) to assess Bexsero effectiveness and impact in infants in the UK upon introduction on the vaccine in the infant National Immunization Program (NIP) administered at 2, 4 and 12 months of age. An updated RMP version 8.0 has also been submitted. This version includes the changes due to this variation and those due to a separate type II variation submitted in parallel to include the final report of an additional PASS V72_82OB" Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0093** GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study V72_82OB listed as a category 3 PASS in the RMP. This is an observational study on the safety of Bexsero in pregnant women and their offspring, the objective of the study was to evaluate pregnancy outcomes among women immunized with the Bexsero vaccine within 30 days prior to the last menstrual period (LMP) or at any time during pregnancy. An updated RMP version 8.0 has also been submitted. This version includes the changes due to this variation and those due to a separate type II variation submitted in parallel to include the final report of an additional PASS V72_38OB"	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 03.09.2020.	
PRAC Led **Conbriza - bazedoxifene - EMEA/H/C/000913/II/0052** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final clinical study report (CSR) for the Conbriza Non-Interventional EU Post Authorisation Safety Study (EU PASS) - Protocol B1781044. This final CSR relates to the Post Approval Measure EMEA/H/C/000913/MEA 012.12." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **DaTSCAN - ioflupane (123I) - EMEA/H/C/000266/II/0060** GE Healthcare B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the first RMP" Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/II/0024** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of the Risk Management Plan (RMP) to V3.0, to include amended study milestones and to revise the RMP document format in line with latest Good Pharmacovigilance Practices Guidance Module V, revision 2 guidelines, as requested during the assessment of the renewal." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 14.05.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/II/0025** Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final clinical study report (CSR) for the Duavive Non-Interventional EU Drug Utilisation Study (DUS) - Study B2311061. This final CSR relates	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

to the Post-Authorisation Measure MEA 003." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 09.07.2020.	
PRAC Led **Erivedge - vismodegib - EMEA/H/C/002602/II/0046** Roche Registration GmbH, Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Update of the Educational Materials provided as part of the Erivedge Pregnancy Prevention Program, following conclusion of PSUSA/00010140/201901. Annex IID is updated accordingly. Additionally, RMP v14.0 is submitted. Furthermore, section 4.4 of the SmPC is updated to remove the warning on cutaneous squamous cell carcinoma. The MAH also took the opportunity to update the Package Leaflet with the recommended wording on sodium content." Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 11.06.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Evoltra - clofarabine - EMEA/H/C/000613/II/0069** Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of the RMP (version 9.0) to reflect updated information regarding the Evoltra European Registry Programme and to remove all safety concerns from the list of important identified and potential risks and missing information to follow revised guidance in the good pharmacovigilance practice (GVP) Module V Rev.2." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **EXJADE - deferasirox - EMEA/H/C/000670/II/0068** Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report related to the Physician Survey (NO6987) conducted for Exjade to assess the impact of educational materials on the prescribers' awareness of	Request for supplementary information adopted with a specific timetable.

doses and biological monitoring recommendations and to assess the awareness and appropriate use of both formulations (Dispersible Tablets and Film-Coated tablets). The updated RMP version 17.1 is submitted as well." Request for Supplementary Information adopted on 03.09.2020, 17.04.2020, 16.01.2020, 03.10.2019.	
PRAC Led **Iressa - gefitinib - EMEA/H/C/001016/II/0033** AstraZeneca AB, Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 11 in order to provide the RMP in revision 2 as per the revised `Guideline on Good Pharmacovigilance Practices: Module V - Risk management systems (Rev. 2)' together with inclusion of RMP changes as per the commitments indicated in PSUSA procedure (EMEA/H/C/PSUSA/00001518/201807)" Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Moventig - naloxegol - EMEA/H/C/002810/II/0029/G** Kyowa Kirin Holdings B.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, "Submission of an updated RMP version 6.1 in order to update the list of safety concerns." Opinion adopted on 04.09.2020. Request for Supplementary Information adopted on 14.05.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Obizur - susoctocog alfa - EMEA/H/C/002792/II/0034** Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of a final report of the survey among Health Care Professionals to Assess their Knowledge on Dosing and Administration of OBIZUR (Susoctocog alfa) in 6 European Countries." Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Orfadin - nitisinone - EMEA/H/C/000555/II/0074**	Request for supplementary information adopted with a specific timetable.

Swedish Orphan Biovitrum International AB, PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Armando Genazzani, "Submission of the final report from study Sobi.NTBC-005 listed as a category 3 study in the RMP. This is a non-interventional Post Authorization Safety Study (PASS) to evaluate long-term safety of Orfadin treatment in hypertyrosinemia type 1 (HT-1) patients in standard clinical care. The RMP version 5.3 has also been submitted." Request for Supplementary Information adopted on 03.09.2020.	
PRAC Led **WS1810** **Juluca-EMEA/H/C/004427/WS1810/0028** **Tivicay-EMEA/H/C/002753/WS1810/0061** **Triumeq-EMEA/H/C/002754/WS1810/0082** ViiV Healthcare B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final report from study EuroSIDA (Study 201177) listed as a category 3 study in the RMP. This is a prospective observational cohort study to monitor and compare the occurrence of hypersensitivity reaction and hepatotoxicity in patients receiving dolutegravir (with or without abacavir) and other integrase inhibitors (with or without abacavir)." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS1849** **Thymanax-EMEA/H/C/000916/WS1849/0045** **Valdoxan-EMEA/H/C/000915/WS1849/0047** Les Laboratoires Servier, Lead Rapporteur: Bjorg Bolstad, Lead PRAC Rapporteur: Pernille Harg, PRAC-CHMP liaison: Bjorg Bolstad, "Submission of an updated RMP version 23.1 in order to revise the safety concerns, important identified and potential risks in line with the new GVP module V. In addition, the completed studies have been deleted and, as agreed in LEG 031, the frequency of the educational material distribution is updated to once a year." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.

PRAC Led **WS1861/G** **Kisplyx-EMEA/H/C/004224/WS1861/0037/G** **Lenvima-EMEA/H/C/003727/WS1861/0037/G** Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn, Lead PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina, "Submission of the final clinical study report (CSR) for Study E7080-G000-201 (Study 201) - To evaluate the long-term safety of lenvatinib in Medullary and Iodine-131 Refractory, Unresectable differentiated thyroid carcinoma (DTC), Stratified by Histology (MEA 001 for Lenvima; from initial MAA for Kisplyx). Submission of the final CSR for Study E7080-G000-303 (Study 303) - To evaluate long-term safety of lenvatinib in patients with RR-DTC (radioiodine refractory differentiated thyroid cancer) in a randomized, double-blind, placebo-controlled Phase 3 study (MEA 004 for Lenvima; MEA 002 for Kisplyx). Submission of an updated integrated summary of safety (ISS) including data from DTC subjects in Studies 201, 303 and E7080-J081-208 (Study 208) - the latter study was to determine the long-term safety profile of lenvatinib in Japanese patients with advanced thyroid cancer (Kisplyx REC from Study 208 variation (procedure EMEA/H/C/003727/II/0008) for Lenvima). The RMP version 12 has also been submitted." Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS1879** **Cymbalta-EMEA/H/C/000572/WS1879/0084** **Duloxetine Lilly-EMEA/H/C/004000/WS1879/0021** **Yentreve-EMEA/H/C/000545/WS1879/0069** Eli Lilly Nederland B.V., Duplicate, Duplicate of Ariclaim, Yentreve, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "This worksharing variation is being submitted to present and discuss the results of Study F1J-MC-B034	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Pregnancy Registry to meet the commitment made during the previous procedure No. EMEA/H/C/WS1527/G which received positive CHMP opinion on 25 July 2019. As a consequence of the submission of the F1J-MC-B034 Study Report, the Risk Management Plan (RMP) for duloxetine has been updated. The RMP for all Lilly duloxetine products are combined. The changes introduced are not specific to one product and are therefore the same for all products." Opinion adopted on 03.09.2020.	
PRAC Led **WS1897** **Mirapexin-EMEA/H/C/000134/WS1897/0096** **Sifrol-EMEA/H/C/000133/WS1897/0087** Boehringer Ingelheim International GmbH, Lead Rapporteur: Kirstine Moll Harboe, Lead PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Kirstine Moll Harboe, "RMP update to implement changes requested by PRAC in the context of the PSUSA procedure (EMEA/H/C/PSUSA/00002491/ 201904) of the PBRER with a DLP on 06 Apr 2019: · to remove `Cardiac failure' from the list of important identified risks; · to amend the information with regard to the important identified risk `Dopamine agonist withdrawal syndrome' (DAWS)." Request for Supplementary Information adopted on 04.09.2020.	Request for supplementary information adopted with a specific timetable.

B.5.5. CHMP-CAT assessed procedures

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0003/G, Orphan, ATMP AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinator: Johann Lodewijk Hillege Request for Supplementary Information adopted on 11.09.2020.	Request for supplementary information adopted with a specific timetable.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

WS1796/G **Aflunov-EMEA/H/C/002094/WS1796/0059/G** **Foclivia-EMEA/H/C/001208/WS1796/0054/G** Seqirus S.r.l, Lead Rapporteur: Armando Genazzani Opinion adopted on 03.09.2020. Request for Supplementary Information adopted on 02.07.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1811 **Olanzapine Glenmark-EMEA/H/C/001085/WS1811/0034** **Olanzapine Glenmark Europe-EMEA/H/C/001086/WS1811/0031** **Olazax-EMEA/H/C/001087/WS1811/0027** **Olazax Disperzi-EMEA/H/C/001088/WS1811/0029** Glenmark Arzneimittel GmbH, Generic, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 17.09.2020.	Request for supplementary information adopted with a specific timetable.
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, Malta Netherlands and	Request for supplementary information adopted with a specific timetable.

Slovakia in section 6 of the Package Leaflet for all products." Request for Supplementary Information adopted on 17.09.2020, 23.07.2020.	
WS1853/G **Ebymect-EMEA/H/C/004162/WS1853/0049/G** **Edistride-EMEA/H/C/004161/WS1853/0040/G** **Forxiga-EMEA/H/C/002322/WS1853/0058/G** **Xigduo-EMEA/H/C/002672/WS1853/0059/G** AstraZeneca AB, Lead Rapporteur: Kristina Dunder Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1857 **Adrovance-EMEA/H/C/000759/WS1857/0042** **FOSAVANCE-EMEA/H/C/000619/WS1857/0045** **VANTAVO-EMEA/H/C/001180/WS1857/0032** Merck Sharp & Dohme B.V., Lead Rapporteur: Andrea Laslop, "To update section 4.4 of the SmPC for excipients lactose and sodium and section 2 of the Package Leaflet for the excipient sodium to comply with the updated Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use" (Revised March 2018) and corresponding Annex (Rev.01, 09Oct2017; Corr.1 19Nov2018). Minor formatting changes and editorial changes to comply with the latest QRD template are also applied in the Product Information. In addition, the MAH took the opportunity to update the list of local representatives as follows: o The Netherlands for the 3 products o Belgium and Portugal for Adrovance and Vantavo o Luxembourg for Adrovance" Opinion adopted on 04.09.2020.	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1859/G **Blitzima-EMEA/H/C/004723/WS1859/0032/G** **Ritemvia-EMEA/H/C/004725/WS1859/0032/G**	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Truxima-EMEA/H/C/004112/WS1859/0035/G Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, "Extension of indication to include treatment of paediatric GPA/MPA patient without new additional clinical data required. Extension of indication to include treatment of paediatric NHL patients without new additional clinical data required. Post-authorisation efficacy study (PAES) randomised phase 3 study without new additional clinical data required." Opinion adopted on 04.09.2020.	
WS1864/G **Kivexa-EMEA/H/C/000581/WS1864/0086/G** **Trizivir-EMEA/H/C/000338/WS1864/0118/G** **Ziagen-EMEA/H/C/000252/WS1864/0113/G** ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 03.09.2020.	Request for supplementary information adopted with a specific timetable.
WS1867/G **Rivastigmine 1A Pharma-EMEA/H/C/001181/WS1867/0029/G** **Rivastigmine Hexal-EMEA/H/C/001182/WS1867/0030/G** **Rivastigmine Sandoz-EMEA/H/C/001183/WS1867/0031/G** Sandoz GmbH, Informed Consent of Exelon, Lead Rapporteur: Alexandre Moreau Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1873/G **Filgrastim Hexal-EMEA/H/C/000918/WS1873/0056/G** **Zarzio-EMEA/H/C/000917/WS1873/0057/G** Sandoz GmbH, Lead Rapporteur: Johann Lodewijk Hillege Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1875/G **Rixathon-EMEA/H/C/003903/WS1875/0042/G** **Riximyo-EMEA/H/C/004729/WS1875/0042/G** Sandoz GmbH, Duplicate, Duplicate of Rixathon, Lead Rapporteur: Jan Mueller-Berghaus, "To update sections 4.8, 5.1 and 5.2 of the SmPC	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

following safety changes for the parent product Mabthera adopted during procedure II-169. To update sections 1, 2, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 8 of the SmPC following adoption of extension of indication to include the induction of remission in paediatric patients (aged ≥ 2 to <18 years old) with severe, active granulomatosis with polyangiitis (GPA) (Wegener's) and microscopic polyangiitis (MPA) for parent product Mabthera during procedure II-162. The PL was updated accordingly. Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC following adoption of extension of indication to include treatment of paediatric patients (aged ≥6 months to <18 years old) with previously untreated advanced stage diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL) in combination with chemotherapy for parent product MabThera during procedure II-168. The Package Leaflet is updated accordingly. The MAH also took this opportunity to introduce minor editorial changes. Amongst these the MAH included in Annex III of the Product Information the text appearing on the peel-off label recently introduced for both, Rixathon and Riximyo." Opinion adopted on 03.09.2020.	
WS1880 **Lixiana-EMEA/H/C/002629/WS1880/0027** **Roteas-EMEA/H/C/004339/WS1880/0015** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1885/G **Silodosin Recordati-EMEA/H/C/004964/WS1885/0005/G** **Silodyx-EMEA/H/C/001209/WS1885/0041/G** **Urorec-EMEA/H/C/001092/WS1885/0044/G** Recordati Ireland Ltd, Generic, Generic of Urorec, Lead Rapporteur: Margareta Bego Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1894/G **Incresync-EMEA/H/C/002178/WS1894/0032/G** **Vipdomet-EMEA/H/C/002654/WS1894/**	Request for supplementary information adopted with a specific timetable.

0028/G **Vipidia-EMEA/H/C/002182/WS1894/0023/G** Takeda Pharma A/S, Lead Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 03.09.2020.	
WS1899/G **Elebrato Ellipta-EMEA/H/C/004781/WS1899/0019/G** **Temybric Ellipta-EMEA/H/C/005254/WS1899/0007/G** **Trelegy Ellipta-EMEA/H/C/004363/WS1899/0016/G** GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Peter Kiely Opinion adopted on 03.09.2020.	Positive Opinion adopted by consensus on 03.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1903 **Actraphane-EMEA/H/C/000427/WS1903/0085** **Actrapid-EMEA/H/C/000424/WS1903/0078** **Insulatard-EMEA/H/C/000441/WS1903/0083** **Mixtard-EMEA/H/C/000428/WS1903/0086** **Protaphane-EMEA/H/C/000442/WS1903/0082** Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe Opinion adopted on 10.09.2020.	Positive Opinion adopted by consensus on 10.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1909 **Humalog-EMEA/H/C/000088/WS1909/0183** **Liprolog-EMEA/H/C/000393/WS1909/0143** Eli Lilly Nederland B.V., Lead Rapporteur: Kristina Dunder, "To update sections 4.2, 4.4 and 4.8 of the SmPC and sections 2 and 4 of the PL to implement the signal recommendations on "Signal assessment report on cutaneous amyloidosis with insulin human (regular and NPH), insulin degludec, insulin aspart, insulin lispro, insulin detemir, insulin glargine, insulin glulisine and insulin porcine (class effect of insulin containing products) " (EPITT no 19499) adopted at the 17/04/2020 PRAC meeting. In addition, the MAH is taking the opportunity to make some corrections to the labelling	Positive Opinion adopted by consensus on 04.09.2020. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

specifically the pictures in the Liprolog instructions Information For Use and some typographic issues in the Icelandic, Danish and Norway, Patient Information Leaflet and Summary of Product Characteristic." Opinion adopted on 04.09.2020.	
Hexacima-EMEA/H/C/002702/WS1872/0104/G **Hexaxim-EMEA/H/W/002495/WS1872/0109/G** **Hexyon-EMEA/H/C/002796/WS1872/0108/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 17.09.2020.	Positive Opinion adopted by consensus on 17.09.2020. 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

Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0042 Orexigen Therapeutics Ireland Limited, Rapporteur: Kirstine Moll Harboe Request for Supplementary Information adopted on 23.07.2020.	Request by the applicant for an extension of the clock stop to respond to the RSI adopted on 28.11.2019. The CHMP agreed to the request by the applicant.
Replagal - agalsidase alfa - EMEA/H/C/000369/II/0106 Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update of sections 4.8 of the Summary of Product Characteristics (SmPC) in order to update the list of adverse drug reactions (ADRs) information based on the final results from study HGT-REP-081 " a Multicenter Open-label Treatment Protocol to observe the safety of Replagal (agalsidase alfa) Enzyme Replacement Therapy in Canadian Patients with Fabry Disease". In addition, the MAH took the opportunity to introduce editorial and QRD changes in sections throughout the Product Information according to the QRD templates and current guidelines, including new warnings related to sodium excipient and traceability of biological medicinal products. The Package Leaflet is updated accordingly."	The CHMP adopted an updated timetable

Request for Supplementary Information adopted on 14.05.2020.	

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

dexamethasone phosphate - EMEA/H/C/005740 indicated for cerebral oedema, post-traumatic shock-lung syndrome, asthma, skin diseases, autoimmune diseases, rheumatoid arthritis, prophylaxis and treatment of post-operative or cytostatic-induced vomiting, treatment of COVID-19, eye inflammation and infection	**Accelerated review**
evinacumab - EMEA/H/C/005449 treatment of Homozygous Familial Hypercholesterolemia (HoFH)	**Accelerated review**
bevacizumab - EMEA/H/C/005640 treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and metastatic or recurrent non-small cell lung cancer, advanced and/or metastatic renal cell cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer and persistent, recurrent, or metastatic carcinoma of the cervix - 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.	

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

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

Diacomit - stiripentol - EMEA/H/C/000664/X/0032 BIOCODEX, Rapporteur: Alar Irs, PRAC Rapporteur: Maia Uusküla, "Extension application to add a new strength of 100 mg capsules. The RMP (version 2.0) is updated in accordance." List of Questions adopted on 25.06.2020.	
Elebrato Ellipta - fluticasone furoate / umeclidinium / vilanterol -	

EMEA/H/C/004781/X/0014/G
GlaxoSmithKline Trading Services Limited, Duplicate, Duplicate of Trelegy Ellipta, Rapporteur: Peter Kiely, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin, "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."
List of Questions adopted on 25.06.2020.

estetrol / drospirenone - EMEA/H/C/005336
oral contraceptive
List of Questions adopted on 25.06.2020.

estetrol / drospirenone - EMEA/H/C/005382
oral contraception
List of Questions adopted on 25.06.2020.

Lacosamide Accord - lacosamide - EMEA/H/C/004443/X/0007
Accord Healthcare S.L.U., Generic, Generic of Vimpat, Rapporteur: John Joseph Borg, PRAC Rapporteur: Ulla Wändel Liminga, "Extension application to introduce a new pharmaceutical form (solution for infusion), a new strength (10 mg/ml) and a new route of administration (intravenous use)."
List of Questions adopted on 26.03.2020.

Temybric Ellipta - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/005254/X/0004/G
GlaxoSmithKline Trading Services Limited, Informed Consent of Trelegy Ellipta, Rapporteur: Peter Kiely, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Annika Folin, "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/1/19/13781237/001-3), the new strength is indicated only for the treatment of asthma.
The RMP (version 2.2) is updated in accordance."

List of Questions adopted on 25.06.2020.

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, "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/1/17/1236/001-3), the new strength is indicated only for the treatment of asthma. The RMP (version 2.2) is updated in accordance."
List of Questions adopted on 25.06.2020.

Tysabri - natalizumab - EMEA/H/C/000603/X/0116

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension application to introduce a new pharmaceutical form (solution for injection), associated with a new strength (150 mg) and a new route of administration (subcutaneous use). The RMP (version 26.1) is updated accordingly."
List of Questions adopted on 23.07.2020.

adalimumab - EMEA/H/C/005188

treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, Juvenile idiopathic arthritis, Enthesitis-related arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis, Paediatric Uveitis
List of Questions adopted on 23.07.2020.

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

Increlex - mecasermin - EMEA/H/C/000704/S/0064

Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka

Lojuxta - lomitapide - EMEA/H/C/002578/S/0043

Amryt Pharmaceuticals DAC, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur:

Menno van der Elst

Strensiq - asfotase alfa - EMEA/H/C/003794/S/0048, Orphan
Alexion Europe SAS, Rapporteur: Armando Genazzani, PRAC Rapporteur: Rhea Fitzgerald

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

EndolucinBeta - lutetium (177Lu) chloride - EMEA/H/C/003999/R/0019
ITM Medical Isotopes GmbH, Rapporteur: Peter Kiely, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Rugile Pilviniene

Neparvis - sacubitril / valsartan - EMEA/H/C/004343/R/0032
Novartis Europharm Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Anette Kirstine Stark

Ongentys - opicapone - EMEA/H/C/002790/R/0031
Bial - Portela & Cª, S.A., Rapporteur: Martina Weise, Co-Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Maria del Pilar Rayon

Palonosetron Accord - palonosetron - EMEA/H/C/004129/R/0009
Accord Healthcare S.L.U., Generic, Generic of Aloxi, Rapporteur: Alar Irs, PRAC Rapporteur: Rhea Fitzgerald

SIRTURO - bedaquiline - EMEA/H/C/002614/R/0040, Orphan
Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - EMEA/H/C/003854/R/0029, Orphan, ATMP
Orchard Therapeutics (Netherlands) BV, Rapporteur: Sol Ruiz, Co-Rapporteur: Egbert Flory, PRAC Rapporteur: Menno van der Elst,

Zavicefta - ceftazidime / avibactam - EMEA/H/C/004027/R/0024
Pfizer Ireland Pharmaceuticals, Rapporteur:

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

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

CABOMETYX - cabozantinib - EMEA/H/C/004163/II/0017 Ipsen Pharma, Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include in combination with nivolumab first line treatment of advanced renal cell carcinoma for CABOMETYX; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been submitted."
Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0011 Sanofi Pasteur, Rapporteur: Christophe Focke, "To modify the approved therapeutic indication to include conditions for the eligibility to pre-vaccination serostatus screening. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC and sections 1, 2 and 3 of the Package Leaflet are updated accordingly."
Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0012 Sanofi Pasteur, Rapporteur: Christophe Focke, "Extension of indication to include paediatric population from 6 years of age for Dengvaxia; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC and sections 1, 2 and 4 of the Package Leaflet are updated. Furthermore, the MAH takes the opportunity to add an instruction for the installation of the needle in the SmPC and the Package Leaflet of the single-dose presentation."
EVOTAZ - atazanavir / cobicistat - EMEA/H/C/003904/II/0038 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Adrien Inoubli, "Extension of indication to include the use of EVOTAZ in combination with other

antiretroviral agents in the treatment of HIV-1 infection in adolescent patients aged ≥ 12 to < 18 years, weighing ≥ 35 kg without known mutations associated with resistance to atazanavir; 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 8.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial corrections."

Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0001, Orphan

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Martin Huber, "Extension of indication of Kaftrio to patients with CF aged 12 years and older who have at least one F508del mutation in the CFTR gene, regardless of the second allele (F/any). Efficacy data are summarized from Study 104, which was conducted in subjects heterozygous for F508del and a gating (G) or residual function (RF) mutation (F/G and F/RF genotypes). As a consequence update of SmPC section 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are requested. Package leaflet is updated accordingly The RMP is updated version 1.1"

Kalydeco - ivacaftor - EMEA/H/C/002494/II/0089, Orphan

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, "Extension of indication to extend the indication of Kalydeco (ivacaftor) tablets in combination regimen with Kaftrio (ivacaftor/tezacaftor/elexacaftor) tablets for the treatment of adults and adolescents aged 12 years and older with cystic fibrosis (CF) who have at least one F508del mutation in the CFTR gene; as a consequence, sections 4.1, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.2 of the RMP has also been submitted."

LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0011

Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Sinan B. Sarac, Co-

Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Menno van der Elst, "Extension of indication for LIBTAYO as monotherapy indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% tumor cells), with no EGFR, ALK or ROS1 aberrations, who have: • locally advanced NSCLC and who are not candidates for surgical resection or definitive chemoradiation, or have progressed after treatment with definitive chemoradiation, or • metastatic NSCLC. The PL is revised accordingly. A revised RMP is submitted." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0012 Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Sinan B. Sarac, Co-Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include : LIBTAYO as monotherapy is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor. SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 have been revised. The PL has been updated accordingly. A revised RMP has been submitted."	
OPDIVO - nivolumab - EMEA/H/C/003985/II/0092 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to include in combination with cabozantinib for the first line treatment of advanced renal cell carcinoma for Opdivo; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 19.0 of the RMP has also been submitted."	
SARCLISA - isatuximab - EMEA/H/C/004977/II/0003, Orphan sanofi-aventis groupe, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Eva	

A. Segovia, "An extension of indication for Sarclisa to add combination with carfilzomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. As a consequence the sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 have been updated. The PL is updated accordingly. The MAH took the opportunity to introduce minor changes in the SmPC sections 4.9, 6.3 and 6.6 and update the details of local representatives. Revised RMP version 1 has been submitted."

TAGRISSO - osimertinib - EMEA/H/C/004124/II/0039/G

AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Menno van der Elst, "Extension of indication of Tagrisso to include the adjuvant treatment after complete tumour resection in EGFR mutant non-small cell lung cancer (NSCLC) patients, based on the results from the pivotal Phase 3 randomised, placebo-controlled study ADAURA (D5164C00001); as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 14.1 of the RMP has also been submitted."

WS1881
OPDIVO-EMEA/H/C/003985/WS1881/0091
Yervoy-EMEA/H/C/002213/WS1881/0085

Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Blanca Garcia-Ochoa, Lead PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to include first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM) for Opdivo in combination with Yervoy; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 20.0 for Opdivo and version 30.0 for Yervoy of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Benlysta - belimumab - EMEA/H/C/002015/II/0084

GlaxoSmithKline (Ireland) Limited, Rapporteur:

Kristina Dunder

Darzalex - daratumumab - EMEA/H/C/004077/II/0040, Orphan
Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac

Gardasil - human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0089/G
MSD Vaccins, Rapporteur: Kristina Dunder

Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0043/G
MSD Vaccins, Rapporteur: Kristina Dunder

Idacio - adalimumab - EMEA/H/C/004475/II/0007
Fresenius Kabi Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege

Kevzara - sarilumab - EMEA/H/C/004254/II/0024/G
sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus

Lokelma - sodium zirconium cyclosilicate - EMEA/H/C/004029/II/0021/G
AstraZeneca AB, Rapporteur: Romaldas Mačiulaitis

Miglustat Gen.Orph - miglustat - EMEA/H/C/004366/II/0013
Gen.Orph, Generic, Generic of Zavesca, Rapporteur: Milena Stain

Mimpara - cinacalcet - EMEA/H/C/000570/II/0068
Amgen Europe B.V., Rapporteur: Kristina Dunder

Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0082
Genzyme Europe BV, Co-Rapporteur: Koenraad Norga

NovoSeven - eptacog alfa (activated) - EMEA/H/C/000074/II/0109/G
Novo Nordisk A/S, Rapporteur: Paula Boudewina van Hennik

Nulojix - belatacept - EMEA/H/C/002098/II/0072/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson

Remsima - infliximab - EMEA/H/C/002576/II/0093/G
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola

Riluzole Zentiva - riluzole - EMEA/H/C/002622/II/0027
Zentiva, k.s., Rapporteur: Kirstine Moll Harboe

Rybelsus - semaglutide - EMEA/H/C/004953/II/0006
Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege

Rybelsus - semaglutide - EMEA/H/C/004953/II/0007
Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege

Simponi - golimumab - EMEA/H/C/000992/II/0093
Janssen Biologics B.V., Rapporteur: Kristina Dunder

Trulicity - dulaglutide - EMEA/H/C/002825/II/0053/G
Eli Lilly Nederland B.V., Rapporteur: Martina Weise

Trulicity - dulaglutide - EMEA/H/C/002825/II/0054
Eli Lilly Nederland B.V., Rapporteur: Martina Weise

WS1926/G
Hexacima-EMEA/H/C/002702/WS1926/0106/G
Hexaxim-EMEA/H/W/002495/WS1926/0111/G
Hexyon-EMEA/H/C/002796/WS1926/0110/G
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

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

Betaferon - interferon beta-1b - EMEA/H/C/000081/II/0130
Bayer AG, Rapporteur: Martina Weise, "C.I.4 Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on

Thrombotic Microangiopathy by adding information about Haemolytic anaemia and add (Haemolytic anaemia) to the list of adverse drug reactions (ADRs) with frequency unknown based on the cumulative review of available data including case reports from post-marketing surveillance and scientific literature. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/II/0034

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to add the Stevens-Johnson Syndrome (SJS) to the list of adverse drug reactions (ADRs) with frequency "rare" based on an internal cumulative safety review performed by the company and prompted by a spontaneous case report of a HIV patient who experienced SJS during treatment with Biktavry. The Package Leaflet is updated accordingly."

Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0008/G

Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke "(Type IB) B.II.b.3.z, (Type II) C.I.11.b - Update to Annex II to delete Specific Obligations 2 and 4 and conversion to marketing authorization not subject to specific obligations. In addition, the MAH is updating section 5.1 of the SmPC and section 6 of the Package Leaflet to delete the conditional marketing authorisation details. The MAH has taken the opportunity to propose a progress report to be provided following a Post-Authorization Measure"

Extavia - interferon beta-1b - EMEA/H/C/000933/II/0103

Novartis Europharm Limited, Informed Consent of Betaferon, Rapporteur: Martina Weise, "Type II variation to update SmPC section 4.8 with the addition of Haemolytic anaemia (HA) as an adverse drug reaction of 'unknown' frequency' based on cumulative review of available data including case reports from post-marketing surveillance and scientific literature.

Section 4.4 of the SmPC and corresponding sections in the PL are updated with a precautionary statement, considering the importance of drug discontinuation for patients with Thrombotic Microangiopathy TMA/HA, to reflect the most recent post-marketing experience."

Eylea - aflibercept - EMEA/H/C/002392/II/0066

Bayer AG, Rapporteur: Alexandre Moreau, "Submission of final CSR for study 17514 (CENTERA). This study was an international, multi-center, prospective, interventional, single-arm, open- label, phase 4 study on the efficacy, durability, posology, and safety of the T&E regimen in subjects with macular edema secondary to CRVO."

LUTATHERA - lutetium (177Lu) oxodotreotide - EMEA/H/C/004123/II/0022, Orphan

Advanced Accelerator Applications, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4, 4.5, 4.6 and 4.8 of the SmPC in order to introduce structural changes in the dosing and administration and warnings and precautions section, include clarifications in the pregnancy and overdose sections, update instructions for use based on end user feedback and update of amino acid solution information based on review and approval of LysaKare; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to include correction of typographical errors and editorial changes in the PI in line with the latest QRD template version 10.1."

Praluent - alirocumab - EMEA/H/C/003882/II/0059

sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations, the undesirable effects section and pharmacokinetic and pharmacodynamic sections with information on paediatric population, based on final results from study EFC14660, a category 3 open-label study in the RMP, to evaluate the efficacy and safety of alirocumab in children and adolescents with homozygous familial hypercholesterolemia;

the Package Leaflet is updated accordingly.”
Spravato - esketamine - EMEA/H/C/004535/II/0004 Janssen-Cilag International N.V., Rapporteur: Martina Weise, “to update the Spravato Product Information at section 4.2 to replace the current dosing recommendation in patients with Japanese ancestry with a statement that efficacy of Spravato in Japanese patients has not been established to date. This dosing recommendation is supported by the completed Phase 2 study 54135419TRD2005”
Venclyxto - venetoclax - EMEA/H/C/004106/II/0031 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, “to update venetoclax SmPC wording regarding Tumor lysis syndrome (TLS) prophylaxis and management following an update to the Company Core Data Sheet (CCDS) as result of a medical safety assessment conducted on TLS post-marketing reports. The proposed changes to the SmPC include sections 4.2 and 4.4: • Section 4.2: A more prescriptive table which replaces the text around the risk assessment, prophylaxis and monitoring measures based on the level of tumour burden. In addition, the text on the recommended dose modifications for toxicities is replaced by a table format for clarity. • Section 4.4: the text is revised to emphasize the fact that TLS occur in all patients and requires adequate risk assessment that considers comorbidities, particularly renal impairment, and other risk factors such as splenomegaly.”
Xarelto - rivaroxaban - EMEA/H/C/000944/II/0081 Bayer AG, Rapporteur: Kristina Dunder, “Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC following the final results from the VOYAGER PAD study, a multicentre, randomised, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures. The Package Leaflet is updated

accordingly.”

WS1891/G
CONTROLOC Control-EMEA/H/C/001097/ WS1891/0036/G
PANTOLOC Control-EMEA/H/C/001100/ WS1891/0041/G
PANTOZOL Control-EMEA/H/C/001013/ WS1891/0038/G
SOMAC Control-EMEA/H/C/001098/ WS1891/0037/G

Takeda GmbH, Lead Rapporteur: Simona Stankeviciute, “Group of variations 1. To update sections 4.4 and 4.8 of the SmPC in order to add warnings related to Hypocalcaemia/Hypokalaemia based on the Signal Evaluation Reports; FORM-0003948 - Takeda Signal Evaluation Report, Products Dexlansoprazole, Lansoprazole and Pantoprazole, Signal: Hypocalcemia, dated February 13, 2020. The Package Leaflet is updated accordingly. 2. To update section 4.8 of the SmPC in order to add DRESS ADR based on the Signal Evaluation Reports; FORM-0003948 - Takeda Signal Evaluation Report, Products Dexlansoprazole, Lansoprazole and Pantoprazole, Signal: Drug reaction with eosinophilia and systemic symptoms (DRESS) dated January 29, 2020. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the last QRD template (version 10.1), to update the list of local representatives and implement to editorial corrections to the PI.”

B.6.10. CHMP-PRAC assessed procedures

Bronchitol - mannitol - EMEA/H/C/001252/II/0042, Orphan

Pharmaxis Europe Limited, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Adrien Inoubli, “Submission of an updated RMP version 9.0 based on the new RMP template (GVP module V, revision 2). The MAH took the opportunity to review the safety information contained in the RMP and proposed to reclassify “Cough” from an important potential risk to an important identified risk; to remove the important identified risks “Bronchospasm during and after the initiation dose assessment” and “Bronchospasm during long term use”; to

remove the important potential risk "Cough-related sequelae"; "Off label use in non-CF bronchiectasis" "Off label use in paediatric/adolescent CF patients (aged 6-17 years)"; "Administration of Bronchitol via the wrong inhaler device"; "Starting Bronchitol treatment without completing the full BIDA dose"; to remove the missing information "Patients requiring home oxygen or needing assisted ventilation"; "Children <6 years of age"; "Pregnancy and lactation"; "Risks associated with long-term use" from the list of safety concerns; to add "Increased risk of respiratory or systemic infection" as an important potential risk combining, replacing "Pulmonary abscess on continued use", "Septicaemia on continued use", "Increased risk of bacteria sputum identified or infections with extended use of Bronchitol", and "Microbial infection via a contaminated inhaler device", previously classified as important potential risks, which are proposed to be removed from the list of safety concerns. In addition, following the completion of UK CF Registry study (cat 2, PASS) EMEA/H/C/001252/SW/0036, this study has been removed from the RMP, and clinical trial and post-marketing exposure and safety information have been updated to reflect the results of the DPM-CF-303 study previously assessed in EMEA/H/C/001252/II/0034 and the information presented in the latest PSUR #9 (PSUSA/ 0009226/201904)."

Imfinzi - durvalumab - EMEA/H/C/004771/II/0023

AstraZeneca AB, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: David Olsen, "Update of sections 4.2 and 5.1 of the SmPC in order to introduce a new posology regimen of 1500 mg every 4 weeks (Q4W) for the approved indication of the treatment of patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum based chemoradiation therapy. The RMP version 4.1 has also been submitted."

NINLARO - ixazomib - EMEA/H/C/003844/II/0022, Orphan

Takeda Pharma A/S, Rapporteur: Armando Genazzani, PRAC Rapporteur: Annika Folin, "To

update section 4.8 undesirable effects of the Ninlaro (Ixazomib) Summary of Product Characteristics (SmPC) following the adoption of the CHMP opinion in 25 June 2020 on PSUR assessment procedure EMEA/H/C/PSUSA/00010535/201911 .”

Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0021

Roche Registration GmbH, Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of section 4.4 in order to include the term ‘anaphylaxis’ among the possible symptoms of infusion-related reactions (IRRs), following an analysis of cases retrieved by anaphylactic reaction MedDRA narrow SMQ. The MAH took the opportunity to update Annex II.C and D in line with the QRD template. The RMP version 6.0 has been submitted.”

Rekovelle - follitropin delta - EMEA/H/C/003994/II/0022

Ferring Pharmaceuticals A/S, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst, “Update of section 4.2 of the SmPC in order to introduce a new anti-Müllerian hormone (AMH) assay to determine the dose of follitropin delta, following an agreed recommendation. In consequence, RMP version 5.0 was submitted and updated in line with GPV Module V rev.2. The MAH took the opportunity to amend section 4.4. of the SmPC with traceability information, to bring the PI in line with the latest QRD template version 10.1.”

Somavert - pegvisomant - EMEA/H/C/000409/II/0098/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Adrien Inoubli, “Variation to update the Risk Management Plan following assessment of the final results of ACROSTUDY, a multicenter, Post Authorisation Safety Study (PASS) of Somavert therapy in patients with acromegaly (procedure number EMEA/H/C/000409/II/0089), grouped with variation to update section 4.4 of the SmPC to remove the warning on growth hormone secreting tumours, consequential to the removal of pituitary tumour growth as a potential risk from the RMP.
The RMP version 2.0 has been submitted and the MAH took the opportunity to update it as

per the revised version of the GVP Module V Risk Management Systems, revision 2. The Package Leaflet is updated accordingly."

Vargatef - nintedanib - EMEA/H/C/002569/II/0035/G

Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Agni Kapou, "Update of sections 4.5, 4.6 and 5.2 of the SmPC to reflect the results of study 1199-0340 conducted in female patients with Systemic Sclerosis associated Interstitial Lung disease (SSc-ILD), to investigate a potential interaction between nintedanib and the oral contraceptive Microgynon, a combination of ethynilestradiol and levonorgestrel.
Update of sections 4.3 and 4.6 of the SmPC to introduce a new contraindication of pregnancy for Vargatef treatment. This follows the same update for Ofev (nintedanib) introduced in the context of procedure EMEA/H/C/3821/II/0026 and the request from the PRAC in the context of procedure EMEA/H/C/PSUSA/00010318/201910 to consider a similar update for Vargatef.
The Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted reflecting the consequential changes to the submission of study 1199-0340, changes submitted further to the agreement on the same changes implemented for Ofev and other changes requested by the PRAC."

WS1915
Epclusa-EMEA/H/C/004210/WS1915/0051
Harvoni-EMEA/H/C/003850/WS1915/0091
Vosevi-EMEA/H/C/004350/WS1915/0043

Gilead Sciences Ireland UC, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the final report from study GS-US-248-0123, listed as a category 3 study in the RMP. This is a long-term observational follow-up registry of subjects who did not achieve sustained virologic response in Gilead-sponsored trials in subjects with chronic hepatitis C infection. The RMPs have also been submitted for each of the products in this work-sharing procedure (Harvoni v7.1, Epclusa v6.1 and Vosevi v3.1)."

B.6.11. PRAC assessed procedures

PRAC Led
Olumiant - baricitinib -
EMEA/H/C/004085/II/0019
Eli Lilly Nederland B.V., PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on diverticulitis following a signal assessment (EPITT: 19496; Procedure EMEA/H/C/4085/SDA/010); the Package Leaflet is updated accordingly."

PRAC Led
Ventavis - iloprost -
EMEA/H/C/000474/II/0066
Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau, "Submission of an updated RMP version 8.0 to introduce respiratory tract infection as an important potential risk as requested by PRAC in the conclusions of the periodic safety update report single assessment (PSUSA) procedure (EMEA/H/C/PSUSA/00001724/201709) adopted in May 2018. In addition the MAH took the opportunity to update the RMP in line with revision 2 of GVP module V on 'Risk management systems'."

PRAC Led
Yondelis - trabectedin -
EMEA/H/C/000773/II/0061
Pharma Mar, S.A., Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of an updated RMP version 9.0 in order to reflect new available data from completed studies, removal of safety concerns, removal of a target follow-up questionnaire and update of the format in line with the guidance "EMA/164014/2018 Rev.2.0.1 accompanying GVP Module V Rev.2"."

PRAC Led
WS1923
Afinitor-EMEA/H/C/001038/WS1923/
0068
Votubia-EMEA/H/C/002311/WS1923/
0067
Novartis Europharm Limited, Lead Rapporteur:

Janet Koenig, Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of the Final Clinical Study Report for study CRAD001MIC03 (TOSCA), an international disease registry collecting data on manifestations, interventions and outcomes in patients with tuberous sclerosis complex (TSC), for Votubia. The RMP version 15.0 is submitted to reflect the completion of MEA 14.4 (Votubia) and to remove important safety concerns as recommended by the PRAC (EMEA/H/C/WS1671)."

B.6.12. CHMP-CAT assessed procedures

Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0028/G, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0007/G, Orphan, ATMP
AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinator: Johann Lodewijk Hillege

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS1896
Keppra-EMEA/H/C/000277/WS1896/0190
UCB Pharma S.A., Lead Rapporteur: Koenraad Norga, "To update section 4.4, Special warnings and precautions for use, to add a warning "Electrocardiogram QT interval prolongation" and section 4.8 of the SmPC, Undesirable effects to add ADR "Electrocardiogram QT prolonged" following outcome of LEG 088.2. Section 2 and 4 of the Package Leaflet were updated accordingly."

WS1902/G
Ambirix-EMEA/H/C/000426/WS1902/0109/G
Fendrix-EMEA/H/C/000550/WS1902/

0072/G
Infanrix hexa-EMEA/H/C/000296/
WS1902/0281/G
Twinrix Adult-EMEA/H/C/000112/
WS1902/0144/G
Twinrix Paediatric-EMEA/H/C/000129/
WS1902/0145/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1913/G
Infanrix hexa-
EMEA/H/C/000296/WS1913/0282/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS1932
Ultibro Breezhaler-
EMEA/H/C/002679/WS1932/0034
Ulunar Breezhaler-
EMEA/H/C/003875/WS1932/0035
Xoterna Breezhaler-
EMEA/H/C/003755/WS1932/0038
Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe, "To update sections 4.4 and 5.1 of the SmPC related to QT interval prolongation by deleting this reference from the "Warnings and Precautions" section of the proposed SmPC. In addition the MAH has brought the annexes in line with the latest QRD template and a mainly format driven update of the SmPC section 6.6 and PL (i.e. addition of bullets, underline, bold/unbold text, adding spaces between lines etc.,)."

WS1933/G
Blitzima-EMEA/H/C/004723/WS1933/
0036/G
Ritemvia-EMEA/H/C/004725/WS1933/
0036/G
Truxima-EMEA/H/C/004112/WS1933/
0039/G
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

WS1934
Azacitidine Celgene-EMEA/H/C/005300/
WS1934/0002
Vidaza-EMEA/H/C/000978/WS1934/0050
Celgene Europe BV, Lead Rapporteur: Paula Boudewina van Hennik, "To update the SmPC sections 4.2, 4.8, 5.1 and 5.2 to reflect the outcome of EMEA/H/C/000978/P46/034 where

the paediatric information was updated.”
WS1947/G **Blitzima-EMEA/H/C/004723/WS1947/** **0037/G** **Ritemvia-EMEA/H/C/004725/WS1947/** **0037/G** **Truxima-EMEA/H/C/004112/WS1947/** **0040/G** Celltrion Healthcare Hungary Kft., Duplicate, Duplicate of Truxima, Lead Rapporteur: Sol Ruiz

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. 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 14-17 September 2020 CHMP plenary:

Oncology	
1. (SME); Treatment of relapse/refractory lymphoplasmacytic lymphoma and Waldenstrom's Macroglobulinemia	The CHMP denied eligibility to PRIME and adopted the critical summary report.
2. **CD30-directed genetically modified autologous T cells (CD30.CAR-T);** ATMP; Treatment of classical Hodgkin lymphoma	The CHMP granted eligibility to PRIME and adopted the critical summary report.
Haematology-haemostaseology	
3. **Autologous CD34+ cell-enriched population from patients with sickle cell disease that contains haematopoietic stem cells transduced with BB305 lentiviral vector encoding the βA-T87Q-globin gene (bb1111);** ATMP; Treatment of Sickle Cell Disease	The CHMP granted eligibility to PRIME and adopted the critical summary report.

4. **CTX001 (Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene);** Treatment of Sickle Cell Disease	The CHMP granted eligibility to PRIME and adopted the critical summary report.
Neurology	
5. Treatment of Duchenne Muscular Dystrophy	The CHMP denied eligibility to PRIME and adopted the critical summary report.
6. **AT-GTX-501 (adeno-associated viral vector, serotype 9, containing the human CLN6 gene)**; ATMP; Slowing disease progression in paediatric patients with variant late infantile neuronal ceroid lipofuscinosis 6 (vLINCL6)	The CHMP granted eligibility to PRIME and adopted the critical summary report.
7. ATMP; Treatment of Parkinson's Disease	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Endocrinology-Gynaecology-Fertility-Metabolism	
8. **Iptacopan;** Treatment of C3 glomerulopathy (complement-driven renal disease)	The CHMP granted eligibility to PRIME and adopted the critical summary report.
9. **OTL-203 (Autologous CD34+ hematopoietic stem and progenitor cells genetically modified with the lentiviral vector (IDUA LV) encoding for the alpha-L-iduronidase gene);** (SME); ATMP; Treatment of Mucopolysaccharidosis type I (MPS-1)	The CHMP granted eligibility to PRIME and adopted the critical summary report.

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

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