



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 January 2023
EMA/CHMP/907832/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 07-10 November 2022

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/127362/2006).



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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. Due to the current coronavirus (COVID-19) pandemic, and the associated EMA Business Continuity Plan (BCP), the meeting was held in-person with some members connected remotely (hybrid setting).

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 07-10 November 2022.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 10-13 October 2022.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 31 October 2022.

The CHMP adopted the CHMP minutes for 10-13 October 2022.

The CHMP adopted the minutes from the PROM meeting held on 31 October 2022.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. miglustat - Orphan - EMEA/H/C/005695

Amicus Therapeutics Europe Limited; treatment of adults aged 18 years and older with a confirmed diagnosis of Pompe disease

Scope: Possible oral explanation

Action: Oral explanation to be held on 09 November 2022 at 11:00

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

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

See 3.2

2.1.2. cipaglucosidase alfa - Orphan - EMEA/H/C/005703

Amicus Therapeutics Europe Limited; treatment of adults aged 18 years and older with a confirmed diagnosis of Pompe disease

Scope: Possible oral explanation

Action: Oral explanation to be held on 09 November 2022 at 09:00

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

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

See 3.2

2.1.3. iodine (131I) omburtamab - Orphan - EMEA/H/C/005499

Y-Mabs Therapeutics A/S; treatment of neuroblastoma

Scope: Oral explanation

Action: Oral explanation to be held on 08 November 2022 at 14:00

List of Outstanding Issues adopted on 23.06.2022. List of Questions adopted on 16.09.2021.

An oral explanation was held on 08 November 2022. The presentation by the applicant focused on the quality data in support of the application.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Eylea - aflibercept - EMEA/H/C/002392/II/0077/G

Bayer AG

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault

Scope: "C.I.6 (Extension of indication) Extension of indication to include the paediatric indication retinopathy of prematurity (ROP) for Eylea; 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. Separate Package Leaflet is proposed for the guardians of preterm babies. Version 32.1 of the RMP has also been submitted.

B.IV.1.a.3"

Possible oral explanation

Action: Oral explanation to be held on 09 November 2022 at 14:00

Request for Supplementary Information adopted on 13.10.2022, 24.02.2022.

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

See 5.1

2.3.2. Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0012

Daiichi Sankyo Europe GmbH

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: "Extension of indication to include monotherapy treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen for Enhertu based on final results from studies DS8201-A-U205 (DESTINY Gastric02) and DS8201 A J202 (DESTINY Gastric01); as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. In addition, changes regarding the dosing recommendation for corticosteroid treatment and the protection of the infusion bag from light have been introduced. Version 3.0 of the RMP has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Oral explanation

Action: Oral explanation to be held on 09 November 2022 at 16:00

Request for Supplementary Information adopted on 23.06.2022, 27.01.2022.

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

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Kauliv - teriparatide - EMEA/H/C/004932

Strides Pharma Cyprus; Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.07.2022, 16.12.2021. List of Questions adopted on 28.01.2021.

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

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

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

The CHMP noted the letter of recommendation dated 10 November 2022.

The summary of opinion was circulated for information.

3.1.2. Pirfenidone Viartis - pirfenidone - EMEA/H/C/005862

Viartis Limited; treatment of Idiopathic Pulmonary Fibrosis (IPF)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

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

The summary of opinion was circulated for information.

3.1.3. Sugammadex - Amomed - sugammadex - EMEA/H/C/005935

AOP Orphan Pharmaceuticals GmbH; reversal of neuromuscular blockade induced by

rocuronium or vecuronium

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

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.

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

The summary of opinion was circulated for information.

3.1.4. [VidPrevtyn Beta - COVID-19 vaccine \(recombinant, adjuvanted\) - EMEA/H/C/005754](#)

Sanofi Pasteur; Active immunisation as a booster to prevent COVID-19 in adults who have previously received an mRNA or adenoviral vector COVID-19 vaccine.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 13.10.2022. List of Questions adopted on 20.06.2022.

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 SARS-CoV-2 prefusion Spike delta TM protein, recombinant (B.1.351) is a new active substance, as claimed by the applicant.

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

The CHMP noted the letter of recommendation dated 10 November 2022.

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. [sodium phenylbutyrate / ursodoxicoltaurine - Orphan - EMEA/H/C/005901](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.06.2022.

The Committee was reminded of the status of this application.

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

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

The CHMP agreed to consult the MWP.

3.2.2. dapagliflozin - EMEA/H/C/006006

treatment of type 2 diabetes mellitus, heart failure and chronic kidney disease

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.3. pegunigalsidase alfa - Orphan - EMEA/H/C/005618

Chiesi Farmaceutici S.p.A.; treatment of Fabry disease

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.4. gadopiclenol - EMEA/H/C/005626

for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate).

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.5. sirolimus - Orphan - EMEA/H/C/005896

Plusultra pharma GmbH; Treatment of angiofibroma associated with tuberous sclerosis complex

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.04.2022.

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. tremelimumab - Orphan - EMEA/H/C/006016

AstraZeneca AB; For use in combination with durvalumab for the treatment of adults with unresectable hepatocellular carcinoma.

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.7. 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 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 list of outstanding issues with a specific timetable.

3.2.8. spironolactone - EMEA/H/C/005535

Management of refractory oedema

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.03.2022.

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 extension to the clock stop to respond to the list of outstanding issues.

3.2.9. [miglustat - Orphan - EMEA/H/C/005695](#)

Amicus Therapeutics Europe Limited; treatment of adults aged 18 years and older with a confirmed diagnosis of Pompe disease

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

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

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

See 2.1

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

3.2.10. [cipaglucosidase alfa - Orphan - EMEA/H/C/005703](#)

Amicus Therapeutics Europe Limited; treatment of adults aged 18 years and older with a confirmed diagnosis of Pompe disease

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 24.03.2022.

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

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

See 2.1

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

3.2.11. [sitagliptin / metformin hydrochloride - EMEA/H/C/005778](#)

treatment of type 2 diabetes mellitus

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.12. gadopiclesol - EMEA/H/C/006172

for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate).

Scope: List of outstanding issues

Action: For adoption

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. filgrastim - EMEA/H/C/005888

Reduction in the duration of neutropenia and the incidence of febrile neutropenia, indicated for the mobilisation of peripheral blood progenitor cells and persistent neutropenia in patients with advanced HIV infection

Scope: List of outstanding issues; Letter by the applicant dated 25.10.2022 requesting an extension to the clock stop to respond to the list of outstanding issues.

Action: For adoption

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 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.

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

3.3.1. piflufolastat (18f) - EMEA/H/C/005520

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

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. dantrolene sodium, hemiheptahydrate - Orphan - EMEA/H/C/006009

Norgine B.V.; treatment of malignant hyperthermia (including suspected cases)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.3. degarelix acetate - EMEA/H/C/006048

treatment of prostate cancer

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.4. trastuzumab duocarmazine - EMEA/H/C/005654

treatment of HER2 (Human Epidermal Growth Factor Receptor 2)-positive 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.

3.3.5. eculizumab - EMEA/H/C/006036

treatment of paroxysmal nocturnal haemoglobinuria

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. natalizumab - EMEA/H/C/005752

Therapy for active relapsing remitting multiple sclerosis (RRMS)

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. [alpelisib - Orphan - EMEA/H/C/005468](#)

Novartis Europharm Limited; treatment of patients with severe manifestations of PIK3CA-related overgrowth spectrum

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. [atogepant monohydrate - EMEA/H/C/005871](#)

Prophylaxis of migraine in adults who have at least 4 migraine days per month.

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. [dabigatran etexilate - EMEA/H/C/005922](#)

prevention of venous thromboembolic events

Scope: Letter by the applicant dated 09.11.2022 requesting an extension to the clock stop to respond to the list of questions adopted in June 2022.

Action: For adoption

List of Questions adopted on 23.06.2022.

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 June 2022.

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Febseltiq - infigratinib - Orphan - EMEA/H/C/005361

Helsinn Birex Pharmaceuticals Limited; treatment of cholangiocarcinoma

Scope: Withdrawal of marketing authorisation application

Action: For information

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

List of Questions adopted on 24.03.2022.

The CHMP noted the withdrawal of the marketing authorisation application.

3.7.2. Imbarkyd - bardoxolone methyl - Orphan - EMEA/H/C/005869

Reata Ireland Limited; treatment of chronic kidney disease

Scope: Withdrawal of marketing authorisation application

Action: For information

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

List of Questions adopted on 24.02.2022.

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. Xofluza - baloxavir marboxil - EMEA/H/C/004974/X/0008/G

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Sonja Hrabcik

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (2 mg/ml granules for oral suspension) grouped with a type II variation (C.I.6.a) to include paediatric use (from 1 year and above). The paediatric indication is applicable to the new presentation (2 mg/ml granules for oral suspension) as well as all approved presentations (EU/1/20/1500/001 and 002). The RMP (version 2.0) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 22.04.2022.

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.

4.1.2. [Comirnaty - COVID-19 mRNA Vaccine \(nucleoside modified\) - EMEA/H/C/005735/X/0147](#)

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to add a new strength of 5/5 µg (tozinameran, famtozinameran) for active immunisation in children between 5 to 11 years of age who have previously received at least a primary vaccination course against COVID-19. The RMP (version 9.0) is updated in accordance."

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.

4.1.3. [Comirnaty - COVID-19 mRNA Vaccine \(nucleoside modified\) - EMEA/H/C/005735/X/0138](#)

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to add a new strength of 3 µg for individuals 6 months to 4 years of age. In addition, the applicant took the opportunity to introduce editorial changes in Annex I, IIIA and IIIB of the PI. The RMP (version 5.1) is updated in accordance."

Positive opinion adopted by consensus at the extraordinary meeting held on 19 October 2022.

Action: For information

Request for Supplementary Information adopted on 13.10.2022.

At an extraordinary CHMP meeting on 19 October 2022, the CHMP discussed this variation.

On 19 October 2022, the Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

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. Byfavo - remimazolam - EMEA/H/C/005246/X/0002

Paion Deutschland GmbH

Rapporteur: Bruno Sepodes, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (50 mg powder for concentrate for solution for injection/infusion). The new presentation is indicated to include the intravenous induction and maintenance of general anesthesia (GA) in adults for Byfavo 50 mg, based on final results from two pivotal trials: Study ONO-2745-05, a phase IIb/III, single-blind, randomised, parallel-group study assessing safety and efficacy in induction and maintenance of anaesthesia in ASA I/II patients (general surgery), and study CNS-7056-022, a phase III, randomized, propofol controlled, parallel group, confirmatory single-blind efficacy and safety trial during induction and maintenance of anaesthesia in ASA III/IV patients.

A new combined version of the SmPC, labelling and package leaflet solely for the 50 mg strength and the GA indication is provided accordingly. Version 1.1 of the RMP has also been submitted. As part of the application, the MAH also requests an extension of the market protection by one additional year."

Action: For adoption

List of Questions adopted on 19.05.2022.

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

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. Entresto - sacubitril / valsartan - EMEA/H/C/004062/X/0044/G

Novartis Europharm Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Anette Kirstine Stark

Scope: "Extension application to introduce a new pharmaceutical form associated with two new strengths (6 mg/6 mg granules in capsule for opening and 15 mg/16 mg granules in capsule for opening), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of children and adolescents aged one year or older with chronic heart failure with left ventricular systolic dysfunction, based on the results of study PANORAMA-HF (CLCZ696B2319); a multicenter, open-label, study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of sacubitril/valsartan followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of sacubitril/valsartan compared with enalapril in paediatric patients

from 1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.2 of the SmPC are being updated and the package leaflet is updated accordingly. In addition, an updated RMP version 4.0 was provided as part of the application. Further, the MAH requested a one year extension of the market protection.”

Action: For adoption

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

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

4.3.2. [Neparvis - sacubitril / valsartan - EMEA/H/C/004343/X/0042/G](#)

Novartis Europharm Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Anette Kirstine Stark

Scope: “Extension application to introduce a new pharmaceutical form associated with two new strengths (6 mg/6 mg granules in capsule for opening and 15 mg/16 mg granules in capsule for opening), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of children and adolescents aged one year or older with chronic heart failure with left ventricular systolic dysfunction, based on the results of study PANORAMA-HF (CLCZ696B2319); a multicenter, open-label, study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of sacubitril/valsartan followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of sacubitril/valsartan compared with enalapril in paediatric patients from 1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.2 of the SmPC are being updated and the package leaflet is updated accordingly. In addition, an updated RMP version 4.0 was provided as part of the application. Further, the MAH requested a one-year extension of the market protection.”

Action: For adoption

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

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

4.3.3. [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 ‘Replacement of endogenous growth hormone (GH) in children and adolescents with growth failure due to growth hormone deficiency (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 and 5.2 of the SmPC have been updated and the package leaflet has been updated accordingly. A revised RMP version 3.0 was provided as part of the application.”

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.

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

4.4.1. [Betmiga - mirabegron - EMEA/H/C/002388/X/0039/G](#)

Astellas Pharma Europe B.V.

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

Scope: Letter by the applicant dated 09.11.2022 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2022.

Action: For adoption

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 22.04.2022.

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 September 2022.

4.4.2. [Ultomiris - ravulizumab - EMEA/H/C/004954/X/0027/G](#)

Alexion Europe SAS

Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Kimmo Jaakkola

Scope: Letter by the applicant dated 27.10.2022 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in October 2022.

Action: For adoption

List of Outstanding Issues adopted on 13.10.2022. 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 October 2022.

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. Ceprothin - human protein c - EMEA/H/C/000334/II/0127

Takeda Manufacturing Austria AG

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include long-term prophylaxis (deletion of wording 'short-term' and currently listed conditions) of purpura fulminans and coumarin induced skin necrosis in patients with severe congenital protein C deficiency, based on a re-analysis of long-term prophylaxis data from the pivotal study 400101; a phase 2/3 clinical study undertaken to evaluate PK, safety and efficacy of CEPROTIN in patients with severe congenital PC deficiency for the treatment of acute thrombotic episodes, for short-term thromboembolic prophylaxis and for long-term prophylactic treatment. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated and the Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet.

Version 2.0 of the RMP has also been submitted. In addition, MAH took the opportunity to correct the address of the manufacturer of the biological active substance in Annex II following variation EMEA/H/C/000334/IAIN/0126/G."

Action: For adoption

Request for Supplementary Information adopted on 21.07.2022.

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.

5.1.2. Dupixent - dupilumab - EMEA/H/C/004390/II/0062

Sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of eosinophilic esophagitis (EoE) in adults and adolescents 12 years and older who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy, based on the pivotal study R668-EE-1774. This is an ongoing phase 3, randomized, double-blind,

placebo-controlled, 3-part (A, B, C) safety and efficacy study with an initial 24-week treatment period in adults (≥ 18 years of age) and adolescents (≥ 12 to < 18 years of age) with EoE, and which includes an extended treatment period to a total of 52 weeks. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 21.07.2022.

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

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

5.1.3. Dupixent - dupilumab - EMEA/H/C/004390/II/0063

Sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Kimmo Jaakkola

Scope: “Extension of indication to include treatment of adults with moderate to severe prurigo nodularis (PN) who are candidates for systemic therapy, based on results from studies EFC16459 and EFC16460 (PRIME and PRIME2); these are two phase 3, 24-week, randomized, double-blind, placebo-controlled, multi-centre, parallel group studies undertaken to evaluate the efficacy and safety of dupilumab in patients 18 years of age and older with moderate to severe PN, who are inadequately controlled on topical prescription therapies or when those therapies are not advisable. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been approved. Furthermore, the PI is brought in line with the current excipients guideline.

The variation leads to amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and to the Risk Management Plan (RMP).

Amendments to the marketing authorisation.

In view of the data submitted with the variation, amendments to Annexes I, IIIA and IIIB and to the Risk Management Plan are recommended.

Additional market protection

Furthermore, the CHMP reviewed the data submitted by the MAH, taking into account the provisions of Article 14(11) of Regulation (EC) No 726/2004, and considers that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies (see appendix).” 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 21.07.2022.

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.

5.1.4. Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0012

Daiichi Sankyo Europe GmbH

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Paula Boudewina van Hennik, PRAC
Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: "Extension of indication to include monotherapy treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen for Enhertu based on final results from studies DS8201-A-U205 (DESTINY Gastric02) and DS8201 A J202 (DESTINY Gastric01); as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. In addition, changes regarding the dosing recommendation for corticosteroid treatment and the protection of the infusion bag from light have been introduced. Version 3.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2022, 27.01.2022.

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

See 2.3

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.

5.1.5. 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."

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.

5.1.6. Eylea - aflibercept - EMEA/H/C/002392/II/0077/G

Bayer AG

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault

Scope: "C.I.6 (Extension of indication) Extension of indication to include the paediatric indication retinopathy of prematurity (ROP) for Eylea; 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. Separate Package Leaflet is proposed for the guardians of preterm babies. Version 32.1 of the RMP has also been submitted.

B.IV.1.a.3"

Action: For adoption

Request for Supplementary Information adopted on 13.10.2022, 24.02.2022.

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

See 2.3

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.

5.1.7. Iclusig - ponatinib - Orphan - EMEA/H/C/002695/II/0064

Incyte Biosciences Distribution B.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Ewa Balkowicz Iskra, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of newly diagnosed adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), either with Iclusig (ponatinib) in combination with chemotherapy, or with Iclusig (ponatinib) monotherapy after corticosteroid induction in patients not eligible to receive chemotherapy-based regimens, based on final results from studies AP24534-11-001 and INCB 84344-201. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22 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.

5.1.8. Imfinzi - durvalumab - EMEA/H/C/004771/II/0045

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi in combination with tremelimumab for the treatment of adults with unresectable hepatocellular carcinoma (uHCC), based on final

results from study D419CC00002 (HIMALAYA); This was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. Version 6.1 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 21.07.2022.

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

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

5.1.9. [Imfinzi - durvalumab - EMEA/H/C/004771/II/0046](#)

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: David Olsen

Scope: “Extension of indication to include Imfinzi in combination with chemotherapy for the treatment of adults with locally advanced or metastatic biliary tract cancer (BTC), based on the second interim analysis from the ongoing pivotal study D933AC00001 (TOPAZ-1); a phase III randomized, double-blind, placebo-controlled, multi-regional, international study conducted to assess the efficacy and safety of durvalumab in combination with the current standard of care Gemcitabine/Cisplatin for the first-line treatment of patients with locally advanced or metastatic BTC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the package leaflet has been updated accordingly. Version 7.1 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 13.10.2022, 21.07.2022.

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.

5.1.10. [Lynparza - olaparib - EMEA/H/C/003726/II/0053](#)

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Amelia Cupelli

Scope: “Extension of indication to include treatment of adults with metastatic castration resistant prostate cancer (mCRPC), with Lynparza in combination with abiraterone and prednisone or prednisolone, based on the results of the pivotal Phase III study PROpel

(D081SC00001) and supportive evidence from study 8 (D081DC00008). PROpel is a Phase III, randomised, double-blind, placebo-controlled, multicentre study evaluating olaparib vs placebo in combination with abiraterone as first line treatment for men with mCRPC. Consequently, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC for Lynparza tablets are being updated. In addition, sections 4.4 and 4.8 of the SmPC for Lynparza hard capsules are revised based on the updated safety data analysis. The Package Leaflet is updated accordingly. The RMP version 24 has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 13.10.2022, 21.07.2022, 22.04.2022.

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.

5.1.11. Reblozyl - luspatercept - Orphan - EMEA/H/C/004444/II/0009

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jo Robays

Scope: "C.I.6 (Extension of indication)

Extension of indication in β -thalassaemia to include adult patients with non-transfusion dependent β -thalassaemia (NTDT) for Reblozyl; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 23.06.2022, 27.01.2022.

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

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

5.1.12. Rinvoq - upadacitinib - EMEA/H/C/004760/II/0027

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication to include treatment of moderately to severely active Crohn's disease in adult patients for Rinvoq, based on final results from three Phase III studies, two confirmatory placebo-controlled induction studies (study M14 431/U-EXCEED/CD-1 and study M14 433/U-EXCEL/CD-2) and a placebo-controlled

maintenance/long-term extension study (study M14-430/U-ENDURE/CD-3).

M14-431 study is a Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Biologic Therapy.

M14-433 study is a Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Conventional and/or Biologic Therapies.

M14-430 study is an ongoing Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease Who Completed the Studies M14-431 or M14-433.

As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 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 a supplementary information with a specific timetable.

5.1.13. [Spikevax - COVID-19 mRNA Vaccine \(nucleoside-modified\) - EMEA/H/C/005791/II/0067](#)

Moderna Biotech Spain, S.L.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include immunisation of paediatric individuals from 6 months through 5 years of age based on results from the study P204 (KidCove); this is a phase 2/3, two-part, open-label, dose-escalation, age de-escalation and randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of mRNA-1273 SARS-CoV-2 vaccine in healthy children 6 months to less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated and the Package Leaflet is updated in accordance. The MAH also took the opportunity to implement minor editorial changes in the product information. A revised RMP version 4.1 has been approved."

Positive opinion adopted by consensus at the extraordinary meeting held on 19 October 2022.

Action: For information

Request for Supplementary Information adopted on 13.10.2022, 23.06.2022.

At an extraordinary CHMP meeting on 19 October 2022, the CHMP discussed this variation.

On 19 October 2022, the Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

5.1.14. Spikevax - COVID-19 mRNA Vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0083/G

Moderna Biotech Spain, S.L.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include a 50-µg booster dose of Spikevax bivalent Original/Omicron BA.1 in children (6 to < 12 years), based on interim results from study P204; this is a Phase 2/3, Three-Part, Open-Label, Dose-Escalation, Age De-escalation and Randomized, Observer-Blind, Placebo-Controlled Expansion Study to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Children 6 Months to Less Than 12 Years of Age; As a consequence, sections 2, 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 4.5 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to implement editorial changes. To update sections 4.8, 5.1 and 6.6 of the SmPC to include additional immunogenicity data for the paediatric population (6 to < 18 years) based on Real-World Safety studies."

Action: For adoption

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

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

5.1.15. Trecondi - treosulfan - Orphan - EMEA/H/C/004751/II/0014

Medac Gesellschaft für klinische Spezialpräparate mbH

Rapporteur: Fátima Ventura, PRAC Rapporteur: Julia Pallos

Scope: "Extension of indication to include additional non-malignant transplant indications (non-malignant diseases in the paediatric population) for Trecondi 1 g/5 g powder for solution for infusion based on final 12-months follow-up results of study MC-FludT.16/NM; a randomised phase II interventional study aimed to compare Treosulfan-based conditioning therapy with Busulfan-based conditioning prior to allogeneic haematopoietic stem cell transplantation in paediatric patients with non-malignant diseases.

Further, the MAH proposes to amend an existing warning on skin toxicity based on new literature data. Moreover, the MAH proposes to introduce a slightly modified dosing regimen according to the patient's body surface based on long-term follow-up data of paediatric study MC-FludT.17/M, a Phase II trial to describe the safety and efficacy of Treosulfan based conditioning therapy prior to allogeneic haematopoietic stem cell transplantation in paediatric patients with haematological malignancies, as well as a final analysis of the population pharmacokinetics of treosulfan in paediatric patients. 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 1.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 21.07.2022.

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

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

5.1.16. [WS2150](#)
[DuoPlavin - clopidogrel / acetylsalicylic acid - EMEA/H/C/001143/WS2150/0060](#)
[Iscover - clopidogrel - EMEA/H/C/000175/WS2150/0146](#)
[Plavix - clopidogrel - EMEA/H/C/000174/WS2150/0145](#)

Sanofi-aventis groupe

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

Scope: "Extension of indication to include clopidogrel in combination with acetylsalicylic acid in ST segment elevation acute myocardial infarction (STEMI) patients undergoing percutaneous coronary intervention (PCI); as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. Version 1.5 of the RMP has also been submitted. In addition, an editorial update has been made to the labelling."

Action: For adoption

Request for Supplementary Information adopted on 21.07.2022, 24.03.2022.

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.

5.1.17. [WS2299](#)
[Edistride - dapagliflozin - EMEA/H/C/004161/WS2299/0055](#)
[Forxiga - dapagliflozin - EMEA/H/C/002322/WS2299/0076](#)

AstraZeneca AB

Lead Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include population with Heart Failure and LVEF > 40% for Forxiga and its duplicate Edistride, based on final results from study D169CC00001 (DELIVER); The DELIVER study is a category 3, Post-Authorisation Safety Study (PASS) listed in the dapagliflozin RMP to evaluate the potential risk of lower limb amputation; This was an international, multi-centre, parallel-group, event-driven, randomised, double-blind, placebo-controlled Phase III study in patients with HF and LVEF > 40%, evaluating the effect of dapagliflozin 10 mg compared with placebo, given once daily in addition to background therapy, including treatments to control co-morbidities, in reducing the composite of CV death or an HF event (hospitalisation for HF or urgent HF visit). As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet are updated in accordance. Version 27 of the RMP has also been submitted."

Action: For adoption

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

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

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. [human albumin solution / gentamicin sulfate - EMEA/H/D/006141](#)

human assisted reproductive techniques including in-vitro fertilisation procedures

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.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

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

8.1.1. talquetamab - Orphan - PRIME - H0005864

Janssen-Cilag International N.V., indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody.

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

Action: For adoption

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

8.1.2. beremagene geperpavec - Orphan - ATMP – PRIME - H0005350

Krystal Biotech, Inc., Dystrophic Epidermolysis Bulbosa

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

Action: For adoption

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

8.2. Priority Medicines (PRIME)

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 1 recommendation for eligibility to PRIME: 1 was 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. Evusheld - tixagevimab / cilgavimab - EMEA/H/C/005788/II/0003

AstraZeneca AB

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

Scope: "Update of sections 4.2, 4.8, 4.9, 5.1 and 5.2 of the SmPC in order to change the posology recommendations in the pre-exposure prophylaxis indication based on study TACKLE (D8851C00001). The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 13.10.2022.

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

The Committee adopted a 2nd request for supplementary information.

9.1.2. Jcovden - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0053/G

Janssen-Cilag International N.V.

Rapporteur: Christophe Focke

Scope: "Update of section 4.2 of the SmPC to introduce a heterologous booster dose of Jcovden following priming with another adenoviral vector-based vaccine based on literature evidence from COV-BOOST study. Update of sections 4.8 and 5.1 of the SmPC to include safety and immunogenicity data of Jcovden as heterologous booster dose based on data from studies COV-BOOST study.

Update of sections 4.8 of the SmPC to include safety and immunogenicity data of Jcovden as homologous and heterologous booster dose based on data from COV2008 study, a randomised, double-blind Phase 2 study.

Update of sections 4.8 and 5.1 of the SmPC to include safety and immunogenicity data of Jcovden as heterologous booster dose based on data from DMID 21-0012 study.

In addition, updated vaccine efficacy by variant has been updated based on updated genomic sequencing data from study COV3009 and some minor corrections have been implemented in section 5.1 of the SmPC.

The Package Leaflet is updated accordingly.”

Action: For adoption

Request for Supplementary Information adopted on 21.07.2022.

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.

9.1.3. [Spikevax - COVID-19 mRNA Vaccine \(nucleoside-modified\) - EMEA/H/C/005791/II/0084/G](#)

Moderna Biotech Spain, S.L.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: “B.I.a.6.a (Type II): Addition of a new strain (Omicron BA.4-5) resulting in a new Spikevax bivalent Original/Omicron BA.4-5 (50 µg elasomeron/50 µg davesomeron)/mL 0.1 mg/mL dispersion for injection presentation (2.5 mL multidose vial containing 5 doses). The Annex A, the SmPC, the Annex II, the labelling and the Package Leaflet are updated accordingly.”

Positive opinion adopted by consensus at the extraordinary meeting held on 19 October 2022.

Action: For information

At an extraordinary CHMP meeting on 19 October 2022, the CHMP discussed this variation.

On 19 October 2022, the Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

9.1.4. [Hepsera - adefovir dipivoxil – EMEA/H/C/000485](#)

Gilead Sciences Ireland UC; treatment of hepatitis B

Rapporteur: Jean-Michel Race, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.5. [Ilaris - canakinumab - EMEA/H/C/001109/II/0075](#)

Novartis Europharm Limited

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: “Extension of indication to include treatment of adult patients with Schnitzler syndrome for Ilaris; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC

are updated. The Package Leaflet is updated in accordance. Version 13.0 of the RMP has also been submitted.”

Withdrawal of application of extension of indication

Action: For information

Request for Supplementary Information adopted on 19.05.2022, 11.11.2021.

The CHMP noted the withdrawal of the application of extension of indication.

9.1.6. [Zejula - niraparib - EMEA/H/C/004249/II/0033, Orphan](#)

GlaxoSmithKline (Ireland) Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser

Scope: “Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning and add MDS/AML to the list of adverse drug reactions (ADRs) with frequency common and update of section 5.1 based on final results from NOVA study (213356); this is a Phase 3 Randomized Double-Blind Trial of Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer. In addition, the MAH also took this opportunity to update sections 4.4 and 4.6 to update information on contraception based on EMA and CTFG recommendations. The Package Leaflet is updated accordingly. The RMP version 6 has also been submitted.”

Update on the status of this application.

Action: For information

Request for Supplementary Information adopted on 19.05.2022, 10.02.2022.

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

9.1.7. [Gavreto - pralsetinib - EMEA/H/C/005413/II/0002/G](#)

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga

Scope: “Extension of indication to include monotherapy treatment of adult and paediatric patients 12 years of age and older with locally advanced or metastatic RET-mutant medullary thyroid cancer for Gavreto; based on the efficacy and safety data obtained from the pivotal study BO42863 (ARROW). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, some minor changes to the PI have been implemented in line with the latest Anticancer Guidelines Recommendations. Extension of indication to include monotherapy treatment of adult and paediatric patients 12 years of age and older with locally advanced or metastatic RET fusion-positive thyroid cancer for Gavreto; based on the efficacy and safety data obtained from the pivotal study BO42863 (ARROW). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Withdrawal of application of extension of indication

Action: For information

Request for Supplementary Information adopted on 15.09.2022, 23.06.2022, 24.03.2022.

The CHMP noted the withdrawal of the application of extension of indication.

9.1.8. Trogarzo – ibalizumab – EMEA/H/C/004961

Theratechnologies Europe Limited; treatment of adults infected with HIV-1 resistant to at least 1 agent in 3 different classes

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

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.9. Beovu - brolocizumab - EMEA/H/C/004913/II/0018

Novartis Europharm Limited

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski

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

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

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

10. Referral procedures

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

10.1.1. Janus kinase (JAK) inhibitors¹: abrocitinib - CIBINQO (CAP); baricitinib - OLUMIANT (CAP); filgotinib - JYSELECA (CAP); tofacitinib - XELJANZ (CAP); upadacitinib - RINVOQ (CAP) – EMEA/H/A-20/1517

AbbVie Deutschland GmbH & Co. KG (Rinvoq), Eli Lilly Nederland B.V. (Olumiant), Galapagos N.V. (Jyseleca), Pfizer Europe MA EEIG (Cibinqo, Xeljanz)

Referral PRAC Rapporteur: Ulla Wändel Liminga; Referral PRAC Co-rapporteur(s): Liana

¹ Indicated for the treatment of inflammatory disorders

Gross-Martirosyan (Olumiant, Xeljanz), Nikica Mirošević Skvrce (Cibinqo, Jyseleca, Rinvoq)

Scope: Review of the benefit-risk balance following notification by the European Commission (EC) of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For adoption

The CHMP adopted an opinion by majority (26 out of 32 votes) based on the PRAC recommendation. The Committee recommended measures to minimise the risk of serious side effects with Janus kinase (JAK) inhibitors used to treat several chronic inflammatory disorders. These side effects include cardiovascular conditions, blood clots, cancer and serious infections.

The divergent position (Margareta Bego, Armando Genazzani, Blanka Hirschlerova, Johann Lodewijk Hillege, Tomas Radimersky and Alexandre Moreau) was appended to the opinion.

The CHMP agreed to the DHPC and communication plan.

The public health communication was circulated for information.

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

10.4.1. Gelisia - EMEA/H/A-29(4)/1522

Sifi S.p.A.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Blanca Garcia-Ochoa

Scope: Appointment of Rapporteurs, Timetable

Action: For adoption

Decentralised procedure number: NL/H/5357/001/DC, notification by the Agency of The Netherlands dated 22 October 2022 notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC

The CHMP appointed Johann Lodewijk Hillege as Rapporteur and Blanca Garcia-Ochoa as Co-Rapporteur.

The CHMP adopted the procedural timetable.

Notification: 22 October 2022

Start of procedure (CHMP): November 2022 CHMP

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 02 December 2022

Comments: 07 December 2022

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 09 December 2022

CHMP list of outstanding issues/CHMP opinion: December 2022 CHMP

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

November 2022 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

No items

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 November 2022

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at November 2022 PDCO

Action: For information

The CHMP noted the information.

Report from the PDCO meeting held on 08-11 November 2022

Action: For information

The CHMP noted the information.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sol Ruiz/ Sean Barry

Reports from the BWP 31 October 2022 meeting to CHMP for adoption:

- 14 reports on products in scientific advice and protocol assistance

- 10 reports on products in pre-authorisation procedures
- 1 report on products in post-authorisation procedures
- 5 reports on products in plasma master file

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 24-27 October 2022. 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.

14.3.3. Non-clinical Working Party (NcWP)

CHMP request for NcWP consultation on nitrosamine impurity

Scope: This is a scenario D where a new nitrosamine has been identified.

Action: For adoption

CHMP adopted the request for NcWP consultation.

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 CHMP noted the information.

Lists of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 07-10 November 2022 CHMP meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphly	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	
Velislava Todorova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Tomas Radimersky	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:	Sogroya - somapacitan - Orphan - EMEA/H/C/005030/X/0006/G
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	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Silvijus Abramavicius	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	Dupixent - dupilumab - EMEA/H/C/0043 90/II/0062 Dupixent - dupilumab - EMEA/H/C/0043 90/II/0063 WS2150 DuoPlavin/Iscover/Plavix VidPrevtyln Beta - COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/0057 54
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
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	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Danica Juricic Nahal	Expert	Croatia	No interests declared	
Lidija Prka	Expert	Croatia	No restrictions applicable to this meeting	
Violette Dirix	Expert	Belgium	No interests declared	
Marta Romano	Expert	Belgium	No interests declared	
Ingrid Bourges	Expert	Belgium	No interests declared	
Inne Crèvecoeur	Expert	Belgium	No restrictions applicable to this meeting	
Roel Van Loock	Expert	Belgium	No interests declared	
Flora Musuamba Tshinanu	Expert	Belgium	No restrictions applicable to this meeting	
Stefan Bonné	Expert	Belgium	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Valerie Lescrainier	Expert	Belgium	No interests declared	
Mas Parra Paloma	Expert	Spain	No restrictions applicable to this meeting	
Carolina Prieto Fernandez	Expert	Spain	No interests declared	
Tomas Arroyo Perez	Expert	Spain	No restrictions applicable to this meeting	
Vincent Gazin	Expert	France	No interests declared	
Wiem Abid	Expert	France	No interests declared	
Fabien Carré	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Ludivine Martin	Expert	France	No restrictions applicable to this meeting	
Norontsoa Rasolondramanitra	Expert	France	No interests declared	
Stephanie Hueber	Expert	France	No interests declared	
Yanna-Marina Chevalme	Expert	France	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Karl Katholnig	Expert	Austria	No restrictions applicable to this meeting	
Elisabeth Wischnitzki	Expert	Austria	No interests declared	
Hannah Münch	Expert	Austria	No interests declared	
Thomas Lang	Expert	Austria	No interests declared	
Christine Schilhart-Wallisch	Expert	Austria	No interests declared	
Maja Sommerfelt Grønvold	Expert	Norway	No interests declared	
Cathrine Wisbech	Expert	Norway	No interests declared	
Marte Fergestad	Expert	Norway	No interests declared	
Fabrice Eroukhmanoff	Expert	Norway	No interests declared	
Therese Solstad Saunders	Expert	Norway	No interests declared	
Annette Lommel	Expert	Germany	No interests declared	
Poleta Luga	Expert	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lars Krueger	Expert	Germany	No restrictions applicable to this meeting	
Robert Pollmann	Expert	Germany	No interests declared	
Maren Richter	Expert	Germany	No restrictions applicable to this meeting	
Claudia Reichmann	Expert	Germany	No interests declared	
Benjamin Hofner	Expert	Germany	No restrictions applicable to this meeting	
Susanne Mueller-Egert	Expert	Germany	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No interests declared	
Olive Smyth	Expert	Ireland	No restrictions applicable to this meeting	
Kairi Rooma	Expert	Estonia	No interests declared	
Lene Weber Vestermark	Expert	Denmark	No interests declared	
Line Praest Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Charlotte Hejl	Expert	Denmark	No restrictions applicable to this meeting	
Meera Varma	Expert	Denmark	No restrictions applicable to this meeting	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Anne-Marie Dalseg	Expert	Denmark	No interests declared	
Kristin Skougaard	Expert	Denmark	No interests declared	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Thadeus Bao Quan Nguyen	Expert	Denmark	No interests declared	
Sine Buhl Naess-Schmidt	Expert	Denmark	No restrictions applicable to this meeting	
Mette Toftegaard Madsen	Expert	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Expert	Denmark	No interests declared	
Lucia De Franceschi	Expert	Expert recommended by EMA	No restrictions applicable to this meeting	
Nikica Mirošević Skvrce	Expert	Croatia	No interests declared	
Muriel Uzzan	Expert	France	No interests declared	
Mats Ökvist	Expert	Norway	No restrictions applicable to this meeting	
Anne-Berit Erdal	Expert	Norway	No interests declared	
Hatice Canan Bayar	Expert	Norway	No interests declared	
Aina Jannicke Øvrebust	Expert	Norway	No interests declared	
Anne Taams	Expert	Netherlands	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
Edward Bojtor	Expert	Netherlands	No restrictions applicable to this meeting	
Adrian Post	Expert	Netherlands	No interests declared	
Taco Monster	Expert	Netherlands	No interests declared	
Jacobus Romme	Expert	Netherlands	No interests declared	
Johannes Petrus Theodorus Span	Expert	Netherlands	No interests declared	
Katrien Oude Rengerink	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/0045 54/II/0025
Chaya Gopie	Expert	Netherlands	No interests declared	
Valentina Lorenzi	Expert	Netherlands	No interests declared	
Nynke Brouwer	Expert	Netherlands	No interests declared	
Inge van Gompel	Expert	Netherlands	No interests declared	
Paul Ten Berg	Expert	Netherlands	No interests declared	
Marianne Klanker	Expert	Netherlands	No interests declared	
Loes den Otter	Expert	Netherlands	No interests declared	
Christine Siezen	Expert	Netherlands	No restrictions applicable to this meeting	
Gunnar Thor Gunnarsson	Expert	Iceland	No interests declared	
Alejandro Montón Silva	Expert	Netherlands	No interests declared	
Illiana Meurs	Expert	Netherlands	No interests declared	
Melanie Diane Klok	Expert	Netherlands	No interests declared	
Patrick Vrijlandt	Expert	Netherlands	No interests declared	
Susanne Breedijk-van den Ende	Expert	Netherlands	No interests declared	
Wouter Iwema Bakker	Expert	Netherlands	No interests declared	
Dace Peiseniece	Expert	Latvia	No interests declared	
Dace Kalke	Expert	Latvia	No interests declared	
Ineke Havinga	Expert	Netherlands	No interests declared	
Peter Van Meer	Expert	Netherlands	No interests declared	
Ingrid Bijsmans	Expert	Netherlands	No interests declared	
Frank Holtkamp	Expert	Netherlands	No interests declared	
Paulo 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 participation in discussion, final deliberations and voting on:	pegunigalsidase alfa - Orphan - EMEA/H/C/0056 18
Antonella Isgrò	Expert	Italy	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Sara Galluzzo	Expert	Italy	No interests declared	
Valentina Conti	Expert	Italy	No interests declared	
Cinzia Ciceroni	Expert	Italy	No interests declared	
Irene Bachmann	Expert	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sofia Kapanadze	Expert	Germany	No restrictions applicable to this meeting	
Sylvia Kuehn	Expert	Germany	No restrictions applicable to this meeting	
Heiko Preusser	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Alfredo García-Arieta	Expert	Spain	No interests declared	
Ulla Wändel Liminga	Expert	Sweden	No interests declared	
Karin Fjordén	Expert	Sweden	No restrictions applicable to this meeting	
Pierre Demolis	Expert	France	No interests declared	
Karoline Buhre	Expert	Germany	No interests declared	
Karl-Heinz Huemer	Expert	Austria	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
Jean-Noel Talbot	Expert	France	No restrictions applicable to this meeting	
Eva Malikova	Expert	Slovakia	No interests declared	
Ivana Povrazníková	Expert	Slovakia	No interests declared	
Jana Klimasová	Expert	Slovakia	No restrictions applicable to this meeting	
Jana Schweigertova	Expert	Slovakia	No interests declared	
Anna Kubandová	Expert	Slovakia	No interests declared	
Peter Sisovsky	Expert	Slovakia	No interests declared	
Amelia Cupelli	Expert	Italy	No interests declared	
Nathalie Dumarcet	Expert	France	No interests declared	
Elena Wolff-Holz	Expert	Germany	No interests declared	
Lothar Bergmann	Expert	Germany	No restrictions applicable to this meeting	
Paula Contreras Alarcón	Expert	Spain	No participation in discussion, final deliberations and voting on:	Janus kinase (JAK) inhibitors - Art 20 referral atogepant monohydrate - EMEA/H/C/0058 71 Rinvoq - upadacitinib - EMEA/H/C/0047 60/II/0027
Susanne Hopner Rasmussen	Expert	Denmark	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Nora Cascante Estepa	Expert	Germany	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.

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the extraordinary CHMP meeting held on 19 October 2022.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Ilko Getov	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	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	
Jean-Michel Race	Alternate	France	No interests declared	
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	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
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	
Paula Boudewina van Hennik	Alternate	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No interests declared	
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	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Meera Varma	Expert	Denmark	No restrictions applicable to this meeting	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Nora Cascante Estepa	Expert	Germany	No interests declared	
Annette Lommel	Expert	Germany	No interests declared	
Poleta Luga	Expert	Germany	No interests declared	
Lars Krueger	Expert	Germany	No restrictions applicable to this meeting	
Elena Grabski	Expert	Germany	No interests declared	
Philipp Janesch	Expert	Austria	No interests declared	
Harald Bernsteiner	Expert	Austria	No interests declared	
Charlotta Bergquist	Expert	Sweden	No interests declared	
Helena Back	Expert	Sweden	No interests declared	
Helena Faust	Expert	Sweden	No interests declared	
Maria Baca-Estrada	Expert	H. Canada	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)

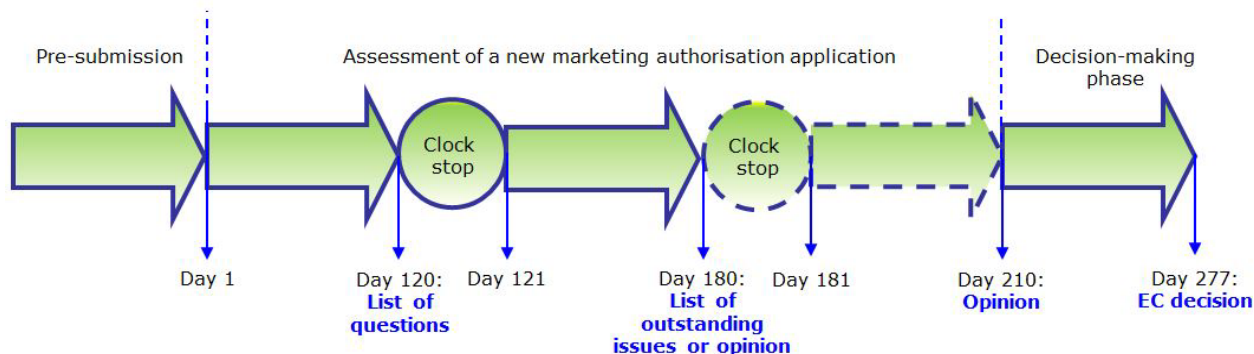
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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 (section 5.3)

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 Pharmacovigilance 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/



18 January 2023
EMA/CHMP/869391/2022

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for November 2022: For adoption	Adopted
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A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for November 2022: For adoption	Adopted
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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

Atriance - nelarabine - EMA/H/C/000752/S/0058 Novartis Europharm Limited, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Imvanex - smallpox vaccine (live modified vaccinia virus Ankara) - EMA/H/C/002596/S/0077 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Lojuxta - lomitapide - EMA/H/C/002578/S/0052 Amryt Pharmaceuticals DAC, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 10.11.2022.	Request for supplementary information adopted with a specific timetable.
Mepsevii - vestronidase alfa - EMA/H/C/004438/S/0032, Orphan	Positive Opinion adopted by consensus together

<p>Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Maria del Pilar Rayon</p>	<p>with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.</p>
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B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

<p>Alofisel - darvadstrocel - EMA/H/C/004258/R/0036, Orphan, ATMP</p> <p>Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, Co-Rapporteur: Margarida Menezes- Ferreira, CHMP Coordinators: Kristina Dunder and Fátima Ventura, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 09.09.2022.</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>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.</p>
<p>Amglidia - glibenclamide - EMA/H/C/004379/R/0014, Orphan</p> <p>Ammtek, Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>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.</p>
<p>Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMA/H/C/004449/R/0052</p> <p>Gilead Sciences Ireland UC, Rapporteur: Jean- Michel Race, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Gross-Martirosyan</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>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.</p>
<p>Fulvestrant Mylan - fulvestrant - EMA/H/C/004649/R/0016</p> <p>Mylan Pharmaceuticals Limited, Generic, Generic of Faslodex, Rapporteur: Elita Poplavska, PRAC Rapporteur: Ulla Wändel Liminga Request for Supplementary Information adopted on 15.09.2022.</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>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.</p>
<p>Juluca - dolutegravir / rilpivirine - EMA/H/C/004427/R/0049</p> <p>ViiV Healthcare B.V., Rapporteur: Janet Koenig,</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and</p>

<p>Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Nathalie Gault</p>	<p>translation timetable.</p> <p>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.</p>
<p>KANJINTI - trastuzumab - EMEA/H/C/004361/R/0022 Amgen Europe B.V., BREDA, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 10.11.2022.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Lamzede - velmanase alfa - EMEA/H/C/003922/R/0029, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 13.10.2022.</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>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.</p>
<p>Prasugrel Mylan - prasugrel - EMEA/H/C/004644/R/0014 Mylan Pharmaceuticals Limited, Generic, Generic of Efient, Rapporteur: Alar Irs, PRAC Rapporteur: Anette Kirstine Stark Request for Supplementary Information adopted on 10.11.2022.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>B.2.3. Renewals of Conditional Marketing Authorisations</p>	
<p>Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0048, Orphan, ATMP Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Concetta Quintarelli, CHMP Coordinators: Jan Mueller-Berghaus and Armando Genazzani, PRAC Rapporteur: Rhea Fitzgerald</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>
<p>Paxlovid - nirmatrelvir/ritonavir - EMEA/H/C/005973/R/0023 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 13.10.2022.</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>

**Sirturo - bedaquiline -
EMA/H/C/002614/R/0050, Orphan**
Janssen-Cilag International N.V., Rapporteur:
Filip Josephson, 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.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 24-27 October 2022
PRAC:

Signal of heavy menstrual bleeding

The CHMP adopted the recommendation.

Comirnaty – tozinameran

Rapporteur: Filip Josephson, Co-Rapporteur:
Jean-Michel Race, PRAC Rapporteur: Menno
van der Elst

PRAC recommendation on a variation

Action: For adoption

Signal of heavy menstrual bleeding

The CHMP adopted the recommendation.

Spikevax – elasomeran

Rapporteur: Jan Mueller-Berghaus, Co-
Rapporteur: Andrea Laslop, PRAC Rapporteur:
Marie Louise Schougaard Christiansen
PRAC recommendation on a variation

Action: For adoption

Signal of myelitis transverse

The CHMP adopted the recommendation.

Imfinzi – durvalumab

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur:
Blanca Garcia-Ochoa, PRAC Rapporteur:
David Olsen

PRAC recommendation on a variation

Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its November 2022 meeting:

EMA/H/C/PSUSA/00009327/202204
(vandetanib)

CAPS:

Caprelsa (EMA/H/C/002315) (vandetanib),
Genzyme Europe BV, Rapporteur: Alexandre
Moreau, PRAC Rapporteur: Tiphaine Vaillant,

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),

"07/04/2021 To: 06/04/2022"

concerning the following change(s):
Update of sections 4.4 and 4.8 of the SmPC to amend the warning/precaution regarding "Skin reactions" and to add the adverse reaction TEN with a frequency "not known". The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010675/202203
(sodium zirconium cyclosilicate)

CAPS:

Lokelma (EMA/H/C/004029) (sodium zirconium cyclosilicate), AstraZeneca AB,
Rapporteur: Silvijus Abramavicius, PRAC
Rapporteur: Kirsti Villikka, "22/03/2021 To: 21/03/2022"

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 4.4 of the SmPC to amend a warning/precaution regarding gastrointestinal perforation, along with the corresponding update of the Package Leaflet.

EMA/H/C/PSUSA/00010765/202203
(risankizumab)

CAPS:

Skyrizi (EMA/H/C/004759) (risankizumab),
AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Finbarr Leacy, PRAC Rapporteur:
Liana Gross-Martirosyan, "25/03/2021 To: 25/03/2022"

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 reactions urticaria and rash with a "not known" frequency. The package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010818/202203
(siponimod)

CAPS:

Mayzent (EMA/H/C/004712) (siponimod),
Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Maria del Pilar Rayon, "26/09/2021 To: 25/03/2022"

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 4.4 of the SmPC to ensure a better monitoring of treatment effects on lymphocytes and align it with the SmPC of the similar product fingolimod. The Annex IID and package leaflet are updated accordingly.

EMA/H/C/PSUSA/00010900/202203
(cabotegravir)

CAPS:

Vocabria (EMA/H/C/004976) (cabotegravir),
ViiV Healthcare B.V., Rapporteur: Jean-Michel

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

Race, PRAC Rapporteur: Martin Huber,
"18/09/2021 To: 17/03/2022"

terms of the marketing authorisation for the above-mentioned medicinal product, concerning the following change:
Update of section 4.8 of the SmPC to amend the adverse reaction "Type I hypersensitivity" by the adverse reaction "Hypersensitivity" with same frequency. The package leaflet is updated accordingly.

B.4. EPARs / WPARs

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - dengue tetravalent vaccine (live, attenuated) - EMEA/H/W/005362, Article 58

Takeda GmbH, prevention of dengue disease, New active substance (Article 8(3) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

Dimethyl fumarate Teva - dimethyl fumarate - EMEA/H/C/005963

TEVA GmbH, treatment of multiple sclerosis, Generic, Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

Ebvallo - tabelecleucel - EMEA/H/C/004577, Orphan, ATMP

Atara Biotherapeutics Ireland Limited, treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLN), 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.

Eladynos - abaloparatide - EMEA/H/C/005928

Radius Health Ireland Ltd, treatment of osteoporosis, 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.

LIVMARLI - maralixibat - EMEA/H/C/005857, Orphan

Mirum Pharmaceuticals International B.V., Treatment of cholestatic liver disease in patients with Alagille syndrome (ALGS) 1 year of age and older, 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.

Locametz - gozetotide - EMEA/H/C/005488

Novartis Europharm Limited, indicated for the identification of prostate-specific membrane antigen (PSMA)-positive lesions after

For information only. Comments can be sent to the PL in case necessary.

radiolabelling with gallium-68, New active substance (Article 8(3) of Directive No 2001/83/EC)

Pemetrexed Baxter - pemetrexed - EMEA/H/C/005848

Baxter Holding B.V., treatment of malignant pleural mesothelioma and non-small cell lung cancer, Generic, Generic of Alimta, Generic application (Article 10(1) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

Plerixafor Accord - plerixafor - EMEA/H/C/005943

Accord Healthcare S.L.U., treatment of lymphoma and multiple myeloma, Generic, Generic of Mozobil, Generic application (Article 10(1) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

Pluvicto - lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483

Novartis Europharm Limited, treatment of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC), 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.

Qdenga - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/005155

Takeda GmbH, prevention of dengue disease, New active substance (Article 8(3) of Directive No 2001/83/EC)

For information only. Comments can be sent to the PL in case necessary.

Spevigo - spesolimab - EMEA/H/C/005874

Boehringer Ingelheim International GmbH, treatment of flares in adult patients with generalised pustular psoriasis, 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.

in vitro diagnostic medical device - EMEA/H/D/006107

In-vitro qualitative immunohistochemical detection of programmed death-ligand 1 (PD-L1), Companion Diagnostics (Article 48 (3), (4), (7), (8) of Regulation (EU) 2017/746)

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

Adjupanrix - pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) - EMEA/H/C/001206/II/0079/G GlaxoSmithkline Biologicals SA, Informed Consent of Pandemrix (EXP), Rapporteur: Johann Lodewijk Hillege Opinion adopted on 20.10.2022.	Positive Opinion adopted by consensus on 20.10.2022.
AMGEVITA - adalimumab - EMEA/H/C/004212/II/0031 Amgen Europe B.V., Rapporteur: Kristina Dunder Opinion adopted on 10.11.2022.	Positive Opinion adopted by consensus on 10.11.2022.
Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0007/G Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy Opinion adopted on 20.10.2022. Request for Supplementary Information adopted on 08.09.2022.	Positive Opinion adopted by consensus on 20.10.2022.
Aranesp - darbepoetin alfa - EMEA/H/C/000332/II/0161 Amgen Europe B.V., Rapporteur: Martina Weise Opinion adopted on 27.10.2022. Request for Supplementary Information adopted on 15.09.2022.	Positive Opinion adopted by consensus on 27.10.2022.
ARIKAYCE liposomal - amikacin - EMEA/H/C/005264/II/0008/G, Orphan Insmed Netherlands B.V., Rapporteur: Jayne Crowe Opinion adopted on 20.10.2022. Request for Supplementary Information adopted on 15.09.2022.	Positive Opinion adopted by consensus on 20.10.2022.
Cosentyx - secukinumab - EMEA/H/C/003729/II/0092/G Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola Opinion adopted on 27.10.2022.	Positive Opinion adopted by consensus on 27.10.2022.
Doptelet - avatrombopag - EMEA/H/C/004722/II/0015/G Swedish Orphan Biovitrum AB (publ), Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 27.10.2022.	Request for supplementary information adopted with a specific timetable.

<p>Foclivia - pandemic influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/001208/II/0079</p> <p>Seqirus S.r.l, Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 10.11.2022.</p>	Request for supplementary information adopted with a specific timetable.
<p>Imfinzi - durvalumab - EMEA/H/C/004771/II/0051</p> <p>AstraZeneca AB, Rapporteur: Aaron Sosa Mejia Opinion adopted on 10.11.2022.</p>	Positive Opinion adopted by consensus on 10.11.2022.
<p>IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0079</p> <p>Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 27.10.2022.</p>	Request for supplementary information adopted with a specific timetable.
<p>Inflectra - infliximab - EMEA/H/C/002778/II/0108/G</p> <p>Pfizer Europe MA EEIG, Duplicate, Duplicate of Remsima, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 20.10.2022.</p>	Request for supplementary information adopted with a specific timetable.
<p>Nulojix - belatacept - EMEA/H/C/002098/II/0082/G</p> <p>Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson Request for Supplementary Information adopted on 10.11.2022.</p>	Request for supplementary information adopted with a specific timetable.
<p>NUVAXOVID - SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from Spodoptera frugiperda - EMEA/H/C/005808/II/0025/G</p> <p>Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege Opinion adopted on 20.10.2022.</p>	Positive Opinion adopted by consensus on 20.10.2022.
<p>Obizur - susoctocog alfa - EMEA/H/C/002792/II/0047/G</p> <p>Baxalta Innovations GmbH, Rapporteur: Andrea Laslop Opinion adopted on 27.10.2022. Request for Supplementary Information adopted on 01.09.2022.</p>	Positive Opinion adopted by consensus on 27.10.2022.
<p>PREVYMIS - letermovir - EMEA/H/C/004536/II/0028/G, Orphan</p> <p>Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson</p>	Positive Opinion adopted by consensus on 10.11.2022.

Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted
on 01.09.2022.

Pyramax - pyronaridine / artesunate -
EMA/H/W/002319/II/0031/G Positive Opinion adopted by consensus on
27.10.2022.
Shin Poong Pharmaceutical Co., Ltd.,
Rapporteur: Jean-Michel Race
Opinion adopted on 27.10.2022.
Request for Supplementary Information adopted
on 07.07.2022.

Reblozyl - luspatercept -
EMA/H/C/004444/II/0013, Orphan Positive Opinion adopted by consensus on
10.11.2022.
Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Daniela Philadelphia
Opinion adopted on 10.11.2022.

Remsima - infliximab -
EMA/H/C/002576/II/0117/G Positive Opinion adopted by consensus on
10.11.2022.
Celltrion Healthcare Hungary Kft., Rapporteur:
Outi Mäki-Ikola
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted
on 29.09.2022.

RINVOQ - upadacitinib -
EMA/H/C/004760/II/0025/G Positive Opinion adopted by consensus on
20.10.2022.
AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder
Opinion adopted on 20.10.2022.
Request for Supplementary Information adopted
on 15.09.2022.

SARCLISA - isatuximab -
EMA/H/C/004977/II/0017/G Request for supplementary information adopted
with a specific timetable.
sanofi-aventis groupe, Rapporteur: Paula
Boudewina van Hennik
Request for Supplementary Information adopted
on 10.11.2022, 13.10.2022.

Shingrix - herpes zoster vaccine
(recombinant, adjuvanted) -
EMA/H/C/004336/II/0059/G Positive Opinion adopted by consensus on
20.10.2022.
GlaxoSmithkline Biologicals SA, Rapporteur:
Christophe Focke
Opinion adopted on 20.10.2022.

Somavert - pegvisomant -
EMA/H/C/000409/II/0104 Request for supplementary information adopted
with a specific timetable.
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel
Race
Request for Supplementary Information adopted

on 10.11.2022.

**Spikevax - COVID-19 mRNA Vaccine
(nucleoside-modified) -
EMA/H/C/005791/II/0084/G**

Moderna Biotech Spain, S.L., Rapporteur: Jan
Mueller-Berghaus "B.I.a.6.a (Type II): Addition
of a new strain (Omicron BA.4-5) resulting in a
new Spikevax bivalent Original/Omicron BA.4-5
(50 µg elasomeran/50 µg davesomeran)/mL 0.1
mg/mL dispersion for injection presentation (2.5
mL multidose vial containing 5 doses). The
Annex A, the SmPC, the Annex II, the labelling
and the Package Leaflet are updated
accordingly.

Opinion adopted on 19.10.2022.

Positive Opinion adopted by consensus on
19.10.2022.

See 9.1

**Spikevax - COVID-19 mRNA Vaccine
(nucleoside-modified) -
EMA/H/C/005791/II/0087/G**

Moderna Biotech Spain, S.L., Rapporteur: Jan
Mueller-Berghaus, Co-Rapporteur: Andrea
Laslop

Opinion adopted on 04.11.2022.

Positive Opinion adopted by consensus on
04.11.2022.

**Terrosa - teriparatide -
EMA/H/C/003916/II/0026/G**

Gedeon Richter Plc., Rapporteur: Daniela
Philadelphly

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted
on 29.09.2022.

Positive Opinion adopted by consensus on
10.11.2022.

**TRODELVY - sacituzumab govitecan -
EMA/H/C/005182/II/0016/G**

Gilead Sciences Ireland UC, Rapporteur: Jan
Mueller-Berghaus

Opinion adopted on 27.10.2022.

Positive Opinion adopted by consensus on
27.10.2022.

**Tysabri - natalizumab -
EMA/H/C/000603/II/0133**

Biogen Netherlands B.V., Rapporteur: Jan
Mueller-Berghaus

Opinion adopted on 20.10.2022.

Request for Supplementary Information adopted
on 08.09.2022.

Positive Opinion adopted by consensus on
20.10.2022.

**Vimizim - elosulfase alfa -
EMA/H/C/002779/II/0039, Orphan**

BioMarin International Limited, Rapporteur:
Johann Lodewijk Hillege

Request for Supplementary Information adopted
on 27.10.2022.

Request for supplementary information adopted
with a specific timetable.

<p>Vydura - rimegepant - EMA/H/C/005725/II/0002/G Biohaven Pharmaceutical Ireland DAC, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 20.10.2022.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Xofigo - radium-223 - EMA/H/C/002653/II/0047 Bayer AG, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 10.11.2022.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>WS2275/G GONAL-f- EMA/H/C/000071/WS2275/0156/G Pergoveris- EMA/H/C/000714/WS2275/0078/G Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 27.10.2022. Request for Supplementary Information adopted on 07.07.2022.</p>	<p>Positive Opinion adopted by consensus on 27.10.2022.</p>
<p>WS2340/G Fluenz Tetra- EMA/H/C/002617/WS2340/0119/G Pandemic influenza vaccine H5N1 AstraZeneca- EMA/H/C/003963/WS2340/0053/G AstraZeneca AB, Lead Rapporteur: Christophe Focke Opinion adopted on 10.11.2022.</p>	<p>Positive Opinion adopted by consensus on 10.11.2022.</p>
<p>WS2344 Ryzodeg- EMA/H/C/002499/WS2344/0048 Tresiba-EMA/H/C/002498/WS2344/0056 Xultophy- EMA/H/C/002647/WS2344/0044 Novo Nordisk A/S, Lead Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 27.10.2022.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>WS2346/G Blitzima- EMA/H/C/004723/WS2346/0059/G Truxima- EMA/H/C/004112/WS2346/0062/G Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz</p>	<p>Positive Opinion adopted by consensus on 20.10.2022.</p>

Opinion adopted on 20.10.2022.

WS2347/G

Infanrix hexa-

EMA/H/C/000296/WS2347/0318/G

GlaxoSmithkline Biologicals SA, Lead

Rapporteur: Christophe Focke

Opinion adopted on 20.10.2022.

Positive Opinion adopted by consensus on
20.10.2022.

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

Adtralza - tralokinumab -

EMA/H/C/005255/II/0001

LEO Pharma A/S, Rapporteur: Jayne Crowe,
"C.I.4

Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with cytochrome P450 and CYP substrates based on final results from study ECZTRA 4 (LP0162-1342). This is an open-label drug-drug interaction trial to investigate the effects of tralokinumab on the pharmacokinetics of selected CYP substrates in adult subjects with moderate-to-severe atopic dermatitis. In addition, the MAH took the opportunity to make editorial changes to sections 4.8, 6.5 and 9 of the SmPC."

Opinion adopted on 20.10.2022.

Request for Supplementary Information adopted on 22.04.2022, 16.12.2021.

Positive Opinion adopted by consensus on
20.10.2022.

Alecensa - alectinib -

EMA/H/C/004164/II/0042

Roche Registration GmbH, Rapporteur: Filip Josephson, "Submission of the final report from study JO28928 (J-ALEX) a Randomized Phase III Open-Label Study Comparing the Efficacy and Safety of Crizotinib and CH5424802 in ALK-Positive Advanced or Recurrent Non-Small Cell Lung Cancer."

Opinion adopted on 27.10.2022.

Positive Opinion adopted by consensus on
27.10.2022.

COMIRNATY - COVID-19 mRNA Vaccine (nucleoside modified) -

EMA/H/C/005735/II/0145

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "To update sections 4.2, 4.8 and 5.1 of the SmPC in order to add recommendations and data for subsequent and booster doses based on real world evidence

Positive Opinion adopted by consensus on
27.10.2022.

(RWE) data as well as interim study results from both sub-study E (SSE) and sub-study D (SSD) C4591031 following procedure II/0140 assessment.

The Package Leaflet is updated accordingly.”

Opinion adopted on 27.10.2022.

**Darzalex - daratumumab -
EMA/H/C/004077/II/0062, Orphan**

Janssen-Cilag International N.V., Rapporteur: Aaron Sosa Mejia, “Update of section 4.8 of the SmPC in order to add COVID-19 to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a pooled dataset from the following interventional studies

4767414MMY2004, 54767414MMY3003, 54767414MMY3006, 54767414MMY3008, and 54767414MMY3013. The Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 20.10.2022, 15.09.2022.

Request for supplementary information adopted with a specific timetable.

**Dificlir - fidaxomicin -
EMA/H/C/002087/II/0049**

Tillotts Pharma GmbH, Rapporteur: Filip Josephson, “Update of sections 4.2 and 5.1 of the SmPC in order to introduce information a new posology regimen based on final results from the EXTEND study - A Phase IIIb/IV Randomized, Controlled, Open-Label, Parallel Group Study to Compare the Efficacy of Vancomycin Therapy to Extended Duration Fidaxomicin Therapy in the Sustained Clinical Cure of Clostridium difficile Infection in an Older Population.

The Package Leaflet is updated accordingly.”

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted on 21.07.2022.

Positive Opinion adopted by consensus on 10.11.2022.

**JCOVDEN - adenovirus type 26 encoding
the SARS-CoV-2 spike glycoprotein -
EMA/H/C/005737/II/0053/G**

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, “Update of section 4.2 of the SmPC to introduce a heterologous booster dose of JCOVDEN following priming with another adenoviral vector-based vaccine based on literature evidence from COV-BOOST study. Update of sections 4.8 and 5.1 of the SmPC to include safety and immunogenicity data of JCOVDEN as heterologous booster dose based

Positive Opinion adopted by consensus on 10.11.2022.

See 9.1

on data from studies COV-BOOST study.
Update of section 4.8 of the SmPC to include safety and immunogenicity data of JCOVDEN as homologous and heterologous booster dose based on data from COV2008 study, a randomised, double-blind Phase 2 study.
Update of sections 4.8 and 5.1 of the SmPC to include safety and immunogenicity data of JCOVDEN as heterologous booster dose based on data from DMID 21-0012 study.
In addition, updated vaccine efficacy by variant has been updated based on updated genomic sequencing data from study COV3009 and some minor corrections have been implemented in section 5.1 of the SmPC.
The Package Leaflet is updated accordingly.”
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted on 21.07.2022.

**Kesimpta - ofatumumab -
EMA/H/C/005410/II/0007**

Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, “Update of sections 5.1 and 5.2 of the SmPC in order to add information on the pharmacologic profile of ofatumumab subcutaneous administration to properly evaluate and group Kesimpta into the therapeutic landscape of Multiple Sclerosis based on feedback from the German and other HTA bodies, requiring additional information on the pharmacologic profile of ofatumumab (s.c.) to adequately inform payors and prescribers.”
Opinion adopted on 20.10.2022.

Positive Opinion adopted by consensus on 20.10.2022.

**Nerlynx - neratinib -
EMA/H/C/004030/II/0029**

Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, “Update of section 5.2 of the SmPC in order to add information on distribution and on the effect of neratinib on CYP substrates based on non-clinical studies XT218036 and 20325317; study XT218036 was designed to evaluate neratinib as a substrate of the human transporters OATP1B1 and OATP1B3 and study 20325317 objective was to determine the inactivation kinetic constants (kinact and KI) of Neratinib and M6 for the human cytochrome P450 (CYP) isoenzymes 2B6 and 3A4 using pooled human liver microsomes (HLM).
In addition, the MAH is taking this opportunity

Positive Opinion adopted by consensus on 10.11.2022.

to introduce editorial changes.”
Opinion adopted on 10.11.2022.

**Paxlovid - nirmatrelvir/ritonavir -
EMA/H/C/005973/II/0017**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “Submission of the final report from study in vivo efficacy of Pf-07321332 as a single agent or in combination with ritonavir in Balb/C Mouse-Adapted SARS-CoV-2 Model. The objective of this study was to evaluate whether Ritonavir has in vivo antiviral activity against SARS-CoV-2 and whether combination of Ritonavir with PF-07321332 increased the exposure of PF-07321332 in the mouse model and further decreased viral lung replication.”
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted on 01.09.2022.

Positive Opinion adopted by consensus on 10.11.2022.

**Paxlovid - nirmatrelvir/ritonavir -
EMA/H/C/005973/II/0026/G**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “Grouped application comprising four type II variations as follows:

- Update of sections 4.6, 5.1 and 5.3 in order to update the latest non-clinical virology and toxicology data based on Phase 2/3 studies C4671002, C4671005 and C4671006 and the pre- and postnatal development study report 21GR149.
- Update of section 5.2 in order to update pertinent clinical pharmacology information based on completed clinical pharmacology studies with Paxlovid in both healthy participants (Phase 1 studies C4671008, C4671012, C4671013, C467104, C4671015, C4671019) and also participants with mild-to-moderate COVID-19 (Pivotal Phase 2/3 Study C4671005) and final PopPK report (PMAR-EQDD-C467a-DP4-1323).
- Update of sections 4.8 and 5.1 in order to include final clinical efficacy and safety data based on the pivotal C4671005 (REC35) study.
- Update of sections 4.8 and 5.1 in order to include final clinical efficacy and safety data based on the supportive C4671006 study and interim clinical efficacy and safety data based on the supportive C4671002 (REC36) study.

The Package Leaflet is updated accordingly.
In addition, MAH is taking this opportunity to

Request for supplementary information adopted with a specific timetable.

introduce editorial changes.”
Request for Supplementary Information adopted
on 10.11.2022.

**Piqray - alpelisib -
EMA/H/C/004804/II/0013**

Positive Opinion adopted by consensus on
20.10.2022.

Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, “Update of the SmPC sections 4.6 and 5.3 in order to add fertility data based on studies 2070119 “BYL719: Oral (Gavage) Study of Fertility in the Male Rat” and 2070120 “BYL719: Oral (Gavage) Study of Fertility and Early Embryonic Development in the Female Rat”.”

Opinion adopted on 20.10.2022.

Request for Supplementary Information adopted
on 21.07.2022.

**Regkirona - regdanvimab -
EMA/H/C/005854/II/0008**

Positive Opinion adopted by consensus on
10.11.2022.

Celltrion Healthcare Hungary Kft., Rapporteur: Filip Josephson, “Update of section 5.1 of the SmPC in order to update the information on the clinical resistance data based on final genotype and phenotype results from study CT-P59 3.2 Part 2; this is a Phase 2/3, randomized, parallel-group, placebo-controlled, double-blind study to evaluate the efficacy and safety of CT-P59 in combination with standard of care in outpatients with Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) infection.”

Opinion adopted on 10.11.2022.

**Retsevmo - selpercatinib -
EMA/H/C/005375/II/0017**

Positive Opinion adopted by consensus on
10.11.2022.

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, “Update of sections 4.5 and 5.2 of the SmPC in order to reflect the final results from the drug-drug interaction (DDI) study J2G-MC-JZJV; this is a phase 1, single-center, open-label, DDI study to investigate the effect of selpercatinib on the pharmacokinetic profiles of dabigatran, a P-glycoprotein (P-gp) substrate, in healthy volunteers. The Package Leaflet is updated accordingly.”

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted
on 06.10.2022.

**Shingrix - herpes zoster vaccine
(recombinant, adjuvanted) -
EMA/H/C/004336/II/0054**

Positive Opinion adopted by consensus on
20.10.2022.

GlaxoSmithkline Biologicals SA, Rapporteur:
Christophe Focke, "Update of section 4.5 of the SmPC based on final results from study ZOSTER-059; this is a Phase IIIB, open label, randomised, controlled study to evaluate the immunogenicity, safety and reactogenicity of Shingrix when co-administered with Prevenar 13 in adults \geq 50 years of age.

In addition, the MAH took the opportunity to update section 4.5 of the SmPC to update the existing statement to specify the incidence percentages of fever and shivering upon co-administration of Shingrix with PPV23 based on study ZOSTER-035."

Opinion adopted on 20.10.2022.

Request for Supplementary Information adopted on 23.06.2022.

**SonoVue - sulfur hexafluoride -
EMA/H/C/000303/II/0049**

Positive Opinion adopted by consensus on 10.11.2022.

Bracco International B.V., Rapporteur:
Alexandre Moreau, "Update of sections 4.1, 4.4 and 5.1 of the SmPC based on final results from study BR1-145 listed as a PAES in the Annex II; this is an observational, retrospective, multicentre, comparative study conducted in patients below 18 years of age who had undergone a VUS exam with intravesically administered SonoVue/Lumason or a VCUg exam as part of their standard of care for evaluation of known or suspected VUR."

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted on 23.06.2022.

**Trecondi - treosulfan -
EMA/H/C/004751/II/0016, Orphan**

Positive Opinion adopted by consensus on 10.11.2022.

medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Fátima Ventura, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study MC-FludT.14/L Trial II; a phase III trial to compare Treosulfan-based conditioning therapy with Busulfan-based reduced-intensity conditioning (RIC) prior to allogeneic haematopoietic stem cell transplantation in patients with AML or MDS considered ineligible to standard conditioning regimens.

The Package Leaflet is updated accordingly."

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted on 01.09.2022, 23.06.2022.

**Veklury - remdesivir -
EMA/H/C/005622/II/0042**

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 to provide in vitro data on the antiviral activity of remdesivir against the Omicron subvariants BA.2.12.1, BA.4 and BA.5 following procedure II/0034/G based on in vitro study "Remdesivir Antiviral Activity against Omicron Subvariants BA.2.12.1, BA.4, and BA.5 in A549-hACE2-TMPRSS2 Cells"."

Opinion adopted on 10.11.2022.

Positive Opinion adopted by consensus on 10.11.2022.

**Venclyxto - venetoclax -
EMA/H/C/004106/II/0042**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to update data supporting the efficacy of the combined regimen of obinutuzumab and venetoclax (VEN+G; also known as GDC-0199 or ABT-199) versus obinutuzumab plus chlorambucil (GClb) in previously untreated CLL patients based on final results from study BO25323/CLL14; this is a prospective, open-label, multicenter randomized phase 3 trial to compare the efficacy and safety of a combined regimen of obinutuzumab and venetoclax (GDC-0199/ABT-199) versus obinutuzumab and chlorambucil in previously untreated patients with CLL and coexisting medical conditions. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Opinion adopted on 20.10.2022.

Request for Supplementary Information adopted on 15.09.2022.

Positive Opinion adopted by consensus on 20.10.2022.

**VEYVONDI - vonicog alfa -
EMA/H/C/004454/II/0026**

Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.8 and 5.1 of the SmPC in order to add 'headache' to the list of adverse drug reactions (ADRs) with frequency very common and to update information based on final results from study 071301 and other available data; study 071301 is a prospective, phase 3, open-label, international multicenter study on efficacy and safety of prophylaxis with rVWF in severe von

Request for supplementary information adopted with a specific timetable.

Willebrand disease. 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 to the PI and bring it in line with the latest QRD template.” Request for Supplementary Information adopted on 20.10.2022.

**Xarelto - rivaroxaban -
EMA/H/C/000944/II/0097**

Positive Opinion adopted by consensus on 20.10.2022.

Bayer AG, Rapporteur: Kristina Dunder, “Update of section 4.8 of the SmPC in order to add ‘eosinophilic pneumonia’ to the list of adverse drug reactions (ADRs) with frequency ‘very rare’, based on post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”
Opinion adopted on 20.10.2022.

**Xevudy - sotrovimab -
EMA/H/C/005676/II/0010/G**

Positive Opinion adopted by consensus on 10.11.2022.

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, “C.I.4: Update of sections 4.4 and 5.1 of the SmPC based on results from study reports PC-22-0108 on the in vitro activity of sotrovimab against Omicron spike variants encoding epitope substitutions in a pseudotyped virus assay, PC-22-0116 on the in vitro activity of sotrovimab against the SARS-CoV-2 XD variant in a live virus assay, PC-22-0117 on the in vitro activity of sotrovimab against the SARS-CoV-2 Omicron BA.2.12.1, BA.4 and BA.5 variants in a live virus assay, and PC-22-0124 on the in vitro activity of sotrovimab against the Omicron BA.2.75 spike variant in a pseudotyped virus assay. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.
C.I.13: Submission of the final study report PC-22-0101 on the in vivo activity of S309 encoding the hamster Fc region in a Syrian golden hamster model of SARS-CoV-2 Omicron BA.2 infection.
C.I.13: Submission of the final study report PC-22-0126 on the in vivo activity of VIR-7831-WT in a Syrian golden hamster model of SARS-CoV-2 Omicron BA.5. infection.”
Opinion adopted on 10.11.2022.

WS2259 Positive Opinion adopted by consensus on
DuoPlavin- 20.10.2022.
EMA/H/C/001143/WS2259/0063
Iscover-
EMA/H/C/000175/WS2259/0149
Plavix-EMA/H/C/000174/WS2259/0147
sanofi-aventis groupe, Lead Rapporteur: Bruno Sepodes, "Update of section 4.4 of the SmPC in order to update an existing warning on 'Bleeding and haematological disorders' by adding a statement on triple antiplatelet therapy (clopidogrel + aspirin + dipyridamole) for stroke secondary prevention. The Package Leaflet is updated accordingly."
Opinion adopted on 20.10.2022.
Request for Supplementary Information adopted on 21.07.2022.

WS2342/G Positive Opinion adopted by consensus on
Prezista- 10.11.2022.
EMA/H/C/000707/WS2342/0119/G
Rezolsta-
EMA/H/C/002819/WS2342/0049/G
Symtuza-
EMA/H/C/004391/WS2342/0046/G
Janssen-Cilag International N.V., Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add 'crystal nephropathy' to the list of adverse drug reactions (ADRs) with frequency rare based on recent post-marketing data; the Package Leaflets are updated accordingly.
In addition, the MAH proposes to update sections 4.4 and 4.6 of the SmPC in order to implement the recommendation of the CHMP to remove the disease information relating to sexual transmission of HIV and to amend the sections related to breast-feeding; the Package Leaflets are updated accordingly."
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted on 29.09.2022.

WS2343 Positive Opinion adopted by consensus on
Ozempic- 20.10.2022.
EMA/H/C/004174/WS2343/0033
Rybelsus-
EMA/H/C/004953/WS2343/0028
Novo Nordisk A/S, Lead Rapporteur: Johann Lodewijk Hillege, "Submission of an updated final report from study NN9535-4386

(SUSTAIN-11) in order to amend an error. This study was listed as a category 3 study in the RMP and was previously assessed in procedure EMEA/H/C/004174/II/WS/2141. This is a Phase IIIb A 52-week, multi-centre, multinational, open-label, active-controlled, two armed, parallel-group, randomised trial in subjects with type 2 diabetes to evaluate the effect of semaglutide once-weekly versus insulin aspart three times daily, both as add on to metformin and optimised insulin glargine (U100) in subjects with type 2 diabetes.”

Opinion adopted on 20.10.2022.

WS2358

Elebrato Ellipta-

EMEA/H/C/004781/WS2358/0028

Trelegy Ellipta-

EMEA/H/C/004363/WS2358/0025

GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy, “Update of section 4.8 of the SmPC in order to add ‘urinary retention’ and ‘dysuria’ to the list of adverse drug reactions (ADRs) with frequency rare; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring it in line with the latest QRD template.” Request for Supplementary Information adopted on 10.11.2022.

Request for supplementary information adopted with a specific timetable.

B.5.3. CHMP-PRAC assessed procedures

Beovu - brolocizumab -

EMEA/H/C/004913/II/0018

Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski, “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 modeling and simulation studies; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted.”

Request for Supplementary Information adopted on 10.11.2022.

Request for supplementary information adopted with a specific timetable.

See 9.1

EVUSHELD - tixagevimab / cilgavimab -

EMEA/H/C/005788/II/0003

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

Request for supplementary information adopted with a specific timetable.

See 9.1

“Update of sections 4.2, 4.8, 4.9, 5.1 and 5.2 of the SmPC in order to change the posology recommendations in the pre-exposure prophylaxis indication based on study TACKLE (D8851C00001).

The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted.”

Request for Supplementary Information adopted on 10.11.2022, 13.10.2022.

HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0078

Positive Opinion adopted by consensus on 27.10.2022.

Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of sections 4.8 and 5.1 of the SmPC in order to update safety data in paediatric population based on final results from study 161504 – Post-Authorisation Safety, Tolerability and Immunogenicity Evaluation of HyQvia in Pediatric Subjects With Primary Immunodeficiency Diseases, listed as a category 3 study in the RMP. This is a paediatric interventional Phase 4 study performed to acquire additional data on safety, tolerability and immunogenicity of HyQvia in paediatric (age two to <18 years) patients with Primary Immunodeficiency Diseases (PID).

In addition, the MAH is taking this opportunity to update Annex II-D of the PI following procedure EMEA/H/C/002491/II/0070/G, and to remove the statement that this medicinal product is subject to additional monitoring from the SmPC and package leaflet following the fulfilment of the PASS 161302.

The RMP version 13.1 has also been adopted.”
Opinion adopted on 27.10.2022.

Request for Supplementary Information adopted on 07.07.2022.

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/II/0059, Orphan

Request for supplementary information adopted with a specific timetable.

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, “Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update information and amend the frequencies of adverse drug reactions (ADRs) based on the final results from study CSL654_3003 listed as a category 3 study in the RMP; this is an open-label, multicentre, uncontrolled study to evaluate the safety, pharmacokinetics and clinical response of rIX-FP

with regard to the prevention and treatment of bleeding in previously untreated patients (PUPs) with Haemophilia B. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. 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 27.10.2022, 10.06.2022.

**Ilumetri - tildrakizumab -
EMA/H/C/004514/II/0036**

Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski

Request for Supplementary Information adopted on 27.10.2022.

Request for supplementary information adopted with a specific timetable.

**Imnovid - pomalidomide -
EMA/H/C/002682/II/0047, Orphan**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Monica Martinez Redondo, “Update of section 4.4 of the SmPC, Annex IID and Article 127a and the tools/documents included in the Educational Healthcare Professional Kit, in order to harmonise the terminology utilised in the RMP and PI documents relating to the safety concern of teratogenicity and its risk minimisation measure of the Pregnancy Prevention Plan across the 3 IMiDs. These proposed changes will only have a limited impact on the National Competent Authority (NCA)-approved content/text of the educational materials, and the key messages to the HCP and patients. Furthermore, the regulatory obligations regarding the PPP will not be impacted. The updated RMP version 16 was provided.”

Request for Supplementary Information adopted on 27.10.2022.

Request for supplementary information adopted with a specific timetable.

**Jorveza - budesonide -
EMA/H/C/004655/II/0015, Orphan**

Dr. Falk Pharma GmbH, Rapporteur: Martina Weise, PRAC Rapporteur: Zane Neikena, “Update of section 4.8 of the SmPC in order to update the list of adverse reactions based on final results from the long-term maintenance study BUL-2/EER; this is a double-blind, randomized, placebo-controlled, phase III study on the efficacy and tolerability of a 48-week treatment with two different doses of

Positive Opinion adopted by consensus on 10.11.2022.

budesonide effervescent tablets vs. placebo for maintenance of clinico-pathological remission in adult patients with eosinophilic esophagitis. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 3.0 has also been submitted. The MAH also submitted the final report of study BUL-6/BIO, which was previously assessed within the scope of extension EMEA/H/C/004655/X/0007/G as applicant's response to CHMP Day 120 List of Questions."

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted on 15.09.2022, 19.05.2022.

**Natpar - parathyroid hormone -
EMEA/H/C/003861/II/0042, Orphan**

Takeda Pharmaceuticals International AG,
Rapporteur: Karin Janssen van Doorn, PRAC
Rapporteur: Rhea Fitzgerald, "Submission of the updated protocol from study SHP634-403 listed as a Specific Obligation in the Annex II of the Product Information with twice-daily (BID) as the proposed alternative dosing regimen to be evaluated. This is a Randomized, 2-Arm, Double-Blind, Phase 4 Study to Evaluate Once Daily (QD) Versus Twice Daily (BID) Administration of Recombinant Human Parathyroid Hormone (rhPTH[1-84]; NATPARA) for the Treatment of Adults with Hypoparathyroidism (HPT).

The Annex II and the RMP (submitted version 3.4) are updated accordingly."

Request for Supplementary Information adopted on 10.11.2022, 21.07.2022.

Request for supplementary information adopted with a specific timetable.

**NexoBrid - concentrate of proteolytic
enzymes enriched in bromelain -
EMEA/H/C/002246/II/0057, Orphan**

MediWound Germany GmbH, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the 24-months' CSR addendum of the MW2010-03-02 (DETECT) category 1 study; a multicentre, multinational, randomized, controlled, assessor blinded study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to gel vehicle and compared to standard of care. The provision of the CSR addresses the post-

Request for supplementary information adopted with a specific timetable.

authorisation measure ANX 001.7. An updated RMP version 8.0 was provided as part of the application.”
Request for Supplementary Information adopted on 10.11.2022.

**Revlimid - lenalidomide -
EMA/H/C/000717/II/0123**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, “Update of section 4.4 of the SmPC, Annex IID and Article 127a and the tools/documents included in the Educational Healthcare Professional Kit, in order to harmonise the terminology utilised in the RMP and PI documents relating to the safety concern of teratogenicity and its risk minimisation measure of the Pregnancy Prevention Plan across the 3 IMiDs. These proposed changes will only have a limited impact on the National Competent Authority (NCA)-approved content/text of the educational materials, and the key messages to the HCP and patients. Furthermore, the regulatory obligations regarding the PPP will not be impacted. The MAH is also taking the opportunity to update the RMP with PASS Protocol milestones. The updated RMP version 38 was provided.”
Request for Supplementary Information adopted on 27.10.2022.

Request for supplementary information adopted with a specific timetable.

**RINVOQ - upadacitinib -
EMA/H/C/004760/II/0020/G**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, “Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on ‘Hypersensitivity’ and to add ‘serious hypersensitivity reactions’ to the list of adverse drug reactions with the frequency “rare”. The Package Leaflet has been updated accordingly.”
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted on 15.09.2022, 10.06.2022.

Positive Opinion adopted by consensus on 10.11.2022.

**Thalidomide BMS - thalidomide -
EMA/H/C/000823/II/0076**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, “Update of section 4.4 of the SmPC, Annex IID and Article 127a and the tools/documents included in the Educational

Request for supplementary information adopted with a specific timetable.

Healthcare Professional Kit, in order to harmonise the terminology utilised in the RMP and PI documents relating to the safety concern of teratogenicity and its risk minimisation measure of the Pregnancy Prevention Plan across the 3 IMiDs. These proposed changes will only have a limited impact on the National Competent Authority (NCA)-approved content/text of the educational materials, and the key messages to the HCP and patients. Furthermore, the regulatory obligations regarding the PPP will not be impacted. The MAH is also taking the opportunity to update the RMP with PASS Protocol milestones, and to make some editorial changes in the labelling. The updated RMP version 20 was provided.”
Request for Supplementary Information adopted on 27.10.2022.

Trecondi - treosulfan - EMEA/H/C/004751/II/0012, Orphan
medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Fátima Ventura, PRAC Rapporteur: Julia Pallos, “Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with regards to CYP3A4, CYP2C19 and P-gp including physiologically based pharmacokinetic (PBPK) modelling. Version 1.0 of the RMP has also been submitted.”
Opinion adopted on 27.10.2022.
Request for Supplementary Information adopted on 07.07.2022.

Positive Opinion adopted by consensus on 27.10.2022.

Vumerity - diroximel fumarate - EMEA/H/C/005437/II/0005
Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, “Submission of the final report from study ALK8700-A301, A Phase 3 Open Label Study to Evaluate the Long-term Safety and Tolerability of ALKS 8700 in Adults with Relapsing Remitting Multiple Sclerosis listed as a category 3 study in the RMP. This is a multicentre, open-label study to evaluate the long-term safety, tolerability, and treatment effect over time of DRF administered for up to 96 weeks in adult participants with RRMS.
The RMP version 1.2 has been agreed.”
Opinion adopted on 27.10.2022.
Request for Supplementary Information adopted

Positive Opinion adopted by consensus on 27.10.2022.

on 01.09.2022.

Vyndaqel - tafamidis -

EMA/H/C/002294/II/0081, Orphan

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Tiphaine Vaillant,

“Update of section 5.1 of the SmPC in order to update information based on final results from study B3461029 listed as a Specific Obligation in the Annex II of the Product Information. This is a non-interventional PASS sub-study evaluating effects of tafamidis on disease progression in patients with non-Val30Met mutations and symptomatic neuropathy. Consequently, the MAH proposes a switch from marketing authorisation under exceptional circumstances to full marketing authorisation given the fulfilment of the SOB. The Annex II and Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 10.11.2022, 15.09.2022, 21.07.2022.

Request for supplementary information adopted with a specific timetable.

WS2187

OPDIVO-

EMA/H/C/003985/WS2187/0121

Yervoy-EMA/H/C/002213/WS2187/0098

Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Blanca Garcia-Ochoa, Lead PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of section 4.8 of the SmPC in alignment with the recommendations made by the CHMP to revise the pooling approach used to describe irARs and tabulated summaries of ADRs following II/0096. Individual study data included within this application has been previously reviewed by the CHMP. The updated Opdivo RMP version 29.0 and Yervoy RMP version 37.0 have also been submitted. The MAH took the opportunity to introduce editorial changes. The Package Leaflet was updated accordingly.”

Opinion adopted on 27.10.2022.

Request for Supplementary Information adopted on 01.09.2022.

Positive Opinion adopted by consensus on 27.10.2022.

B.5.4. PRAC assessed procedures

PRAC Led

Brintellix - vortioxetine -

Request for supplementary information adopted with a specific timetable.

EMA/H/C/002717/II/0037

H. Lundbeck A/S, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report from study PASS 16034N listed as a category 3 study in the RMP. This is a non-interventional post-authorisation safety study (PASS) of vortioxetine in Europe - An analysis of European automated healthcare databases. The RMP version 4.0 has also been submitted."

Request for Supplementary Information adopted on 27.10.2022, 07.07.2022.

PRAC Led

Kaletra - lopinavir / ritonavir -**EMA/H/C/000368/II/0193**

AbbVie Deutschland GmbH & Co. KG, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Jean-Michel Race, "Submission of the final report from study P19-106 listed as a category 3 study in the RMP. This is a European Pregnancy and Paediatric Infections Cohort Collaboration (EPPICC) observational study assessing the safety and effectiveness of Kaletra oral solution in children aged 14 days to 2 years with human immunodeficiency virus 1 (HIV-1) infection in Europe. The RMP version 10.0 has also been submitted."

Opinion adopted on 27.10.2022.

Positive Opinion adopted by consensus on 27.10.2022.

PRAC Led

Menveo - meningococcal group A, C, W135 and Y conjugate vaccine -**EMA/H/C/001095/II/0112**

GSK Vaccines S.r.l, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 10 in order to remove several safety concerns."

Opinion adopted on 27.10.2022.

Positive Opinion adopted by consensus on 27.10.2022.

PRAC Led

SCENESSE - afamelanotide -**EMA/H/C/002548/II/0042, Orphan**

Clinuvel Europe Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of an updated RMP in order to update the allergy and hypersensitivity risk from potential to identified, following reported cases of positive allergy test results, confirming the causal association between the allergies to afamelanotide. Consequently, the RMP has been

Positive Opinion adopted by consensus on 27.10.2022.

revised to reclassify the important potential risk Allergy and hypersensitivity to important identified risk.”
Opinion adopted on 27.10.2022.
Request for Supplementary Information adopted on 01.09.2022.

PRAC Led
Spikevax - COVID-19 mRNA Vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0077
Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, “Update of section 4.8 of the SmPC to include ‘Urticaria’ as an adverse reaction, with the frequency ‘Uncommon’, as requested by the PRAC in the 13th Safety Summary Report (EMEA/H/C/005791/MEA/011.12). The Package Leaflet is updated accordingly.”
Opinion adopted on 27.10.2022.
Request for Supplementary Information adopted on 29.09.2022.

Positive Opinion adopted by consensus on 27.10.2022.

PRAC Led
Stelara - ustekinumab - EMEA/H/C/000958/II/0091
Janssen-Cilag International N.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, “Update of the SmPC sections 4.4, 4.5 and 4.6 with recommendation not to administer live vaccines to infants for six months following birth unless ustekinumab infant serum levels are undetectable or there is clear clinical benefit for the individual infant. The update follows assessment of the final safety registry report of CNTO1275PSO4007 "Pregnancy Research Initiative: Exposure to ustekinumab during pregnancy: A review and analysis of birth outcomes from the Swedish, Danish, and Finnish medical birth registers." Consequently, the PL and the RMP version 22.1 have also been updated. Additionally, minor editorial changes and updates to the list of representatives were introduced.”
Opinion adopted on 27.10.2022.
Request for Supplementary Information adopted on 10.06.2022, 10.02.2022.

Positive Opinion adopted by consensus on 27.10.2022.

PRAC Led

Request for supplementary information adopted

SYLVANT - siltuximab -

with a specific timetable.

EMA/H/C/003708/II/0038, Orphan

EUSA Pharma (Netherlands) B.V., PRAC Rapporteur: Brigitte Keller-Stanislawski, "Submission of the report from study ACCELERATE (Advancing Castleman Care with an Electronic Longitudinal Registry, E-Repository, And Treatment/Effectiveness Research): An International Registry for Patients with Castleman Disease - NCT02817997 listed as an obligation in the Annex II of the Product Information.

This is a study report to cover the data collected for 100 patients over a 5-year period in the ACCELERATE Registry study to collect information on patients with Castleman's Disease who are candidates to receive Sylvant or are currently receiving treatment with Sylvant.

The Annex II is updated accordingly."

Request for Supplementary Information adopted on 27.10.2022.

PRAC Led

Positive Opinion adopted by consensus on 27.10.2022.

VIZAMYL - flutemetamol (18F) -**EMA/H/C/002557/II/0029**

GE Healthcare AS, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final report from study (GE067-027) listed as a category 3 study in the RMP in addition to a comprehensive root-cause analysis on the contributing factors having an impact on reader performance as requested by PRAC. This is a non-interventional post-authorisation safety study (PASS) to evaluate the effectiveness of VIZAMYL reader training in Europe. The RMP version 3.4 has also been agreed and was updated to reflect the completion of study GE067-028, previously assessed in MEA 003.3."

Opinion adopted on 27.10.2022.

Request for Supplementary Information adopted on 01.09.2022, 10.06.2022.

B.5.5. CHMP-CAT assessed procedures**CARVYKTI - ciltacabtagene autoleucel -**

Positive Opinion adopted by consensus on 10.11.2022.

EMA/H/C/005095/II/0002, Orphan, ATMP

Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan

Mueller-Berghaus,
Opinion adopted on 10.11.2022, 04.11.2022.

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0031, Orphan, ATMP Positive Opinion adopted by consensus on 10.11.2022.

Novartis Europharm Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Jan Mueller-Berghaus
Opinion adopted on 10.11.2022, 04.11.2022.
Request for Supplementary Information adopted on 09.09.2022.

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0034/G, Orphan, ATMP Positive Opinion adopted by consensus on 10.11.2022.

Novartis Europharm Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Jan Mueller-Berghaus
Opinion adopted on 10.11.2022, 04.11.2022.

B.5.6. CHMP-PRAC-CAT assessed procedures

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0033/G, Orphan, ATMP Request for supplementary information adopted with a specific timetable.

Novartis Europharm Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to introduce additional guidance on liver function laboratory tests and monitoring before and after infusion and update information based on new safety information on the topic of acute liver failure (ALF) following two reports of fatal ALF.

Update of sections 4.2 and 4.4 of the SmPC in order to provide additional guidance relevant to patient's overall health status prior to dosing and to strengthen the existing description and guidance on systemic immune response.

Update of the section 4.4 of the SmPC in order to indicate prompt attention to thrombotic microangiopathy (TMA) and to reflect the risk of life-threatening or fatal outcomes.

The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update the Annex II."

Request for Supplementary Information adopted on 04.11.2022.

B.5.7. PRAC assessed ATMP procedures

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

WS2243/G Herceptin- EMA/H/C/000278/WS2243/0184/G MabThera- EMA/H/C/000165/WS2243/0193/G Roche Registration GmbH, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.11.2022.	Positive Opinion adopted by consensus on 10.11.2022.
WS2278/G Copalia- EMA/H/C/000774/WS2278/0125/G Copalia HCT- EMA/H/C/001159/WS2278/0100/G Dafiro- EMA/H/C/000776/WS2278/0129/G Dafiro HCT- EMA/H/C/001160/WS2278/0102/G Exforge- EMA/H/C/000716/WS2278/0124/G Exforge HCT- EMA/H/C/001068/WS2278/0099/G Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 27.10.2022. Request for Supplementary Information adopted on 23.06.2022.	Positive Opinion adopted by consensus on 27.10.2022.
WS2308/G AZILECT- EMA/H/C/000574/WS2308/0090/G Rasagiline ratiopharm- EMA/H/C/003957/WS2308/0022/G Teva B.V., Lead Rapporteur: Bruno Sepodes Opinion adopted on 10.11.2022. Request for Supplementary Information adopted on 08.09.2022.	Positive Opinion adopted by consensus on 10.11.2022.
WS2315/G Biktarvy- EMA/H/C/004449/WS2315/0051/G Descovy- EMA/H/C/004094/WS2315/0058/G Genvoya- EMA/H/C/004042/WS2315/0084/G Odefsey- EMA/H/C/004156/WS2315/0055/G Vemlidy-	Positive Opinion adopted by consensus on 10.11.2022.

EMA/H/C/004169/WS2315/0041/G

Gilead Sciences Ireland UC, Lead Rapporteur:
Bruno Sepodes,
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted
on 06.10.2022.

WS2324/G**Suboxone-****EMA/H/C/000697/WS2324/0053/G**

Indivior Europe Limited, Lead Rapporteur: Janet
Koenig
Opinion adopted on 10.11.2022.
Request for Supplementary Information adopted
on 15.09.2022.

Positive Opinion adopted by consensus on
10.11.2022.

WS2331**Descovy-****EMA/H/C/004094/WS2331/0059****Emtriva-****EMA/H/C/000533/WS2331/0140****Odefsey-****EMA/H/C/004156/WS2331/0056**

Gilead Sciences Ireland UC, Lead Rapporteur:
Bruno Sepodes, "To update sections 4.4 and 4.6
of the SmPC to implement modifications of the
HIV SmPC/PL to update wording related to the
risk of HIV transmission in accordance with the
January 2022 CHMP adoption of an update to
the Product Information for all approved HIV
products, recommending the removal of the
disease information relating to sexual
transmission of HIV and amendment of the
sections relating to breast-feeding.
The MAH has taken the opportunity to update
the contact details of the local representative
listed in the Package Leaflet for Estonia, Latvia,
Lithuania and Romania. An editorial change has
also been made to the SmPC and Patient
Information Leaflet for Emtriva 10 mg/ml oral
solution to correct an error in the sodium
content."
Opinion adopted on 10.11.2022.

Positive Opinion adopted by consensus on
10.11.2022.

WS2337/G**Copalia-****EMA/H/C/000774/WS2337/0126/G****Dafiro-****EMA/H/C/000776/WS2337/0130/G****Exforge-****EMA/H/C/000716/WS2337/0125/G**

Novartis Europharm Limited, Lead Rapporteur:

Positive Opinion adopted by consensus on
10.11.2022.

Thalia Marie Estrup Blicher, "C.I.z - To update section 4.9 of the SmPC, to implement the wording related to the risk of non-cardiogenic pulmonary oedema in amlodipine overdose, following finalisation of procedure PSUSA/00010434/202107.

C.I.11.a - To update Annex II to reflect the fulfilment of Condition B, as set out by the Commission Decision as an outcome of the assessment for the impact of the Article 5(3) scientific opinion on nitrosamines in human medicinal products on the opinion adopted pursuant to Article 31 of Directive 2001/83/EC for angiotensin-II-receptor antagonists (sartans) containing a tetrazole group."

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted on 08.09.2022.

WS2338

Copalia HCT-

EMA/H/C/001159/WS2338/0102

Dafiro HCT-

EMA/H/C/001160/WS2338/0104

Exforge HCT-

EMA/H/C/001068/WS2338/0101

Novartis Europharm Limited, Lead Rapporteur:

Thalia Marie Estrup Blicher, "C.I.z - To update section 4.9 of the SmPC, to implement the wording related to the risk of non-cardiogenic pulmonary oedema in amlodipine overdose, following finalisation of procedure PSUSA/00010434/202107."

Opinion adopted on 10.11.2022.

Request for Supplementary Information adopted on 08.09.2022.

Positive Opinion adopted by consensus on 10.11.2022.

WS2348

Ongentys-

EMA/H/C/002790/WS2348/0052

Ontilyv-EMA/H/C/005782/WS2348/0007

Bial - Portela & C^a, S.A., Lead Rapporteur:

Martina Weise

Opinion adopted on 10.11.2022.

Positive Opinion adopted by consensus on 10.11.2022.

WS2379/G

Lixiana-

EMA/H/C/002629/WS2379/0039/G

Roteas-

EMA/H/C/004339/WS2379/0026/G

Daiichi Sankyo Europe GmbH, Lead Rapporteur:

Maria Concepcion Prieto Yerro

Positive Opinion adopted by consensus on 10.11.2022.

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

**Jardiance - empagliflozin -
EMA/H/C/002677/II/0071**

Boehringer Ingelheim International GmbH,
Rapporteur: Johann Lodewijk Hillege, "Update of
section 5.1 of the SmPC based on a meta-
analysis report for the non-interventional study
EMPRISE–Europe and Asia (1245.195),
undertaken to assess the effectiveness and
safety of empagliflozin compared with DPP-4
inhibitors in adult patients with type 2 diabetes.
The MAH took the opportunity to implement
minor editorial changes in the SmPC and
Package Leaflet and to update the list of local
representatives in the Package Leaflet."
Request for Supplementary Information adopted
on 22.09.2022.

The MAH withdrew the procedure on
03.11.2022.

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

WS2318/G

Ebymect-

EMA/H/C/004162/WS2318/0058/G

Edistride-

EMA/H/C/004161/WS2318/0056/G

Forxiga-

EMA/H/C/002322/WS2318/0077/G

Qtern-

EMA/H/C/004057/WS2318/0036/G

Xigduo-

EMA/H/C/002672/WS2318/0068/G

AstraZeneca AB, Lead Rapporteur: Kristina
Dunder, Lead PRAC Rapporteur: Mari Thorn,
"C.I.4

Update of section 4.4 of the SmPC in order to
remove the potential risk of Lower Limb
Amputation (LLA) based on studies
D1690C00018, D1690C00019, DECLARE, DAPA-
HF, DAPA-CKD, and DELIVER.

The Package Leaflet are updated accordingly. In
addition, the MAH took the opportunity to
introduce minor editorial changes to the PI and
to align it with the latest QRD template.

In addition, the MAH took the opportunity to
update the list of local representatives in the
Qtern Package Leaflet.

C.I.11.z

Request by the applicant for an extension to the
clock stop to respond to the RSI adopted in
September 2022.

The CHMP agreed to the request by the
applicant.

Submission of an updated RMP in order to align the EU RMPs for the FDCs Xigduo, Ebymect and Qtern, to recently approved updates to the Forxiga EU RMP.

C.I.z

Update of section 4.5 of the SmPC to include a further PI harmonisation to address the consideration raised by PRAC and CHMP during the ongoing dapagliflozin procedure PSUSA/00010029/202110.

The Forxiga RMP and Edistride RMP version 28 have been submitted.

The Qtern RMP version 7 has been submitted.

The Xigduo RMP and Ebymect RMP version 13 have been submitted.”

Request for Supplementary Information adopted on 29.09.2022.

Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0115

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, “Submission of the final report from study HPV-027 listed as a category 3 study in the RMP to fulfil MEA 024.2; this is a long-term follow-up registry-based cohort study of HPV vaccine effectiveness against cervical pre-cancerous lesions and cervical cancer in a cohort of females previously enrolled from Finland in study HPV-008, as compared to an unvaccinated population-based reference cohort of females from Finland.”

Request for Supplementary Information adopted on 15.09.2022.

Request by the applicant for an extension to the clock stop to respond to the RSI adopted in September 2022.

The CHMP agreed to the request by the applicant.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

vamorolone - EMEA/H/C/005679, Orphan

Santhera Pharmaceuticals (Deutschland) GmbH,
Treatment of Duchenne muscular dystrophy (DMD)

cabotegravir - EMEA/H/C/005756

pre-exposure prophylaxis of HIV-1 infection

recombinant respiratory syncytial virus pre-fusion f protein, adjuvanted with as01e - EMEA/H/C/006054

Accelerated review

active immunisation or the prevention of lower respiratory tract disease (LRTD)

lebrikizumab - EMEA/H/C/005894

Treatment of moderate-to-severe atopic dermatitis in adults and adolescents

eribulin - EMEA/H/C/006134

treatment of breast cancer and liposarcoma

epcoritamab - EMEA/H/C/005985, Orphan

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

leniolisib - EMEA/H/C/005927, Orphan

Accelerated review

Pharming Technologies B.V., Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

epinephrine - EMEA/H/C/006139

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

ranibizumab - EMEA/H/C/006055

treatment of neovascular age-related macular degeneration (AMD)

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

COMIRNATY - COVID-19 mRNA Vaccine (nucleoside modified) - EMEA/H/C/005735/X/0147

See 4.1

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, "Extension application to add a new strength of 5/5 µg (tozinameran, famtozinameran) for active immunisation in children between 5 to 11 years of age who have previously received at least a primary vaccination course against COVID-19. The RMP (version 9.0) is updated in accordance."

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

niraparib / abiraterone acetate - EMEA/H/C/005932

treatment of adult patients with prostate cancer
List of Questions adopted on 15.09.2022.

eculizumab - EMEA/H/C/005652

treatment of paroxysmal nocturnal

haemoglobinuria

List of Questions adopted on 21.07.2022.

trastuzumab - EMEA/H/C/005769

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

List of Questions adopted on 19.05.2022.

raltegravir potassium - EMEA/H/C/005813

treatment of human immunodeficiency virus
(HIV-1)

List of Questions adopted on 21.07.2022.

ivosidenib - EMEA/H/C/005936, Orphan

Les Laboratoires Servier, treatment of acute
myeloid leukaemia and treatment of metastatic
cholangiocarcinoma

List of Questions adopted on 21.07.2022.

ivosidenib - EMEA/H/C/006174, Orphan

Les Laboratoires Servier, treatment of acute
myeloid leukaemia

List of Questions adopted on 21.07.2022.

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

Myalepta - metreleptin -

EMEA/H/C/004218/S/0030, Orphan

Amryt Pharmaceuticals DAC, Rapporteur: Karin

Janssen van Doorn, Co-Rapporteur: Agnes

Gyurasics, PRAC Rapporteur: Adam

Przybylkowski

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

BLINCYTO - blinatumomab -

EMEA/H/C/003731/R/0048, Orphan

Amgen Europe B.V., Rapporteur: Alexandre

Moreau, Co-Rapporteur: Armando Genazzani,

PRAC Rapporteur: Eva Jirsová

Deltyba - delamanid -

EMEA/H/C/002552/R/0062, Orphan

Otsuka Novel Products GmbH, Rapporteur:

Christophe Focke, PRAC Rapporteur: Jo Robays

Dzuveo - sufentanil -

EMEA/H/C/004335/R/0009

Laboratoire Aguetant, Rapporteur: Hrefna

Gudmundsdottir, PRAC Rapporteur: Adam

Przybylkowski

**JCOVDEN - adenovirus type 26 encoding
the SARS-CoV-2 spike glycoprotein -
EMA/H/C/005737/R/0063**

Janssen-Cilag International N.V., Rapporteur:
Christophe Focke, PRAC Rapporteur: Ulla
Wandel Liminga

**JEMPERLI - dostarlimab -
EMA/H/C/005204/R/0017**

GlaxoSmithKline (Ireland) Limited, Rapporteur:
Blanca Garcia-Ochoa, PRAC Rapporteur: Inês
Ribeiro-Vaz

**Lojuxta - lomitapide -
EMA/H/C/002578/R/0054**

Amryt Pharmaceuticals DAC, Rapporteur:
Johann Lodewijk Hillege, Co-Rapporteur:
Armando Genazzani, PRAC Rapporteur: Menno
van der Elst

**Lonquex - lipegfilgrastim -
EMA/H/C/002556/R/0077**

Teva B.V., Rapporteur: Outi Mäki-Ikola, Co-
Rapporteur: Johann Lodewijk Hillege, PRAC
Rapporteur: Kirsti Villikka

**Myalepta - metreleptin -
EMA/H/C/004218/R/0031, Orphan**

Amryt Pharmaceuticals DAC, Rapporteur: Karin
Janssen van Doorn, Co-Rapporteur: Agnes
Gyurasics, PRAC Rapporteur: Adam
Przybylkowski

**Natpar - parathyroid hormone -
EMA/H/C/003861/R/0046, Orphan**

Takeda Pharmaceuticals International AG,
Rapporteur: Karin Janssen van Doorn, Co-
Rapporteur: Agnes Gyurasics, PRAC Rapporteur:
Rhea Fitzgerald

**Nerlynx - neratinib -
EMA/H/C/004030/R/0031**

Pierre Fabre Medicament, Rapporteur: Bruno
Sepodes, Co-Rapporteur: Alexandre Moreau,
PRAC Rapporteur: Menno van der Elst

**Nityr - nitisinone -
EMA/H/C/004582/R/0015**

Cycle Pharmaceuticals (Europe) Limited,
Generic, Generic of Orfadin, Rapporteur: Jayne
Crowe, PRAC Rapporteur: Amelia Cupelli

**Pemazyre - pemigatinib -
EMA/H/C/005266/R/0007, Orphan**

Incyte Biosciences Distribution B.V.,
Rapporteur: Alexandre Moreau, Co-Rapporteur:
Janet Koenig, PRAC Rapporteur: Menno van der
Elst

**RXULTI - brexpiprazole -
EMA/H/C/003841/R/0014**

Otsuka Pharmaceutical Netherlands B.V.,
Rapporteur: Armando Genazzani, Co-
Rapporteur: Martina Weise, PRAC Rapporteur:
Lucia Kuráková

**Tegsedi - inotersen -
EMA/H/C/004782/R/0035, Orphan**

Akcea Therapeutics Ireland Limited, Rapporteur:
Martina Weise, Co-Rapporteur: Outi Mäki-Ikola,
PRAC Rapporteur: Rhea Fitzgerald

**Trazimera - trastuzumab -
EMA/H/C/004463/R/0020**

Pfizer Europe MA EEIG, Rapporteur: Jan
Mueller-Berghaus, Co-Rapporteur: Sol Ruiz,
PRAC Rapporteur: Brigitte Keller-Stanislawski

**Verkazia - ciclosporin -
EMA/H/C/004411/R/0021, Orphan**

Santen Oy, Duplicate, Duplicate of IKERVIS,
Rapporteur: Jayne Crowe, Co-Rapporteur:
Alexandre Moreau, PRAC Rapporteur: Jan
Neuhauser

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

**Valdoxan - agomelatine -
EMA/H/C/000915/II/0051**

Les Laboratoires Servier, Rapporteur: Eva
Skovlund, PRAC Rapporteur: Pernille Harg,
"Extension of indication to include a new
therapeutic indication in adolescents aged 12 to
17 years for the treatment of moderate to
severe major depressive episodes, if depression
is unresponsive to psychological therapy alone,
for Valdoxan, further to the results of the phase
2 (CL2-20098-075) and phase 3 (CL3-20098-
076) paediatric clinical studies included in the
Paediatric Investigation Plan number EMA-
001181-PIP-11; As a consequence, sections 4.1,
4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are
updated. The Package Leaflet is updated

accordingly. The updated RMP version 25.1 has also been submitted.”

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

**Beovu - brolocizumab -
EMA/H/C/004913/II/0019**

Novartis Europharm Limited, Rapporteur:
Alexandre Moreau

**COMIRNATY - COVID-19 mRNA Vaccine
(nucleoside modified) -
EMA/H/C/005735/II/0156/G**

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson

**Ervebo - recombinant vesicular stomatitis
virus - Zaire ebolavirus vaccine (live) -
EMA/H/C/004554/II/0027**

Merck Sharp & Dohme B.V., Rapporteur:
Christophe Focke

**Flucelvax Tetra - influenza vaccine surface
antigen inactivated prepared in cell
cultures - EMA/H/C/004814/II/0031**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

**Gardasil 9 - human papillomavirus vaccine
[types 6, 11, 16, 18, 31, 33, 45, 52, 58]
(recombinant, adsorbed) -**

EMA/H/C/003852/II/0061
Merck Sharp & Dohme B.V., Rapporteur:
Kristina Dunder

**JCOVDEN - adenovirus type 26 encoding
the SARS-CoV-2 spike glycoprotein -
EMA/H/C/005737/II/0067**

Janssen-Cilag International N.V., Rapporteur:
Christophe Focke

**Lumivity - perflutren -
EMA/H/C/000654/II/0042/G**

Lantheus EU Limited, Rapporteur: Finbarr Leacy

**Nimenrix - meningococcal group A, C,
W135 and Y conjugate vaccine -
EMA/H/C/002226/II/0120/G**

Pfizer Europe MA EEIG, Rapporteur: Ingrid
Wang

**Nivestim - filgrastim -
EMA/H/C/001142/II/0070/G**

Pfizer Europe MA EEIG, Rapporteur: Outi Mäki-

Ikola

**NUVAXOVID - SARS-CoV-2, spike protein,
recombinant, expressed in Sf9 cells derived
from Spodoptera frugiperda -
EMA/H/C/005808/II/0034**

Novavax CZ, a.s., Rapporteur: Johann Lodewijk
Hillege

**Padcev - enfortumab vedotin -
EMA/H/C/005392/II/0005/G**

Astellas Pharma Europe B.V., Rapporteur: Aaron
Sosa Mejia

**Rapiscan - regadenoson -
EMA/H/C/001176/II/0041/G**

GE Healthcare AS, Rapporteur: Maria
Concepcion Prieto Yerro

**Ryego - relugolix / estradiol /
norethisterone acetate -**

EMA/H/C/005267/II/0012

Gedeon Richter Plc., Rapporteur: Paula
Boudewina van Hennik

**Spikevax - COVID-19 mRNA Vaccine
(nucleoside-modified) -**

See B.5.1

EMA/H/C/005791/II/0087/G

Moderna Biotech Spain, S.L., Rapporteur: Jan
Mueller-Berghaus, Co-Rapporteur: Andrea
Laslop

**Spikevax - COVID-19 mRNA Vaccine
(nucleoside-modified) -**

EMA/H/C/005791/II/0089/G

Moderna Biotech Spain, S.L., Rapporteur: Jan
Mueller-Berghaus

Zaltrap - aflibercept -

EMA/H/C/002532/II/0067/G

sanofi-aventis groupe, Rapporteur: Filip
Josephson

WS2302/G

Fiasp-

EMA/H/C/004046/WS2302/0031/G

NovoMix-

EMA/H/C/000308/WS2302/0112/G

NovoRapid-

EMA/H/C/000258/WS2302/0142/G

Ryzodeg-

EMA/H/C/002499/WS2302/0049/G

Novo Nordisk A/S, Lead Rapporteur: Kristina
Dunder

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

Brintellix - vortioxetine -

EMA/H/C/002717/II/0038

H. Lundbeck A/S, Rapporteur: Karin Janssen van Doorn, "Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to include clinically relevant information on the efficacy, safety, tolerability and PK of vortioxetine in the paediatric population based on final results from studies 12709A, 12712A and 12712B.

Study 12709A is an interventional, randomized, double-blind, placebo-controlled, active-reference (fluoxetine), fixed-dose study of vortioxetine in paediatric patients aged 7 to 11 years, with Major Depressive Disorder (MDD) to evaluate efficacy and safety. Whereas studies 12712A and 12712B are 2 open-label, long-term safety and efficacy studies in children and adolescents: one 6-month extension study (study 12712A) to studies 12709A and 12710A, and one 18-month extension study (study 12712B) to study 12712A. The Package Leaflet is updated accordingly."

Calquence - acalabrutinib -

EMA/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, multicenter, 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 leukemia."

COVID-19 Vaccine (inactivated, adjuvanted) Valneva - SARS-CoV-2 virus, strain Wuhan hCoV-19/Italy/INMI1-isl/2020, inactivated -

EMA/H/C/006019/II/0004

Valneva Austria GmbH, Rapporteur: Andrea Laslop, "Update of sections 4.2 and 5.1 of the SmPC in order to include a booster dose for adults 18 to 50 years of age based on the interim results from study VLA2001-301 (Booster part); this is a randomized, observer-blind, controlled, superiority study to compare the immunogenicity of COVID-19 Vaccine (inactivated, adjuvanted) Valneva to AZD1222, where participants received a booster dose of

COVID-19 vaccine Valneva; the Package Leaflet is updated accordingly.”

Hepcludex - bulevirtide -

EMA/H/C/004854/II/0019, Orphan

Gilead Sciences Ireland Unlimited Company,
Rapporteur: Filip Josephson, “Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions (ADRs) and efficacy information based on interim results from study MYR301 listed as a Specific Obligation in the Annex II of the Product Information; this is a Multicenter, Open-label, Randomized Phase III Clinical Study to Assess Efficacy and Safety of Bulevirtide in Patients with Chronic Hepatitis Delta. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation given the fulfilment of the SOB. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC.”

Imfinzi - durvalumab -

EMA/H/C/004771/II/0052

AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, “Update of section 4.2 of the SmPC in order to update the recommendation for dose modification for ‘other immune-mediated adverse reactions’ as well as immune-mediated encephalitis, meningitis, Guillain-Barré syndrome and myasthenia gravis based on the National Comprehensive Cancer Network (NCCN) guideline recommendations (2022).”

Myocet liposomal - doxorubicin hydrochloride -

EMA/H/C/000297/II/0070

Teva B.V., Rapporteur: Filip Josephson, “Update of section 4.6 of the SmPC, upon request by PRAC following the assessment of EMA/H/C/PSUSA/00001172/202111, to align the wording with the published CHMP SWP advice on the duration of contraception in female patients after cessation of treatment with genotoxic drug. The Package Leaflet has been updated accordingly.”

**NUVAXOVID - SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from Spodoptera frugiperda -
EMA/H/C/005808/II/0030**

Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege, "Submission of 6-month efficacy and safety interim data from the ongoing randomized, observer-blinded, placebo-controlled clinical studies 2019nCoV-501, 2019nCoV-301 and 2019nCoV-302."

**SARCLISA - isatuximab -
EMA/H/C/004977/II/0018/G**

sanofi-aventis groupe, Rapporteur: Paula Boudewina van Hennik, "C.I.4: Update of sections 4.5, 5.1 and 5.2 of the SmPC in order to update the efficacy and pharmacokinetic data based on final progression-free survival (PFS) efficacy results from IKEMA study (EFC15246) and to introduce the Sebia Hydrashift assay, a validated assay to determine the complete response rate. IKEMA study (EFC15246) is a phase 3 randomized, open label, multicenter study assessing the clinical benefit of isatuximab combined with carfilzomib (Kymriah) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with 1 to 3 prior lines.

A.6: Update of section 5.1 of the SmPC in order to update the ATC code following amendment by WHO."

**SIRTURO - bedaquiline -
EMA/H/C/002614/II/0051, Orphan**

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update information on breast-feeding based on new literature."

**Supemtek - quadrivalent influenza vaccine
(recombinant, prepared in cell culture) -
EMA/H/C/005159/II/0009**

Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to update the efficacy information based on final results from study VAP00003 listed as a category 3 study in the RMP; this is a phase 4, multi-center, modified-cluster randomized study to assess the effectiveness of Flublok Quadrivalent vaccine compared to standard dose inactivated influenza vaccine in adults. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Vaxelis - diphtheria, tetanus, pertussis

(acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0110

MCM Vaccine B.V., Rapporteur: Christophe Focke, "Update of section 4.8 of the SmPC in order to add 'hypersensitivity' and 'anaphylactic reaction' to the list of adverse drug reactions (ADRs) with frequency not known based on the safety assessment of post-marketing reports of hypersensitivity including anaphylactic reactions; the Package Leaflet is updated accordingly."

Veklury - remdesivir - EMEA/H/C/005622/II/0043

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update information based on the final virology report (PC-540-2040) for study GS-US-540-9012 in order to fulfil the recommendation by CHMP in the AR for (EMEA/H/C/005622/II/0016); this is a phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of RDV in an outpatient setting in participants with confirmed COVID-19 who were at risk for disease progression. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Velphoro - iron - EMEA/H/C/002705/II/0028

Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.1 of the SmPC, upon request by the PRAC following the assessment of PSUSA/00010296/202111, to include information on the effect on iron parameters and haemoglobin, based on results from the previously submitted post-hoc analysis of study PA-CL-05A; a Phase 3, open-label, randomised, active-controlled, parallel group, multicentre clinical study, and its extension study PA-CL-05B."

Zejula - niraparib - EMEA/H/C/004249/II/0037, Orphan

GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, "Update of section 5.2 of the SmPC in order to update information on absorption based on results from food effect"

study 3000-01-004; this is an Open-Label, Randomized-Sequence, Multicenter, Single-Crossover Study to Assess the Relative Bioavailability and Bioequivalence of Niraparib Tablet Formulation Compared to Niraparib Capsule Formulation in Patients with Advanced Solid Tumours.”

WS2339/G

Kepra-

EMA/H/C/000277/WS2339/0198/G

UCB Pharma S.A., Lead Rapporteur: Karin Janssen van Doorn, “Grouped application comprising two type II variations as follows: C.I.4 – Update of section 4.4 of the SmPC in order to add a new warning on lack of efficacy or seizure worsening based on the cumulative review of MAH Global Safety database and published literature.

C.I.4 – Update of section 4.8 of the SmPC in order to add a note on obsessive compulsive disorder in the ADR table based on the cumulative review of MAH Global Safety database, clinical studies, data from external spontaneous reporting database and published literature.

The Package Leaflet is updated accordingly. In addition, the MAH proposes minor editorial changes of the Labelling.”

B.6.10. CHMP-PRAC assessed procedures

Rubraca - rucaparib -

EMA/H/C/004272/II/0037

Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.8 and 5.1 of the SmPC in order to update the efficacy and safety information and the list of adverse drug reactions (ADRs) 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. The Package Leaflet is updated accordingly. The RMP version 6.4 has also been submitted. In addition, the MAH took

the opportunity to introduce minor editorial changes to the PI.”

B.6.11. PRAC assessed procedures

B.6.12. CHMP-CAT assessed procedures

Abecma - idecabtagene vicleucel - EMA/H/C/004662/II/0019, Orphan, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Rune Kjekken, CHMP Coordinator: Ingrid Wang

Abecma - idecabtagene vicleucel - EMA/H/C/004662/II/0020, Orphan, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Rune Kjekken, CHMP Coordinator: Ingrid Wang

Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMA/H/C/004731/II/0009, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Concetta Quintarelli, CHMP Coordinator:
Armando Genazzani

Carvykti - ciltacabtagene autoleucel - EMA/H/C/005095/II/0005, Orphan, ATMP

Janssen-Cilag International NV, Rapporteur: Jan
Mueller-Berghaus, CHMP Coordinator: Jan
Mueller-Berghaus

Upstaza - eladocagene exuparvovec - EMA/H/C/005352/II/0004/G, Orphan, ATMP

PTC Therapeutics International Limited,
Rapporteur: Maura O'Donovan, CHMP
Coordinator: Finbarr Leacy

B.6.13. CHMP-PRAC-CAT assessed procedures

Carvykti - ciltacabtagene autoleucel - EMA/H/C/005095/II/0003, Orphan, ATMP

Janssen-Cilag International NV, Rapporteur: Jan
Mueller-Berghaus, CHMP Coordinator: Jan
Mueller-Berghaus, PRAC Rapporteur: Jo
Robays, , “Update of sections 4.4 and 4.8 of the
SmPC in order to update the existing warnings
on cytokine release syndrome (CRS), neurologic

toxicities and grading of related events and to update the list of adverse drug reactions (ADRs) based on previously reviewed data from studies MMY2001 and MMY2003, and an additional internal characterisation of neurotoxicity risk; the Package Leaflet is updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

**Carvykti - ciltacabtagene autoleucel -
EMA/H/C/005095/II/0004/G, Orphan,
ATMP**

Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays, “Grouped application comprising of two type II variations as follows:

- Update of section 4.4 of the SmPC in order to add a new warning on increased risk of severe/fatal COVID-19 infections following COVID-19 signal evaluation from the ongoing study 68284528MMY3002 (CARTITUDE-4) based on a cumulative review of all clinical trials, registries and literature.
- Update of section 4.4 of the SmPC in order to add a new warning Risk of severe bleeding in the context of hemophagocytic lymphohistiocytosis syndrome (HLH) following a signal evaluation from the ongoing study 68284528MMY3002 (CARTITUDE-4) based on cumulative review of all clinical trials, registries and literature.

The Package Leaflet is updated accordingly. The RMP version 2.2 has also been submitted.”

**Libmeldy - atidarsagene autotemcel -
EMA/H/C/005321/II/0011/G, Orphan,
ATMP**

Orchard Therapeutics (Netherlands) B.V., Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Type II (C.I.4): Update of sections 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to remove ANX/002 from the Annex II and to introduce minor editorial changes to the PI. The RMP version 1.3 has also been submitted.”

B.6.14. PRAC assessed ATMP procedures

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

WS2364/G

Herceptin-

EMA/H/C/000278/WS2364/0185/G

MabThera-

EMA/H/C/000165/WS2364/0194/G

Roche Registration GmbH, Lead Rapporteur:

Aaron Sosa Mejia

WS2373

Copalia HCT-

EMA/H/C/001159/WS2373/0103

Dafiro HCT-

EMA/H/C/001160/WS2373/0105

Exforge HCT-

EMA/H/C/001068/WS2373/0102

Novartis Europharm Limited, Lead Rapporteur:

Thalia Marie Estrup Blicher, "To update Annex II to request an extension of the due date for the fulfilment of condition B.

In addition, the marketing authorisation holder has taken the opportunity to implement a minor editorial change in the PI for Dafiro HCT."

WS2380/G

Filgrastim Hexal-

EMA/H/C/000918/WS2380/0067/G

Zarzio-

EMA/H/C/000917/WS2380/0068/G

Sandoz GmbH, Lead Rapporteur: Johann

Lodewijk Hillege, "To update section 4.4 of the SmPC to add information about myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) in patients with breast and lung cancer to align the PI with the PI of the reference product, Neupogen according to the update published by Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) on 4 August 2022.

Sections 2 and 3 of the Package Leaflet have been updated accordingly.

Additionally, a Type IA variation has been submitted as the MAH proposes to remove pre-filled syringes without a needle safety guard (NSG) from the dossier (EU/1/08/495/009-12, EU/1/08/495/013-16).

Finally, some minor editorial changes were introduced to the PI, in particular the ET, FI, IT, MT and RO annexes."

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

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 07-10 November 2022 CHMP plenary

Neurology

Treatment of Parkinson's disease
(SME)

The CHMP denied eligibility to PRIME and adopted
the critical summary report.

G.2.2. List of procedures starting in November 2022 for December 2022 CHMP adoption of outcomes

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