17 July 2023
EMA/CHMP/262270/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 22-25 May 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this set of 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/729522/2016).

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1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held in-person with some members connected 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 meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants 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. Restrictions applicable to this meeting are captured in the list of participants included in the minutes.

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. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 22-25 May 2023.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 24-26 April 2023.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 15 May 2023.

The CHMP adopted the CHMP minutes for 24-26 April 2023.

The CHMP adopted the minutes from the PROM meeting held on 15 May 2023.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. sodium phenylbutyrate / ursodoxicoltaurine - Orphan - EMEA/H/C/005901

Amylyx Pharmaceuticals EMEA B.V.; treatment of amyotrophic lateral sclerosis (ALS)

Scope: Oral explanation

Action: Oral explanation to be held on 24 May 2023 at 14:00

List of Outstanding Issues adopted on 23.02.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

An oral explanation was held on 24 May 2023. The presentation by the MAH focused on the clinical data in support of the application.

2.1.2. daprodustat - EMEA/H/C/005746

treatment of anaemia associated with chronic kidney disease (CKD) in adults

Scope: Oral explanation

Action: Oral explanation to be held on 23 May 2023 at 16:00

List of Outstanding Issues adopted on 30.03.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

An oral explanation was held on 24 May 2023. The presentation by the MAH focused on the clinical data in support of the application.

See 3.2

2.1.3. Pylclari - piflufolastat (18F) - EMEA/H/C/005520

Curium Pet France; imaging in patients undergoing oncologic diagnostic procedures when increased expression of prostate specific membrane antigen is a diagnostic target

Scope: Possible oral explanation

Action: Oral explanation to be held on 23 May 2023 at 11:00

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

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 10.11.2022.

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

See 3.1

2.2. Re-examination procedure oral explanations

2.2.1. Sohonos - palovarotene - Orphan - EMEA/H/C/004867

Ipsen Pharma; treatment of fibrodysplasia ossificans progressiva

Scope: Oral explanation

Action: Oral explanation to be held on 23 May 2023 at 14:00

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

Opinion adopted on 26.01.2023. List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 16.09.2021.

An oral explanation was held on 23 May 2023. The presentation by the MAH focused on the clinical data in support of the application.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Brintellix – vortioxetine - EMEA/H/C/PSUSA/00010052/202209

H. Lundbeck A/S

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Jo Robays

Scope: Company disagreement on PRAC recommendation on the frequency of the ADR 'sexual dysfunction' and that a frequency calculated based on clinical data should be 'common' instead of 'very common'

Scope: Oral explanation

Action: Oral explanation to be held on 23 May 2023 at 09:00

The CHMP was updated on discussions at the PRAC.

An oral explanation was held on 23 May 2023. The presentation by the MAH focused on available data on adverse events.

See 9.1

2.4. Referral procedure oral explanations

2.4.1. Adakveo - crizanlizumab - EMEA/H/A-20/1525

Novartis Europharm Limited

Referral Rapporteur: Daniela Philadelphy, Referral Co-Rapporteur: Johanna Lähteenvuo

Scope: The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of the centrally authorised medicinal product Adakveo (crizanlizumab) in its approved indication.

The initiation of the review followed preliminary results from the Phase III study

(CSEG101A2301, STAND) which was a specific obligation to the conditional marketing authorisation for Adakveo. The preliminary results for STAND study showed no superiority of crizanlizumab over placebo in annualised rates of vaso-occlusive crises leading to a healthcare visit over the first-year post randomisation.

Scope: Oral explanation

Action: Oral explanation to be held on 22 May 2023 at 16:00

Participation of patient representative and healthcare professional representative.

List of questions adopted on 26.01.2023.

An oral explanation was held on 22 May 2023. The presentation by the MAH focused on the results of the STAND study and the MAH's views on the benefits of Adakveo.

See 10.1

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Pylclari - piflufolastat (18F) - EMEA/H/C/005520

Curium Pet France; imaging in patients undergoing oncologic diagnostic procedures when increased expression of prostate specific membrane antigen is a diagnostic target

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 10.11.2022.

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 piflufolastat (18F) is a new active substance, as claimed by the applicant.

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

The CHMP noted the letter of recommendation dated 24 May 2023.

The summary of opinion was circulated for information.

3.1.2. Ztalmy - ganaxolone - Orphan - EMEA/H/C/005825

Marinus Pharmaceuticals Emerald Limited; treatment of epileptic seizures associated with cyclindependent kinase-like 5 deficiency disorder (CDD)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 26.04.2023, 26.01.2023. List of Questions adopted on 25.01.2022.

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 ganaxolone is a new active substance, as claimed by the applicant.

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

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. aflibercept - EMEA/H/C/006022

treatment of age-related macular degeneration (AMD) and visual impairment

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.09.2022.

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. cabotegravir - EMEA/H/C/005756

pre-exposure prophylaxis of HIV-1 infection

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.02.2023.

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

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

3.2.3. enalapril maleate - PUMA - EMEA/H/C/005731

treatment of heart failure

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 21.07.2022.

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.

3.2.4. dabigatran etexilate - EMEA/H/C/005922

prevention of venous thromboembolic events

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 23.06.2022.

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. crisantaspase - EMEA/H/C/005917

Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.10.2022.

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. epcoritamab - Orphan - EMEA/H/C/005985

AbbVie Deutschland GmbH & Co. KG; treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.02.2023.

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

issues.

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

3.2.7. sparsentan - Orphan - EMEA/H/C/005783

Vifor France; for the treatment of primary immunoglobulin A nephropathy (IgAN).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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

The Committee adopted a list of outstanding issues.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues with a specific timetable.

3.2.8. dabrafenib - Orphan - EMEA/H/C/005885

Novartis Europharm Limited; Treatment of glioma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.01.2023.

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. decitabine / cedazuridine - Orphan - EMEA/H/C/005823

Otsuka Pharmaceutical Netherlands B.V.; treatment of myeloid leukaemia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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

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

3.2.10. daprodustat - EMEA/H/C/005746

treatment of anaemia associated with chronic kidney disease (CKD) in adults

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 30.03.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

See 2.1

An oral explanation was held on 24 May 2023. The presentation by the MAH focused on the clinical data in support of the application.

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

3.2.11. adagrasib - EMEA/H/C/006013

treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 15.09.2022.

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. ritlecitinib - EMEA/H/C/006025

indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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. masitinib - Orphan - EMEA/H/C/005897

AB Science; in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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.

3.2.14. elacestrant - EMEA/H/C/005898

treatment of postmenopausal woman and men with breast cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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.

3.2.15. trametinib - Orphan - EMEA/H/C/005886

Novartis Europharm Limited; Treatment of paediatric patients aged 1 year and older with glioma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.01.2023.

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. sugammadex - EMEA/H/C/006115

reversal of neuromuscular blockade induced by rocuronium or vecuronium

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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

The Committee adopted a list of outstanding issues.

The CHMP did not agree to the request by the applicant for an extension to the clock stop but agreed to a shorter clock stop to respond to the list of outstanding issues with a specific timetable.

3.2.17. tocilizumab - EMEA/H/C/005984

treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA) and COVID-19

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.01.2023.

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

The Committee adopted a list of outstanding issues.

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

3.2.18. tocilizumab - EMEA/H/C/005781

treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), Giant Cell Arteritis (GCA), chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) and COVID-19

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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.

3.2.19. quizartinib - Orphan - EMEA/H/C/005910

Daiichi Sankyo Europe GmbH; Treatment of adult patients with diagnosed acute myeloid leukaemia (AML)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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

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

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

3.2.20. oteseconazole - EMEA/H/C/005682

treatment and prevention of recurrent vulvovaginal candidiasis (RVVC) including the acute episodes of RVVC in adult women

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.09.2022.

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. concizumab - EMEA/H/C/005938

routine prophylaxis to prevent or reduce the frequency of bleeding in patients with: haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors ≥ 12 years of age; haemophilia B (congenital factor IX deficiency) with FIX inhibitors of any age

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.2. exagamglogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005763

Vertex Pharmaceuticals (Ireland) Limited; treatment of transfusion-dependent β-thalassemia and sickle cell disease

Scope: List of questions

Action: For information

The CHMP was updated on discussions at the CAT. The CHMP discussed the issues identified in this application.

The Committee endorsed the CHMP recommendation and scientific discussion together with the list of questions as adopted by the CAT.

3.3.3. elranatamab - PRIME - Orphan - EMEA/H/C/005908

Pfizer Europe MA EEIG; Treatment of adult patients with relapsed or refractory multiple myeloma

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. cefepime / enmetazobactam - EMEA/H/C/005431

treatment of: 1) complicated urinary tract infections (including pyelonephritis); 2) hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); 3) patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above and 4) infections due to aerobic Gram-negative organisms in adults with limited treatment options

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. insulin human - EMEA/H/C/006011

treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis

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. lecanemab - EMEA/H/C/005966

a disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer's disease and Mild Alzheimer's disease (Early Alzheimer's disease)

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. paclitaxel - EMEA/H/C/006173

treatment of metastatic 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.

3.3.8. paliperidone - EMEA/H/C/006185

Treatment of schizophrenia

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. pegcetacoplan - EMEA/H/C/005954

Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

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. epinephrine - EMEA/H/C/006139

Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

Scope: Letter by the applicant dated 28.04.2023 requesting an extension to the clock stop to respond to the list of questions adopted in February 2023.

Action: For adoption

List of questions adopted on 23.02.2023.

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 February 2023.

3.4.2. catumaxomab - EMEA/H/C/005697

indicated for the treatment of malignant ascites

Scope: Letter by the applicant dated 28.04.2023 requesting an extension to the clock stop to respond to the list of questions adopted in December 2022.

Action: For adoption

List of questions adopted on 15.12.2022.

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 December 2022.

3.4.3. ranibizumab - EMEA/H/C/006055

treatment of neovascular age-related macular degeneration (AMD)

Scope: Letter by the applicant dated 27.04.2023 requesting an extension to the clock stop to respond to the list of questions adopted in February 2023; adopted via written procedure on 15 May 2023.

Action: For information

List of Questions adopted on 23.02.2023.

The CHMP noted the new timetable, which was adopted via written procedure.

3.4.4. tislelizumab - EMEA/H/C/005542

treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in adults, treatment of locally advanced or metastatic squamous non-small cell lung cancer in adults, locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults.

Scope: Letter by the applicant dated 17.05.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in March 2023.

Action: For adoption

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 21.07.2022.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in March 2023.

3.4.5. bevacizumab - EMEA/H/C/005574

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

Scope: Letter by the applicant dated 09.05.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in February 2022.

Action: For adoption

List of Outstanding Issues adopted on 24.02.2022. List of Questions adopted on 22.04.2021.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in February 2022.

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

3.5.1. Lagevrio - molnupiravir - EMEA/H/C/005789

Merck Sharp & Dohme B.V.; treatment of coronavirus disease 2019 (COVID-19)

Scope: List of questions; questions to the SAG

Action: For adoption

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

Opinion adopted on 23.02.2023. List of Outstanding Issues adopted on 22.04.2022. List of

Questions adopted on 24.02.2022, 16.12.2021.

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

The Committee adopted a list of questions to the SAG.

3.5.2. Sohonos - palovarotene - Orphan - EMEA/H/C/004867

Ipsen Pharma; treatment of fibrodysplasia ossificans progressiva

Scope: Opinion

Action: For adoption

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

Opinion adopted on 26.01.2023. List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 16.09.2021.

See 2.2

An oral explanation was held on 23 May 2023. The presentation by the MAH focused on the clinical data in support of the application.

The CHMP adopted a negative opinion by consensus recommending the refusal of the granting of the marketing authorisation. The CHMP assessment report was adopted.

The CHMP noted the question-and-answer document.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Asimtufii - aripiprazole - EMEA/H/C/005929

Otsuka Pharmaceutical Netherlands B.V.; Maintenance treatment of schizophrenia

Scope: Withdrawal of marketing authorisation application

Action: For information

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

List of Outstanding Issues adopted on 26.01.2023. List of Questions adopted on 13.10.2022.

The CHMP noted the withdrawal of the marketing authorisation application.

3.7.2. Susvimo - ranibizumab - EMEA/H/C/005610

Roche Registration GmbH; treatment of neovascular age-related macular degeneration in adults

Scope: Withdrawal of marketing authorisation application

Action: For information

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

List of Outstanding Issues adopted on 24.02.2022. List of Questions adopted on 16.09.2021.

The CHMP noted the withdrawal of the marketing authorisation application.

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

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

4.1.1. Sogroya - somapacitan - Orphan - EMEA/H/C/005030/X/0006/G

Novo Nordisk A/S

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber

Scope: "Extension application to add a new strength of 15 mg/1.5 mL solution for injection in pre-filled pen grouped with a type II variation C.I.6 to add a new indication 'Sogroya is indicated for the replacement of endogenous growth hormone (GH) in children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD).', based on results from the completed main 52-week period of the confirmatory phase 3 trial (4263), supported with long-term data from the phase 2 trial (4172), up to week 208 completed. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC have been updated and the Package Leaflet has been updated accordingly. A revised RMP version 3.2 was provided as part of the application."

Action: For adoption

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 10.11.2022.

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 summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

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. Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/X/0016

Novo Nordisk A/S

Rapporteur: Daniela Philadelphy

Scope: "Extension application to add two new strengths of 4000 IU and 5000 IU powder and solvent for solution for injection."

Action: For adoption

List of Questions adopted on 26.01.2023.

The Committee was reminded of the status of this application and its remaining outstanding issues, relating to quality aspects.

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

4.2.2. Olumiant - baricitinib - EMEA/H/C/004085/X/0035/G

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new strength (1 mg film-coated tablet), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment, as monotherapy or in combination with conventional synthetic disease modifying antirheumatic drugs (DMARDs), of active juvenile idiopathic arthritis (JIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs, based on final results from the pivotal study JAHV (I4V-MC-JAHV); this is a multicentre, double-blind, randomised, placebo-controlled, medication-withdrawal Phase 3 study in children from 2 years to less than 18 years of age with JIA who have had an inadequate response or intolerance to treatment with at least 1 cDMARD or bDMARD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.1 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 26.01.2023.

The Committee was reminded of the status of this application and its remaining outstanding issues, relating to quality and clinical aspects as well as the RMP.

The Committee adopted a list of outstanding issues with 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. Cufence - trientine - EMEA/H/C/004111/X/0014/G

Univar Solutions BV

Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to add a new strength (100 mg capsule, hard) grouped with a type IA variation (B.II.b.4.b). The RMP (version 1.3) is updated in accordance.
The marketing authorisation holder took the opportunity to align the PI to the latest QRD template (version 10.3)."

Action: For adoption

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

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

4.3.2. Kalydeco - ivacaftor - EMEA/H/C/002494/X/0115/G

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension application to introduce a new strength (13.4 mg of ivacaftor granules in sachet), grouped with a type II variation (C.I.6.a) in order to extend the indication of the granule presentations to include children with cystic fibrosis aged 1 to less than 4 months of age and weighing 3 kg or more who have an R117H CFTR mutation or one of the approved 9 gating (class III) mutations based on interim results from study VX15-770-124 (study 124); this is a phase 3, 2-part, open-label study to evaluate the safety, pharmacokinetics, and pharmacodynamics of ivacaftor (IVA) in subjects with CF who are less than 24 months of age at treatment initiation and have a CFTR gating mutation. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3 and 8 of the SmPC of the granules presentations and sections 4.2, 4.8, 5.1 and 5.2 of the SmPC of the tablets presentations are updated. The Labelling for the 13.4 mg granule presentation and the Package Leaflet of the granules and tablets presentations are updated in accordance. Version 15.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.
Type IA A.5.b
Type IA B.II.b.2.a"

Action: For adoption

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

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

4.3.3. Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0035

Eurocept International B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (350 mg/ml oral solution). The RMP (version 0.1) is updated in accordance."

Action: For adoption

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

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

4.3.4. Yuflyma - adalimumab - EMEA/H/C/005188/X/0022

Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to add a new strength (20 mg solution for injection). The indications for the new strength are identical to those already approved for the 40 mg strength. The RMP (version 2.1) has also been submitted.
In addition, the MAH took the opportunity to include editorial changes."

Action: For adoption

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

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

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

No items

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

No items

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

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

5.1.1. Foclivia - pandemic influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/001208/II/0081

Seqirus S.r.l

Rapporteur: Maria Grazia Evandri, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include children from 6 months to less than 18 years of age for Foclivia, based on final results from study V87_30; this is a phase 2, randomized, observer-blind, multicenter study to evaluate the immunogenicity and safety of several doses of antigen and MF59 adjuvant content in a monovalent H5N1 pandemic influenza vaccine in healthy paediatric subjects 6 months to less than 9 years of age. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.9 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template."

Action: For adoption

Request for Supplementary Information adopted on 30.03.2023.

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

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

5.1.2. HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0087

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in adults for HyQvia, based on final results from studies 161403 and ABV-771-1001; and interim results from study 161505. 161403 and 161505 are interventional Phase III efficacy and safety studies respectively, while ABV-771-1001 is an interventional Phase I safety study. 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 and Labelling are updated in accordance. Version 14.0 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.3. Imjudo - tremelimumab - EMEA/H/C/006016/II/0001

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia

Scope: "Extension of indication to include in combination with durvalumab and platinum-based chemotherapy, the first-line treatment of adults with metastatic non-small cell lung cancer (NSCLC) with no sensitising EGFR mutations or ALK positive mutations for Imjudo, based on the final analysis from the pivotal study D419MC00004, a Randomised, Multi-center, Open-Label, Comparative Global Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Patients with Metastatic Non Small-Cell Lung Cancer (NSCLC) (POSEIDON). As a consequence, sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to include editorial changes."

Action: For adoption

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

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

5.1.4. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0133

Merck Sharp & Dohme B.V.

Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy for treatment of locally advanced unresectable or metastatic HER2- positive gastric or gastro-oesophageal junction adenocarcinoma for Keytruda, based on interim results from study KEYNOTE-811, an ongoing Phase 3, double-blind trial comparing trastuzumab plus chemotherapy and pembrolizumab with trastuzumab plus chemotherapy and placebo as first-line treatment in participants with HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 40.1 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.5. Lonsurf - trifluridine / tipiracil - EMEA/H/C/003897/II/0026

Les Laboratoires Servier

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

Scope: "Extension of indication to include treatment of patients with refractory metastatic colorectal cancer, for Lonsurf in combination with bevacizumab based on results from study SUNLIGHT (CL3-95005-007); This is an open-label, randomised, phase III study comparing trifluridine/tipiracil in combination with bevacizumab to trifluridine/tipiracil monotherapy in patients with refractory metastatic colorectal cancer. 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. The updated RMP version 9.1 has also been submitted. In addition, the MAH took the opportunity to update section 4.6 of the SmPC and the package leaflet accordingly."

Action: For adoption

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

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

5.1.6. Nordimet - methotrexate - EMEA/H/C/003983/II/0027

Nordic Group B.V.

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include treatment of moderate to severe recalcitrant disabling psoriasis for Nordimet, based on literature; As a consequence, sections 4.1 and 4.2 of the SmPC were updated. The package leaflet is updated in accordance. Version 6.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 23.02.2023.

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

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

5.1.7. Opdivo - nivolumab - EMEA/H/C/003985/II/0117

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include Opdivo in combination with platinum-based chemotherapy for neoadjuvant treatment of adult patients with resectable Stage IB-IIIA non-small cell lung cancer (NSCLC), based on results from study CA209816; a randomised, open-label, phase 3 trial of nivolumab plus ipilimumab or nivolumab plus platinum-doublet chemotherapy versus platinum-doublet chemotherapy in early-stage NSCLC. 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 27.4 of the RMP has also been submitted."

Action: For adoption

Oral explanation held on 26.04.2023. Request for Supplementary Information adopted on 26.04.2023, 23.02.2023, 13.10.2022, 23.06.2022.

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 summary of opinion was circulated for information.

5.1.8. Opdivo - nivolumab - EMEA/H/C/003985/II/0130

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include Opdivo for the adjuvant treatment of adults and adolescents 12 years of age and older with stage IIB or IIC melanoma who have undergone complete resection, based on results from study CA20976K; This is a phase III, randomized, double-blind study of adjuvant immunotherapy with nivolumab versus placebo after complete resection of stage IIB/C melanoma. 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 33.0 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.9. Rubraca - rucaparib - EMEA/H/C/004272/II/0036

Clovis Oncology Ireland Limited

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include maintenance treatment of adult patients with advanced (FIGO Stages III and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first-line platinum-based chemotherapy for Rubraca, based on interim results from study CO-338-087 (ATHENA); this is a Phase III, randomized, double-blind, dual placebo controlled study of rucaparib as monotherapy and in combination with nivolumab in patients with newly diagnosed EOC, FTC, or PPC who have responded to their first-line treatment (surgery and platinum-based chemotherapy). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.3 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection." 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 15.12.2022.

The Committee discussed the issues identified in this application, relating to clinical aspects and the request for 1 year of market protection.

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

5.1.10. Scenesse - afamelanotide - Orphan - EMEA/H/C/002548/II/0044

Clinuvel Europe Limited

Rapporteur: Janet Koenig, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication for the prevention of phototoxicity in adolescent patients (12 to under 18 years of age) with erythropoietic protoporphyria (EPP), based on the analysis of the safety and efficacy data available. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.4 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial correction to the PI."

Action: For adoption

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

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

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

5.2.1. Ervebo - recombinant vesicular stomatitis virus - Zaire Ebolavirus vaccine (live) - EMEA/H/C/004554/II/0025

Merck Sharp & Dohme B.V.

Rapporteur: Christophe Focke, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include the paediatric population from 1 year to less than 18 years of age based on final results from study V920-016 (PREVAC); this is a phase 2, randomized, double-blind, placebo-controlled study of 2 leading Ebola vaccine candidates (Ad26.ZEBOV/MVA-BN-Filo and V920) and 3 vaccine strategies (Ad26.ZEBOV/MVABN-Filo, 1-dose V920, and 2 dose V920) to evaluate immunogenicity and safety in healthy children and adolescents from 1 to 17 years of age and adults 18 years of age and older. 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 in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the Annex II and the list of local representatives in the Package Leaflet."

Letter by the applicant dated 12.05.2023 requesting an extension to the clock stop to respond to the RSI adopted in April 2023.

Action: For adoption

Request for Supplementary Information adopted on 26.04.2023, 10.11.2022.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the RSI adopted in April 2023.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. in vitro diagnostic medical device - EMEA/H/D/006255

is indicated as an aid in the selection of adult haemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered

Scope: Opinion

Action: For adoption

Request for Supplementary Information adopted on 21.04.2023

The CHMP was updated on discussions at the CAT.

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.

6.4. Companion diagnostics – follow-up consultation

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

8.2. Priority Medicines (PRIME)

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 list of applications received.

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 7 recommendations for eligibility to PRIME: 2 were accepted and 5 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. JCOVDEN - COVID-19 vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0072/G

Janssen-Cilag International N.V.

Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder

Scope: "Update of section 4.4 of the SmPC in order to add a new warning on myocarditis and pericarditis and update of section 4.8 of the SmPC to add myocarditis and pericarditis to the list of adverse drug reactions (ADRs) with frequency not known based on post-marketing data and three observational claims databases in US. The Package Leaflet is updated accordingly. A revised RMP version 6.4 has been approved.
In addition, the MAH took the opportunity to update the ATC Code as amended by the WHO."

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.

9.1.2. Voxzogo - vosoritide - EMEA/H/C/005475/II/0007, Orphan

BioMarin International Limited

Rapporteur: Martina Weise, PRAC Rapporteur: Zane Neikena

Scope: quality variation

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 CHMP endorsed the DHPC.

9.1.3. Rubraca - rucaparib - EMEA/H/C/004272/II/0037

Clovis Oncology Ireland Limited

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Update of sections 4.4 and 5.1 of the SmPC in order to update the efficacy and safety information based on the final results from study CO-338-014 (ARIEL 3) listed as a category 1 PAES in the Annex II; this is a phase 3, multicenter, randomized, double-blind, placebo-controlled study of rucaparib as switch maintenance following platinum-based chemotherapy in patients with platinum-sensitive, high grade serous or endometrioid epithelial ovarian, primary peritoneal or fallopian tube cancer. Annex II and the RMP version 7.1 are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022.

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.

9.1.4. Translarna - ataluren - EMEA/H/C/002720/R/0071, Orphan

PTC Therapeutics International Limited

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Renewal of conditional marketing authorisation

Action: For adoption

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

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

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

9.1.5. Translarna - ataluren - EMEA/H/C/002720/II/0069, Orphan

PTC Therapeutics International Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information following results from study PTC124-GD-041-DMD, listed as a specific obligation in the Annex II; This is a Phase 3 multicentre, randomised, double-blind, 18-month, placebo-controlled study, followed by a 18-month open label extension to confirm the efficacy and safety of ataluren in the treatment of ambulant patients with mnDMD aged 5 years or older.
Annex II, and Annex IIB are updated to delete the SOB and to reflect the switch from conditional to full marketing authorisation.
The Package Leaflet is updated accordingly. The RMP version 11.0 has also been submitted. Minor corrections were done to align the PI with the latest QRD templates."

Action: For adoption

Request for Supplementary Information adopted on 26.01.2023.

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

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

9.1.6. Lumykras - sotorasib - EMEA/H/C/005522/II/0010/G

Amgen Europe B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change in the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B.
Study 20190009 is a Phase 3 Multicentre, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumours With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC."

Action: For adoption

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

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

9.1.7. Nuvaxovid - Covid-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0048/G

Novavax CZ, a.s.

Rapporteur: Johann Lodewijk Hillege

Scope: quality variation

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.

9.1.8. Beovu - brolucizumab - EMEA/H/C/004913/II/0018

Novartis Europharm Limited

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to introduce an alternative posology regimen for wet AMD and update information based on modelling and simulation studies; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.03.2023, 10.11.2022.

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.

9.1.9. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0056

Orexigen Therapeutics Ireland Limited

Scope: Re-examination; endorsement by CHMP of the need for an expert meeting

Action: For adoption

Opinion adopted on 30.03.2023. Request for Supplementary Information adopted on 26.01.2023, 15.09.2022, 24.03.2022.

The CHMP agreed to consult a SAG and adopted the re-examination timetable.

9.1.10. Brintellix – vortioxetine - EMEA/H/C/PSUSA/00010052/202209

H. Lundbeck A/S

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Jo Robays

Scope: Company disagreement on PRAC recommendation on the frequency of the ADR 'sexual dysfunction' and that a frequency calculated based on clinical data should be 'common' instead of 'very common'

Action: For adoption

See 2.3

The CHMP was updated on discussions at the PRAC.

An oral explanation was held on 23 May 2023. The presentation by the MAH focused on available data on adverse events.

CHMP did not agree with the PRAC recommendation and adopted a revised opinion by consensus.

10. Referral procedures

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

10.1.1. Adakveo - crizanlizumab - EMEA/H/A-20/1525

Novartis Europharm Limited

Referral Rapporteur: Daniela Philadelphy, Referral Co-Rapporteur: Johanna Lähteenvuo

Scope: The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of the centrally authorised medicinal product Adakveo (crizanlizumab) in its approved indication.

The initiation of the review followed preliminary results from the Phase III study (CSEG101A2301, STAND) which was a specific obligation to the conditional marketing authorisation for Adakveo. The preliminary results for STAND study showed no superiority of crizanlizumab over placebo in annualised rates of vaso-occlusive crises leading to a healthcare visit over the first-year post randomisation.

Scope: Opinion

Action: For adoption

List of questions adopted on 26.01.2023.

See 2.4

An oral explanation was held on 22 May 2023. The presentation by the MAH focused on the results of the STAND study and the MAH's views on the benefits of Adakveo.

The CHMP adopted an opinion by consensus, recommending to revoke the marketing authorisation for Adakveo. The CHMP concluded that the benefits of the medicine did not

outweigh its risks. The CHMP assessment report was adopted.

The CHMP endorsed the DHPC and the EMA press release.

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

May 2023 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

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by proxy

No topics

14.1.2. CHMP membership

The Chair welcomed Carolina Prieto Fernandez as new alternate for Spain and Andreja Kranic as new alternate for Slovenia.

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for May 2023

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Draft agenda for the May 2023 PDCO meeting

Action: For information

The CHMP noted the agenda.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry/Francesca Luciani

Reports from BWP May 2023 meeting to CHMP for adoption:

- 7 reports on products in scientific advice and protocol assistance
- 10 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: Paolo Foggi

Report from the SAWP meeting held on 08-12 May 2023. Table of conclusions

Action: For information

Scientific advice letters:

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

The CHMP noted the update.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

The update was postponed to the June PROM.

15.1.2. Control options for nitrosamines: update and way forward

Action: For information

The CHMP was updated on future control options for nitrosamines.

Lists of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 22-25 May 2023 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	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Ilko Getov	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No participation in final deliberations and voting on:	COVID-19 vaccines
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	concizumab - EMEA/H/C/005938 Sogroya - somapacitan - EMEA/H/C/005030/X/0006/G Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/X/0016
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	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	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No participation in discussion, final deliberations and voting on:	Imjudo - tremelimumab - EMEA/H/C/006016/II/0001
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sol Ruiz	Co-opted member	Spain	No interests declared	
Karri Penttila	Expert	Finland	No interests declared	
Paula Grönroos	Expert	Finland	No interests declared	
Eva Malikova	Expert	Slovakia	No interests declared	
Anna Kubandová	Expert	Slovakia	No interests declared	
Vincent Gazin	Expert	France	No interests declared	
Simin Oveisi	Expert	France	No restrictions applicable to this meeting	
Susanne Urach	Expert	Austria	No interests declared	
Elisabeth Wischnitzki	Expert	Austria	No interests declared	
Angelina Doriguzzi	Expert	Austria	No restrictions applicable to this meeting	
Christine Vaculik	Expert	Austria	No interests declared	
Thomas Lang	Expert	Austria	No interests declared	
Walter Johannes Beiersdorf	Expert	Austria	No restrictions applicable to this meeting	
Hannah Münch	Expert	Austria	No interests declared	
Nadine Sider	Expert	Austria	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Katja Findeisen	Expert	Germany	No restrictions applicable to this meeting	
Juliane Rau	Expert	Germany	No interests declared	
Attila Sebe	Expert	Germany	No interests declared	
Michal Zwiewka	Expert	Germany	No interests declared	
Irene Nowotny	Expert	Germany	No restrictions applicable to this meeting	
Samira Alina Marx	Expert	Germany	No interests declared	
Susanne Mueller-Egert	Expert	Germany	No interests declared	
Yasmin Molter	Expert	Germany	No interests declared	
Nina Hessvik	Expert	Norway	No interests declared	
Lena Eroukhmanoff	Expert	Norway	No participation in discussion, final deliberations and voting on:	daprodustat - EMEA/H/C/005746
Jolita Pancere	Expert	Lithuania	No interests declared	
Nathalie Parij	Expert	Belgium	No interests declared	
Sophie Goethals	Expert	Belgium	No restrictions applicable to this meeting	
Jo Robays	Expert	Belgium	No interests declared	
Inne Crèvecoeur	Expert	Belgium	No restrictions applicable to this meeting	
Valerie Lescrainier	Expert	Belgium	No interests declared	
Karin Fjordén	Expert	Sweden	No participation in final deliberations and voting on:	Keytruda - pembrolizumab - EMEA/H/C/003820/II/0133 epcoritamab - Orphan - EMEA/H/C/005985

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jenny-Maria Jönsson	Expert	Sweden	No participation in final deliberations and voting on:	Rubraca - rucaparib - EMEA/H/C/004272/II/0036 EMEA/H/C/004272/II/0037 Opdivo - nivolumab - EMEA/H/C/003985/II/0117 EMEA/H/C/003985/II/0130
Charlotte Anderberg	Expert	Sweden	No interests declared	
Maria Winqvist	Expert	Sweden	No interests declared	
Luca Fancsalszky	Expert	Hungary	No interests declared	
Judit dr Perbiróné Szabó	Expert	Hungary	No interests declared	
Viktor Billes	Expert	Hungary	No interests declared	
Gabriella Passacquale	Expert	Italy	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Valeria Di Muzio	Expert	Italy	No interests declared	
Odoardo Maria Olimpieri	Expert	Italy	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Adriana Ammassari	Expert	Italy	No interests declared	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert	Italy	No restrictions applicable to this meeting	
Federico De Angelis	Expert	Italy	No interests declared	
Valentina Conti	Expert	Italy	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Pia Rivetti di Val Cervo	Expert	Italy	No interests declared	
Doris Sommer	Expert	Austria	No interests declared	
Meera Varma	Expert	Denmark	No restrictions applicable to this meeting	
Bibi Fatima Syed Shah	Expert	Denmark	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Torsten Holm Nielsen	Expert	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Expert	Denmark	No interests declared	
Lene Weber Vestermark	Expert	Denmark	No interests declared	
Deidre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Sine Buhl Naess-Schmidt	Expert	Denmark	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Anne Hasle Buur	Expert	Denmark	No interests declared	
Kinga Nowicka-Matus	Expert	Denmark	No interests declared	
Kristin Skougaard	Expert	Denmark	No interests declared	
Claus Stage	Expert	Denmark	No restrictions applicable to this meeting	
Nanna Borup Johansen	Expert	Denmark	No interests declared	
Jacob Alsbæk Olsen	Expert	Denmark	No restrictions applicable to this meeting	
Ebru Karakoc Madsen	Expert	Denmark	No interests declared	
Kairi Rooma	Expert	Estonia	No interests declared	
Keiu Heinla	Expert	Estonia	No interests declared	
Aina Jannicke Øvrebust	Expert	Norway	No interests declared	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Nicolas Camhaji	Expert	France	No participation in discussion, final deliberations and voting on:	Adakveo - crizanlizumab - EMEA/H/A-20/1525 dabrafenib - EMEA/H/C/005885 trametinib - EMEA/H/C/005886 tislelizumab - EMEA/H/C/005542 Beovu - brolucizumab - EMEA/H/C/004913/II/0018
Marta Lafuente Gonzalez	Expert	Spain	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Beatriz Gutiérrez Eugenio	Expert	Spain	No interests declared	
Andrea García Caballero	Expert	Spain	No interests declared	
Agata Arias Sánchez	Expert	Spain	No interests declared	
Lourdes Rodriguez Rojas	Expert	Spain	No interests declared	
Luisa Valer	Expert	Spain	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Eva Maria Nadal Elduayen	Expert	Spain	No interests declared	
Tomas Arroyo Perez	Expert	Spain		
Teresa Llacer Delicado	Expert	Spain	No interests declared	
Julia Ruiz Gutierrez	Expert	Spain	No interests declared	
Daniel Fernández Soto	Expert	Spain	No interests declared	
Sara Camilleri	Expert	Malta	No interests declared	
Elizabeth Jacoba Johanna Berm	Expert	Netherlands	No restrictions applicable to this meeting	
Frank Holtkamp	Expert	Netherlands	No interests declared	
Marika van Leeuwen	Expert	Netherlands	No interests declared	
Adrian Post	Expert	Netherlands	No interests declared	
Kommerie Hendrik	Expert	Netherlands	No interests declared	
Lieke Sandberg Smits	Expert	Netherlands	No interests declared	
Hinke Johanna Van der Woude	Expert	Netherlands	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Jessica Harskamp	Expert	Netherlands	No interests declared	
Laura Rodwell	Expert	Netherlands	No interests declared	
Quirine Fillekes	Expert	Netherlands	No interests declared	
Lies (Elizabeth) Van Vlijmen	Expert	Netherlands	No interests declared	
Rou-Afza Gunput	Expert	Netherlands	No interests declared	
Cristel Loeb	Expert	Netherlands	No interests declared	
Gerlienke Geurts-Voerman	Expert	Netherlands	No interests declared	
Emmely de Vries	Expert	Netherlands	No interests declared	
Katrien Oude Rengerink	Expert	Netherlands	No interests declared	
Jakob Fransen	Expert	Netherlands	No interests declared	
Siona Slob	Expert	Netherlands	No interests declared	
Chaya Gopie	Expert	Netherlands	No interests declared	
Christine Siezen	Expert	Netherlands	No restrictions applicable to this meeting	
Esther Brandon	Expert	Netherlands	No interests declared	
Ingrid Bijsmans	Expert	Netherlands	No interests declared	
Taco Monster	Expert	Netherlands	No interests declared	
Victoriia Starokozhko	Expert	Netherlands	No interests declared	
Marjolijn Schalk	Expert	Netherlands	No interests declared	
Ineke Havinga	Expert	Netherlands	No interests declared	
Charlotte Welsh	Expert	Sweden	No restrictions applicable to this meeting	
Johan Sällström	Expert	Sweden	No restrictions applicable to this meeting	
Nikolina Torti	Expert	Croatia	No interests declared	
Tihana Slezak	Expert	Croatia	No interests declared	
Norontsoa Rasolondramanitra	Expert	France	No interests declared	
Andrea Laslop	Expert	Austria	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anders Lignell	Expert	Sweden	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Nora Cascante Estepa	Expert	Germany	No interests declared	
Susanna Hausmann	Expert	Germany	No interests declared	
Heiko Preusser	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Ulrike Hermes	Expert	Germany	No interests declared	
Ola Nilsson	Expert	Expert recommended by EMA	No restrictions applicable to this meeting	
Jutta Dedorath	Expert	Germany	No interests declared	
Leonard Held	Expert	Expert recommended by EMA	No participation in discussion, final deliberations and voting on:	tocilizumab - EMEA/H/C/005984
Maria Elisabeth Kalland	Expert	Norway	No interests declared	
Muriel Uzzan	Expert	France	No interests declared	
Andreas Brandt	Expert	Germany	No interests declared	
Lucia Lopez-Anglada Fernandez	Expert	Spain	No interests declared	
Leon van Aerts	Expert	Netherlands	No interests declared	
Marianne Schmidt	Expert	Denmark	No interests declared	
Philipp Janesch	Expert	Austria	No interests declared	
Karl Katholnig	Expert	Austria	No restrictions applicable to this meeting	
Robine Donken	Expert	Netherlands	No interests declared	
Priscilla Schoondermark	Expert	Netherlands	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Line Praest Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Ann-Cathrine Bach Dunvald	Expert	Denmark	No interests declared	
Mette Tranholm	Expert	Denmark	No interests declared	
Paula Contreras Alarcón	Expert	Spain	No participation in discussion, final deliberations and voting on:	epcoritamab - Orphan - EMEA/H/C/005985
Loes den Otter	Expert	Netherlands	No interests declared	
Carla Herberts	Expert	Netherlands	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with the help of EMA staff				

Experts were evaluated against the agenda topics or activities they participated in.

Experts from international organisations or regulatory authorities in third countries cannot participate in the adoption of any procedural decision, scientific opinion or recommendation by the Committee at any step of the procedure.

Explanatory notes

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

Oral explanations *(section 2)*

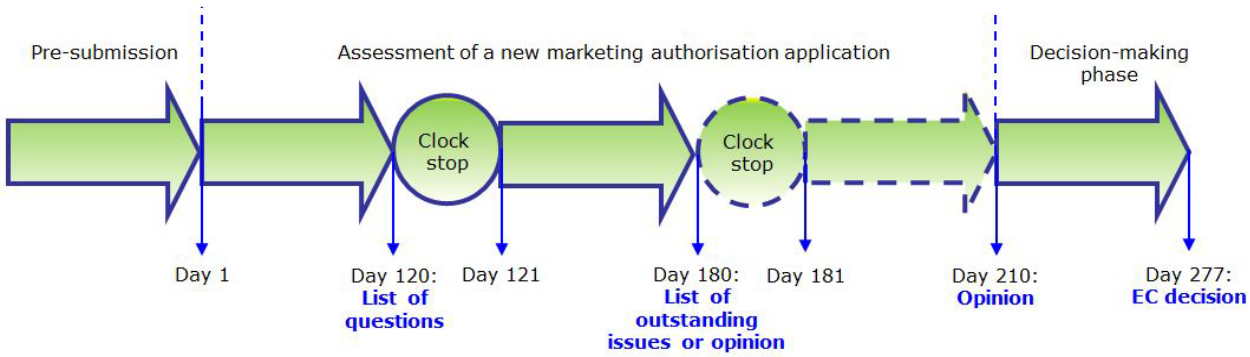
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

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A. PRE-SUBMISSION ISSUES

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Report on Eligibility to Centralised Procedure for May 2023: **For adoption**	Adopted.

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

Final Outcome of Rapporteurship allocation for May 2023: **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

Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/S/0004 SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Voraxaze - glucarpidase - EMEA/H/C/005467/S/0013, Orphan SERB S.A.S., Rapporteur: Petr Vrbata, PRAC Rapporteur: Martin Huber	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Luxturna - voretigene neparvovec - EMEA/H/C/004451/R/0040, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Sol Ruiz, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer	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.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Alunbrig - brigatinib / brigatinib - EMEA/H/C/004248/R/0049 Takeda Pharma A/S, Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Inês Ribeiro-Vaz	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.
Apealea - paclitaxel - EMEA/H/C/004154/R/0017 Inceptua AB, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Inês Ribeiro-Vaz Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Buvidal - buprenorphine - EMEA/H/C/004651/R/0021 Camurus AB, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Tiphaine Vaillant Request for Supplementary Information adopted on 26.04.2023.	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.
Emgality - galcanezumab - EMEA/H/C/004648/R/0023 Eli Lilly Nederland B.V., Rapporteur: Armando Genazzani, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Fulphila - pegfilgrastim - EMEA/H/C/004915/R/0042 Viatris Limited, Rapporteur: Martina Weise, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Hulio - adalimumab - EMEA/H/C/004429/R/0041 Viatris Limited, Rapporteur: Christophe Focke, Co-Rapporteur: Christian Gartner, PRAC Rapporteur: Ulla Wändel Liminga Request for Supplementary Information adopted on 30.03.2023.	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.
Ilumetri - tildrakizumab - EMEA/H/C/004514/R/0042 Almirall S.A, Rapporteur: Jan Mueller-Berghaus,	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.

Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Adam Przybylkowski Request for Supplementary Information adopted on 30.03.2023.	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.
Mepsevii - vestronidase alfa - EMEA/H/C/004438/R/0033, Orphan Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Maria del Pilar Rayon Request for Supplementary Information adopted on 30.03.2023.	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.
TAKHZYRO - lanadelumab - EMEA/H/C/004806/R/0035, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Kirsti Villikka Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Vaborem - meropenem / vaborbactam - EMEA/H/C/004669/R/0019 Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Maria del Pilar Rayon	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.
Xofigo - radium-223 - EMEA/H/C/002653/R/0049 Bayer AG, Rapporteur: Janet Koenig, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Rugile Pilviniene Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/R/0056, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, CHMP Coordinators: Jan Mueller-Berghaus and Karin Janssen van Doorn, PRAC Rapporteur: Anette Kirstine Stark Request for Supplementary Information adopted on 17.02.2023.	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.

B.2.3. Renewals of Conditional Marketing Authorisations

AYVAKYT - avapritinib - EMEA/H/C/005208/R/0025, Orphan Blueprint Medicines (Netherlands) B.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
Idefirix - imlifidase - EMEA/H/C/004849/R/0014, Orphan Hansa Biopharma AB, Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 26.04.2023.	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.
Kinpeygo - budesonide - EMEA/H/C/005653/R/0003, Orphan STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
MINJUVI - tafasitamab - EMEA/H/C/005436/R/0009, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
ROCTAVIAN - valoctocogene roxaparvovec - EMEA/H/C/005830/R/0003, Orphan, ATMP BioMarin International Limited, Rapporteur: Violaine Closson Carella, Co-Rapporteur: Silke Dorner, CHMP Coordinators: Jean-Michel Race and Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 21.04.2023.	Positive Opinion adopted by consensus together with the CAT/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.
Tecvayli - teclistamab - EMEA/H/C/005865/R/0002 Janssen-Cilag International N.V., Rapporteur:	Positive Opinion adopted by consensus together with the CHMP assessment report and

Johanna Lähteenvuo, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Jana Lukacisinova	translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
Translarna - ataluren - EMEA/H/C/002720/R/0071, Orphan PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Liana Gross-Martirosyan Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable. See 9.1
VITRAKVI - larotrectinib - EMEA/H/C/004919/R/0031 Bayer AG, Rapporteur: Filip Josephson, PRAC Rapporteur: Rugile Pilviniene	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 10-12 May 2023 PRAC:	
Signal of adrenal insufficiency Lenvima; Kisplyx – Lenvatinib Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Ulla Wändel Liminga PRAC recommendation on a variation **Action:** For adoption	The CHMP adopted the PRAC recommendation.
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its May 2023 meeting:	
EMEA/H/C/PSUSA/00000873/202210 (conestat alfa) CAPS: **Ruconest** (EMEA/H/C/001223) (conestat alfa), Pharming Group N.V, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Jan Neuhauser, "28/04/2022 To: 28/10/2022"	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(s) 4.8. of the SmPC to add the adverse reactions "Hypersensitivity reactions" and "Anaphylaxis" with a frequency "Not known" and "Uncommon", respectively; and a warning/precaution regarding Thromboembolic events and Hypersensitivity reactions is added and /or updated in the SmPC section 4.4. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00002653/202209 (rivaroxaban) CAPS: **Xarelto** (EMEA/H/C/000944) (Rivaroxaban), Bayer AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "15/09/2020 To: 15/09/2022"	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 add the adverse reaction anticoagulant related nephropathy with a frequency not known. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010052/202209 (vortioxetine) CAPS: **Brintellix** (EMEA/H/C/002717) (vortioxetine), H. Lundbeck A/S, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Jo Robays, "29/09/2020 To: 29/09/2022"	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, together with the detailed explanation of the scientific grounds for the differences with the PRAC recommendation, 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 4.2 regarding treatment discontinuation, and update of section 4.8 of the SmPC to add dyspepsia, akathisia, bruxism, trismus, restless leg syndrome, tremor, discontinuation syndrome, vision blurred, and galactorrhoea as adverse reactions and addition of information on post-marketing cases of sexual dysfunction in the relevant part of section 4.8. The package leaflet is updated accordingly. See 2.3 and 9.1
EMEA/H/C/PSUSA/00010370/202209 (tobramycin (nebuliser solution) (centrally authorised product only)) CAPS: **Vantobra** (EMEA/H/C/005086) (tobramycin), PARI Pharma GmbH, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga,	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),

"19/09/2020 To: 18/09/2022"	concerning the following change(s): Update of section 4.4 of the SmPC to add a warning/precaution regarding an increased risk of aminoglycoside-associated ototoxicity in patients with mitochondrial rRNA mutations to the subsection Ototoxicity. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010387/202210 (edoxaban) CAPS: **Lixiana** (EMEA/H/C/002629) (edoxaban), Daiichi Sankyo Europe GmbH, Rapporteur: Maria Concepcion Prieto Yerro **Roteas** (EMEA/H/C/004339) (edoxaban), Berlin Chemie AG, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Nathalie Gault, "22/10/2021 To: 21/10/2022"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above-mentioned medicinal product(s), concerning the following change(s): Update of sections 4.5 of the SmPC to add an interaction(s) regarding clarithromycin and Edoxaban and of section 4.8 of the SmPC to add "anticoagulated-related nephropathy" in the table of adverse effects under SOC "Renal disorders" and in the sentence below the table. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010868/202210 (ivacaftor / tezacaftor / elexacaftor) CAPS: **Kaftrio** (EMEA/H/C/005269) (ivacaftor / tezacaftor / elexacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "21/04/2022 To: 20/10/2022"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above-mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add "depression" as an adverse drug reaction with a frequency not known and introduce a warning to inform prescribers about the risk of depression. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010923/202210 (pemigatinib) CAPS: **Pemazyre** (EMEA/H/C/005266) (pemigatinib), Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst, "17/04/2022 To: 16/10/2022"	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 add the adverse reaction cutaneous calcification with a frequency uncommon. The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00011008/202210 (asciminib) CAPS: **Scemblix** (EMEA/H/C/005605) (asciminib), Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "29/10/2021 To: 28/10/2022"	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 Table 2 of the SmPC to add Hypersensitivity with a frequency uncommon into the SOC Immune system disorders. The package leaflet is updated accordingly.

B.4. EPARs / WPARs

AREXVY - recombinant respiratory syncytial virus pre-fusion f protein, adjuvanted with as01e - EMEA/H/C/006054 GlaxoSmithkline Biologicals S.A., indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV, 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.
CAMZYOS - mavacamten - EMEA/H/C/005457 Bristol-Myers Squibb Pharma EEIG, treatment of symptomatic obstructive hypertrophic cardiomyopathy, 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.
Columvi - glofitamab - EMEA/H/C/005751, Orphan Roche Registration GmbH, treatment of diffuse large B-cell lymphoma, 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.
Jaypirca - pirtobrutinib - EMEA/H/C/005863, Orphan Eli Lilly Nederland B.V., treatment of mantle cell lymphoma (MCL), 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.
Lytgobi - futibatinib - EMEA/H/C/005627, Orphan Taiho Pharma Netherlands B.V., treatment of cholangiocarcinoma, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0036/G Baxalta Innovations GmbH, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Azacitidine Mylan - azacitidine - EMEA/H/C/004984/II/0014 Mylan Ireland Limited, Generic, Generic of Vidaza, Rapporteur: Hrefna Gudmundsdottir Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
CEVENFACTA - eptacog beta (activated) - EMEA/H/C/005655/II/0005 Laboratoire Francais du Fractionnement et des Biotechnologies, Rapporteur: Daniela Philadelphy Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
COMIRNATY - tozinameran - EMEA/H/C/005735/II/0174/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 04.05.2023.	Positive Opinion adopted by consensus on 04.05.2023.
Elaprase - idursulfase - EMEA/H/C/000700/II/0109 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Eptifibatide Accord - eptifibatide - EMEA/H/C/004104/II/0015/G Accord Healthcare S.L.U., Generic, Generic of Integrilin, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
Eptifibatide Accord - eptifibatide - EMEA/H/C/004104/II/0016/G Accord Healthcare S.L.U., Generic, Generic of Integrilin, Rapporteur: Jayne Crowe Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 04.05.2023.	
EXPAREL liposomal - bupivacaine - EMEA/H/C/004586/II/0011/G Pacira Ireland Limited, Rapporteur: Elita Poplavska Opinion adopted on 04.05.2023. Request for Supplementary Information adopted on 16.03.2023.	Positive Opinion adopted by consensus on 04.05.2023.
HEPLISAV B - hepatitis B surface antigen - EMEA/H/C/005063/II/0024 Dynavax GmbH, Rapporteur: Filip Josephson Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Idefirix - imlifidase - EMEA/H/C/004849/II/0015, Orphan Hansa Biopharma AB, Rapporteur: Martina Weise Opinion adopted on 04.05.2023.	Positive Opinion adopted by consensus on 04.05.2023.
Insulin aspart Sanofi - insulin aspart - EMEA/H/C/005033/II/0013/G Sanofi Winthrop Industrie, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
LIVMARLI - maralixibat - EMEA/H/C/005857/II/0001/G, Orphan Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Lunsumio - mosunetuzumab - EMEA/H/C/005680/II/0002/G, Orphan Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Methylthioninium chloride Proveblue - methylthioninium chloride - EMEA/H/C/002108/II/0055/G Provepharm SAS, Rapporteur: Kristina Dunder Opinion adopted on 04.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 04.05.2023.
Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0069 GlaxoSmithkline Biologicals SA, Rapporteur: Jan	Request for supplementary information adopted with a specific timetable.

Mueller-Berghaus Request for Supplementary Information adopted on 25.05.2023.	
Mounjaro - tirzepatide - EMEA/H/C/005620/II/0006/G Eli Lilly Nederland B.V., Rapporteur: Martina Weise Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
Naglazyme - galsulfase - EMEA/H/C/000640/II/0090 BioMarin International Limited, Rapporteur: Fátima Ventura Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Nimenrix - meningococcal group A, C, W135 and y conjugate vaccine - EMEA/H/C/002226/II/0125/G Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Nucala - mepolizumab - EMEA/H/C/003860/II/0057/G GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 23.03.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Nucala - mepolizumab - EMEA/H/C/003860/II/0059/G GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Nulojix - belatacept - EMEA/H/C/002098/II/0088/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Pazenir - paclitaxel - EMEA/H/C/004441/II/0014 ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Daniela Philadelphy Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0021/G, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 04.05.2023.	
Ronapreve - casirivimab / imdevimab - EMEA/H/C/005814/II/0010/G Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 04.05.2023.	Positive Opinion adopted by consensus on 04.05.2023.
Surgiflo Haemostatic Matrix Kit - human thrombin - EMEA/H/D/002301/II/0033/G Ferrosan Medical Devices A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 20.04.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Truvelog Mix 30 - insulin aspart - EMEA/H/C/005635/II/0003/G Sanofi Winthrop Industrie, Rapporteur: Martina Weise Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Voxzogo - vosoritide - EMEA/H/C/005475/II/0007, Orphan BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Zane Neikena Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023. See 9.1
WS2401/G **Hexacima- EMEA/H/C/002702/WS2401/0143/G** **Hexyon- EMEA/H/C/002796/WS2401/0147/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 16.02.2023.	Positive Opinion adopted by consensus on 12.05.2023.
WS2454 **Fluenz Tetra- EMEA/H/C/002617/WS2454/0127** **Pandemic influenza vaccine H5N1 AstraZeneca- EMEA/H/C/003963/WS2454/0062** AstraZeneca AB, Lead Rapporteur: Christophe Focke Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
WS2457/G **Riltrava Aerosphere- EMEA/H/C/005311/WS2457/0005/G** **Trixeo Aerosphere-**	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/004983/WS2457/0012/G AstraZeneca AB, Lead Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 12.05.2023.	

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

Aimovig - erenumab - EMEA/H/C/004447/II/0026/G Novartis Europharm Limited, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update clinical efficacy and safety information based on final results from studies CAMG334A2301 (LIBERTY) and CAMG334ADE01 (HER-MES). The 'LIBERTY' study is a randomized, double-blind, parallel-group, placebo-controlled phase 3 study to assess the efficacy and tolerability of Aimovig in adult patients with episodic migraine who had previously failed 2- 4 prophylactic migraine treatments, while the 'HER-MES' study is a randomized, double-blind, double-dummy, multicenter, parallel group, phase 4 study to assess tolerability and efficacy of Aimovig against topiramate in adult patients with episodic and chronic migraine." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
Ameluz - 5-aminolevulinic acid - EMEA/H/C/002204/II/0055 Biofrontera Bioscience GmbH, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.8, 5.1 and 6.6 of the SmPC in order to include artificial daylight lamps as an additional light source for photodynamic therapy in combination with Ameluz for the treatment of actinic keratoses based on final results from non-clinical study PT-0042-A and literature (investigator-initiator trials). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. " Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Amglidia - glibenclamide - EMEA/H/C/004379/II/0015, Orphan Ammtek, Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC in order to update	Positive Opinion adopted by consensus on 25.05.2023.

information regarding sulphonylurea effects on neurological abnormalities in children and adults with KCNJ11- and ABCC8-related neonatal diabetes based on literature." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 23.03.2023, 09.02.2023.	
Brukinsa - zanubrutinib - EMEA/H/C/004978/II/0013 BeiGene Ireland Ltd, Rapporteur: Aaron Sosa Mejia, "Update of section 5.1 of the SmPC in order to update efficacy information based on final efficacy results of 'progression-free survival' (PFS) analysis from study BGB-3111-305; this is a Phase III, randomized study of Zanubrutinib compared with Ibrutinib in patients with Relapsed/Refractory Chronic Lymphocytic Leukaemia or Small Lymphocytic Lymphoma. In addition, the MAH took the opportunity to update section 4.4 of the SmPC in order to align the wording with the approved Package Leaflet." Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Calquence - acalabrutinib - EMEA/H/C/005299/II/0015 AstraZeneca AB, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC based on the interim report of study ACE-CL-007; a randomized, multicentre, open-Label, 3-arm phase 3 study of obinutuzumab in combination with chlorambucil, ACP-196 in combination with obinutuzumab, and ACP-196 monotherapy in subjects with previously untreated chronic lymphocytic leukaemia." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 23.03.2023, 15.12.2022.	Positive Opinion adopted by consensus on 12.05.2023.
Eliquis - apixaban - EMEA/H/C/002148/II/0088 Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy and safety information in the paediatric population based on results of the paediatric studies performed in compliance with the paediatric investigation plan (PIP), including studies CV185155 and CV185362. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.

Request for Supplementary Information adopted on 26.01.2023.	
Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0030 Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.8 and 5.1 of the SmPC in order to update transfusion data for subjects with human epidermal growth factor receptor 2 (HER2)-positive GC or GEJ adenocarcinoma and to update the overall response rate for study DS8201-A-J202 (following the assessment of procedure II/0012) based on studies DS8201-A-J101, DS8201-A-J202 (DESTINY-Gastric01) and DS8201-A-U205 (DESTINY-Gastric02). DS8201-A-J101 is a Phase 1, Two-part, Multicentre, Non-randomised, Open-label, Multiple Dose First-in-Human Study in Advanced Solid Malignant Tumour. DS8201-A-J202 is a Phase 2, Multicentre, Open-label Study of DS-8201a in Subjects with HER2-Expressing Advanced GC/GEJ Adenocarcinoma. DS8201-A-U205 is a Phase 2, Multicentre, Open-label, Single-arm Trial of Trastuzumab Deruxtecan in HER2-Positive, Unresectable or Metastatic GC or GEJ Adenocarcinoma Subjects who have progressed on or after a Trastuzumab-containing Regimen. In addition, the MAH took this opportunity to implement minor editorial changes to the SmPC." Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Fasenra - benralizumab - EMEA/H/C/004433/II/0047 AstraZeneca AB, Rapporteur: Fátima Ventura, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric population information based on final results from study D3250C00025; this is an Open-label Study to Evaluate the Pharmacokinetics and Pharmacodynamics and Long-term Safety of Benralizumab Administered Subcutaneously in Children with Severe Eosinophilic Asthma." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0136 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "Update of section 5.1 of	Request for supplementary information adopted with a specific timetable.

the SmPC in order to provide the final OS data (including analyses/KM plots from favourable prognosis subgroups) following the assessment of procedure II/0104, based on results from study E7080-G000-307/KEYNOTE 581 (REC); A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Everolimus or Pembrolizumab Versus Sunitinib Alone in First-Line Treatment of Subjects with Advanced Renal Cell Carcinoma (CLEAR)." Request for Supplementary Information adopted on 25.05.2023.	
Kisplyx - lenvatinib - EMEA/H/C/004224/II/0055 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "Update of section 5.1 of the SmPC in order to update efficacy information in first-line treatment of patients with renal cell carcinoma (in combination with pembrolizumab), based on the OS final analysis for the overall population from study E7080-G000-307/KEYNOTE 581; this is a multicenter, randomized, open-label, phase 3 study comparing the efficacy and safety of lenvatinib in combination with either pembrolizumab or everolimus versus sunitinib alone in first-line treatment of subjects with advanced renal cell carcinoma (RCC)." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Lumeblue - methylthioninium chloride - EMEA/H/C/002776/II/0004 Alfasigma S.p.A., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.2 of the SmPC in order to introduce a new posology regimen based on scientific literature and PK/PD results from studies CB-17-01/17 and CB-17-01/15; CB-17-01/17 is an open-label, randomized, cross-over, safety and bioavailability descriptive study in healthy volunteers receiving a full and a split dose regimen of bowel cleansing preparation for colonoscopy; CB-17-01/15 is a single dose, randomised, parallel groups, open label, efficacy study in patients receiving a split dose regimen of bowel cleansing preparation for colonoscopy." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 23.02.2023, 15.09.2022.	Positive Opinion adopted by consensus on 25.05.2023.

Lupkynis - voclosporin - EMEA/H/C/005256/II/0005 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, "Update of sections 4.5 and 5.2 of the SmPC in order to update safety information based on final results from study AUR-VCS-2021-02 / Statin-DDI listed as REC in the Letter of Recommendation and study AUR-VCS-2016-02. AUR-VCS-2021-02 / Statin-DDI is an in-vivo DDI study, investigating the effects of voclosporin on simvastatin and its active metabolite simvastatin acid as substrates for OATP1B1/OATP1B3 and AUR-VCS-2016-02 was to show long-term (3 years) safety data from subjects receiving voclosporin and concomitant statins." Request for Supplementary Information adopted on 25.05.2023, 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Lynparza - olaparib - EMEA/H/C/003726/II/0059 AstraZeneca AB, Rapporteur: Alexandre Moreau, "Submission of the final report from study AME02164. This is a Genetic Toxicity Evaluation using a Bacterial Reverse Mutation Test with Salmonella typhimurium LT2 Strains TA1535, TA1537, TA98 and TA100, and Escherichia coli WP2 Strain uvrA/pKM101." Opinion adopted on 04.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 04.05.2023.
Methylthioninium chloride Proveblue - methylthioninium chloride - EMEA/H/C/002108/II/0056 Provepharm SAS, Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.5 of the SmPC to update the warning and add information regarding the potential increase of the risk of serotonin syndrome when used in combination with opioids, as well as, to add information regarding the potent reversible monoamine oxidase (MAO) inhibitory activity of Methylthioninium chloride based on post-marketing data and literature; the Package Leaflet is updated accordingly." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 12.05.2023.
MVABEA - Ebola vaccine (rDNA, replication-	Request for supplementary information adopted

incompetent) - EMEA/H/C/005343/II/0018/G Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, "Grouped application comprising three type II variations as follows: - Update of sections 4.8 and 5.1 of the SmPC in order to add crying, screaming and hyperhidrosis to the list of adverse drug reactions (ADRs) in children with frequency very common, common and common, respectively and to add immunogenicity data from study VAC52150EBL2004 (PREVAC), listed as a Study 3 in the agreed PIP. This was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 study conducted at multiple sites in West Africa to investigate the immunogenicity and safety of 3 Ebola vaccine regimens versus placebo in adults (aged ≥18 years), adolescents (aged 12-17 years), and children (2 age strata: 5-11 years and 1-4 years) who never received a candidate Ebola vaccine (self-report) and had no history of Ebola virus disease (self-report). - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add interim safety and immunogenicity data from study VAC52150EBL2005, a study conducted by the MAH in infants 4-11 months of age. - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add final safety and immunogenicity data from study VAC52150EBL2011, a study in which an Ad26.ZEBOV booster dose was evaluated in children 1 to 11 years of age (at the time of first vaccination in EBL3001). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes and update the contact details of the local representatives in the Package Leaflet." Request for Supplementary Information adopted on 25.05.2023, 30.03.2023.	with a specific timetable.
NUVAXOVID - Covid-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0048/G Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023. See 9.1
Orgovyx - relugolix - EMEA/H/C/005353/II/0008 Accord Healthcare S.L.U., Rapporteur: Johann	Positive Opinion adopted by consensus on 25.05.2023.

Lodewijk Hillege, "Submission of the final report from study MVT-601-055; this is an open-label, fixed (single)-sequence crossover phase 1 study to assess the sufficiency of dose separation to mitigate absorption-mediated increases in exposure to relugolix resulting from inhibition of intestinal P-gp by azithromycin in healthy adult men." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 09.02.2023.	
Orgovyx - relugolix - EMEA/H/C/005353/II/0009 Accord Healthcare S.L.U., Rapporteur: Johann Lodewijk Hillege, "Submission of the bioanalytical report for testosterone measurement in the clinical study MVT-601-3201." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 09.02.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Oxlumo - lumasiran - EMEA/H/C/005040/II/0014, Orphan Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from study ALN-GO1; this is a 105 week Subcutaneous Carcinogenicity Study in Rats with Toxicokinetics. In addition, the MAH took the opportunity to implement editorial changes and to bring the PI in line with the latest QRD template version 10.3." Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.
Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0037 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Submission of the updated population modelling analysis report (PMAR-EQDD-C467a-Other-1463): population pharmacokinetics of nirmatrelvir/ritonavir after oral administration in adults with/without COVID-19 - a pooled analysis of phase 1/2/3 data." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0042 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy, safety and	Request for supplementary information adopted with a specific timetable.

pharmacokinetic information, based on updated results from studies C4671005 (EPIC-HR), C4671002 (EPIC-SR) and C4671006 (EPIC-PEP) as well as a supplemental report to Pop PK analysis PMAR-EQDD-C467a-DP4-1323, following the reanalysis of data after the removal of data related to four sites from the Paxlovid data analysis." Request for Supplementary Information adopted on 25.05.2023.	
QUVIVIQ - daridorexant - EMEA/H/C/005634/II/0009/G Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information with midazolam, dabigatran, rosuvastatin and warfarin, based on studies ID-078-125 and ID-078-126. Study ID-078-125 is a single-center, open-label, three-period, fixed-sequence design study to investigate the effect of daridorexant on the pharmacokinetics of dabigatran and rosuvastatin in healthy male subjects, while study ID-078-126 is a single-center, open-label study to investigate the effect of single- and multiple-dose daridorexant on the pharmacokinetics of midazolam and its metabolite 1-hydroxymidazolam, and the effect of single-dose daridorexant on the pharmacokinetics and pharmacodynamics of warfarin in healthy male subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Retsevmo - selpercatinib - EMEA/H/C/005375/II/0016 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to add chylothorax and chylous ascites to the list of adverse drug reactions (ADRs) based on a review of adverse events. The Package Leaflet is updated accordingly." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 23.03.2023, 19.01.2023, 06.10.2022.	Positive Opinion adopted by consensus on 25.05.2023.
Revolade - eltrombopag - EMEA/H/C/001110/II/0070 Novartis Europharm Limited, Rapporteur: Maria	Positive Opinion adopted by consensus on 12.05.2023.

Concepcion Prieto Yerro, "C.I.4 C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data. Update of section 5.1 of the SmPC based on primary analysis results from study TAPER (CETB115J2411). This is a Phase II, open-label, prospective, single-arm, study to assess ability of eltrombopag to induce sustained remission in subjects with immune thrombocytopenia (ITP) who are refractory or relapsed after first-line steroids. In addition, the MAH took the opportunity to implement editorial changes in the SmPC." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 08.12.2022.	
Reyataz - atazanavir - EMEA/H/C/000494/II/0137 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.3 and 4.5 in order to add drug-drug interaction information with antiplatelet therapies classified as P2Y12 platelet inhibitors (ticagrelor, clopidogrel and prasugrel), dexamethasone or other corticosteroids, antineoplastics encorafenib or ivosidenib, gonadotropin-releasing hormone (GnRH) receptor antagonist elagolix, kinase inhibitor fostamatinib and antineoplastic apalutamide based on the cumulative review of literature search. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
RINVOQ - upadacitinib - EMEA/H/C/004760/II/0033 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Submission of the final report from study M16-098 listed as a category 3 study in the RMP. This is a multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of upadacitinib in subjects with active ankylosing spondylitis." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Tecvayli - teclistamab - EMEA/H/C/005865/II/0003	Request for supplementary information adopted with a specific timetable.

Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, "Update of sections 4.2, 4.6 and 5.2 of the SmPC in order to revise the dosing schedule, amend recommendations on contraception and breast-feeding and to update pharmacokinetic information, based on the latest data available; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 25.05.2023.	
TEZSPIRE - Tezepelumab - EMEA/H/C/005588/II/0008 AstraZeneca AB, Rapporteur: Finbarr Leacy, "Update of section 4.5 of the SmPC in order to include information relating to the humoral antibody responses induced by the seasonal influenza virus based on final results from study VECTOR (D5180C00031); this is a multicenter, randomized, double-blind, parallel group, placebo-controlled, phase IIIb study to evaluate the potential effect of tezepelumab on the humoral immune response to seasonal quadrivalent influenza vaccination in adolescent and young adult participants with moderate to severe asthma. In addition, the MAH took the opportunity to implement editorial changes to section 5.1 of the SmPC." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Vaxzevria - COVID 19 vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0090 AstraZeneca AB, Rapporteur: Sol Ruiz, "Submission of the final report from study D8111R00007 (RAVEN) listed as a category 3 study in the RMP. This is an Observational Retrospective Cohort Study Using Secondary Databases to Establish Effectiveness of the Oxford/AstraZeneca COVID-19 Vaccine in England." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Veklury - remdesivir - EMEA/H/C/005622/II/0049 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in	Positive Opinion adopted by consensus on 25.05.2023.

order to update preclinical data on the antiviral activity of remdesivir against the Omicron subvariants BA.2.75, BA.4.6, BF.5, XBB, and BQ.1.1 based on results from study PC-540-2044." Opinion adopted on 25.05.2023.	
Victoza - liraglutide - EMEA/H/C/001026/II/0066 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add Dysgeusia to the list of adverse drug reactions (ADRs) with frequency Uncommon based on the cumulative review of scientific literature. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
Vipidia - alogliptin - EMEA/H/C/002182/II/0035 Takeda Pharma A/S, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information following positive opinion of procedure P46/013 and confirmation of full compliance of PIP EMEA-000496-PIP01-08-M08 based on reports from study studies SYR-322_104 and SYR-322_309. 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 introduce editorial changes." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 25.05.2023.
VITRAKVI - larotrectinib - EMEA/H/C/004919/II/0030 Bayer AG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC in order to change posology recommendations in patients with liver function abnormalities, amend an existing warning on hepatotoxicity, update information on drug-drug interaction information with regards of effects CYP3A, P-gp and BCRP inhibitors and CYP3A and P-gp inducers, updates to the list of adverse drug reactions (ADRs), update efficacy data based on interim results from studies 20289 and 2090. The Package Leaflet is updated	Request for supplementary information adopted with a specific timetable.

accordingly." Request for Supplementary Information adopted on 25.05.2023.	
VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0054 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC to reflect the results of study SHP-GCB-402: A multicenter, open-label, single-arm, phase 4 study designed to prospectively evaluate the effects of VPRIV on bone-related pathology in treatment-naïve subjects with type 1 Gaucher disease. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 23.03.2023, 12.01.2023, 28.04.2022.	Positive Opinion adopted by consensus on 25.05.2023.
Xevudy - sotrovimab - EMEA/H/C/005676/II/0014 Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.4 and 5.1 of the SmPC with data on epitope conservation and activity of sotrovimab against pseudotyped virus encoding epitope variants (PC-7831-0143 v15), as well as data on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron BA.4.6 spike variant (PC-22-0130), the Omicron BQ.1.1 spike variant (PC-22-0142), the Omicron BQ.1, BF.7, BA.2.75.2 and XBB.1 spike variants (PC-22-0145). In addition, an editorial change is made to section 4.2 of the SmPC for increased clarity as to the settings in which sotrovimab can be administered, and to section 4.1 to advise prescribers on the activity of sotrovimab against SARS-CoV2 viral variants of concern." Opinion adopted on 04.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 04.05.2023.
ZABDENO - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/II/0015/G Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, "Grouped application comprising three type II variations as follows:	Request for supplementary information adopted with a specific timetable.

- Update of sections 4.8 and 5.1 of the SmPC in order to add crying, screaming and hyperhidrosis to the list of adverse drug reactions (ADRs) in children with frequency very common, common and common, respectively and to add immunogenicity data from study VAC52150EBL2004 (PREVAC), listed as a study 3 in the agreed PIP. This was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 study conducted at multiple sites in West Africa to investigate the immunogenicity and safety of 3 Ebola vaccine regimens versus placebo in adults (aged ≥18 years), adolescents (aged 12-17 years), and children (2 age strata: 5-11 years and 1-4 years) who never received a candidate Ebola vaccine (self-report) and had no history of Ebola virus disease (self-report). - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add interim safety and immunogenicity data from study VAC52150EBL2005, a study conducted by the MAH in infants 4-11 months of age. - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add final safety and immunogenicity data from study VAC52150EBL2011, a study in which an Ad26.ZEBOV booster dose was evaluated in children 1 to 11 years of age (at the time of first vaccination in EBL3001). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes and update the contact details of the local representatives in the Package Leaflet." Request for Supplementary Information adopted on 25.05.2023, 30.03.2023.	
WS2368 **Invokana-** **EMEA/H/C/002649/WS2368/0061** **Vokanamet-** **EMEA/H/C/002656/WS2368/0066** Janssen-Cilag International N.V., Lead Rapporteur: Martina Weise, "To update section 4.4 of the SmPC in order amend an existing warning on the diabetic ketoacidosis, to indicate that glucosuria may persist longer than expected and that DKA may be prolonged after discontinuation of canagliflozin in some patients based on a cumulative review of literature, MAH global safety database, preclinical and clinical pharmacology data, and clinical study data	Request for supplementary information adopted with a specific timetable.

including cases reports." Request for Supplementary Information adopted on 12.05.2023, 08.12.2022.	
WS2405 **BYANNLI-** **EMEA/H/C/005486/WS2405/0004** **Trevicta-** **EMEA/H/C/004066/WS2405/0030** **Xeplion-** **EMEA/H/C/002105/WS2405/0055** Janssen-Cilag International N.V., Lead Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC for Xeplion and Trevicta in order to modify the frequencies of the list of adverse drug reactions (ADRs) to align with the Product Information of BYANNLI. In addition, the MAH took the opportunity to introduce administrative corrections and minor editorial changes to the PI as well as to update the list of local representatives in the Package Leaflet." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 16.02.2023.	Positive Opinion adopted by consensus on 25.05.2023.
WS2418 **Lyxumia-** **EMEA/H/C/002445/WS2418/0039** **Suliqua-EMEA/H/C/004243/WS2418/0030** Sanofi Winthrop Industrie, Lead Rapporteur: Kristina Dunder, "Update of section 4.4 of the SmPC in order to add a new special warning on acute gallbladder disease based on cumulative review of the pharmacovigilance databases, worldwide scientific literature, labelling documents of other GLP-1RAs, and biological plausibility. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 04.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 04.05.2023.
WS2460 **Elebrato Ellipta-** **EMEA/H/C/004781/WS2460/0032** **Trelegy Ellipta-** **EMEA/H/C/004363/WS2460/0029** GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy, "Update of sections 4.4 and 4.8 of the SmPC in order to add	Request for supplementary information adopted with a specific timetable.

'Anxiety', 'Tremor', 'Muscle spasms', 'Hyperglycaemia' and 'Palpitations' to the list of adverse drug reactions (ADRs) with frequency rare, based on an internal safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 25.05.2023.	
WS2465 **Entresto-** **EMEA/H/C/004062/WS2465/0051** **Neparvis-** **EMEA/H/C/004343/WS2465/0049** Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Anette Kirstine Stark, "Submission of the final report from study B2320 listed as a category 3 study in the RMP in order to fulfil MEA/001. This is a multicenter, randomized, double-blind, active-controlled study to evaluate the effects of sacubitril/valsartan compared to valsartan on cognitive function in patients with chronic heart failure and preserved ejection fraction. The RMP version 6 has also been submitted." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.

B.5.3. CHMP-PRAC assessed procedures

Beovu - brolucizumab - **EMEA/H/C/004913/II/0018** Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 5.1 of the SmPC in order to introduce an alternative posology regimen for wet AMD and update information based on modelling and simulation studies; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 30.03.2023, 10.11.2022.	Positive Opinion adopted by consensus on 25.05.2023. See 9.1
Beovu - brolucizumab - **EMEA/H/C/004913/II/0021** Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2, 4.8, 5.1 and	Positive Opinion adopted by consensus on 25.05.2023.

5.2 of the SmPC in order to change posology recommendation in including an additional dose regimen (q16w) for DME patients during the maintenance phase, update the frequency of adverse drug reactions, update pharmacokinetic, pharmacodynamic, efficacy and safety information, following the assessment of procedure II/10, based on final results from studies CRTH258B2301 (KESTREL) and CRTH258B2302 (KITE). The Package Leaflet is updated accordingly. The RMP version 10 has also been submitted." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 26.01.2023.	
Brineura - cerliponase alfa - EMEA/H/C/004065/II/0039, Orphan BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 9 of the SmPC in order to state that clinical data are available for patients aged 1 year and older and to include updates to the frequency of adverse reactions, immunogenicity, pharmacokinetic, and paediatric population sections based on the final results from studies 190-203, listed as a specific obligation and 190-202 (submitted in P46/013). Study 190-203 was a Phase 2, open-label, multicenter study in paediatric patients < 18 years of age with CLN2 disease, confirmed by deficiency of TPP1 enzyme activity and mutation of the CLN2 gene. The Package Leaflet, Annex II and Annex IV are updated accordingly. The RMP version 4.0 has also been submitted." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Brukinsa - zanubrutinib - EMEA/H/C/004978/II/0009 BeiGene Ireland Ltd, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Menno van der Elst, "Submission of the final report from study BGB-3111-113 - A Drug-Drug Interaction Study of Zanubrutinib with Moderate and Strong CYP3A Inhibitors in Patients With B-Cell Malignancies, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted." Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023.

Request for Supplementary Information adopted on 14.04.2023.	
Bylvay - odevixibat - EMEA/H/C/004691/II/0013, Orphan Albireo, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.4, 4.5 and 4.6 of the SmPC in order to update an existing warning, add drug-drug interaction (DDI) information with oral contraceptives and update information for women of childbearing potential, based on study A4250-022 listed as a category 3 study in the RMP; this is an open-label, phase 1 DDI study to evaluate the interaction of odevixibat with oral lipophilic contraceptives in healthy volunteers. The Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Fintepla - fenfluramine - EMEA/H/C/003933/II/0015, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "To update sections 4.2 and 5.2 of the SmPC to update the safety information based on final results from study ZX008-1903 listed as a category 3 study in the RMP; this is a Phase 1, Open-Label, Single-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ZX008 (Fenfluramine Hydrochloride) in Subjects with Varying Degrees of Hepatic Impairment. The primary objective of this study was to compare the PK of a single dose of ZX008 (fenfluramine HCl) in subjects with varying degrees of hepatic impairment with that of healthy matched control subjects. The updated RMP version 2.7 has also been submitted." Request for Supplementary Information adopted on 25.05.2023, 30.03.2023, 12.01.2023, 29.09.2022.	Request for supplementary information adopted with a specific timetable.
GAVRETO - pralsetinib - EMEA/H/C/005413/II/0010 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information in the treatment of adult patients with RET fusion-positive advanced NSCLC based	Request for supplementary information adopted with a specific timetable.

on final results (NSCLC indication) from study ARROW/BO42863, a Phase 1/2 Study of the Highly-selective RET Inhibitor, BLU 667, in Patients With Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC), and Other Advanced Solid Tumours listed as a specific obligation in the Annex II. The RMP version 1.5 has also been submitted." Request for Supplementary Information adopted on 25.05.2023, 23.02.2023.	
GIVLAARI - givosiran - EMEA/H/C/004775/II/0013/G, Orphan Alnylam Netherlands B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Submission of the final reports from studies ALN-AS1-003 (study 003) and ALN-AS1-002 (study 002) listed as category 3 studies in the RMP. Study 003 is a phase 3 randomized, double-blind, placebo-controlled multicenter study with an open-label extension to evaluate the efficacy and safety of givosiran in patients with acute hepatic porphyrias, while study 002 is a multicenter, open-label extension study to evaluate the long-term safety and clinical activity of subcutaneously administered ALN AS1 in patients with acute intermittent porphyria who have completed a previous clinical study with ALN-AS1. The RMP version 2.2 has also been submitted." Request for Supplementary Information adopted on 25.05.2023, 23.02.2023, 13.10.2022.	Request for supplementary information adopted with a specific timetable.
Glivec - imatinib - EMEA/H/C/000406/II/0133 Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Monica Martinez Redondo, "Submission of the final report from study CSTI571I2201 - A European observational registry collecting efficacy and safety data in newly diagnosed paediatric Ph+ ALL patients treated with chemotherapy + imatinib ± HSCT, listed as an obligation in the Annex II of the Product Information. This study has been designed as an observational, multi-centre registry to collect efficacy and safety data in Ph+ ALL paediatric patients (ages 1 to <18 years old) treated with chemotherapy + imatinib, with or without (± HSCT) primarily in European countries. The Annex II and the RMP (version 13.0) are	Request for supplementary information adopted with a specific timetable.

updated accordingly." Request for Supplementary Information adopted on 12.05.2023.	
Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0035, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Update of sections 4.8 and 5.1 of the SmPC based on interim results from study VX19-445-107 (study 107) listed as a category 3 study in the RMP; this is a Phase III, open-label study evaluating the long-term safety and efficacy of VX445/TEZ/IVA combination therapy in subjects with cystic fibrosis 6 years of age and older. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
LIVTENCITY - maribavir - EMEA/H/C/005787/II/0004, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Submission of the final report from study SHP620-302 listed as a category 3 study in the RMP. This is a Phase III, multicenter, randomized, double-blind, double-dummy, active-controlled study of maribavir compared to valganciclovir for the treatment of asymptomatic Cytomegalovirus (CMV) Infection in Hematopoietic Stem Cell Transplant recipients. The RMP version 2.0 has also been submitted." Request for Supplementary Information adopted on 25.05.2023.	Request for supplementary information adopted with a specific timetable.
LUMYKRAS - sotorasib - EMEA/H/C/005522/II/0010/G Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B.	Request for supplementary information adopted with a specific timetable. See 9.1

Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC."	
MINJUVI - tafasitamab - EMEA/H/C/005436/II/0008, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.4 of the SmPC in order to add a new warning on Progressive Multifocal Leukoencephalopathy (PML) based on post-marketing data; the Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to bring the PI in line with the latest QRD template version 10.3." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 16.03.2023.	Positive Opinion adopted by consensus on 12.05.2023.
Prolia - Denosumab - EMEA/H/C/001120/II/0098 Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 5.1 and 5.2 in order to update efficacy, pharmacokinetic and safety information for paediatric population following the assessment of P46/043 and P46/044 based on final results from study 20130173, listed as a category 3 study in the RMP and study 20170534. Study 20130173 was a prospective, multicentre, open-label, single-arm phase 3 study to evaluate the safety, efficacy, and PK of	Request for supplementary information adopted with a specific timetable.

denosumab in children 2 to 17 years of age with OI. Study 20170534 was an open-label, prospective, extension study of study 20130173. The RMP version 31 has also been submitted. In addition, the MAH took this opportunity to introduce minor editorial changes." Request for Supplementary Information adopted on 12.05.2023.	
Rubraca - rucaparib - EMEA/H/C/004272/II/0037 Clovis Oncology Ireland Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.4 and 5.1 of the SmPC in order to update the efficacy and safety information based on the final results from study CO-338-014 (ARIEL 3) listed as a category 1 PAES in the Annex II; this is a phase 3, multicenter, randomized, double-blind, placebo-controlled study of rucaparib as switch maintenance following platinum-based chemotherapy in patients with platinum-sensitive, high grade serous or endometrioid epithelial ovarian, primary peritoneal or fallopian tube cancer. Annex II and the RMP version 7.1 are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 15.12.2022.	Positive Opinion adopted by consensus on 25.05.2023. See 9.1
Simponi - golimumab - EMEA/H/C/000992/II/0113 Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final report from study CNTO148UCO1001 (PURSUIT PEDS PK) listed as a category 3 study in the RMP. This is a phase 1b open-label study to assess the safety and pharmacokinetics of subcutaneously administered golimumab, a human anti-TNFα antibody, in paediatric subjects with moderately to severely active ulcerative colitis. The RMP version 24.1 has also been submitted." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
Stelara - ustekinumab - EMEA/H/C/000958/II/0098/G Janssen-Cilag International N.V., Rapporteur:	Positive Opinion adopted by consensus on 25.05.2023.

Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald Opinion adopted on 25.05.2023.	
Translarna - ataluren - EMEA/H/C/002720/II/0069, Orphan PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information following results from study PTC124-GD-041-DMD, listed as a specific obligation in the Annex II; This is a Phase 3 multicentre, randomised, double-blind, 18-month, placebo-controlled study, followed by a 18-month open label extension to confirm the efficacy and safety of ataluren in the treatment of ambulant patients with mnDMD aged 5 years or older. Annex II, and Annex IIB are updated to delete the SOB and to reflect the switch from conditional to full marketing authorisation. The Package Leaflet is updated accordingly. The RMP version 11.0 has also been submitted. Minor corrections were done to align the PI with the latest QRD templates." Request for Supplementary Information adopted on 26.01.2023.	Request for supplementary information adopted with a specific timetable. See 9.1
Vaxzevria - COVID 19 vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0089 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of 'dizziness' and 'abdominal pain' in the list of adverse drug reactions (ADRs) to common and to update safety and efficacy information, based on final results and final pooled analysis for studies COV001, COV002, COV003 and COV005 as well as the final manuscript for COV004, listed as category 3 studies in the RMP. Study COV001 is phase I/II, single-blind, randomised, active-controlled, multicenter study in healthy adults aged 18-55 years; Study COV002 is a phase II/III, single-blind, randomised, active-controlled, multicenter study in adults ≥ 18 years of age and at high risk of exposure to COVID-19; Study COV003 is a phase III, single-blind, randomised, controlled, multicenter study in adults ≥ 18 years of age at high risk of	Request for supplementary information adopted with a specific timetable.

exposure to SARS-CoV-2; Study COV005 is a phase I/II, double-blind, randomised, placebo-controlled, multicenter study in adults 18 to 65 years of age with or without HIV. Study COV004 a phase IB/II single-blind, randomized controlled trial of the (AZD1222) vaccine in adults in Kenya. The Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted." Request for Supplementary Information adopted on 25.05.2023.	
Veklury - remdesivir - EMEA/H/C/005622/II/0044/G Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations for patients with renal impairment, update an existing warning on renal impairment and update the safety and efficacy information based on final results from studies GS-US-540-5912 and GS-US-540-9015, listed as category 3 studies in the RMP. Study GS-US-540-5912 is a Phase 3 randomised, double-blind, placebo-controlled, parallel group, multicenter study evaluating the efficacy and safety of remdesivir in participants with severely reduced kidney function who were hospitalised for COVID-19, while study GS-US-540-9015 is a Phase 1, multicenter, open-label, single-dose study to evaluate the single-dose PK of remdesivir in participants with normal and impaired renal function. The Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor edits to the PI." Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 23.02.2023.	Positive Opinion adopted by consensus on 25.05.2023.
WS2438/G **Relvar Ellipta- EMEA/H/C/002673/WS2438/0061/G** **Revinty Ellipta- EMEA/H/C/002745/WS2438/0058/G** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Monica Martinez Redondo, "Grouped application consisting of 1)	Request for supplementary information adopted with a specific timetable.

Update sections 4.2 and 5.1 of the SmPC to include results from study HZA107116. This is a randomised, double-blind, parallel group, multicentre, stratified, study evaluating the efficacy and safety of once daily fluticasone furoate/vilanterol inhalation powder compared to once daily fluticasone furoate inhalation powder in the treatment of asthma in participants aged 5 to 17 years old (inclusive) currently uncontrolled on inhaled corticosteroids. The Package Leaflet and Labelling are updated accordingly. The RMP version 12.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC; 2) Submission of final report from Phase 2b study HZA106855 (FF dose ranging) which gives information regarding the dose selection for FF combination in study HZA107116; 3) Submission of final report from Phase 2b study HZA106853 (VI dose ranging) which gives information regarding the dose selection for VI combination in study HZA107116." Request for Supplementary Information adopted on 12.05.2023.	
WS2451 **Bondronat-** **EMEA/H/C/000101/WS2451/0090** **Bonviva-** **EMEA/H/C/000501/WS2451/0075** Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Lead PRAC Rapporteur: Anette Kirstine Stark, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add information regarding the risk of "Atypical fractures of other long bones"; based on literature. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **AJOVY - fremanezumab -** **EMEA/H/C/004833/II/0039** TEVA GmbH, PRAC Rapporteur: Kirsti Villikka,	Positive Opinion adopted by consensus on 12.05.2023.

PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 4.0 in order to replace PASS TV48125-MH-50039 with PASS TV48125-MH-40217 following MEA/005.3 and MEA/005.4." Opinion adopted on 12.05.2023.	
PRAC Led **Benlysta - belimumab - EMEA/H/C/002015/II/0111** GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from year 5 Post-Treatment Follow-Up from study BEL 115467/HGS1006-C113 listed as a category 3 study in the RMP. This is a 52-week, global, multi-center, randomized, placebo-controlled, double-blind study conducted to evaluate mortality and AESI in adults with active, autoantibody-positive SLE treated with belimumab plus standard therapy vs. placebo plus standard therapy. The RMP version 44 was approved." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
PRAC Led **Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/II/0032** Pfizer Europe MA EEIG, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of an updated RMP version 3.2 in order to reflect the updated study milestones and completion of the post-authorisation safety study of CE/BZA in the United States (US PASS, study B2311060) previously assessed as part of II/0030 (MEA002.15), as well as to update the post-marketing data with the data lock point of 31 October 2021." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 01.12.2022, 07.07.2022.	Positive Opinion adopted by consensus on 12.05.2023.
PRAC Led **Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0063** Merck Sharp & Dohme B.V., PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "Update of section 4.6 of	Positive Opinion adopted by consensus on 12.05.2023.

the SmPC in order to include additional information on exposure during pregnancy based on the final report of the US Pregnancy Registry, listed as a category 3 study in the RMP (MEA 003.1 is fulfilled with this procedure). The Package Leaflet is updated accordingly. The RMP version 5.1 has been approved with this procedure." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 09.02.2023.	
PRAC Led **JCOVDEN - COVID-19 vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0072/G** Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.4 of the SmPC in order to add a new warning on myocarditis and pericarditis and update of section 4.8 of the SmPC to add myocarditis and pericarditis to the list of adverse drug reactions (ADRs) with frequency not known based on post-marketing data and three observational claims databases in US. The Package Leaflet is updated accordingly. A revised RMP version 6.4 has been approved. In addition, the MAH took the opportunity to update the ATC Code as amended by the WHO." Opinion adopted on 25.05.2023.	Positive Opinion adopted by consensus on 25.05.2023. See 9.1
PRAC Led **Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0032** Pfizer Europe MA EEIG, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.4 of the SmPC in order to include a warning on the risk of hypertension and to recommend a monitoring of blood pressure, and update of section 4.8 to add 'hypertension' to the list of adverse drug reactions (ADRs) with frequency 'uncommon', based on a review of aggregate post-marketing data. The Package Leaflet is updated accordingly." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 16.03.2023, 12.01.2023.	Positive Opinion adopted by consensus on 12.05.2023.
PRAC Led	Request for supplementary information adopted

Sialanar - glycopyrronium - EMEA/H/C/003883/II/0026 Proveca Pharma Limited, PRAC Rapporteur: Zane Neikena, PRAC-CHMP liaison: Elita Poplavska, "Submission of an updated RMP version 3.1 in order to remove a Drug Utilisation Study (DUS)." Request for Supplementary Information adopted on 12.05.2023, 16.03.2023, 12.01.2023.	with a specific timetable.
PRAC Led **Simponi - golimumab - EMEA/H/C/000992/II/0111** Janssen Biologics B.V., PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from PASS study CNTO148ART4001 listed as a category 3 study in the RMP; this is an observational prospective cohort study to collect and analyse information pertaining to pregnancy outcomes of women exposed to golimumab during pregnancy. The package leaflet is updated accordingly. The RMP version 25.1 has also been submitted." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 16.03.2023.	Positive Opinion adopted by consensus on 12.05.2023.
PRAC Led **Skilarence - dimethyl fumarate - EMEA/H/C/002157/II/0032** Almirall S.A, Rapporteur: Janet Koenig, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study M-41008-44 listed as a category 3 study in the RMP. This is a non-interventional Post-Authorisation Safety Study titled 'A retrospective chart review to assess the effectiveness of the Skilarence risk minimisation activities in daily practice'. The RMP version 2.1 has also been submitted." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Spikevax - elasomeran - EMEA/H/C/005791/II/0085/G** Moderna Biotech Spain, S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "C.I.13 - To submit the final CSR from study	Positive Opinion adopted by consensus on 12.05.2023.

mRNA-1273-P201, a Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults ≥= 18 Years listed as a category 3 study including addition of clinical trial exposure data for part C of the study mRNA-1273-P201." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 16.03.2023, 12.01.2023.	
PRAC Led **TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0082** Biogen Netherlands B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on results from study 109MS402 - Tecfidera (dimethyl fumarate) Pregnancy Exposure Registry, listed as a category 3 study in the RMP; This is an observational study and aims to address the safety concern of effects on pregnancy outcome and prospectively evaluates pregnancy outcomes in women with MS who were exposed to a Registry-specified Biogen MS product during the eligibility window for that product. The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted. In addition, the MAH has taken the opportunity to introduce editorial changes to the Product Information." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/II/0006** SIGA Technologies Netherlands B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of substantial updates to the protocol of study SIGA-246-021 listed as a specific obligation in the Annex II of the Product Information in order to reflect the transfer of sponsorship from SIGA Technologies, Inc. to the NIH Division of Microbiology and Infection Disease protocol. This is a phase 4, observational field study to evaluate safety and clinical benefit in tecovirimat-treated patients	Request for supplementary information adopted with a specific timetable.

following exposure to variola virus and clinical diagnosis of smallpox disease. The Annex II and the RMP submitted version 1.2 are updated accordingly." Request for Supplementary Information adopted on 25.05.2023, 14.04.2023.	
PRAC Led **Xeljanz - tofacitinib -** **EMEA/H/C/004214/II/0052** Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from study A3921334 listed as a category 3 study in the RMP. This is a Non-Interventional Post Authorisation Safety Study to evaluate the effectiveness of additional risk minimisation measures materials for tofacitinib in Europe via a survey of healthcare professionals." Request for Supplementary Information adopted on 12.05.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2270** **Vfend-EMEA/H/C/000387/WS2270/0147** Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "To update the Annex II and RMP to version 6.0 to include the results from final clinical study report (CSR) following the completion of a non-interventional (NI) post-authorisation safety study (PASS), A1501103 "An Active Safety Surveillance Program to Monitor Selected Events in Patients with Long-term Voriconazole Use" - MEA091. In addition, the MAH is taking this opportunity to introduce editorial changes." Request for Supplementary Information adopted on 12.05.2023, 12.01.2023, 01.09.2022.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2431** **Tadalafil Mylan-** **EMEA/H/C/003787/WS2431/0023** Mylan Pharmaceuticals Limited, Generic, Generic of Cialis, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "To update the RMP to: -develop follow-up forms in line with the reference product, Cialis, and to update Part III	Positive Opinion adopted by consensus on 12.05.2023.

of RMP and Annex, Specific Adverse Drug Reaction Follow-up Forms accordingly, following CHMP and PRAC Rapporteurs Joint Assessment Report (EMEA/H/C/003787/R/0014, dated 15-Apr-2019). -adopt the safety concerns in the RMP from the ones available on the CMDh website (Revision 35, dated Sep-2022) for generic RMP version 1.1 dated 01 Apr 2020 approved via procedure PT/H/1982/001-002/DC. -submit the updates in the new template (EMA/164014/2018 Rev.2.0.1 accompanying GVP Module V Rev.2)." Opinion adopted on 12.05.2023.	
PRAC Led **WS2434** **Entresto-** **EMEA/H/C/004062/WS2434/0049** **Neparvis-** **EMEA/H/C/004343/WS2434/0047** Novartis Europharm Limited, Lead PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "C.I.11.z - To amend the RMP for Ernestro and its duplicate marketing authorisation Neparvis to update the milestones for MEA 002 (study CLCZ696B2014) and MEA 004 (study CLCZ696B2015) ." Opinion adopted on 12.05.2023. Request for Supplementary Information adopted on 16.03.2023.	Positive Opinion adopted by consensus on 12.05.2023.
PRAC Led **WS2453** **ProQuad-** **EMEA/H/C/000622/WS2453/0160** **Zostavax-** **EMEA/H/C/000674/WS2453/0145** Merck Sharp & Dohme B.V., Lead PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of updated RMPs for ProQuad and Zostavax versions 9.0 and 11.0 respectively, in order to remove the Varicella Zoster Virus Identification Program (VZVIP) as a routine pharmacovigilance activity beyond adverse reactions reporting and signal detection from the RMP Part III: pharmacovigilance plan." Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.

B.5.5. CHMP-CAT assessed procedures

Abecma - idecabtagene vicleucel - EMEA/H/C/004662/II/0032/G, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang Request for Supplementary Information adopted on 17.05.2023.	Request for supplementary information adopted with a specific timetable.
Alofisel - darvadstrocel - EMEA/H/C/004258/II/0044/G, Orphan, ATMP Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, "Grouped application comprising one type II variation and two type IB as follows: - Update of section 4.8 of the SmPC in order to update the Summary of the safety profile and to add anal abscess, proctalgia and anal fistula to the list of adverse drug reactions on post-marketing experience following the assessment of R/0036 based on a review of the MAH's Global Safety Database. - Update of section 4.2 of the SmPC in order to add the term Perilesional as an EDQM term, following the assessment of R/0036. - Update of sections 1, 2.2, 3, 4.2, 6.5 and 6.6 of the SmPC in order to replace the term "suspension for injection" for "dispersion for injection", following the assessment of R/0036. The Annex A, Package Leaflet and Labelling are updated in accordance." Request for Supplementary Information adopted on 17.05.2023.	Request for supplementary information adopted with a specific timetable.
Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0062/G, ATMP Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo Request for Supplementary Information adopted on 17.05.2023.	Request for supplementary information adopted with a specific timetable.
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0069, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang Request for Supplementary Information adopted on 17.05.2023.	Request for supplementary information adopted with a specific timetable.
Yescarta - axicabtagene ciloleucel -	Positive Opinion adopted by consensus on

EMEA/H/C/004480/II/0057, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Opinion adopted on 25.05.2023, 17.05.2023. Request for Supplementary Information adopted on 24.03.2023, 20.01.2023.	25.05.2023.
WS2389/G **Tecartus-** **EMEA/H/C/005102/WS2389/0031/G** **Yescarta-** **EMEA/H/C/004480/WS2389/0059/G** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Opinion adopted on 25.05.2023, 17.05.2023. Request for Supplementary Information adopted on 17.02.2023.	Positive Opinion adopted by consensus on 25.05.2023.

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

WS2413/G **Axura-** **EMEA/H/C/000378/WS2413/0083/G** **Memantine Merz-** **EMEA/H/C/002711/WS2413/0019/G** Merz Pharmaceuticals GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 16.03.2023.	Positive Opinion adopted by consensus on 25.05.2023.
WS2439/G **Edistride-** **EMEA/H/C/004161/WS2439/0060/G** **Forxiga-** **EMEA/H/C/002322/WS2439/0081/G** AstraZeneca AB, Lead Rapporteur: Kristina Dunder Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
WS2440/G **Riarify-** **EMEA/H/C/004836/WS2440/0026/G** **Trimbow-**	Positive Opinion adopted by consensus on 04.05.2023.

EMEA/H/C/004257/WS2440/0032/G **Trydonis-** **EMEA/H/C/004702/WS2440/0029/G** Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig Opinion adopted on 04.05.2023.	
WS2441/G **Exelon-** **EMEA/H/C/000169/WS2441/0142/G** **Prometax-** **EMEA/H/C/000255/WS2441/0143/G** Novartis Europharm Limited, Lead Rapporteur: Alexandre Moreau Opinion adopted on 25.05.2023. Request for Supplementary Information adopted on 30.03.2023.	Positive Opinion adopted by consensus on 25.05.2023.
WS2452 **CoAprovel-** **EMEA/H/C/000222/WS2452/0213** **Karvezide-** **EMEA/H/C/000221/WS2452/0213** Sanofi Winthrop Industrie, Duplicate, Duplicate of Karvezide, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.
WS2459 **Abseamed-** **EMEA/H/C/000727/WS2459/0101** **Binocrit-** **EMEA/H/C/000725/WS2459/0100** **Epoetin alfa Hexal-** **EMEA/H/C/000726/WS2459/0100** Sandoz GmbH, Lead Rapporteur: Alexandre Moreau Opinion adopted on 12.05.2023.	Positive Opinion adopted by consensus on 12.05.2023.

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

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

apadamtase alfa - EMEA/H/C/006198, **Orphan** Takeda Manufacturing Austria AG, treatment of	

congenital thrombotic thrombocytopenic purpura (cTTP) due to ADAMTS13 deficiency

efanesoctocog alfa - EMEA/H/C/005968, Orphan
Swedish Orphan Biovitrum AB (publ), Treatment and prophylaxis of bleeding in patients with haemophilia A

insulin icodec - EMEA/H/C/005978
treatment of diabetes mellitus in adults

fidanacogene elaparvovec - EMEA/H/C/004774, Orphan, ATMP
Pfizer Europe MA EEIG, indicated for the treatment of severe and moderately severe haemophilia B

Capivasertib - EMEA/H/C/006017
is indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic breast cancer following recurrence or progression on or after an endocrine based regimen

dasatinib - EMEA/H/C/006251
Indicated for the treatment of chronic myelogenous leukaemia (CML)

eribulin - EMEA/H/C/006191
treatment of breast cancer and liposarcoma

Iptacopan - EMEA/H/C/005764, Orphan
Novartis Europharm Limited, treatment of paroxysmal nocturnal haemoglobinuria

rituximab - EMEA/H/C/006224
treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis

Denosumab - EMEA/H/C/005964
treatment of osteoporosis

omalizumab - EMEA/H/C/005958
treatment of asthma

ustekinumab - EMEA/H/C/006183
treatment of Crohn’s disease

vibegron - EMEA/H/C/005957
treatment of micturition frequency and/or urgency incontinence as may occur in adult

patients with Over Active Bladder (OAB) syndrome

Ustekinumab - EMEA/H/C/006132
treatment Crohn's Disease and ulcerative colitis

Denosumab - EMEA/H/C/005965
prevention of skeletal related events

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

COMIRNATY - tozinameran - EMEA/H/C/005735/X/0180
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, "Extension application to add a new pharmaceutical form of Comirnaty 5/5 µg (tozinameran, famtozinameran) dispersion for injection for active immunisation for children aged 5 to 11 years of age."

OPDIVO - nivolumab - EMEA/H/C/003985/X/0132
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber

Rozlytrek - entrectinib - EMEA/H/C/004936/X/0017/G
Roche Registration GmbH, Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst, "Extension application to:
1) Introduce a new pharmaceutical form (coated granules) associated with a new strength (50 mg).
2) Introduce a new route of administration (gastroenteral use) for the already authorised 100 mg and 200 mg hard capsules presentations.
The above two line extensions are grouped with 3 type II variations:
- C.I.6.a - To extend the currently approved indication in solid tumours with NTRK gene fusion to patients from birth to 12 years of age (both for the coated granules and already approved hard capsules presentations).
- C.I.6.a - To add a new paediatric indication from birth to 18 years of age for patients with solid tumours with a ROS1 gene fusion (both for the coated granules and already approved hard capsules presentations).

Based on final results from studies CO40778 (STARTRK-NG), GO40782 (STARTRK-2) and BO41932 (TAPISTRY). Study CO40778 is a Phase I/II open-label, dose-escalation and expansion study of entrectinib in paediatrics with locally advanced or metastatic solid or primary CNS tumours and/or who have no satisfactory treatment options; Study GO40782 is an open-label, multicentre, global Phase II basket study of entrectinib for the treatment of patients with solid tumours that harbour an NTRK1/2/3, ROS1, or ALK gene rearrangement (fusion), and study BO41932 is a Phase II, global, multicentre, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in participants with unresectable, locally advanced or metastatic solid tumours determined to harbour specific oncogenic genomic alterations or who are tumour mutational burden (TMB)-high as identified by a validated next-generation sequencing (NGS) assay. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated accordingly. The Package Leaflet and Labelling are updated in accordance. - C.I.4 - To add wording regarding the option of suspension in water of the content of the capsules to be used orally or via the e.g., gastric or nasogastric tube (in sections 4.2 and 5.2 of the SmPC). The RMP (version 5) is updated in accordance. The MAH took the opportunity to introduce minor editorial changes to the PI and to update Annex II of the SmPC.”	

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

in vitro diagnostic medical device - EMEA/H/D/006255 is indicated as an aid in the selection of adult haemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered Request for Supplementary Information adopted on 21.04.2023.	See 6.3
respiratory syncytial virus vaccines - EMEA/H/C/006027	

prevention of respiratory tract disease
List of Questions adopted on 24.04.2023.

vamorolone - EMEA/H/C/005679, Orphan
Santhera Pharmaceuticals (Deutschland) GmbH, Treatment of Duchenne muscular dystrophy (DMD)
List of Questions adopted on 23.02.2023.

lebrikizumab - EMEA/H/C/005894
Treatment of moderate-to-severe atopic dermatitis in adults and adolescents
List of Questions adopted on 23.02.2023.

trastuzumab duocarmazine - EMEA/H/C/005654
treatment of HER2 (Human Epidermal Growth Factor Receptor 2)-positive metastatic breast cancer
List of Questions adopted on 10.11.2022.

leniolisib - EMEA/H/C/005927, Orphan
Pharming Technologies B.V., Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)
List of Questions adopted on 24.01.2023.

Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/X/0033, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Extension application to add a new pharmaceutical form (granules) associated with 2 new strengths (60 mg/40 mg/80 mg and 75 mg/50 mg/100 mg) to support a new indication in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in paediatric patients aged 2 to less than 6 years who have at least one F508del mutation in the CFTR gene (see section 5.1). The new indication is only applicable to the new granules pharmaceutical form. As a consequence of the line extension, the PI for the film coated tablets is also updated to reflect the addition of a new pharmaceutical form. The RMP (version 6.2) has also been submitted."
List of Questions adopted on 26.04.2023.

Kalydeco - ivacaftor - EMEA/H/C/002494/X/0114/G
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Beata Maria Jakline Ullrich, PRAC

Rapporteur: Monica Martinez Redondo, "Extension application to add a new strength (59.5 mg) of the granules pharmaceutical form grouped with C.I.6.a, to support a new indication in a combination regimen with ivacaftor/tezacaftor/elexacaftor for the treatment of cystic fibrosis (CF) in paediatric patients aged 2 to less than 6 years who have at least one F508del mutation in the CFTR gene (see section 5.1).
The RMP (version 15.1) has also been submitted.
Type IB B.II.f.1.b
The Product information has been updated accordingly."
List of Questions adopted on 26.04.2023.

pegzilarginase - EMEA/H/C/005484, Orphan
Immedica Pharma AB, treatment of hyperargininemia
List of Questions adopted on 15.12.2022.

rezafungin - EMEA/H/C/005900, Orphan
Mundipharma GmbH, treatment of invasive candidiasis
List of Questions adopted on 15.12.2022.

TAKHZYRO - lanadelumab - EMEA/H/C/004806/X/0034/G, Orphan
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, "Extension application to add a new strength of 150 mg for lanadelumab solution for injection in pre-filled syringe and to extend the indication to include paediatric use (2 to <12 years).
The new indication is only applicable to the new 150 mg strength presentations.
The RMP (version 3.0) is updated in accordance.
A type IB variation (C.I.z) has been submitted to update section 7 of the Package Leaflet (PL) for the 300 mg in 2 ml pre-filled syringe (EU/1/18/1340/004-006) in line with the proposed PL for the 150 mg in 1 ml pre-filled syringe (new strength).
In addition, the MAH has requested an extension of the Orphan Market Exclusivity from 10 to 12 years."
List of Questions adopted on 30.03.2023.

talquetamab - EMEA/H/C/005864, Orphan
Janssen-Cilag International N.V., monotherapy treatment of adult patients with relapsed and refractory multiple myeloma
List of Questions adopted on 24.04.2023.

talquetamab - EMEA/H/C/005864, Orphan
Janssen-Cilag International N.V., monotherapy treatment of adult patients with relapsed and refractory multiple myeloma
List of Questions adopted on 24.04.2023.

Tecentriq - atezolizumab - EMEA/H/C/004143/X/0076
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Inês Ribeiro-Vaz, "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (1875 mg) and new route of administration (subcutaneous use).
The RMP (version 24.0) is updated in accordance."
List of Questions adopted on 30.03.2023.

Vyvgart - efgartigimod alfa - EMEA/H/C/005849/X/0003, Orphan
Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (1000 mg) and a new route of administration (subcutaneous use)."
List of Questions adopted on 30.03.2023.

palopegteriparatide - EMEA/H/C/005934, Orphan
Ascendis Pharma Bone Diseases A/S, PTH replacement therapy indicated for the treatment of hypoparathyroidism in adults.
List of Questions adopted on 30.03.2023.

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

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

GAVRETO - pralsetinib - EMEA/H/C/005413/R/0014
Roche Registration GmbH, Rapporteur: Aaron

Sosa Mejia, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ulla Wändel Liminga

NINLARO - ixazomib - EMEA/H/C/003844/R/0043, Orphan
Takeda Pharma A/S, Rapporteur: Armando Genazzani, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

RYBREVANT - amivantamab - EMEA/H/C/005454/R/0007
Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Spevigo - spesolimab - EMEA/H/C/005874/R/0005
Boehringer Ingelheim International GmbH, Rapporteur: Kristina Dunder, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Nathalie Gault

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Aflunov - prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/002094/II/0084/G
Seqirus S.r.l, Rapporteur: Maria Grazia Evandri

Alymsys - bevacizumab - EMEA/H/C/005286/II/0022
Mabxience Research SL, Rapporteur: Christian Gartner

Cetrotide - cetrorelix - EMEA/H/C/000233/II/0090
Merck Europe B.V., Rapporteur: Martina Weise

COMIRNATY - tozinameran - EMEA/H/C/005735/II/0181
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Cosentyx - secukinumab - EMEA/H/C/003729/II/0101
Novartis Europharm Limited, Rapporteur: Outi

Mäki-Ikola

CRYSVITA - Burosumab - EMEA/H/C/004275/II/0035/G, Orphan
Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer

Erleada - apalutamide - EMEA/H/C/004452/II/0032/G
Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez

Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/II/0020/G
Novo Nordisk A/S, Rapporteur: Daniela Philadelphy

Eylea - aflibercept - EMEA/H/C/002392/II/0087
Bayer AG, Rapporteur: Alexandre Moreau

Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0045
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0037
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0132
AstraZeneca AB, Rapporteur: Christophe Focke

Herceptin - trastuzumab - EMEA/H/C/000278/II/0189
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0064, Orphan
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Kadcyla - trastuzumab emtansine - EMEA/H/C/002389/II/0069/G
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia

KANJINTI - trastuzumab - EMEA/H/C/004361/II/0023
Amgen Europe B.V., BREDA, Rapporteur: Jan Mueller-Berghaus

LEDAGA - chlormethine - EMEA/H/C/002826/II/0035/G, Orphan
Helsinn Birex Pharmaceuticals Limited, Rapporteur: Aaron Sosa Mejia

Metalyse - tenecteplase - EMEA/H/C/000306/II/0069/G
Boehringer Ingelheim International GmbH, Rapporteur: Martina Weise

Mounjaro - tirzepatide - EMEA/H/C/005620/II/0008
Eli Lilly Nederland B.V., Rapporteur: Martina Weise

Nimenrix - meningococcal group A, C, W135 and y conjugate vaccine - EMEA/H/C/002226/II/0126/G
Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang

Ogluo - glucagon - EMEA/H/C/005391/II/0011
Tetris Pharma B.V., Rapporteur: Karin Janssen van Doorn

Oyavas - bevacizumab - EMEA/H/C/005556/II/0022
STADA Arzneimittel AG, Duplicate, Duplicate of Alymsys, Rapporteur: Christian Gartner

Praluent - alirocumab - EMEA/H/C/003882/II/0081
Sanofi Winthrop Industrie, Rapporteur: Johann Lodewijk Hillege

Ranivisio - ranibizumab - EMEA/H/C/005019/II/0005
Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus

Ranivisio - ranibizumab - EMEA/H/C/005019/II/0006
Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus

Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0066/G
CSL Behring GmbH, Rapporteur: Kristina Dunder

Rybelsus - Semaglutide - EMEA/H/C/004953/II/0033/G
Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege

Vaxchora - cholera vaccine, oral, live - EMEA/H/C/003876/II/0020
Emergent Netherlands B.V., Rapporteur: Ingrid Wang

Vocabria - cabotegravir - EMEA/H/C/004976/II/0016/G
ViiV Healthcare B.V., Rapporteur: Jean-Michel Race

Zerbaxa - ceftolozane / tazobactam - EMEA/H/C/003772/II/0041
Merck Sharp & Dohme B.V., Rapporteur: Ingrid Wang

Zolsketil pegylated liposomal - doxorubicin - EMEA/H/C/005320/II/0004
Accord Healthcare S.L.U., Rapporteur: Carolina Prieto Fernandez

WS2419/G
Herceptin- EMEA/H/C/000278/WS2419/0188/G
Kadcyla- EMEA/H/C/002389/WS2419/0068/G
Roche Registration GmbH, Lead Rapporteur: Jan Mueller-Berghaus

WS2471/G
Mosquirix- EMEA/H/W/002300/WS2471/0070/G
Shingrix- EMEA/H/C/004336/WS2471/0066/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2507
Bondronat- EMEA/H/C/000101/WS2507/0092
Bonviva- EMEA/H/C/000501/WS2507/0076
Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher

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

Artesunate Amivas - artesunate - EMEA/H/C/005550/II/0004, Orphan
Amivas Ireland Ltd, Rapporteur: Jayne Crowe, "Update of sections 4.6 and 5.3 of the SmPC in order to update non-clinical information based on study 362163, which studies cytogenetic damage in rats, and study 9001907, which

studies fertility and embryonic development in female rats, listed as a category 3 study in the RMP. In addition, the MAH took the opportunity to introduce minor changes to the PI."

BLINCYTO - blinatumomab - EMEA/H/C/003731/II/0051, Orphan

Amgen Europe B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to update immunogenicity information to remove reference to antibody testing based on an analysis of all completed clinical studies and post-marketing data."

Cerdelga - eliglustat - EMEA/H/C/003724/II/0032, Orphan

Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add cough to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of clinical trial data, MAH global pharmacovigilance database and literature search. The Package Leaflet is updated accordingly."

Cometriq - cabozantinib - EMEA/H/C/002640/II/0053, Orphan

Ipsen Pharma, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add embolism arterial to the list of adverse drug reactions (ADRs) with frequency Uncommon based on literature search. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

GAVRETO - pralsetinib - EMEA/H/C/005413/II/0013

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.4, 4.6 and 5.3 of the SmPC in order to update information on fertility based on final results from study 00571044 (21-0310); this is a 9-week fertility and toxicokinetic study of pralsetinib administered via oral gavage in male Sprague Dawley rats. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor change to the PI and update the list of local representatives in the Package Leaflet."

HEPLISAV B - hepatitis B surface antigen -

EMEA/H/C/005063/II/0026

Dynavax GmbH, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add a 4-dose regimen posology for patients with renal insufficiency including those undergoing haemodialysis and to update safety and pharmacodynamic information based on final results from study HBV-24 "An Open-label, Single Arm Study, Evaluating the Immunogenicity and Safety of HEPLISAV-B in Adults With End-Stage Renal Disease Undergoing Hemodialysis". The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make some editorial updates to the PI mainly to align the wording with the QRD guidance and templates."

Instanyl - fentanyl -
EMEA/H/C/000959/II/0077

Takeda Pharma A/S, Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to add hypersensitivity, anaphylactic reaction and anaphylactic shock to the list of adverse drug reactions (ADRs) with frequency not known based on a cumulative review on safety databases, clinical trials data, fentanyl labels and scientific literature. The Package Leaflet is updated accordingly."

Kisqali - ribociclib -
EMEA/H/C/004213/II/0040

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to update non-clinical safety data information on carcinogenicity based on final results from the following non-clinical studies: DIS R1470078, DIS R0870393, DIS R1470078b and DIS R1370292."

LUMYKRAS - sotorasib -
EMEA/H/C/005522/II/0011

Amgen Europe B.V., Rapporteur: Alexandre Moreau, "Update of sections 4.2 and 4.5 of the SmPC in order to update information regarding the co-administration of sotorasib with acid reducing agents, based on the results from study 20220024; this is a phase 1, single-center, open-label drug-drug interaction study to evaluate the impact of omeprazole, a proton pump inhibitor, on the pharmacokinetics of sotorasib co-administered with an acidic beverage in healthy volunteers. The Package

Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Natpar - parathyroid hormone - EMEA/H/C/003861/II/0050, Orphan
Takeda Pharmaceuticals International AG, Rapporteur: Karin Janssen van Doorn, "Submission of the final report from study SHP634-401 (BALANCE). This is a phase 3b-4, randomized, double-blind, placebo controlled, adaptive study to evaluate symptom improvement and metabolic control among adult subjects with symptomatic hypoparathyroidism treated with recombinant human parathyroid hormone [rhPTH(1-84)]."

Norvir - ritonavir - EMEA/H/C/000127/II/0169
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.3 and 4.5 of the SmPC in order to remove information regarding the DDI with piroxicam based on a review of clinical studies, post-marketing data and literature. The Package Leaflet is updated accordingly."

RINVOQ - upadacitinib - EMEA/H/C/004760/II/0038
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Update of sections 4.4 and 5.1 of the SmPC in order to include results from the Recombinant Zoster Vaccine (RZV; Shingrix) sub-study M14-465. The objective of the sub-study was to assess the immunogenicity of the adjuvanted recombinant glycoprotein E (gE) herpes zoster vaccine (Shingrix) in rheumatoid arthritis (RA) subjects receiving upadacitinib 15 mg once daily (QD) with background MTX."

Saxenda - liraglutide - EMEA/H/C/003780/II/0036
Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add 'rash' to the list of adverse drug reactions (ADRs) with frequency common; the Package Leaflet is updated accordingly."

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0065
GlaxoSmithkline Biologicals SA, Rapporteur:

Christophe Focke, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information with COVID-19 mRNA-1273 booster vaccine, based on final results from study ZOSTER-091; this is a phase 3, randomized, open-label, controlled, multi-center clinical study to evaluate the immune response and safety of both herpes zoster subunit vaccine (HZ/su or Shingrix) in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine (Flu D-QIV or Fluarix Quadrivalent) in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination. In addition, the MAH took the opportunity to introduce a minor change to the PI."

Skyrizi - risankizumab - EMEA/H/C/004759/II/0035

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Update of sections 4.8 and 5.1 of the SmPC based on final results from study M15-997; this is a Phase 3, single-arm, multicenter, open label study to assess the safety and efficacy of risankizumab for maintenance in moderate to severe plaque type psoriasis. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Spravato - esketamine - EMEA/H/C/004535/II/0018

Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study 54135419TRD3013 (ESCAPE). This is A Randomized, Open-label, Rater-Blinded, Active-Controlled, International, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Flexibly Dosed Esketamine Nasal Spray Compared With Quetiapine Extended-Release in Adult and Elderly Participants With Treatment-Resistant Major Depressive Disorder Who are Continuing a Selective Serotonin Reuptake Inhibitor/Serotonin-Norepinephrine Reuptake Inhibitor.
In addition, the MAH took the opportunity to introduce minor editorial changes, to update Annex IV and to update the list of local

representatives in the Package Leaflet."

TAVNEOS - avacopan -
EMEA/H/C/005523/II/0007, Orphan
Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, "Update of sections 4.4 and 5.1 of the SmPC in order to correct a recently identified calculation error that occurred in the conversion of various non-prednisolone glucocorticoids to their prednisolone-equivalent doses in the pivotal Phase 3 study CL010_168 (ADVOCATE)."

Tivicay - dolutegravir -
EMEA/H/C/002753/II/0089
ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 5.2 of the SmPC in order to update Tmax data for the dolutegravir dispersible tablet formulation."

Toviaz - fesoterodine -
EMEA/H/C/000723/II/0068
Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC in order to add hypoaesthesia to the list of adverse drug reactions (ADRs) with frequency Uncommon based on a cumulative review of safety database cases and literature. The Package Leaflet is updated accordingly. In addition, the MAH would like to take this opportunity to make minor linguistic corrections in line with the QRD template v10.3."

Vipdomet - alogliptin / metformin -
EMEA/H/C/002654/II/0044
Takeda Pharma A/S, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Vitamin B12 decrease or deficiency and to update the list of adverse drug reactions (ADRs) in accordance with the recent update of the PI for Glucophage, which is the reference label for the compound metformin, and following the request by MHRA on 20 June 2022 for all products containing metformin."

Vyndaqel - tafamidis -
EMEA/H/C/002294/II/0087, Orphan
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to remove the adverse reaction 'vaginal infection' based on a search of cumulative post-marketing cases. The Package Leaflet and

Annex IV are updated accordingly. In addition, the MAH takes the opportunity to update the company logo on the Package Leaflet."

WS2481
TOBI Podhaler-
EMEA/H/C/002155/WS2481/0058
Viatris Healthcare Limited, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.4 of the SmPC in order to amend an existing warning on ototoxicity based on literature review. 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 introduce minor editorial changes."

WS2485
Incruse Ellipta-
EMEA/H/C/002809/WS2485/0037
Rolufta Ellipta-
EMEA/H/C/004654/WS2485/0021
GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.2, 4.6 and 4.8 of the SmPC in order to add 'Dysphonia' and 'Oropharyngeal pain' to the list of adverse drug reactions (ADRs) with frequency rare, and to update the wording regarding the administration instructions and for pregnancy and breast-feeding. The Package Leaflet and Labelling are also updated. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

B.6.10. CHMP-PRAC assessed procedures

Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0016
Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Jean-Michel Dogné, "Submission of an updated RMP version 4 in order to update post-approval commitments. In addition, the MAH took the opportunity to update Annex II of the SmPC to expand the B4741015 PAES study protocol to sites in Europe and Israel for Apexxnar. B4741015 is a Phase 4 study using a test negative design to evaluate the effectiveness of Apexxnar against vaccine type radiologically

confirmed community acquired pneumonia in adults ≥ 65 years of age."

Dovato - dolutegravir / lamivudine - EMEA/H/C/004909/II/0040/G

ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: David Olsen, "Submission of the final reports from study 204861 (GEMINI-1) and study 205543 (GEMINI-2) listed as category 3 studies in the RMP; these are phase 3, randomised, double-blind, multicentre, parallel group, non-inferiority studies evaluating the efficacy, safety and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment-naïve adults. The RMP version 4.0 has also been submitted."

EVUSHELD - tixagevimab / cilgavimab - EMEA/H/C/005788/II/0009/G

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising two type II variations (REC 23) as follows:
C.I.4 - Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study TACKLE (D8851C00001).
C.I.4 - Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information based on final results from studies PROVENT (D8850C00002) and STORM CHASER (D8850C00003).
The RMP version 4.1 has also been submitted."

Lynparza - olaparib - EMEA/H/C/003726/II/0061

AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Amelia Cupelli, "Update of sections 4.8 and 5.1 of the SmPC in order to update the overall survival and safety information following procedure H/C/003726/II/0048, based on the final results from study D081SC00001 (PROpel), listed as a PAES in the Annex II; this is a randomised, double-blind, placebo-controlled, multicentre phase III study of olaparib plus abiraterone relative to placebo plus abiraterone as first-line therapy in men with metastatic castration resistant prostate cancer; The RMP version 27

has also been submitted."

Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0043/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber, "C.I.4: Update of section 5.1 of the SmPC in order to include new virology updates.
C.I.4: Update of sections 4.5 and 5.2 of the SmPC in order to update interaction information related to CYP2B6, MATE1 and OCT1.
The RMP version 3.0 has also been submitted."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0078

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Inês Ribeiro-Vaz, "Update of section 5.1 of the SmPC in order to include the final overall survival (OS) analysis results based on final results from study WO30070 listed as a PAES in the Annex II to fulfil ANX/PAE 003; this is a Phase III, multicenter, randomized, placebo-controlled study of atezolizumab as monotherapy and in combination with platinum-based chemotherapy in patients with untreated locally advanced or metastatic urothelial carcinoma. The RMP version 27 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC."

Tecvayli - teclistamab - EMEA/H/C/005865/II/0006

Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Jana Lukacisinova, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update the posology recommendations to include the possibility of bi-weekly dosing, based on interim results from study 64007957MMY1001 (MajesTEC-1); this is a phase 1/2, single-arm, open-label, multicenter study of teclistamab administered as monotherapy to adult subjects with relapsed or refractory multiple myeloma. The Package Leaflet is updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and update the list of local representatives in the Package Leaflet."

Tysabri - natalizumab -

EMEA/H/C/000603/II/0136
Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 4.4 of the SmPC to modify administration instructions and update educational guidance to enable the subcutaneous formulation to be administered outside a clinical setting by healthcare professionals based on the cumulative review of post-marketing and clinical study data. The Package Leaflet and Annex IID are updated accordingly. The RMP version 29.1 has also been submitted. In addition, the MAH took this opportunity to introduce minor editorial changes."

Vyvgart - efgartigimod alfa - EMEA/H/C/005849/II/0006, Orphan
Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.5 of the SmPC in order to amend an existing warning on use of vaccination and update drug-drug interaction information on vaccines based on final results from study ARGX-113-2102; this is a phase 1, randomized, open-label, placebo-controlled, parallel-group study to evaluate the immune response to PNEUMOVAX 23 in healthy participants receiving efgartigimod IV 10 mg/kg or placebo. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

B.6.11. PRAC assessed procedures

PRAC Led

Fasenra - benralizumab - EMEA/H/C/004433/II/0049/G
AstraZeneca AB, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Grouped application consisting of:
1) Submission of an updated RMP version 5 in order to remove the safety concern of missing information on use in pregnant and lactating women. Consequently, the MAH proposes to remove study D3250R00026 as an additional pharmacovigilance activity, and to remove the commitment to conduct additional pharmacovigilance for the use of benralizumab in pregnant and lactating women with severe

eosinophilic asthma. 2) Submission of an updated RMP version 5 in order to remove the safety concern of important potential risk of serious infections.”	
PRAC Led **Halaven - eribulin - EMEA/H/C/002084/II/0067** Eisai GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, “Submission of the final report from study IRENE 504 (E7389-M044-504), listed as a category 3 study in the RMP. This was a post-authorisation non-interventional safety study to characterise and determine the incidence of eribulin-induced peripheral neuropathy (PN), and frequency and time to resolution of eribulin-induced PN in adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease treated with eribulin. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. The RMP version 8 has also been submitted.”	
PRAC Led **Kineret - anakinra - EMEA/H/C/000363/II/0090** Swedish Orphan Biovitrum AB (publ), PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, “Submission of an updated RMP version 6.2 in order to add DRESS as an important potential risk as well as the removal of the additional risk minimisation measures for serious infections, following the assessment of procedure PSUSA/00000209/202205. Annexes II and IV are updated in accordance.”	
PRAC Led **Remicade - infliximab - EMEA/H/C/000240/II/0241** Janssen Biologics B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “Submission of the final report for the PSOLAR (C0168Z03) registry “A Multicentre, Open Registry of Patients with Psoriasis Who Are Candidates for Systemic Therapy Including Biologics: PSOLAR”, listed as a category 3 study in the RMP (MEA114). This is an international,	

multicentre, prospective observational registry for monitoring the long-term safety experience and clinical status of patients ≥18 years of age who are eligible to receive or are actively receiving any systemic therapies for psoriasis, including those currently receiving or planning to receive infliximab. The RMP version 21.1 has also been submitted."

PRAC Led

Replagal - agalsidase alfa - EMEA/H/C/000369/II/0126

Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from the Fabry Outcome Survey (FOS) registry study. The FOS (Fabry Outcome Survey) was a prospective, multicenter, observational, open-ended disease registry designed to document the clinical outcome over time of patients with Fabry disease, irrespective of their treatment."

PRAC Led

Zytiga - abiraterone acetate - EMEA/H/C/002321/II/0072

Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Submission of an updated RMP version 15.1 in order to align with Good Pharmacovigilance Practices Module V, Revision 2."

PRAC Led

WS2491

Lantus-EMEA/H/C/000284/WS2491/0127

Toujeo-EMEA/H/C/000309/WS2491/0122

Sanofi-Aventis Deutschland GmbH, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "C.I.11.z - To update the RMP of Toujeo and Lantus following removal of the "Medication error due to non-compliance with instructions to use a new needle for each injection: wrong dose injected due to blocked needle" from the list of safety concerns (EMEA/H/C/000309/II/0105/G), to: -remove the follow-up questionnaire for the topic "Medication error due to non-compliance with instructions to use a new needle for each injection: wrong dose injected due to blocked needle" from routine pharmacovigilance

activities (Part III);
-remove the suspected blockage of needle questionnaire (Annex 4);
-update with the revised DLP (Part II).”

B.6.12. CHMP-CAT assessed procedures

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0021, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Armando Genazzani

CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0018, Orphan, ATMP
Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus,

CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0019, Orphan, ATMP
Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Libmeldy - atidarsagene autotemcel - EMEA/H/C/005321/II/0017, Orphan, ATMP
Orchard Therapeutics (Netherlands) B.V., Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

B.6.13. CHMP-PRAC-CAT assessed procedures

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0040, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.4 and 5.1 of the SmPC in order to add a new warning and precaution capturing the theoretical risk of tumorigenicity as a result of vector integration and to include a new statement indicating random instances of vector integration are possible; based on final results from studies 2220205, 2220117 and literature. The Package Leaflet is updated accordingly. The RMP version 3 has also been

submitted."

B.6.14. PRAC assessed ATMP procedures

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

WS2474
Nuwiq-EMEA/H/C/002813/WS2474/0054
Vihuma-
EMEA/H/C/004459/WS2474/0036
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS2476
Ambirix-
EMEA/H/C/000426/WS2476/0128
Fendrix-
EMEA/H/C/000550/WS2476/0083
Infanrix hexa-
EMEA/H/C/000296/WS2476/0331
Twinrix Adult-
EMEA/H/C/000112/WS2476/0163
Twinrix Paediatric-
EMEA/H/C/000129/WS2476/0164
GlaxoSmithKline Biologicals, Lead Rapporteur: Christophe Focke

WS2480
Esperoct-
EMEA/H/C/004883/WS2480/0019
NovoEight-
EMEA/H/C/002719/WS2480/0041
NovoSeven-
EMEA/H/C/000074/WS2480/0122
Refixia-EMEA/H/C/004178/WS2480/0034
Novo Nordisk A/S, Lead Rapporteur: Jan Mueller-Berghaus

WS2482/G
Vfend-
EMEA/H/C/000387/WS2482/0150/G
Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege

WS2484
Filgrastim Hexal-
EMEA/H/C/000918/WS2484/0071
Zarzio-EMEA/H/C/000917/WS2484/0072
Sandoz GmbH, Lead Rapporteur: Johann Lodewijk Hillege

WS2490

HyQvia-EMEA/H/C/002491/WS2490/0090
Kiovig-EMEA/H/C/000628/WS2490/0122
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

WS2495
Hexacima-EMEA/H/C/002702/WS2495/0149
Hexyon-EMEA/H/C/002796/WS2495/0153
MenQuadfi-EMEA/H/C/005084/WS2495/0024
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS2498/G
EVOTAZ-EMEA/H/C/003904/WS2498/0045/G
Reyataz-EMEA/H/C/000494/WS2498/0138/G
Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Bruno Sepodes

WS2499
Circadin-EMEA/H/C/000695/WS2499/0069
Melatonin Neurim-EMEA/H/C/005603/WS2499/0001
RAD Neurim Pharmaceuticals EEC SARL, Lead Rapporteur: Bruno Sepodes

WS2504/G
Anoro Ellipta-EMEA/H/C/002751/WS2504/0041/G
Elebrato Ellipta-EMEA/H/C/004781/WS2504/0033/G
Incruse Ellipta-EMEA/H/C/002809/WS2504/0038/G
Laventair Ellipta-EMEA/H/C/003754/WS2504/0044/G
Rolufta Ellipta-EMEA/H/C/004654/WS2504/0022/G
Trelegy Ellipta-EMEA/H/C/004363/WS2504/0030/G
GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy

WS2505/G
Rixathon-EMEA/H/C/003903/WS2505/0066/G
Riximyo-EMEA/H/C/004729/WS2505/0067/G
Sandoz GmbH, Lead Rapporteur: Jan Mueller-

Berghaus, "C.I.2.a - To update section 6.6 of the SmPC of Rixathon and Riximyo (duplicate of Rixathon) to remove the additional paragraph 'Aseptic preparation' to be in line with the reference product, Mabthera. A6 - To change the ATC Code of rituximab from L01X C02 to L01FA0. Furthermore, the MAH has taken the opportunity to include minor editorial changes in the EN, DA, DE, FR, HR, IS, LV and MT translations."	
WS2510 **Lixiana-EMEA/H/C/002629/WS2510/0047** **Roteas-EMEA/H/C/004339/WS2510/0034** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro	

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. Timetables – 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

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. PRIME

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

G.2.1. List of procedures concluding at 22-25 May 2023 CHMP plenary:

Oncology	
ABSK021 Treatment of tenosynovial giant cell tumour (TGCT)	The CHMP granted eligibility to PRIME and adopted the critical summary report.
Treatment of B Cell Lymphoma (SME) ATMP	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Treatment of primary indeterminate lesions and small choroidal melanoma (SME)	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Vaccines	
Prevention of LRTI caused by RSV or hMPV in infants and children aged 6 weeks to < 5 years, and children and adolescents from 5 years to < 18 years of age with certain chronic conditions	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Cardiovascular Diseases	
RP-A501 Treatment of Danon disease	The CHMP granted eligibility to PRIME and adopted the critical summary report.
Infectious Diseases	
Adjunct treatment of S. aureus pneumonia	The CHMP denied eligibility to PRIME and adopted the critical summary report.

Critical care	
Treatment of sepsis	The CHMP denied eligibility to PRIME and adopted the critical summary report.

G.2.2. List of procedures starting in May 2023 for June 2023 CHMP adoption of outcomes

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