06 March 2024
EMA/CHMP/3867/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 11-14 December 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

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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Table of contents

1. Introduction 8

1.1. Welcome and declarations of interest of members, alternates and experts 8

1.2. Adoption of agenda 8

1.3. Adoption of the minutes 8

2. Oral Explanations 8

2.1. Pre-authorisation procedure oral explanations 8

2.1.1. sparsentan - Orphan - EMEA/H/C/005783 8

2.1.2. leriglitazone - Orphan - EMEA/H/C/005757 9

2.1.3. pegcetacoplan - EMEA/H/C/005954 9

2.2. Re-examination procedure oral explanations 9

2.2.1. Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan 9

2.3. Post-authorisation procedure oral explanations 10

2.4. Referral procedure oral explanations 10

2.4.1. Synapse Labs Pvt. Ltd. – various – EMEA/H/A-31/1529 10

3. Initial applications 10

3.1. Initial applications; Opinions 10

3.1.1. Arpraziquantel - arpraziquantel - Article 58 - EMEA/H/W/004252 10

3.1.2. Casgevy - exagamglogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005763 11

3.1.3. Dabigatran etexilate Leon Farma - dabigatran etexilate - EMEA/H/C/005922 11

3.1.4. MEVLYQ - eribulin - EMEA/H/C/006134 12

3.1.5. Ibuprofen Gen.Orph - ibuprofen - EMEA/H/C/006129 12

3.1.6. Pomalidomide Viatris - Pomalidomide - EMEA/H/C/006195 12

3.1.7. SKYCLARYS - omaveloxolone - Orphan - EMEA/H/C/006084 13

3.1.8. VELSIPITY - etrasimod - EMEA/H/C/006007 13

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable) 14

3.2.1. concizumab - EMEA/H/C/005938 14

3.2.2. apremilast - EMEA/H/C/006208 14

3.2.3. aumolertinib - EMEA/H/C/006069 14

3.2.4. buprenorphine - EMEA/H/C/006188 15

3.2.5. sugemalimab - EMEA/H/C/006088 15

3.2.6. sparsentan - Orphan - EMEA/H/C/005783 15

3.2.7. serplulimab - Orphan - EMEA/H/C/006170 16

3.2.8. aprocitentan - EMEA/H/C/006080 16

3.2.9. omecamtiv mecarbil - EMEA/H/C/006112 16

3.2.10. nintedanib - EMEA/H/C/006179 16

3.2.11. ustekinumab - EMEA/H/C/006183 17
3.2.12. flortaucipir (18F) - EMEA/H/C/006064 17
3.2.13. retifanlimab - Orphan - EMEA/H/C/006194 17
3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable) 18
3.3.1. delgocitinib - EMEA/H/C/006109 18
3.3.2. givinostat - Orphan - EMEA/H/C/006079 18
3.3.3. aztreonam / avibactam - EMEA/H/C/006113 18
3.3.4. enzalutamide - EMEA/H/C/006299 18
3.3.5. insulin glargine - EMEA/H/C/006136 19
3.3.6. vilobelimab - EMEA/H/C/006123 19
3.3.7. trastuzumab - EMEA/H/C/006252 19
3.3.8. avacincaptad pegol - EMEA/H/C/006153 19
3.3.9. donanemab - EMEA/H/C/006024 20
3.3.10. temozolomide - Orphan - EMEA/H/C/006169 20
3.3.11. zapomeran – OPEN – EMEA/H/C/006207 20
3.3.12. odronextamab - Orphan - EMEA/H/C/006215 20
3.3.13. lutetium (177Lu) chloride - EMEA/H/C/005882 21
3.3.14. ciclosporin - EMEA/H/C/006250 21
3.4. Update on on-going initial applications for Centralised procedure 21
3.4.1. catumaxomab - EMEA/H/C/005697 21
3.4.2. methylphenidate hydrochloride - PUMA - EMEA/H/C/005975 21
3.4.3. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/006053 22
3.4.4. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165 22
3.4.5. polihexanide - Orphan - EMEA/H/C/005858 22
3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004 22
3.6. Initial applications in the decision-making phase 22
3.7. Withdrawals of initial marketing authorisation application 23

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 23

4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion 23
4.1.1. Entyvio - vedolizumab - EMEA/H/C/002782/X/0075 23
4.1.2. Viagra - sildenafil - EMEA/H/C/000202/X/0115 23
4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues 24
4.2.1. Kalydeco - ivacaftor - EMEA/H/C/002494/X/0115/G 24
4.2.2. Lumykras - sotorasib - EMEA/H/C/005522/X/0009 24
4.2.3. Opdivo - nivolumab - EMEA/H/C/003985/X/0132 25

4.2.4. Teriflunomide Accord - teriflunomide - EMEA/H/C/005960/X/0002 25

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question 25

4.3.1. Edurant - rilpivirine - EMEA/H/C/002264/X/0042/G 25

4.3.2. Eliquis - apixaban - EMEA/H/C/002148/X/0089/G 26

4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008 26

4.4.1. Reagila - Cariprazine - EMEA/H/C/002770/X/0033 26

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 27

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008 27

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information 27

5.1.1. Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0012 27

5.1.2. CARVYKTI - ciltacabtagene autoleucel - Orphan - ATMP - EMEA/H/C/005095/II/0021 27

5.1.3. Cibinqo - abrocitinib - EMEA/H/C/005452/II/0010 28

5.1.4. Fexinidazole Winthrop - fexinidazole - EMEA/H/W/002320/II/0016 28

5.1.5. HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0087 29

5.1.6. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0134 29

5.1.7. Kisqali - ribociclib - EMEA/H/C/004213/II/0045 30

5.1.8. LIVMARLI - maralixibat - Orphan - EMEA/H/C/005857/II/0003/G 30

5.1.9. Metalyse - Tenecteplase - EMEA/H/C/000306/II/0070/G 31

5.1.10. Palforzia - defatted powder of arachis hypogaea L., semen (peanuts) - EMEA/H/C/004917/II/0014/G 31

5.1.11. SCENESSE - afamelanotide - Orphan - EMEA/H/C/002548/II/0044 32

5.1.12. TAGRISSO - osimertinib - EMEA/H/C/004124/II/0053 32

5.1.13. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0081 33

5.1.14. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0082 33

5.1.15. Valdoxan - agomelatine - EMEA/H/C/000915/II/0051 34

5.1.16. VeraSeal - human fibrinogen / human thrombin - EMEA/H/C/004446/II/0027 34

5.1.17. Xtandi - enzalutamide - EMEA/H/C/002639/II/0063 35

5.1.18. Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0037 35

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 36

5.2.1. CellCept - mycophenolate mofetil - EMEA/H/C/000082/II/0170/G 36

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 36

6. Medical devices 36

6.1. Ancillary medicinal substances - initial consultation 36

6.2. Ancillary medicinal substances – post-consultation update 36

6.3. Companion diagnostics - initial consultation 37

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006372 37

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006373 37

6.3.3. in vitro diagnostic medical device - EMEA/H/D/006341 37

6.4. Companion diagnostics – follow-up consultation 37

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 38

7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 38

8. Pre-submission issues 38

8.1. Pre-submission issue 38

8.1.1. obecabtagene autoleucel – ATMP - H0005907 38

8.1.2. Sipavibart - H0006291 38

8.1.3. lazertinib - H0006074 38

8.1.4. Dorocubicel/Allogeneic umbilical cord-derived CD34- cells, non-expanded – PRIME - H0005772 39

8.2. Priority Medicines (PRIME) 39

9. Post-authorisation issues 39

9.1. Post-authorisation issues 39

9.1.1. Bimervax - COVID-19 vaccine - EMEA/H/C/006058/II/0004 39

9.1.2. Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan 40

9.1.3. LUMYKRAS - Sotorasib - EMEA/H/C/005522/II/0010/G 40

9.1.4. Translarna - ataluren - EMEA/H/C/002720/R/0071, Orphan 41

9.1.5. Tremelimumab AstraZeneca - tremelimumab - EMEA/H/C/004650/II/0002 41

9.1.6. Clopidogrel BGR (SRD) – clopidogrel – EMEA/H/C/001138 41

9.1.7. Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0095 . 41

9.1.8. Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP 42

10. Referral procedures 42

10.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004 42

10.1.1. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065 42

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 . 43

10.3. Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004 43

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 43
10.4.1. Ibuprofen NVT – ibuprofen - EMEA/H/A-29(4)/1533 43
10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC 44
10.5.1. Havrix – Hepatitis A virus (inactivated, adsorbed) - EMEA/H/A-30/1527 44
10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC 44
10.6.1. Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/153244
10.6.2. Synapse Labs Pvt. Ltd. – various – EMEA/H/A-31/1529 45
10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC..... 46
10.8. Procedure under Article 107(2) of Directive 2001/83/EC 46
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 46
10.10. Procedure under Article 29 of Regulation (EC) 1901/2006..... 46
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 46

11. Pharmacovigilance issue 46
11.1. Early Notification System 46

12. Inspections 47
12.1. GMP inspections 47
12.2. GCP inspections 47
12.3. Pharmacovigilance inspections..... 47
12.4. GLP inspections 47

13. Innovation Task Force 47
13.1. Minutes of Innovation Task Force..... 47
13.2. Innovation Task Force briefing meetings..... 47
13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004 47
13.4. Nanomedicines activities 47

14. Organisational, regulatory and methodological matters 48
14.1. Mandate and organisation of the CHMP 48
14.1.1. Vote by proxy 48
14.1.2. CHMP membership..... 48
14.2. Coordination with EMA Scientific Committees..... 48
14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC) 48
14.2.2. Paediatric Committee (PDCO)..... 48
14.2.3. Joint CHMP-CAT membership 48

14.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups 49
14.3.1. Biologics Working Party (BWP) 49
14.3.2. Call for nomination of new members (BWP) 49
14.3.3. Name Review Group (NRG) 49
14.3.4. Scientific Advice Working Party (SAWP) 49
14.3.5. Call for interest for nomination of a replacement SAWP member 50
14.3.6. Nominations of PRAC and QRD representatives 50
14.4. Cooperation within the EU regulatory network 50
14.5. Cooperation with International Regulators 50
14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee 50
14.7. CHMP work plan 50
14.7.1. CHMP Workplan 2024 50
14.8. Planning and reporting 51
14.8.1. Update of the Business Pipeline report for the human scientific committees 51
14.9. Others 51
14.9.1. CHMP Learnings 51

15. Any other business 51
15.1. AOB topic 51

List of participants 51
Explanatory notes 57

1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared. Restrictions applicable to this meeting are captured in the list of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 11-14 December 2023.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 06-09 November 2023.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 04 December 2023.

The CHMP adopted the minutes for the 06-09 November 2023 plenary and the minutes for the 04 December 2023 PROM meeting.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Possible oral explanation

Action: Possible oral explanation to be held on 12 December 2023 at 16:00

List of Outstanding Issues adopted on 12.10.2023, 25.05.2023. List of Questions adopted on 15.12.2022.

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

See 3.2

2.1.2. leriglitazone - Orphan - EMEA/H/C/005757

Minoryx Therapeutics S.L.; the treatment of cerebral progression and myelopathy in male patients with adrenoleukodystrophy (ALD).

Scope: Oral explanation

Action: Oral explanation to be held on 12 December 2023 at 11:00

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 15.12.2022.

An oral explanation was held on 12 December 2023. The presentation by the applicant focused on clinical aspects.

2.1.3. pegcetacoplan - EMEA/H/C/005954

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

Scope: Oral explanation

Action: Oral explanation to be held on 13 December 2023 at 14:00

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 25.05.2023.

An oral explanation was held on 13 December 2023. The presentation by the applicant focused on clinical aspects.

2.2. Re-examination procedure oral explanations

2.2.1. Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan

GlaxoSmithKline (Ireland) Limited

Re-examination Rapporteur: Filip Josephson, Re-examination Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Oral explanation

Action: Oral explanation to be held on 12 December 2023 at 14:00

Opinion adopted in September 2023. Request for Supplementary Information adopted on 26.04.2023.

An oral explanation was held on 12 December 2023. The presentation by the applicant

focused on clinical aspects.

See 9.1

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

2.4.1. Synapse Labs Pvt. Ltd. – various – EMEA/H/A-31/1529

MAH various

Referral Rapporteur: Maria Concepcion Prieto Yerro, Referral Co-Rapporteur: Janet Koenig

Scope: Oral explanation

Action: Oral explanation to be held on 12 December 2023 at 09:00

Article 31 procedure triggered by the Agency of Medicines and Medical Devices (AEMPS) in Spain, concerning the contract research organisation (CRO) Synapse Labs Pvt. Ltd., located in Kharadi, Pune, India.

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

See 10.6

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Arpraziquantel - arpraziquantel - Article 58 - EMEA/H/W/004252

Merck Europe B.V.; treatment of schistosomiasis in children

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 30.03.2023.

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

The Committee adopted the scientific opinion for Arpraziquantel in accordance with Article 58 of Regulation (EC) No. 726/2004.

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

The CHMP noted the letter of recommendation dated 11 December 2023.

The summary of opinion was circulated for information.

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

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

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 31.10.2023, 08.09.2023. List of Questions adopted on 17.05.2023.

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

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

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

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

The CHMP noted the letter of recommendation dated 07 December 2023.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.3. Dabigatran etexilate Leon Farma - dabigatran etexilate - EMEA/H/C/005922

Laboratorios Leon Farma S.A.; prevention of venous thromboembolic events

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 12.10.2023, 25.05.2023, 23.02.2023. List of Questions adopted on 23.06.2022.

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.

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

The CHMP noted the letter of recommendation dated 11 December 2023.

The summary of opinion was circulated for information.

3.1.4. MEVLYQ - eribulin - EMEA/H/C/006134

YES Pharmaceutical Development Services GmbH; treatment of breast cancer and liposarcoma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 23.02.2023.

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.

3.1.5. Ibuprofen Gen.Orph - ibuprofen - EMEA/H/C/006129

Gen.Orph; Treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 30.03.2023.

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.

3.1.6. Pomalidomide Viatris - Pomalidomide - EMEA/H/C/006195

Viatris Limited; in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 20.07.2023.

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.

The CHMP adopted the similarity assessment report.

3.1.7. SKYCLARYS - omaveloxolone - Orphan - EMEA/H/C/006084

Reata Ireland Limited; Treatment of Friedreich's ataxia

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 26.04.2023.

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

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

The CHMP noted the letter of recommendation dated 11 December 2023.

The summary of opinion was circulated for information.

3.1.8. VELSIPITY - etrasimod - EMEA/H/C/006007

Pfizer Europe MA EEIG; treatment of patients with moderately to severely active ulcerative colitis (UC)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 30.03.2023.

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

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

The CHMP noted the letter of recommendation dated 11 December 2023.

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. concizumab - EMEA/H/C/005938

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

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 25.05.2023.

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

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

3.2.2. apremilast - EMEA/H/C/006208

treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

3.2.3. aumolertinib - EMEA/H/C/006069

treatment of non-small cell lung cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.03.2023.

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

The Committee adopted a list of outstanding issues.

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

3.2.4. buprenorphine - EMEA/H/C/006188

treatment of opioid drug dependence

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.06.2023.

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

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

3.2.5. sugemalimab - EMEA/H/C/006088

treatment of adults with metastatic non-small-cell lung cancer (NSCLC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.06.2023.

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

The Committee adopted a list of outstanding issues.

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

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

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

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023, 25.05.2023. List of Questions adopted on 15.12.2022.

See 2.1

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

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

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

3.2.7. serplulimab - Orphan - EMEA/H/C/006170

Henlius Europe GmbH; first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

3.2.8. aprocitentan - EMEA/H/C/006080

treatment of resistant hypertension

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.06.2023.

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

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

3.2.9. omecamtiv mecarbil - EMEA/H/C/006112

treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

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

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

3.2.10. nintedanib - EMEA/H/C/006179

treatment of idiopathic pulmonary fibrosis (IPF), chronic fibrosing interstitial lung diseases (ILDs) and lung diseases (ILDs) systemic sclerosis associated interstitial lung disease (SSc-ILD)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

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

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

3.2.11. ustekinumab - EMEA/H/C/006183

treatment of Crohn's disease, Ulcerative colitis, Plaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

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

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

3.2.12. flortaucipir (18F) - EMEA/H/C/006064

indicated for Positron Emission Tomography (PET) imaging of the brain

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

3.2.13. retifanlimab - Orphan - EMEA/H/C/006194

Incyte Biosciences Distribution B.V.; Treatment of Merkel cell carcinoma (MCC).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

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

3.3.1. delgocitinib - EMEA/H/C/006109

treatment of moderate to severe chronic hand eczema (CHE)

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.

The CHMP agreed to consult the Non-clinical Working Party and the QRD group and adopted lists of questions to these groups.

3.3.2. givinostat - Orphan - EMEA/H/C/006079

Italfarmaco S.p.A.; treatment of Duchenne muscular dystrophy (DMD)

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. aztreonam / avibactam - EMEA/H/C/006113

Accelerated assessment

treatment of complicated Intra-Abdominal Infection (cIAI), complicated Urinary Tract Infection (cUTI), including pyelonephritis, Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), and aerobic Gram-negative infections with limited treatment options

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.4. enzalutamide - EMEA/H/C/006299

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.

3.3.5. insulin glargine - EMEA/H/C/006136

treatment of diabetes mellitus

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.6. vilobelimab - EMEA/H/C/006123

treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

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. trastuzumab - EMEA/H/C/006252

is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and HER2 positive early breast cancer (EBC)

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. avacincaptad pegol - EMEA/H/C/006153

is indicated for the treatment of adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.9. donanemab - EMEA/H/C/006024

to slow disease progression in adult patients with Alzheimer's disease (AD).

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.

3.3.10. temozolomide - Orphan - EMEA/H/C/006169

Orphelia Pharma; treatment of neuroblastoma

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.

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

3.3.11. zapomeran – OPEN – EMEA/H/C/006207

active immunisation to prevent COVID-19

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.12. odronextamab - Orphan - EMEA/H/C/006215

Regeneron Ireland Designated Activity Company; treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)

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.

3.3.13. lutetium (177Lu) chloride - EMEA/H/C/005882

radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide

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.

3.3.14. ciclosporin - EMEA/H/C/006250

Treatment of dry eye disease in adult patients

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. catumaxomab - EMEA/H/C/005697

indicated for the treatment of malignant ascites

Scope: Letter by the applicant dated 22.11.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in November 2023.

Action: For adoption

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 15.12.2022.

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

3.4.2. methylphenidate hydrochloride - PUMA - EMEA/H/C/005975

treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age and over

Scope: Letter by the applicant dated 23.11.2023 requesting an extension to the clock stop to respond to the list of questions adopted in June 2023.

Action: For adoption

List of questions adopted on 22.06.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to

respond to the list of questions adopted in June 2023.

3.4.3. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/006053

indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

Scope: Letter by the applicant dated 30.11.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

Action: For adoption

List of outstanding issues adopted on 14.09.2023. List of Questions adopted on 26.04.2023.

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 2023.

3.4.4. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165

indicated for in vitro labelling of kits for radiopharmaceutical preparation

Scope: Letter by the applicant dated 07.12.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in October 2023.

Action: For adoption

List of outstanding issues adopted on 12.10.2023. List of Questions adopted on 16.12.2021.

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

3.4.5. polihexanide - Orphan - EMEA/H/C/005858

SIFI SPA; treatment of acanthamoeba keratitis

Scope: Letter by the applicant dated 06.12.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in November 2023.

Action: For adoption

List of outstanding issues adopted on 09.11.2023. List of Questions adopted on 15.09.2022.

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 November 2023.

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

No items

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. Entyvio - vedolizumab - EMEA/H/C/002782/X/0075

Takeda Pharma A/S

Rapporteur: Paolo Gasparini

Scope: quality

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 26.04.2023.

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.

4.1.2. Viagra - sildenafil - EMEA/H/C/000202/X/0115

Upjohn EESV

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible film)."

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 26.01.2023.

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.

4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues

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

Vertex Pharmaceuticals (Ireland) Limited

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

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

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 25.05.2023.

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

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

4.2.2. Lumykras - sotorasib - EMEA/H/C/005522/X/0009

Amgen Europe B.V.

Rapporteur: Alexandre Moreau

Scope: "Extension application to add a new strength of 240 mg film-coated tablet."

Action: For adoption

List of Questions adopted on 22.06.2023.

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

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

4.2.3. Opdivo - nivolumab - EMEA/H/C/003985/X/0132

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber

Scope: quality

Action: For adoption

List of Questions adopted on 14.09.2023.

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

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

4.2.4. Teriflunomide Accord - teriflunomide - EMEA/H/C/005960/X/0002

Accord Healthcare S.L.U.

Rapporteur: Kristina Nadrah, PRAC Rapporteur: Martin Huber

Scope: "Extension application to add a new strength of 7 mg film-coated tablets. The bioequivalence study data were submitted."

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

4.3.1. Edurant - rilpivirine - EMEA/H/C/002264/X/0042/G

Janssen-Cilag International N.V.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg dispersible tablets). The new presentation is indicated, in combination with other antiretroviral medicinal products, for the treatment of HIV-1 infection in patients ≥2 to <18 years of age and weighing at least 10 kg to less than 25 kg. The PI and RMP have been updated in accordance.
Type II variation (C.I.6.a) to modify the approved therapeutic indication of the already authorised 25 mg film-coated tablets presentation to include, in combination with other antiretroviral medicinal products, treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve and virologically suppressed (HIV-1 RNA less than 50 copies per ml) paediatric patients from 2 to less than 12 years weighing at least 25 kg, based on final results from study TMC278-TiDP38-C213 Cohort 2. 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 and Labelling are updated in accordance. The updated RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to Annex II and to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

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

4.3.2. Eliquis - apixaban - EMEA/H/C/002148/X/0089/G

Bristol-Myers Squibb / Pfizer EEIG

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to:
1) Introduce a new pharmaceutical form (granules in single-dose container) associated with a new strength (0.15 mg).
2) Introduce a new pharmaceutical form (coated granules in sachet) associated with 3 new strengths (0.5 mg, 1.5 mg and 2 mg).
The above two line extensions are grouped with a type II - C.I.6.a variation:
Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age for Eliquis (all strengths), based on a pre-specified interim analysis from study CV185325; this is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children who require anticoagulation for a venous thromboembolism; As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPCs are updated. The Package Leaflet and Annex II are updated in accordance. Version 21.0 of the RMP has also been submitted."

Action: For adoption

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

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

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

4.4.1. Reagila - Cariprazine - EMEA/H/C/002770/X/0033

Gedeon Richter Plc.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible

tablets). The RMP (version 3.0) is updated in accordance."
Change of timetable to respond to the list of questions adopted in November 2023.

Action: For adoption

List of Questions adopted on 09.11.2023.

The CHMP noted the change of timetable to respond to the list of questions and adopted the new timetable.

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. Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0012

Pfizer Europe MA EEIG

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of indication to include infants, children and adolescents from 6 weeks to less than 18 years of age for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae, based on final results from studies B7471003, B7471011, B7471012, B7471013 and B7471014. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 12.10.2023, 20.07.2023, 30.03.2023.

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

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

5.1.2. CARVYKTI - ciltacabtagene autoleucel - Orphan - ATMP - EMEA/H/C/005095/II/0021

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays

Scope: "Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 1 prior therapy, including an IMiD and a PI, have demonstrated disease progression on or after the last therapy and are refractory to lenalidomide for CARVYKTI, based on interim results from study MMY3002 listed as a specific obligation (SOB/006) in the Annex II. This is an ongoing, Phase 3, randomized, open-label, multicentre study to determine whether treatment with cilta-cel provides an efficacy benefit compared to standard therapy in participants with relapsed and lenalidomide-refractory multiple myeloma. As a consequence, sections 4.1, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 08.09.2023.

The CHMP was updated on the discussions at the CAT. The Committee discussed the issues identified in this application relating to clinical aspects and the request for 1 year market protection.

The CHMP endorsed a 2nd request for supplementary information with a specific timetable, as adopted by CAT.

5.1.3. Cibinqo - abrocitinib - EMEA/H/C/005452/II/0010

Pfizer Europe MA EEIG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication to include treatment of adolescents 12 to < 18 years of age with moderate to severe atopic dermatitis for CIBINQO based on final results from non-clinical study 00655292 [21GR211] and interim results from clinical study B7451015; this is a Phase III multi-centre, long-term extension study investigating the efficacy and safety of abrocitinib, with or without topical medications, administered to subjects aged 12 years and older with moderate to severe atopic dermatitis. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

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

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

5.1.4. Fexinidazole Winthrop - fexinidazole - EMEA/H/W/002320/II/0016

Sanofi Winthrop Industrie

Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include treatment of both first stage (haemo-lymphatic) and second stage (meningo-encephalitic) of human African trypanosomiasis (HAT) due to Trypanosoma brucei rhodesiense for FEXINIDAZOLE WINTHROP based final results from study DNDI-FEX-07-HAT - Efficacy and safety of fexinidazole in patients with Human African Trypanosomiasis (HAT) due to Trypanosoma brucei rhodesiense: a multicentre, open-label clinical trial; this is a phase-II/III, multicenter, open-label, non-randomized, single-arm clinical trial to assess the efficacy and safety of fexinidazole in patients with r-HAT. As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

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

Baxalta Innovations GmbH

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

Scope: "Extension of indication to include treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) as maintenance therapy after stabilization with IVIg in adults, children and adolescents for HyQvia, based on final results from studies 161403 and TAK-771-1001; and interim results from study 161505. 161403 and 161505 are interventional Phase III efficacy and safety studies, while TAK-771-1001 is an interventional Phase I safety study. As a consequence, sections 4.1, 4.2, 4.4, 4.7, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.3 of the RMP has also been accepted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023, 25.05.2023.

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.

5.1.6. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0134

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant, treatment of resectable stage II, IIIA, or IIIB (T3 4N2) non-small cell lung carcinoma in adults for Keytruda based on study KEYNOTE-671, a phase III, randomized, double-blind trial of platinum doublet chemotherapy +/- pembrolizumab as neoadjuvant/adjuvant therapy for participants with resectable stage II, IIIA, and resectable IIIB (T3-4N2) non-small cell lung cancer. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023.

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

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

5.1.7. Kisqali - ribociclib - EMEA/H/C/004213/II/0045

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, stage II or stage III early breast cancer, irrespective of nodal status, in combination with an AI for Kisqali based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. 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 8.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

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

5.1.8. LIVMARLI - maralixibat - Orphan - EMEA/H/C/005857/II/0003/G

Mirum Pharmaceuticals International B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski

Scope: "Grouped variation consisting of:
1) Extension of indication to include treatment of Progressive Familial Intrahepatic Cholestasis (PFIC) in patients 2 months of age and older for LIVMARLI, based on results from studies MRX-502, LUM001-501, MRX-503, MRX-800 and MRX-801; MRX-502 is an international, multicenter, randomized, double-blind, placebo-controlled, parallel group Phase 3 study that evaluated the efficacy and safety of maralixibat in PFIC participants

aged >12 months to <18 years on a proposed dosage of up to 600 µg/kg BID over 6 months. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes.
2) B.I.b.1.b" 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 20.07.2023.

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

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

5.1.9. Metalyse - Tenecteplase - EMEA/H/C/000306/II/0070/G

Boehringer Ingelheim International GmbH

Rapporteur: Martina Weise

Scope: "Grouped application consisting of:
C.I.6.a (Type II): To add the new therapeutic indication Acute Ischemic Stroke (AIS) for the new 25 mg presentation. Consequently, a separate SmPC and Package Leaflet are provided for the 25 mg presentation with the new indication. In addition, the MAH took the opportunity to implement editorial changes and minor updates to the PI of Metalyse 40 mg (8,000 U) and 50 mg (10,000 U).
B.II.e.5.c
B.II.b.3.a
B.II.e.1.b.2"

Action: For adoption

Request for Supplementary Information adopted on 09.11.2023.

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.

5.1.10. Palforzia - defatted powder of arachis hypogaea L., semen (peanuts) - EMEA/H/C/004917/II/0014/G

Aimmune Therapeutics Ireland Limited

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kirsti Villikka

Scope: "Grouped variation consisting of:
C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomized, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON) to evaluate the safety and efficacy of peanut

powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling were updated accordingly. Version 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet. As part of the application the MAH is requesting a 1-year extension of the market protection.
B.II.e.5.a: Introduction of a new pack-size of 16 capsules of 1 mg (Level 0) in blisters for PALFORZIA, 1 mg, oral powder in capsules for opening.
Due to the lack of a suitable pack-size for the up-dosing phase for patients 1 to 3 years old, a new pack size Level 0 for the up-dosing phase will be introduced. Labelling was updated accordingly." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

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

5.1.11. SCENESSE - afamelanotide - Orphan - EMEA/H/C/002548/II/0044

Clinuvel Europe Limited

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

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

Action: For adoption

Request for Supplementary Information adopted on 25.05.2023.

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

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

5.1.12. TAGRISSO - osimertinib - EMEA/H/C/004124/II/0053

AstraZeneca AB

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include TAGRISSO in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations, based on final results from study FLAURA2 (D5169C00001); this is a Phase III, open-label, randomized study of osimertinib with or

without platinum plus pemetrexed chemotherapy, multicentre study to assess the efficacy and safety of TAGRISSO as first-line treatment in patients with EGFR mutation-positive, locally advanced or metastatic NSCLC. 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 16 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.

5.1.13. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0081

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include, in combination with bevacizumab, adjuvant treatment of adult patients with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation for TECENTRIQ, based on final results from study WO41535 (IMbrave050); this is a phase III, randomized, multi-centre, international, open-label study, conducted to evaluate the efficacy and safety of adjuvant therapy of atezolizumab in combination with bevacizumab in patients with completely resected or ablated HCC who were at high risk for disease recurrence. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 28.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes."

Action: For adoption

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

The Committee adopted a request for supplementary information. The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the RSI.

5.1.14. Tecentriq - atezolizumab - EMEA/H/C/004143/II/0082

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include first-line treatment of adult patients with non-small cell lung cancer (NSCLC) who are ineligible for platinum-based chemotherapy and who do not have EGFR mutant or ALK-positive disease, who have: locally advanced unresectable NSCLC not amenable for definitive chemoradiotherapy, or metastatic NSCLC, for TECENTRIQ, based on final results from study MO29872 (IPSOS); this is a phase 3, open-label, multicenter, randomized study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment naive advanced or recurrent (stage IIIB not amenable for multimodality treatment) or metastatic (stage IV) non-small cell lung cancer who are deemed unsuitable for platinum-containing therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. Version 29.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

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.

5.1.15. Valdoxan - agomelatine - EMEA/H/C/000915/II/0051

Les Laboratoires Servier

Rapporteur: Eva Skovlund, PRAC Rapporteur: Pernille Harg

Scope: "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 EMEA-001181-PIP-11; As a consequence, the 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."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023, 26.01.2023.

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

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

5.1.16. VeraSeal - human fibrinogen / human thrombin - EMEA/H/C/004446/II/0027

Instituto Grifols, S.A.

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of children for VeraSeal, based on final results from study IG1405; this is a prospective, randomized, active-controlled, single-blind, parallel group clinical trial to evaluate the safety and efficacy of VeraSeal as an adjunct to haemostasis during surgery in paediatric subjects. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

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. Xtandi - enzalutamide - EMEA/H/C/002639/II/0063

Astellas Pharma Europe B.V.

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy, for Xtandi, based on final results from study MDV3100-13 (EMBARK); this is a phase 3, randomized, efficacy and safety study of enzalutamide plus leuprolide, enzalutamide monotherapy, and placebo plus leuprolide in men with high-risk nonmetastatic prostate cancer progressing after definitive therapy. 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 18.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet."

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.

5.1.18. Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0037

Merck Sharp & Dohme B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of the paediatric population (1 to 18 years of age) for ZINPLAVA, based on final results from study MK-6072-001 (MODIFY III) listed as a category 3 study in the RMP; this is a phase 3, randomised, placebo-controlled, parallel-group, multi-site, double-blind trial evaluating the safety, tolerability, pharmacokinetics (PK) and efficacy of a single infusion of bezlotoxumab in paediatric participants from 1 to <18 years of age receiving antibacterial drug treatment for Clostridioides difficile infection (CDI). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. A revised RMP version 3.0 has been approved. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 12.10.2023, 22.06.2023.

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.

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

5.2.1. CellCept - mycophenolate mofetil - EMEA/H/C/000082/II/0170/G

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: "C.I.6.a: Extension of indication to include paediatric patients (3 months to 18 years of age) for hepatic and cardiac transplants and to extend the indication for renal transplants for paediatric patients starting from 3 months, based on pharmacokinetic data, published literature and the Roche Global Safety Database. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.
Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets formulation in order to be in line with the other three CellCept formulations. And for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.
In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring the PI in line with the latest QRD template version 10.3."

Request for an extension to the clock stop to respond to the request for supplementary information adopted in September 2023.

Action: For adoption

Request for supplementary information adopted on 14.09.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in September 2023.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006372

next generation sequencing (NGS) assay for tumour mutation profiling

Scope: Request for supplementary information

Action: For adoption

Request for supplementary information adopted on 09.11.2023.

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

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

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006373

detection of PD-L1 protein

Scope: Opinion

Action: For adoption

Request for supplementary information adopted on 09.11.2023, 12.10.2023.

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

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

6.3.3. in vitro diagnostic medical device - EMEA/H/D/006341

detection of the anaplastic lymphoma kinase (ALK) protein

Scope: Request for supplementary information

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.

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. obecabtagene autoleucel – ATMP - H0005907

Obecabtagene autoleucel is indicated for the treatment of adult patients with relapsed or refractory B cell acute lymphoblastic leukaemia

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

Action: For adoption

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

8.1.2. Sipavibart - H0006291

Pre-exposure prophylaxis of COVID-19

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

Action: For adoption

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

8.1.3. lazertinib - H0006074

in combination with amivantamab is indicated for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations

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

Action: For adoption

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

8.1.4. Dorocubicel/Allogeneic umbilical cord-derived CD34- cells, non-expanded – PRIME - H0005772

Treatment of adult patients with haematological malignancies requiring an allogeneic haematopoietic stem cell transplantation who lack a readily available suitable donor

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.

The CHMP adopted the recommendations for PRIME eligibility.

The individual outcomes are listed in the PRIME Monthly Report on the EMA website, in the PRIME homepage, under Outcome of eligibility section.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Bimervax - COVID-19 vaccine - EMEA/H/C/006058/II/0004

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to add safety and immunogenicity information after a fourth dose based on interim results from study HIPRA-HH-2) listed as a category 3 study in the RMP; this is A Phase IIb, Double-Blind, Randomised, Active -Controlled, Multicentre, Non-Inferiority Trial Followed By A Phase III, Single-Arm, Open-Label Trial To Assess Immunogenicity And Safety Of A Booster Vaccination With A Recombinant Protein RBD Fusion Dimer Candidate (PHH-1V) Against SARS-COV-2 In Adults Fully Vaccinated Against Covid-19 Followed By An Extension Period To Study A Fourth Dose Administration Of PHH-1V. The Package Leaflet is updated accordingly. In addition, the MAH submitted the full user consultation with target patient groups."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023

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

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

9.1.2. Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan

GlaxoSmithKline (Ireland) Limited

Re-examination Rapporteur: Filip Josephson, Re-examination Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Renewal of conditional marketing authorisation, re-examination

Action: For adoption

Opinion adopted in September 2023. Request for Supplementary Information adopted on 26.04.2023.

An oral explanation was held on 12 December 2023. The presentation by the applicant focused on clinical aspects.

See 2.2

The CHMP adopted a negative opinion by consensus, recommending not to renew the conditional marketing authorisation in accordance with Article 6(3) of Regulation (EC) No 507/2006 for the above mentioned medicinal product.

The CHMP adopted the assessment report.

The EMA communication was circulated for information.

9.1.3. LUMYKRAS - Sotorasib - EMEA/H/C/005522/II/0010/G

Amgen Europe B.V.

Rapporteur: Alexandre Moreau

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

Action: For adoption

Request for Supplementary Information adopted on 25.05.2023.

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

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

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

PTC Therapeutics International Limited

Re-examination Rapporteurs

Scope: intervention by a third party; list of experts of the SAG, list of questions to the SAG

Action: For adopted

Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 25.05.2023.

The CHMP noted the interventions by third parties.

The CHMP adopted the list of experts for the SAG and a list of questions to this group.

9.1.5. Tremelimumab AstraZeneca - tremelimumab - EMEA/H/C/004650/II/0002

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia

Scope: "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the paediatric information based on final results from study D419EC00001; this is a Phase I/II, open-label, multicenter study to evaluate the safety, tolerability, and preliminary efficacy of durvalumab monotherapy or durvalumab in combination with tremelimumab in pediatric patients with advanced solid tumors and hematological malignancies."

Withdrawal of Type II variation procedure

Action: For information

The CHMP noted the withdrawal of the Type II variation procedure.

9.1.6. Clopidogrel BGR (SRD) – clopidogrel – EMEA/H/C/001138

Laboratoires BIOGARAN; prevention of atherothrombotic events

Rapporteur: Alexandre Moreau

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.7. Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0095

AstraZeneca AB

Rapporteur: Sol Ruiz

Scope: "Update of sections 4.1, 4.4 and 5.1 of the SmPC in order to update clinical information, following a critical evaluation of the benefit-risk profile of Vaxzevria against currently circulating variants of concern based on available data and structured benefit risk assessment."

Action: For adoption

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

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

9.1.8. Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP

Holostem Terapie Avanzate s.r.l.

Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Eamon O Murchu

Scope: Switch to standard MA

Action: For adoption

Request for Supplementary Information adopted on 06.10.2023.

The CHMP was updated on discussions at the CAT.

The CHMP adopted a positive opinion by consensus, supporting the switch to a standard MA.

The CHMP adopted the assessment report.

10. Referral procedures

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

10.1.1. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065

Orexigen Therapeutics Ireland Limited

Referral Rapporteur: Thalia Marie Estrup Blicher, Referral Co-Rapporteur: Daniela Philadelphy

Scope: List of outstanding issues, timetable

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Mysimba (naltrexone/bupropion), taking into account any consequences from the failure to comply with the obligations laid down in the marketing authorisation.
This review of all available data on the potential long-term cardiovascular risk and its impact on the benefit-risk balance of Mysimba in its approved indication was considered needed in view of the remaining concern and lack of adequate study plan to address the uncertainty about this risk.

The CHMP adopted a list of outstanding issues to the MAH with a procedural timetable.

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

CHMP list of outstanding issues: 14 December 2023

Submission of responses: 01 February 2024

Re-start of the procedure: 21 February 2024

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 28 February 2024

Scientific Advisory Group meeting: Date to be confirmed

Comments: 06 March 2024

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 12 March 2024

CHMP opinion: March, 2024 CHMP

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. Ibuprofen NVT – ibuprofen - EMEA/H/A-29(4)/1533

Laboratorios Liconsa, S.A.

Referral Rapporteur: Vilma Petrikaite, Referral Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: Appointment of rapporteurs, timetable

Action: For adoption

Mutual Recognition Procedure number: LT/H/0162/002/E/001, notification sent by the Agency of Lithuania dated 17 November 2023 notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC.

The CHMP appointed Vilma Petrikaite as referral rapporteur and Maria Concepcion Prieto Yerro as referral Co-Rapporteur.

The CHMP agreed on a rapporteur-led procedure (no list of questions) with a specific timetable.

Notification: 17 November 2023

Start of procedure (CHMP): December 2023 CHMP

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 11 January 2024

Comments: 16 January 2024

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 18 January 2024

CHMP list of questions/CHMP opinion: January 2024 CHMP

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

10.5.1. Havrix – Hepatitis A virus (inactivated, adsorbed) - EMEA/H/A-30/1527

GlaxoSmithKline Biologicals

Referral Rapporteur: Maria Grazia Evandri, Referral Co-Rapporteur: Lyubina Racheva

Scope: Revised timetable

Action: For adoption

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

The CHMP adopted the revised timetable.

CHMP list of questions: November 2023 CHMP

Submission of responses: 01 February 2024

Re-start of the procedure: 22 February 2024

Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 29 February 2024

Comments: 07 March 2024

Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 13 March 2024

CHMP list of outstanding issues or CHMP opinion: March 2024 CHMP

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

10.6.1. Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/1532

MAH various (NAPs only)

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: Update of timetable (extension of clock-stop)

Action: For adoption

Need to re-evaluate the benefit-risk ratio of the approved indications considering the current scientific knowledge, the increasing resistance rate, the consumption data suggesting overuse and the different indications in the EU Member States. Furthermore, the appropriate dose and duration of administration for both oral and intravenous formulations need to be discussed as well as the adequacy of safety relevant information, information on pregnancy and breastfeeding and pharmacological properties.
The German National Competent Authority triggered a referral under Article 31 of Directive 2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended, or revoked.

Two requests were received from MAHs to extend the submission deadline for responses.

The CHMP adopted the new timetable.

Start of the procedure (CHMP): November 2023 CHMP

List of questions: 9 November 2023

Submission of responses: 1 February 2024

Re-start of the procedure: 22 February 2022

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 4 April 2024

Comments: 11 April 2024

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 17 April 2024

CHMP list of outstanding issues / CHMP opinion: 25 April 2024 CHMP

10.6.2. Synapse Labs Pvt. Ltd. – various – EMEA/H/A-31/1529

MAH various

Referral Rapporteur: Maria Concepcion Prieto Yerro, Referral Co-Rapporteur: Janet Koenig

Scope: Opinion

Action: For adoption

Article 31 procedure triggered by the Agency of Medicines and Medical Devices (AEMPS) in Spain, concerning the contract research organisation (CRO) Synapse Labs Pvt. Ltd., located in Kharadi, Pune, India.

See 2.4

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

The CHMP adopted an opinion by consensus recommending the suspension of the marketing authorisations of medicinal products which bioequivalence data or justification were not submitted or considered insufficient by the CHMP to establish bioequivalence vis-à-vis the EU reference medicinal product/medicinal product referred in the scientific literature. In Member States where the medicinal product is considered critical, the suspension can be deferred for up to 24 months. The suspensions can be lifted once alternative data establishing bioequivalence are provided.

The CHMP also recommended that medicines that were being evaluated for authorisation for which bioequivalence data or justification were not submitted or considered insufficient to establish bioequivalence vis-à-vis the EU reference medicinal product do not currently satisfy the criteria for authorisation.

For some medicinal products the CHMP concluded that there was alternative data to establish bioequivalence vis-à-vis the EU reference medicinal product and recommended the maintenance of these marketing authorisations.

Bioequivalence vis-à-vis the EU reference medicinal product has been established for a marketing authorisation application.

The CHMP adopted the assessment report.

The EMA public health communication was circulated for information.

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

December 2023 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by proxy

No items

14.1.2. CHMP membership

The Chair welcomed Jana Klimasova as new alternate for Slovakia.

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 December 2023

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Agenda of the December 2023 PDCO plenary meeting

Action: For information

The CHMP noted the PDCO agenda.

14.2.3. Joint CHMP-CAT membership

Nomination by CHMP of joint members to CAT. According to the ATMP Regulation, CAT membership includes five members or co-opted members of the CHMP from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the CHMP, identified by the latter on the advice of the corresponding co-opted member. The mandates for the current joint CHMP-CAT memberships will expire on 17.12.2023.

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: Sean Barry, Vice-chair: Francesca Luciani

Reports from BWP December 2023 meeting to CHMP for adoption:

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

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Call for nomination of new members (BWP)

Following the resignation of two BWP members, a call for nomination of new members is being launched. Applications should be sent by 14 January 2024. The appointment of the new members will take place at the January 2024 CHMP plenary meeting.

Action: For information

The CHMP noted the call for nomination of new members.

14.3.3. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 14-15 November 2023.

Action: For adoption

The CHMP adopted the table of decisions.

14.3.4. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 27-30 November 2023. Table of conclusions

Action: For information

Scientific advice letters:

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

The CHMP noted the update.

14.3.5. Call for interest for nomination of a replacement SAWP member

Call for interest for nomination of a replacement SAWP member following departure of Nanna Borup Johansen.

Required areas of expertise: endocrinology/ diabetes/ metabolism, real-world evidence/ pharmacoepidemiology.

Applications should be sent by Thursday, 4 January 2024 EOB. The new SAWP member and his/her alternate starting date will immediately follow their nomination by the CHMP PROM (15 January 2024).

Action: For information

The CHMP noted the call for interest for nomination of a replacement SAWP member.

14.3.6. Nominations of PRAC and QRD representatives

Following recent departure of their current SmPC AG representative, PRAC and QRD have nominated new representatives.

Nomination(s) received

Action: For endorsement

The CHMP endorsed the new PRAC and QRD representatives.

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

14.7.1. CHMP Workplan 2024

CHMP: Harald Enzmann

Action: For adoption

The CHMP adopted the CHMP workplan for 2024.

14.8. Planning and reporting

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

Q4-23 forecast report, covering initial marketing authorisation application submissions in 2024 via the central procedure.

Action: For information

The CHMP noted the update.

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

The CHMP noted the information.

15. Any other business

15.1. AOB topic

No items

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 11-14 December 2023 CHMP meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	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	
Emilia Mavrokordatou	Alternate	Cyprus	No restrictions applicable to this meeting	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	concizumab - EMEA/H/C/005938
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	
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	
Beata Maria Jakline Ullrich	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	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	Fexinidazole Winthrop - fexinidazole - EMEA/H/W/002320 /II/0016
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Patrick Vrijlandt	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	
Grzegorz Cessak	Alternate	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
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No participation in discussion, final deliberations and voting on:	TAGRISSO - osimertinib - EMEA/H/C/004124 /II/0053 Sipavibart - H0006291 Tremelimumab AstraZeneca - tremelimumab - EMEA/H/C/004650 /II/0002 Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675 /II/0095
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	
Melanie Ramberger	Expert	Austria	No interests declared	
Susanne Urach	Expert	Austria	No interests declared	
Bojana Divkovic	Expert	Austria	No interests declared	
Maximilian Koblischke	Expert	Austria	No participation in discussion, final deliberations and voting on:	Edurant - rilpivirine EMEA/H/C/002264 /X/0042/G

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0021 lazertinib - H0006074
Thomas Lang	Expert	Austria	No interests declared	
Elisabeth Wischnitzki	Expert	Austria	No interests declared	
Lisa Nika	Expert	Austria	No restrictions applicable to this meeting	
Eva Malikova	Expert	Slovakia	No interests declared	
Yseult Brun	Expert	France	No interests declared	
Norontsoa Rasolondramanitra	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Attila Megyeri	Expert	Hungary	No interests declared	
Janne Komi	Expert	Finland	No restrictions applicable to this meeting	
Karri Penttilä	Expert	Finland	No interests declared	
John Aspegren	Expert	Finland	No restrictions applicable to this meeting	
Greta Budukevičiūtė	Expert	Lithuania	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No interests declared	
Agustín Portela	Expert	Spain	No interests declared	
Alfredo García-Arieta	Expert	Spain	No interests declared	
Danica Juričić Nahal	Expert	Croatia	No interests declared	
Lidija Prka	Expert	Croatia	No interests declared	
Heidi Mestl	Expert	Norway	No interests declared	
Anne Figenschou Soleng	Expert	Norway	No interests declared	
Ole Henrik Myrdal	Expert	Norway	No interests declared	
Kine Marita Knudsen Sand	Expert	Norway	No interests declared	
Gro Dahlseng Håkonsen	Expert	Norway	No interests declared	
Torunn Lisbeth Wangen	Expert	Norway	No interests declared	
Marianne Loeiten Dalhus	Expert	Norway	No interests declared	
Ingrid Lund	Expert	Norway	No interests declared	
Mária Kováčová	Expert	Czechia	No interests declared	
Lenka Králová	Expert	Czechia	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Alexandru-Mihail Simion	Expert	Belgium	No interests declared	
Martin Bronislaw Oleksewicz	Expert	Denmark	No restrictions applicable to this meeting	
Kristin Skougaard	Expert	Denmark	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Mogens Westergaard	Expert	Denmark	No interests declared	
Sine Buhl Næss-Schmidt	Expert	Denmark	No restrictions applicable to this meeting	
Céline Jumeau	Expert	France	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Cecile Dop	Expert	France	No interests declared	
Lieke Sandberg-Smits	Expert	Netherlands	No interests declared	
Sabine van der Putten-Brouwer	Expert	Netherlands	No restrictions applicable to this meeting	
Peter van de Ven	Expert	Netherlands	No participation in discussion, final deliberations and voting on:	Keytruda - pembrolizumab - EMEA/H/C/003820 /II/0134 Zinplava - bezlotoxumab - EMEA/H/C/004136 /II/0037 Arpraziquantel - arpraziquantel - Article 58 - EMEA/H/W/004252
			No participation in final deliberations and voting on:	Opdivo - nivolumab - EMEA/H/C/003985 /X/0132 Tremelimumab AstraZeneca - tremelimumab - EMEA/H/C/004650 /II/0002
Frank Holtkamp	Expert	Netherlands	No interests declared	
Adrian Post	Expert	Netherlands	No interests declared	
Illiana Meurs	Expert	Netherlands	No interests declared	
Sara Ambrosino	Expert	Netherlands	No restrictions applicable to this meeting	
Taina Mattila	Expert	Netherlands	No interests declared	
Nynke Brouwer	Expert	Netherlands	No interests declared	
Ira Koval	Expert	Netherlands	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Friederike Marei Feldmann	Expert	Germany	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Sofia Kapanadze	Expert	Germany	No restrictions applicable to this meeting	
Georgios Aislaitner	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Christine Greiner	Expert	Germany	No interests declared	
Gabriele Schlosser-Weber	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Susanna Hausmann	Expert	Germany	No interests declared	
Sylvia Kühn	Expert	Germany	No restrictions applicable to this meeting	
Katalina Mettke	Expert	Germany	No interests declared	
Torsten Stemmler	Expert	Germany	No interests declared	
Susanne Kaul	Expert	Germany	No interests declared	
Christina Reeb	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
Juliane Rau	Expert	Germany	No interests declared	
Samira Alina Marx	Expert	Germany	No interests declared	
Susanne Müller-Egert	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Joerg Zinserling	Expert	Germany	No interests declared	
Elina Rönnemaa	Expert	Sweden	No interests declared	
André Elferink	Expert	Netherlands	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Federico De Angelis	Expert	Italy	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with the help of EMA staff.				

Experts were evaluated against the agenda topics or activities they participated in.
Experts from international organisations or regulatory authorities in third countries cannot participate in the adoption of any procedural decision, scientific opinion or recommendation by the Committee at any step of the procedure.

Explanatory notes

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

Oral explanations *(section 2)*

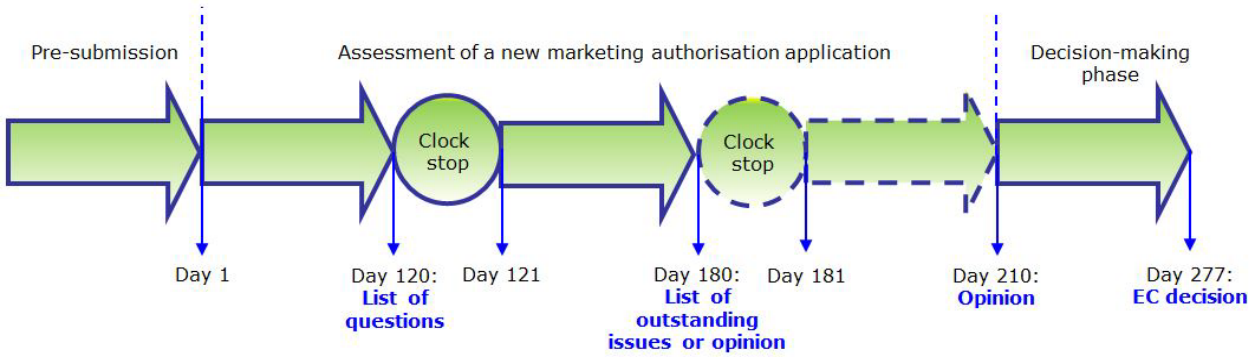
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 March 2024
EMA/CHMP/570453/2023

Annex to 11-14 December 2023 CHMP Minutes

Pre-submission and post-authorisations issues

A. PRE-SUBMISSION ISSUES 3
A.1. ELIGIBILITY REQUESTS 3
A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications 3
A.3. PRE-SUBMISSION ISSUES FOR INFORMATION 3

B. POST-AUTHORISATION PROCEDURES OUTCOMES 3
B.1. Annual re-assessment outcomes 3
B.1.1. Annual reassessment for products authorised under exceptional circumstances 3
B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES 4
B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal 4
B.2.2. Renewals of Marketing Authorisations for unlimited validity 4
B.2.3. Renewals of Conditional Marketing Authorisations 5
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES 6
B.4. EPARs / WPARs 11
B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES 12
B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects 12
B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects 21
B.5.3. CHMP-PRAC assessed procedures 38
B.5.4. PRAC assessed procedures 43
B.5.5. CHMP-CAT assessed procedures 49
B.5.6. CHMP-PRAC-CAT assessed procedures 50
B.5.7. PRAC assessed ATMP procedures 50
B.5.8. Unclassified procedures and worksharing procedures of type I variations 50
B.5.9. Information on withdrawn type II variation / WS procedure 53
B.5.10. Information on type II variation / WS procedure with revised timetable 54
B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION 54
B.6.1. Start of procedure for New Applications: timetables for information 54
B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information 54

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B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information 54
B.6.4. Annual Re-assessments: timetables for adoption 55
B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed 56
B.6.6. VARIATIONS – START OF THE PROCEDURE 57
B.6.7. Type II Variations scope of the Variations: Extension of indication 57
B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects 59
B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects 64
B.6.10. CHMP-PRAC assessed procedures 76
B.6.11. PRAC assessed procedures 81
B.6.12. CHMP-CAT assessed procedures 88
B.6.13. CHMP-PRAC-CAT assessed procedures 89
B.6.14. PRAC assessed ATMP procedures 89
B.6.15. Unclassified procedures and worksharing procedures of type I variations 89
B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY 91
B.7.1. Yearly Line listing for Type I and II variations 91
B.7.2. Monthly Line listing for Type I variations 91
B.7.3. Opinion on Marketing Authorisation transfer (MMD only) 91
B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only) 91
B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only) 91
B.7.6. Notifications of Type I Variations (MMD only) 91

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) 91

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) 91

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES 91
E.1. PMF Certification Dossiers 91
E.2. Time Tables – starting & ongoing procedures: For information 91

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver 91

G. ANNEX G 91
G.1. Final Scientific Advice (Reports and Scientific Advice letters): 91
G.2. PRIME 92

H. ANNEX H - Product Shared Mailboxes – e-mail address 92

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for December 2023: **For adoption**	Adopted

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Information related to pre-submission of initial applications cannot be released at the present time as these contain commercially confidential information.

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Brineura - Cerliponase alfa - EMEA/H/C/004065/S/0042, Orphan BioMarin International Limited, Rapporteur: Martina Weise, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Mari Thorn	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) - EMEA/H/C/002596/S/0095 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Increlex - Mecasermin - EMEA/H/C/000704/S/0081 Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Lojuxta - Lomitapide - EMEA/H/C/002578/S/0057 Amryt Pharmaceuticals DAC, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 14.12.2023.	
Strensiq - Asfotase alfa - EMEA/H/C/003794/S/0066, Orphan Alexion Europe SAS, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Rhea Fitzgerald	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/S/0017, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Maura O'Donovan, CHMP Coordinator: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 08.12.2023.	Request for supplementary information adopted with a specific timetable.
Vyndaqel - Tafamidis - EMEA/H/C/002294/S/0090, Orphan Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Tiphaine Vaillant	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Ambrisentan Mylan - Ambrisentan - EMEA/H/C/004985/R/0009 Mylan Pharmaceuticals Limited, Generic, Generic of Volibris, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Maria del Pilar Rayon Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Doptelet - Avatrombopag - EMEA/H/C/004722/R/0018 Swedish Orphan Biovitrum AB (publ), Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Monica Martinez Redondo	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/R/0022 Novo Nordisk A/S, Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Gabriele Maurer	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that

	the renewal of the marketing authorisation can be granted with unlimited validity.
Grasustek - Pegfilgrastim - EMEA/H/C/004556/R/0014 Juta Pharma GmbH, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.

B.2.3. Renewals of Conditional Marketing Authorisations

Blenrep - Belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan GlaxoSmithKline (Ireland) Limited Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 26.04.2023.	Re-examination Negative opinion adopted by consensus together with the CHMP assessment report. See 2.1 and 9.1
Deltyba - Delamanid - EMEA/H/C/002552/R/0070, Orphan Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Jo Robays	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Concetta Quintarelli, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Eamon O Murchu Request for Supplementary Information adopted on 06.10.2023.	The CHMP adopted a positive opinion supporting the switch to full MA. See 9.1
JEMPERLI - Dostarlimab - EMEA/H/C/005204/R/0026 GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ana Sofia Diniz Martins	Withdrawn, following the switch to full marketing authorisation within variation II-23.
Natpar - Parathyroid hormone - EMEA/H/C/003861/R/0054, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Beata Maria Jakline	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.

Ullrich, PRAC Rapporteur: Rhea Fitzgerald	The Marketing Authorisation remains conditional.
Pemazyre - Pemigatinib - EMEA/H/C/005266/R/0013, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
WAYLIVRA - Volanesorsen - EMEA/H/C/004538/R/0026, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 27-30 November 2023 PRAC:	
Signal of drug reaction with eosinophilia and systemic symptoms (DRESS) Pirfenidone – Esbriet, Pirfenidone Axumio, Pirfenidone Viatris (CAP) Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Rhea Fitzgerald PRAC recommendation on a variation **Action:** For adoption	Adopted
Signal of progressive multifocal leukoencephalopathy (PML) Axicabtagene Ciloleucel – Yescarta (CAP) Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Karin Ernholm PRAC recommendation on a variation **Action:** For adoption	Adopted

Signal of peripheral neuropathy Dabrafenib, Trametinib – Tafinlar, Mekinist (CAP) Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: David Olsen PRAC recommendation on a variation **Action:** For adoption	Adopted
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its December 2023 meeting:	
EMEA/H/C/PSUSA/00001210/202304 (emtricitabine / tenofovir disoproxil) CAPS: **Truvada** (EMEA/H/C/000594) (Emtricitabine / Tenofovir disoproxil), Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, "01/04/2020 To: 01/04/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following changes: Update of section 4.4 of the SmPC to amend a warning/precaution regarding Bone effects. Update of section 4.8 of the SmPC to add the adverse reaction bone mineral density decreased with a frequency common. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00001363/202304 (fenofibrate / pravastatin) CAPS: **Pravafenix** (EMEA/H/C/001243) (Fenofibrate / Pravastatin sodium), Laboratoires SMB s.a., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault, "14/04/2021 To: 14/04/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction muscle rupture with a frequency "not known". The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00002314/202303 (parecoxib) CAPS: **Dynastat** (EMEA/H/C/000381) (Parecoxib), Pfizer Europe MA EEIG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Rhea Fitzgerald, "01/04/2022 To: 31/03/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.6 of the SmPC to amend the available data on use during pregnancy, based on the PRAC advice for non-steroidal anti-inflammatory drugs (NSAID)-containing medicinal products (EMA/CMDh/642745/2022). The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00002840/202303 (tacrolimus (topical formulations)) CAPS: **Protopic** (EMEA/H/C/000374) (Tacrolimus), LEO Pharma A/S, Rapporteur: Finbarr Leacy NAPS: **NAPs** - EU PRAC Rapporteur: Rhea Fitzgerald, "01/04/2021 To: 31/03/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance, concerning the following change(s): Update of section 4.4 of the SmPC to amend the warning/precaution recommending against use in patients with a skin barrier defect. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00002892/202303 (tenofovir disoproxil) CAPS: **Viread** (EMEA/H/C/000419) (Tenofovir disoproxil), Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault, "01/04/2020 To: 31/03/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following changes: Update of section 4.4 of the SmPC to amend a warning/precaution regarding Bone effects. Update of section 4.8 of the SmPC to add the adverse reaction bone mineral density decreased with a frequency common. The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00010213/202304 (delamanid) CAPS: **Deltyba** (EMEA/H/C/002552) (Delamanid), Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Jo Robays, "26/10/2022 To: 26/04/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above-mentioned medicinal product, concerning the following changes: Update of sections 4.4 and 4.8 of the SmPC to add a warning and the adverse reaction 'Paradoxical drug reaction' with a frequency 'not known', respectively, and update of section 4.8 of the SmPC to add 'Nightmare', with specific information for the paediatric population. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010644/202305 (atezolizumab) CAPS: **Tecentriq** (EMEA/H/C/004143) (Atezolizumab), Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, "17/05/2022 To: 17/05/2023"	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 the risk of immune-related adverse reactions in patients with pre-existing autoimmune disease. The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00010723/202304 (durvalumab) CAPS: **Imfinzi** (EMEA/H/C/004771) (Durvalumab), AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen, "01/05/2022 To: 30/04/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.2, 4.4 and 4.8 of the SmPC to add the adverse reactions of 'uveitis' and 'arthritis', a warning/precaution regarding these adverse reactions, and recommendations for treatment modifications when these adverse reactions occur. The package leaflet is updated accordingly. Update of section 4.4. of the SmPC to add a warning regarding patients with pre-existing autoimmune disease.
EMEA/H/C/PSUSA/00010868/202304 (ivacaftor / tezacaftor / elexacaftor) CAPS: **Kaftrio** (EMEA/H/C/005269) (Ivacaftor / Tezacaftor / Elexacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "21/10/2022 To: 20/04/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.6 of the SmPC to amend the wording regarding breast-feeding. The package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00011035/202305 (SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant) CAPS: **VidPrevtyn Beta** (EMEA/H/C/005754) (SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant), Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jana Lukacisinova, "09/11/2022 To: 09/05/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above-mentioned medicinal product, concerning the following change: Update of section 4.8 of the SmPC to add the adverse reaction dizziness with a frequency rare. The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00011038/202304 (tremelimumab) CAPS: **IMJUDO** (EMEA/H/C/006016) (Tremelimumab), AstraZeneca AB, Rapporteur: Aaron Sosa Mejia **Tremelimumab AstraZeneca (SRD)** (EMEA/H/C/004650) (Tremelimumab), AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen, "21/10/2022 To: 20/04/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.2, 4.4 and 4.8 of the SmPC to add the adverse reactions of 'uveitis' and 'arthritis', a warning/precaution regarding these ADRs, and recommendations for treatment modifications when these ADRs occur. The package leaflet is updated accordingly.

B.4. EPARs / WPARs

Azacitidine Kabi - Azacitidine - EMEA/H/C/006154 Fresenius Kabi Deutschland GmbH, Treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and acute myeloid leukemia (AML), Generic, Generic of Vidaza, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Krazati - Adagrasib - EMEA/H/C/006013 Mirati Therapeutics B.V., treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation, 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.
Naveruclif - Paclitaxel - EMEA/H/C/006173 Accord Healthcare S.L.U., treatment of metastatic breast cancer, Generic, Generic of Abraxane, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Omjjara - Momelotinib - EMEA/H/C/005768, Orphan Glaxosmithkline Trading Services Limited, treatment of disease-related splenomegaly or symptoms and anaemia, 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.
Rimmyrah - Ranibizumab - EMEA/H/C/006055 QILU PHARMA SPAIN S.L., treatment of neovascular age-related macular degeneration	For information only. Comments can be sent to the PL in case necessary.

(AMD), Similar biological application (Article 10(4) of Directive No 2001/83/EC)	
Rystiggo - Rozanolixizumab - EMEA/H/C/005824, Orphan UCB Pharma, Treatment of generalised myasthenia gravis (gMG), 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.
Spexotras - Trametinib - EMEA/H/C/005886, Orphan Novartis Europharm Limited, treatment of paediatric patients aged 1 year and older with glioma, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Uzpruvo - Ustekinumab - EMEA/H/C/006101 STADA Arzneimittel AG, treatment of plaque psoriasis, arthritis psoriatic, Crohn's Disease and ulcerative colitis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Abiraterone Krka - Abiraterone acetate - EMEA/H/C/005649/II/0004 KRKA, d.d., Novo mesto, Generic, Generic of Zytiga, Rapporteur: Andreja Kranjc Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0001 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Adjupanrix - Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) - EMEA/H/C/001206/II/0086/G GlaxoSmithkline Biologicals SA, Informed Consent of Pandemrix (EXP), Rapporteur: Patrick Vrijlandt Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.

Request for Supplementary Information adopted on 26.10.2023.	
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0005/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Opinion adopted on 23.11.2023. Request for Supplementary Information adopted on 28.09.2023.	Positive Opinion adopted by consensus on 23.11.2023.
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0007/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Request for Supplementary Information adopted on 16.11.2023, 05.10.2023.	Request for supplementary information adopted with a specific timetable.
Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0023/G UCB Pharma S.A., Rapporteur: Finbarr Leacy Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Briumvi - Ublituximab - EMEA/H/C/005914/II/0003 Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra Opinion adopted on 07.12.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Cerezyme - Imiglucerase - EMEA/H/C/000157/II/0131 Sanofi B.V., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0192 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Cosentyx - Secukinumab - EMEA/H/C/003729/II/0107 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023.	Positive Opinion adopted by consensus on 14.12.2023.

CRYSVITA - Burosumab - EMEA/H/C/004275/II/0035/G, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 06.07.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Darunavir Mylan - Darunavir - EMEA/H/C/004068/II/0021 Mylan Pharmaceuticals Limited, Generic, Generic of Prezista, Rapporteur: John Joseph Borg Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 30.11.2023.
DaTSCAN - Ioflupane (123I) - EMEA/H/C/000266/II/0066/G GE Healthcare B.V., Rapporteur: Alexandre Moreau Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 12.10.2023.	Positive Opinion adopted by consensus on 16.11.2023.
Diacomit - Stiripentol - EMEA/H/C/000664/II/0045/G BIOCODEX, Rapporteur: Alar Irs Request for Supplementary Information adopted on 23.11.2023.	Request for supplementary information adopted with a specific timetable.
Elaprase - Idursulfase - EMEA/H/C/000700/II/0109 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 14.12.2023, 31.08.2023, 25.05.2023.	Request for supplementary information adopted with a specific timetable.
Entyvio - Vedolizumab - EMEA/H/C/002782/II/0079/G Takeda Pharma A/S, Rapporteur: Paolo Gasparini Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0041 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 14.12.2023. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 14.12.2023.

on 09.11.2023.	
Ibandronic Acid Teva - Ibandronic acid - EMEA/H/C/001195/II/0021 Teva B.V., Generic, Generic of Bondronat, Bonviva, Rapporteur: Hrefna Gudmundsdottir Request for Supplementary Information adopted on 16.11.2023.	Request for supplementary information adopted with a specific timetable.
Ilumetri - Tildrakizumab - EMEA/H/C/004514/II/0052 Almirall S.A, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Kalydeco - Ivacaftor - EMEA/H/C/002494/II/0120/G Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0143 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Opinion adopted on 07.12.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0144 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Lacosamide Accord - Lacosamide - EMEA/H/C/004443/II/0023/G Accord Healthcare S.L.U., Generic, Generic of Vimpat, Rapporteur: John Joseph Borg Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 05.10.2023.	Positive Opinion adopted by consensus on 14.12.2023.
LIVMARLI - Maralixibat - EMEA/H/C/005857/II/0008/G, Orphan Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise Request for Supplementary Information adopted on 07.12.2023.	Request for supplementary information adopted with a specific timetable.
MINJUVI - Tafasitamab - EMEA/H/C/005436/II/0012/G, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.

Request for Supplementary Information adopted on 05.10.2023.	
Nepexto - Etanercept - EMEA/H/C/004711/II/0024 Biosimilar Collaborations Ireland Limited, Rapporteur: Martina Weise Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023, 07.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0066 MediWound Germany GmbH, Rapporteur: Janet Koenig Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Nuceiva - Botulinum toxin type A - EMEA/H/C/004587/II/0029 Evolus Pharma B.V., Rapporteur: Finbarr Leacy Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Omnitrope - Somatropin - EMEA/H/C/000607/II/0076 Sandoz GmbH, Rapporteur: Patrick Vrijlandt Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Opzelura - Ruxolitinib - EMEA/H/C/005843/II/0002/G Incyte Biosciences Distribution B.V., Rapporteur: Peter Mol Request for Supplementary Information adopted on 30.11.2023, 31.08.2023.	Request for supplementary information adopted with a specific timetable.
Orencia - Abatacept - EMEA/H/C/000701/II/0161/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 12.10.2023.	Positive Opinion adopted by consensus on 16.11.2023.
Orgalutran - Ganirelix - EMEA/H/C/000274/II/0057/G Organon N.V., Rapporteur: Outi Mäki-Ikola Opinion adopted on 23.11.2023.	Positive Opinion adopted by consensus on 23.11.2023.
Ovaleap - Follitropin alfa - EMEA/H/C/002608/II/0039	Request for supplementary information adopted with a specific timetable.

Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 07.12.2023.	
Ovitrelle - Choriogonadotropin alfa - EMEA/H/C/000320/II/0089 Merck Europe B.V., Rapporteur: Patrick Vrijlandt Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 05.10.2023.	Positive Opinion adopted by consensus on 16.11.2023.
Pluvicto - Lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483/II/0010 Novartis Europharm Limited, Rapporteur: Janet Koenig Opinion adopted on 07.12.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Polivy - Polatuzumab vedotin - EMEA/H/C/004870/II/0026, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 16.11.2023.	Request for supplementary information adopted with a specific timetable.
Praluent - Alirocumab - EMEA/H/C/003882/II/0081 Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 13.07.2023.	Positive Opinion adopted by consensus on 16.11.2023.
Pyrukynd - Mitapivat - EMEA/H/C/005540/II/0003/G, Orphan Agios Netherlands B.V., Rapporteur: Alexandre Moreau Opinion adopted on 07.12.2023. Request for Supplementary Information adopted on 26.10.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Ryeqo - Relugolix / Estradiol / Norethisterone acetate - EMEA/H/C/005267/II/0019/G Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Opinion adopted on 07.12.2023. Request for Supplementary Information adopted on 28.09.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Ryeqo - Relugolix / Estradiol / Norethisterone acetate - EMEA/H/C/005267/II/0020/G Gedeon Richter Plc., Rapporteur: Patrick	Positive Opinion adopted by consensus on 07.12.2023.

Vrijlandt Opinion adopted on 07.12.2023. Request for Supplementary Information adopted on 28.09.2023.	
Ryzodeg - Insulin aspart / Insulin degludec - EMEA/H/C/002499/II/0054 Novo Nordisk A/S, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0069 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke Opinion adopted on 16.11.2023.	Positive Opinion adopted by consensus on 16.11.2023.
Soliris - Eculizumab - EMEA/H/C/000791/II/0128/G, Orphan Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez Opinion adopted on 07.12.2023. Request for Supplementary Information adopted on 19.10.2023, 31.08.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0116/G Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Suliqua - Insulin glargine / Lixisenatide - EMEA/H/C/004243/II/0037/G Sanofi Winthrop Industrie, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Surgiflo Haemostatic Matrix Kit - Human thrombin - EMEA/H/D/002301/II/0036/G Ferrosan Medical Devices A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0125/G Corza Medical GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 14.12.2023.	
Toujeo - Insulin glargine - EMEA/H/C/000309/II/0127/G Sanofi-Aventis Deutschland GmbH, Duplicate, Duplicate of Lantus, Rapporteur: Patrick Vrijlandt Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Tresiba - Insulin degludec - EMEA/H/C/002498/II/0060 Novo Nordisk A/S, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0029 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0050/G Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0131 MCM Vaccine B.V., Rapporteur: Christophe Focke Opinion adopted on 23.11.2023. Request for Supplementary Information adopted on 28.09.2023.	Positive Opinion adopted by consensus on 23.11.2023.
Xeljanz - Tofacitinib - EMEA/H/C/004214/II/0053/G Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 30.11.2023.
XGEVA - Denosumab - EMEA/H/C/002173/II/0082/G Amgen Europe B.V., Rapporteur: Kristina	Request for supplementary information adopted with a specific timetable.

Dunder Request for Supplementary Information adopted on 14.12.2023, 19.10.2023.	
Xofigo - Radium-223 - EMEA/H/C/002653/II/0053 Bayer AG, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Yselty - Linzagolix choline - EMEA/H/C/005442/II/0009 Theramex Ireland Limited, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Zaltrap - Aflibercept - EMEA/H/C/002532/II/0069/G Sanofi Winthrop Industrie, Rapporteur: Filip Josephson Opinion adopted on 07.12.2023. Request for Supplementary Information adopted on 19.10.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Zejula - Niraparib - EMEA/H/C/004249/II/0046/G, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Ziextenzo - Pegfilgrastim - EMEA/H/C/004802/II/0030/G Sandoz GmbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 23.11.2023.	Request for supplementary information adopted with a specific timetable.
WS2362 **Edistride-** **EMEA/H/C/004161/WS2362/0057** **Forxiga-** **EMEA/H/C/002322/WS2362/0078** AstraZeneca AB, Lead Rapporteur: Kristina Dunder Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 19.01.2023.	Positive Opinion adopted by consensus on 14.12.2023.
WS2507 **Bondronat-** **EMEA/H/C/000101/WS2507/0092** **Bonviva-** **EMEA/H/C/000501/WS2507/0076**	Positive Opinion adopted by consensus on 23.11.2023.

Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 23.11.2023. Request for Supplementary Information adopted on 07.09.2023, 06.07.2023.	
WS2525/G **Hexacima-** **EMEA/H/C/002702/WS2525/0151/G** **Hexyon-** **EMEA/H/C/002796/WS2525/0155/G** **MenQuadfi-** **EMEA/H/C/005084/WS2525/0025/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 07.09.2023.	Positive Opinion adopted by consensus on 16.11.2023.
WS2574 **Nilemdo-** **EMEA/H/C/004958/WS2574/0033** **Nustendi-** **EMEA/H/C/004959/WS2574/0037** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 16.11.2023.	Request for supplementary information adopted with a specific timetable.
WS2575 **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-** **EMEA/H/W/005362/WS2575/0009** **Qdenga-** **EMEA/H/C/005155/WS2575/0010** Takeda GmbH, Lead Rapporteur: Sol Ruiz Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.

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

Alkindi - Hydrocortisone - **EMEA/H/C/004416/II/0019** Diurnal Europe BV, Rapporteur: Karin Janssen van Doorn, "Update of section 4.2 of the SmPC in order to update posology recommendations in case of incomplete dosing, following the request by PRAC in the AR for procedure PSUSA/00010674/202208; the Package Leaflet is updated accordingly." Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Ameluz - 5-aminolevulinic acid -	Positive Opinion adopted by consensus on

EMEA/H/C/002204/II/0055 Biofrontera Bioscience GmbH, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4, 4.5, 4.8, 5.1 and 6.6 of the SmPC in order to include artificial daylight lamps as an additional light source for photodynamic therapy in combination with Ameluz for the treatment of actinic keratoses based on final results from non-clinical study PT-0042-A and literature (investigator-initiator trials). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 12.10.2023, 25.05.2023.	14.12.2023.
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0004 Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Update of sections 4.8 and 5.1 of the SmPC in order to add safety and immunogenicity information after a fourth dose based on interim results from study HIPRA-HH-2) listed as a category 3 study in the RMP; this is A Phase IIb, Double-Blind, Randomised, Active-Controlled, Multicentre, Non-Inferiority Trial Followed By A Phase III, Single-Arm, Open-Label Trial To Assess Immunogenicity And Safety Of A Booster Vaccination With A Recombinant Protein RBD Fusion Dimer Candidate (PHH-1V) Against SARS-COV-2 In Adults Fully Vaccinated Against Covid-19 Followed By An Extension Period To Study A Fourth Dose Administration Of PHH-1V. The Package Leaflet is updated accordingly. In addition, the MAH submitted the full user consultation with target patient groups." Request for Supplementary Information adopted on 14.12.2023, 14.09.2023.	Request for supplementary information adopted with a specific timetable. See 9.1
BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0006 Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final report from study HAN-01 listed as a category 3 study in the RMP (MEA/006). This is a phase	Request for supplementary information adopted with a specific timetable.

IIb, randomised, controlled, observer-blinded study to evaluate safety and immunogenicity of a recombinant protein RBD fusion dimer candidate vaccine against SARS-CoV-2 in adult healthy volunteers." Request for Supplementary Information adopted on 16.11.2023, 28.09.2023.	
Braftovi - Encorafenib - EMEA/H/C/004580/II/0031 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information on effect of encorafenib in combination with binimetinib on the single oral dose PK of specific CYP isozymes substrates, and effect of multiple doses of modafinil, a moderate CYP3A4 inducer, on the multiple oral dose PK of encorafenib administered with binimetinib based on final results from arm 1 and 3 of clinical study ARRAY-818-103/C4221003 (REC). ARRAY-818-103/ C4221003 study is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 21.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Drovelis - Drospirenone / Estetrol - EMEA/H/C/005336/II/0021 Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label, parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in subjects with varying degrees of hepatic function." Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Dupixent - Dupilumab - EMEA/H/C/004390/II/0078 Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2 of the SmPC in order to allow the use of the Dupixent Prefilled Pen presentations for patients aged 2	Request for supplementary information adopted with a specific timetable.

to < 12 years of age based on final results of the R668-AD-1434 sub-study; this is an interventional open-label sub-study which purpose is to evaluate the PK, safety, immunogenicity, and efficacy of repeat doses of dupilumab (200 mg Q4W, 300 mg Q4W, and 200 mg Q2W) administered SC using a PFP with a skin pinch in children ≥2 to <12 years of age. The Package Leaflet is updated accordingly. In addition, the MA took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 14.12.2023.	
Epidyolex - Cannabidiol - EMEA/H/C/004675/II/0028/G, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Grouped application comprising three type II variations (C.I.13) as follows: - Submission of the final report from study GWTX21068 – Genotoxicity study with 7-OH-CBD (Bacterial Reverse Mutation Assay). The objective of this study was to evaluate the ability of GWP4200370 (also known as 7-COOH-CBD) to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolizing system (S-9). - Submission of the final report from study GWTX21028 – Genotoxicity study with 7-COOH-CBD (Bacterial Reverse Mutation Assay). The objective of this study was to evaluate the ability of GWP4200307 to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolizing system (S-9). - Submission of the final report from GWTX18015 – Genotoxicity study with 7-COOH-CBD (Rat Micronucleus and Alkaline Comet Assay). The objective of this study was to evaluate the ability of GWP4200370 (also known as 7-COOH-CBD) to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolizing system (S-9)." Request for Supplementary Information adopted on 23.11.2023.	Request for supplementary information adopted with a specific timetable.

Epidyolex - Cannabidiol - EMEA/H/C/004675/II/0029, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Submission of the final report from study GWCP18055. This is a randomized, double-blind, placebo- and positive-controlled, parallel group trial to investigate the effects of multiple therapeutic and supratherapeutic doses of cannabidiol (GWP42003-P) in the fed state on the QT/QTc interval in healthy subjects." Opinion adopted on 23.11.2023.	Positive Opinion adopted by consensus on 23.11.2023.
Ervebo - Recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0034 Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, "Update of section 5.1 of the SmPC in order to update long-term of immunogenicity information and safety results based on final results from study V920-009 (Partnership for Research on Ebola Vaccines in Liberia). In addition, the MAH took the opportunity to implement editorial changes to the SmPC." Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Evrysdi - Risdiplam - EMEA/H/C/005145/II/0017 Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC in order to add information on cardiac electrophysiology based on final results from study BP42817 (QTc study), listed as a category 3 PASS in the RMP. This is a Phase 1, double-blind, placebo and positive controlled crossover study to investigate the effects of risdiplam on QTc interval in healthy subjects." Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Evrysdi - Risdiplam - EMEA/H/C/005145/II/0018 Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of section 5.3 of the SmPC in order to update carcinogenicity information based on final results from study 8447237. This is a 104 Week Oral (Gavage) Administration Carcinogenicity Study in the Wistar Rat to investigate the tumorigenic potential of Evrysdi. In addition, the MAH took the opportunity to update the list of local representatives in the	Positive Opinion adopted by consensus on 07.12.2023.

Package Leaflet." Opinion adopted on 07.12.2023.	
Fetcroja - Cefiderocol - EMEA/H/C/004829/II/0017 Shionogi B.V., Rapporteur: Filip Josephson, "Update of sections 4.5 and 5.2 of the SmPC in order to update drug-drug interaction information with CYP3A4 based on final results from study 2136R2118; this is a Phase 1, open-label, 1-sequence crossover, drug-drug interaction study to assess the effect of repeated doses of cefiderocol on the pharmacokinetics of midazolam in healthy adult participants." Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Filsuvez - Birch bark extract - EMEA/H/C/005035/II/0006, Orphan Amryt Pharmaceuticals DAC, Rapporteur: Kristina Dunder, "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study EASE (BEB-13); this is a double-blind, randomised, placebo (vehicle) controlled trial to evaluate efficacy and safety of birch bark extract on top of standard of care in children from birth to less than 18 years of age (and adults) with epidermolysis bullosa. In addition, the MAH took the opportunity to introduce minor changes to the PI." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 12.10.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Inrebic - Fedratinib - EMEA/H/C/005026/II/0017, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.5 of the SmPC in order to update drug-drug interaction information with dual inhibitors of CYP3A4 and CYP2C19, based on final results from study FEDR-CP-004; this is a phase 1, open-label study to evaluate the effect of a dual CYP2C19 and CYP3A4 inhibitor, fluconazole, on the pharmacokinetics of fedratinib in healthy adult subjects." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 05.10.2023, 31.08.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Kesimpta - Ofatumumab -	Request for supplementary information adopted

EMEA/H/C/005410/II/0013/G Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application consisting of: Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on injection-related reactions and to add 'Hypersensitivity reactions' to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. Type IB (C.I.z): Addition of a statement in the pre-filled syringes (PFS) instructions for use when PFS has been dropped on a hard surface. Type IA (A.6): To change the ATC Code of ofatumumab from L04AA52 to L04AG12. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 14.12.2023.	with a specific timetable.
Kyprolis - Carfilzomib - EMEA/H/C/003790/II/0058, Orphan Amgen Europe B.V., Rapporteur: Carolina Prieto Fernandez, "Submission of the final report from study 20160275 (CANDOR). This is a randomized, open-label, Phase 3 study comparing carfilzomib, dexamethasone, and daratumumab to carfilzomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 14.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
LIVTENCITY - Maribavir - EMEA/H/C/005787/II/0008, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, "Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on the updated Population PK analysis data. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 16.11.2023.	Request for supplementary information adopted with a specific timetable.
Lokelma - Sodium zirconium cyclosilicate - EMEA/H/C/004029/II/0033 AstraZeneca AB, Rapporteur: Larisa Gorobets, "Update of section 4.8 of the SmPC to include information on constipation to the summary of	Positive Opinion adopted by consensus on 14.12.2023.

safety profile and to add constipation to the list of adverse drug reactions (ADRs) with frequency Common based on literature review and MAH safety database. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 07.09.2023.	
Lupkynis - Voclosporin - EMEA/H/C/005256/II/0010 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, "Submission of the final study report from AUR-VCS-2016-02 (AURORA 2) Kidney Biopsy Substudy, listed as a category 3 study in the RMP. The AURORA 2 extension trial included an optional biopsy substudy which was designed to assess renal histology from tissue samples taken prior to and after approximately 18 months of randomized treatment with voclosporin or placebo." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 14.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0021 Estetra SRL, Duplicate, Duplicate of Drovelis, Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label, parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in subjects with varying degrees of hepatic function." Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Mayzent - Siponimod - EMEA/H/C/004712/II/0023 Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to present data on the effect of siponimod on delaying the progression to EDSS ≥7 (time-to-wheelchair) based on post-hoc analysis of study CBAF312A2304 (EXPAND)."	Positive Opinion adopted by consensus on 30.11.2023.

Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 14.09.2023.	
Mektovi - Binimetinib - EMEA/H/C/004579/II/0027 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of the final report from study ARRAY 818-103 on Arms 1 and 3. This is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours, to assess drug-drug interactions between encorafenib + binimetinib combination and midazolam (CYP3A4 substrate), caffeine (CYP1A2 substrate), omeprazole (CYP2C19 substrate), losartan (CYP2C9 substrate), dextromethorphan (CYP2D6 substrate) and modafinil (moderate CYP3A4 inducer)." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 21.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Nexviadyme - Avalglucosidase alfa - EMEA/H/C/005501/II/0008 Sanofi B.V., Rapporteur: Christian Gartner, "Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update the list of adverse drug reactions (ADRs) and to update the safety and efficacy information, based on interim results from the open-label extension period of study EFC14028 as well as pooled safety and immunogenicity data. EFC14028 is a phase 3 randomized, multicenter, multinational, double-blinded study comparing the efficacy and safety of repeated biweekly infusions of avalglucosidase alfa and alglucosidase alfa in treatment naïve patients with late-onset Pompe disease. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 14.09.2023, 08.06.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Nexviadyme - Avalglucosidase alfa - EMEA/H/C/005501/II/0012 Sanofi B.V., Rapporteur: Christian Gartner, "Submission of the final report from study LTS13769 listed as a category 3 study in the	Positive Opinion adopted by consensus on 16.11.2023.

RMP. This is an interventional, open-label, multicenter, multinational extension study to evaluate long-term safety and pharmacokinetics of repeated biweekly infusions of avalglucosidase alfa in patients with Pompe disease." Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 31.08.2023.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0049/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Grouped application comprising two type II variations (C.I.4) as follows: - Update of sections 4.4 and 4.8 of the SmPC in order to clarify that toxic epidermal necrolysis has been reported with Paxlovid and to add toxic epidermal necrolysis to the list of adverse drug reactions (ADRs) with frequency Rare based on the cumulative review of MAH safety database and literature. - Update of sections 4.4 and 4.8 of the SmPC in order to clarify that Stevens-Johnson syndrome has been reported with Paxlovid and to add Stevens-Johnson syndrome to the list of adverse drug reactions (ADRs) with frequency Rare, based on the cumulative review of MAH safety database and literature. The Package Leaflet is updated accordingly." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023.	Positive Opinion adopted by consensus on 14.12.2023.
RAYVOW - Lasmiditan - EMEA/H/C/005332/II/0004 Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with dabigatran and rosuvastatin based on the results from study LAIO, An Open-Label, 2-Part Study to Investigate the Effect of Lasmiditan on the Pharmacokinetics of Dabigatran and Rosuvastatin in Healthy Volunteers. The aim of study LAIO was to investigate the effect of lasmiditan on the pharmacokinetic profiles of dabigatran (a P-glycoprotein substrate) and rosuvastatin (breast cancer resistance protein substrate) in healthy volunteers. The Package Leaflet is updated accordingly. In addition, the MAH took the	Positive Opinion adopted by consensus on 14.12.2023.

opportunity to introduce minor editorial changes to the PI." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023.	
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0045 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Submission of the final report from study M15-555, listed as a category 3 study in the RMP. This is phase 3, randomized, double-blind study comparing upadacitinib (ABT-494) monotherapy to methotrexate (MTX) in subjects with moderately to severely active rheumatoid arthritis with inadequate response to MTX." Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Scemblix - Asciminib - EMEA/H/C/005605/II/0008, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add interaction information between asciminib and OATP1B and BCRP substrates, based on results from three PBPK simulation reports: DMPK-R2001088, DMPK-R2270328 and DMPK-R2300226. The Package Leaflet is updated accordingly." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 21.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Skilarence - Dimethyl fumarate - EMEA/H/C/002157/II/0034 Almirall S.A, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update long-term efficacy and safety information based on final results from study M-41008-41 (Dimeskin 1); this is a phase IV non-randomised, non-interventional, open label study in adult patients with moderate to severe chronic plaque psoriasis to further assess long-term (12 months) efficacy and safety of Skilarence in routine daily practice in Spain." Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0114/G	Positive Opinion adopted by consensus on 14.12.2023.

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, "Grouped application consisting of: C.I.4 (Type II): Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC to update the safety information regarding the administration of Spikevax to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, based on updated clinical literature and internal data; the Package Leaflet is updated accordingly. C.I.Z (Type IB): To update section 6.6 of the SmPC in order to clarify the handling instructions for the pre-filled syringes; the Package Leaflet is updated accordingly." Opinion adopted on 14.12.2023.	
Translarna - Ataluren - EMEA/H/C/002720/II/0074, Orphan PTC Therapeutics International Limited, Rapporteur: Peter Mol, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations in the paediatric population, to update the summary of safety profile and to update efficacy, safety and pharmacokinetic information on the paediatric population based on the final results from study PTC124-GD-048-DMD "A Phase 2, multiple-dose, open-label study evaluating the safety and PK of ataluren in patients with nmDMD aged ≥6 months to <2 years old" (MEA-018). The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0126 MCM Vaccine B.V., Rapporteur: Christophe Focke, "Update of sections 4.2 and 5.1 of the SmPC in order to add information on interchangeable use of Vaxelis with other hexavalent vaccines based on final results from study V419-016. In addition, the MAH took this opportunity to	Positive Opinion adopted by consensus on 30.11.2023.

introduce minor editorial changes." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 31.08.2023.	
Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0128 MCM Vaccine B.V., Rapporteur: Christophe Focke, "Update of section 4.5 in order to add drug-drug interaction information with meningococcal B conjugate vaccine based on final results from study OVG 2018/05 - Immunogenicity and reactogenicity of concomitantly administered hexavalent and group B meningococcal vaccines in infancy; this is an open-label, non-inferiority, randomized clinical trial that compared the immune response and assessed the safety of Vaxelis and control vaccine (Infanrix hexa) when co-administered with 4 component meningococcal B vaccine (4CMenB) along with other routine infant vaccines. The Package Leaflet is updated accordingly." Opinion adopted on 07.12.2023. Request for Supplementary Information adopted on 07.09.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0134 MCM Vaccine B.V., Rapporteur: Christophe Focke, "Update of section 4.8 of the SmPC in order to add Extensive swelling of vaccinated limb to the list of adverse drug reactions (ADRs) with frequency rare and to update its description based on the cumulative review of clinical studies, literature and safety database. The Package Leaflet is updated accordingly." Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0095 AstraZeneca AB, Rapporteur: Sol Ruiz, "Update of sections 4.1, 4.4 and 5.1 of the SmPC in order to update clinical information, following a critical evaluation of the benefit-risk profile of	Request for supplementary information adopted with a specific timetable. See 9.1

Vaxzevria against currently circulating variants of concern based on available data and structured benefit risk assessment." Request for Supplementary Information adopted on 14.12.2023.	
VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMEA/H/C/005754/II/0007/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, "A grouped application consisting of: Type II (C.I.4): Update of section 4.8 of the SmPC in order to include additional safety data based on safety update reports from studies VAT00008 booster extension and VAT00002 Cohort 2, in order to fulfil REC 20. Type IA (A.6): To change the ATC Code of the COVID-19 protein subunit vaccine from J07BX03 to J07BN04." Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
Vokanamet - Canagliflozin / Metformin - EMEA/H/C/002656/II/0072 Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on literature and post-marketing data." Opinion adopted on 07.12.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Xultophy - Insulin degludec / Liraglutide - EMEA/H/C/002647/II/0050 Novo Nordisk A/S, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add Dizziness and Delayed gastric emptying to the list of adverse drug reactions (ADRs) with frequency common and unknown, respectively, based on the cumulative review of clinical studies data, post-marketing data, class labels and biological plausibility. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI." Opinion adopted on 07.12.2023.	Positive Opinion adopted by consensus on 07.12.2023.
Yselty - Linzagolix choline - EMEA/H/C/005442/II/0010 Theramex Ireland Limited, Rapporteur: Finbarr Leacy, "Submission of the final report from study PRIMROSE 3 (20-OBE2109-007), listed as	Positive Opinion adopted by consensus on 14.12.2023.

a category 3 study in the RMP. This is a long-term follow-up study to assess bone mineral density in subjects with uterine fibroids completing the Phase 3 studies of linzagolix, PRIMROSE 1 or PRIMROSE 2." Opinion adopted on 14.12.2023.	
Zejula - Niraparib - EMEA/H/C/004249/II/0044, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, "Submission of the modelling report with the results from the population pharmacokinetic and exposure-response modelling exercises (REC 7)." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 07.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Zinforo - Ceftaroline fosamil - EMEA/H/C/002252/II/0063 Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, "Update of section 4.8 of the SmPC in order to add 'Kounis Syndrome' to the list of adverse drug reactions (ADRs). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0002, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, "Submission of the final report from study 1042-HME-1001 listed as post-authorisation measure (PAM) recommendation. This is an interventional Phase 1 Single Dose, Open-Label Crossover Comparative Bioavailability Study of Two Oral Formulations of Ganaxolone. The primary objective of this study was to evaluate and compare the pharmacokinetics of a new ganaxolone formulation (hot-melt extrusion [HME]) with ganaxolone oral suspension after a single oral dose administration under fed conditions." Request for Supplementary Information adopted on 14.12.2023.	Request for supplementary information adopted with a specific timetable.
WS2467 Adrovance-	Positive Opinion adopted by consensus on 30.11.2023.

EMEA/H/C/000759/WS2467/0051 **FOSAVANCE-** **EMEA/H/C/000619/WS2467/0054** **VANTAVO-** **EMEA/H/C/001180/WS2467/0041** Organon N.V., Lead Rapporteur: Christian Gartner, "Update of section 4.4 of the SmPC in order to include information on the risk of 'atypical fractures of other bones' (than the femur), and update of section 4.8 to add 'atypical fractures of other bones' as a new ADR with frequency 'not known' and to include further information about the risk of 'atypical subtrochanteric and diaphyseal femoral fractures', based on post-marketing case reports and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes and to bring the product information in line with the latest QRD template and to update the list of local representatives in the Package Leaflet." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 15.06.2023.	
WS2485 **Incruse Ellipta-** **EMEA/H/C/002809/WS2485/0037** **Rolufta Ellipta-** **EMEA/H/C/004654/WS2485/0021** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.2, 4.6 and 4.8 of the SmPC in order to add 'Dysphonia' and 'Oropharyngeal pain' to the list of adverse drug reactions (ADRs) with frequency rare, and to update the wording regarding the administration instructions and for pregnancy and breast-feeding. The Package Leaflet and Labelling are also updated. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 14.09.2023, 20.07.2023.	Positive Opinion adopted by consensus on 14.12.2023.
WS2502 **CoAprovel-** **EMEA/H/C/000222/WS2502/0214** **Karvezide-**	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/000221/WS2502/0214 Sanofi Winthrop Industrie, Lead Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.3 of the SmPC in order to update information on hydrochlorothiazide monocomponent based on literature review." Request for Supplementary Information adopted on 23.11.2023.	
WS2543 **Imfinzi-EMEA/H/C/004771/WS2543/0062** **IMJUDO-EMEA/H/C/006016/WS2543/0003** AstraZeneca AB, Lead Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to include paediatric information based on final results from study D419EC00001 "Phase I/II, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy or Durvalumab in Combination with Tremelimumab in Pediatric Patients with Advanced Solid Tumors and Hematological Malignancies". In addition, the MAH took this opportunity to introduce editorial changes." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 09.11.2023.	Positive Opinion adopted by consensus on 14.12.2023.
WS2573/G **Kinzalkomb-EMEA/H/C/000415/WS2573/0122/G** **MicardisPlus-EMEA/H/C/000413/WS2573/0129/G** **PritorPlus-EMEA/H/C/000414/WS2573/0132/G** Boehringer Ingelheim International GmbH, Lead Rapporteur: Paolo Gasparini, "Grouped application consisting of: C.I.4 (Type II): Update of section 4.8 of the SmPC in accordance with the "Guideline on fixed combination medicinal products, Doc. Ref. CPMP/EWP/240/95 Rev. 1". The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Annex II of the PI, as well as, to update the list of local representatives in the Package Leaflet. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template	Request for supplementary information adopted with a specific timetable.

version 10.3. C.I.4 (Type II): Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to align with reference labels for both active substances. The Package Leaflet is updated accordingly. C.I.z (type IB unforeseen): Update of section 4.7 of the SmPC to replace the term "drowsiness" by "syncope or vertigo" to align it with adverse reactions table in section 4.8 of the SmPC. The Package Leaflet is updated accordingly. C.I.3.a (type IAIN): Update of section 5.3 of the SmPC based on the EMA request dated 31 Jan 2023 for the HCTZ containing medicinal products to remove the sentence '…the extensive human experience with hydrochlorothiazide has failed to show an association between its use and an increase in neoplasms' in order to address an inconsistency in the PI." Request for Supplementary Information adopted on 07.12.2023.	

B.5.3. CHMP-PRAC assessed procedures

BESPONSA - Inotuzumab ozogamicin - EMEA/H/C/004119/II/0026, Orphan Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2, 4.6, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information based on final results from studies ITCC-059 (WI203581) and INO-Ped-ALL-1 (WI235086). Study WI203581 is a Phase 1/2, multicenter, European, multi-cohort, open-label study in paediatric patients (≥1 and <18 years of age) with R/R CD22-positive Acute Lymphoblastic Leukaemia (ALL); and study WI235086 is an open-label, multi-center Phase 1 study to assess safety and tolerability of InO in Japanese paediatric patients with R/R CD22-positive ALL. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted." Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 14.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
GAVRETO - Pralsetinib - EMEA/H/C/005413/II/0017 Roche Registration GmbH, Rapporteur: Aaron	Request for supplementary information adopted with a specific timetable.

Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2 and 5.2 of the SmPC in order to include information regarding moderate and severe hepatic impairment based on final results from study GP43163 listed as a category 3 study in the RMP; this is a Phase I, open-label, single-dose study to evaluate the pharmacokinetics and safety of pralsetinib in subjects with moderate or severe hepatic impairment compared to healthy subjects. The RMP version 1.8 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the marketing authorisation renewal date in Annex I." Request for Supplementary Information adopted on 14.12.2023.	
Isturisa - Osilodrostat - EMEA/H/C/004821/II/0017/G, Orphan Recordati Rare Diseases, Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon, "Grouped application comprising two type II variations (C.I.4) as follows: - 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 LINC4 (study CLCI699C2302 - A Phase III, multi-center, randomized, double-blind, 48 week study with an initial 12 week placebo-controlled period to evaluate the safety and efficacy of osilodrostat in patients with Cushing's disease). - 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 LINC3 (study CLCI699C2301 - A Phase III, multi-center, double-blind, randomized withdrawal study of LCI699 following a 24 week, single-arm, open-label dose titration and treatment period to evaluate the safety and efficacy of LCI699 for the treatment of patients with Cushing's disease). The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the PI." Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
Kaftrio - Ivacaftor / Tezacaftor /	Positive Opinion adopted by consensus on

Elexacaftor - EMEA/H/C/005269/II/0039, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "Update of sections 4.8 and 5.1 of the SmPC in order to update information based on final results from study VX17-445-105 (study 105); this is a phase 3, open-label, extension study evaluating the long-term safety and efficacy of ELX/TEZ/IVA treatment in cystic fibrosis (CF) subjects 12 years of age and older, homozygous, or heterozygous for the F508del-CFTR mutation who participated in study VX17-445-102 (study 102) or study VX17-445-103 (study 103). The RMP version 7.2 has also been submitted." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 31.08.2023.	30.11.2023.
LUMYKRAS - Sotorasib - EMEA/H/C/005522/II/0010/G Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B. Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable. See 9.1

on 14.12.2023, 25.05.2023.	
Mavenclad - Cladribine - EMEA/H/C/004230/II/0027 Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of sections 4.5 and 4.6 of the SmPC in order to add information regarding the use of mavenclad with oral contraceptives based on the final study results from the drug-drug interaction study (MS 700568-0031). This is a randomized, double-blind, 2-period, 2-sequence, crossover Phase I study with a 1-month run-in period to examine the effect of cladribine tablets on the pharmacokinetics of a monophasic oral contraceptive containing ethinyl estradiol and levonorgestrel (microgynon) in pre-menopausal women with Relapsing Multiple Sclerosis (RMS). The Annex II and Package Leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to sections 4.2 and 4.4 of the SmPC." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Piqray - Alpelisib - EMEA/H/C/004804/II/0022/G Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst, "Grouped application comprising two type II variations (C.I.4) as follows: - Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information on prophylactic use of metformin for hyperglycaemia based on the results from study CBYL719CES01T (METALLICA). METALLICA is a Phase II study aimed to evaluate the effect of prophylactic use of metformin for hyperglycaemia in HR-positive, HER2-negative, PIK3CA-mutated advanced breast cancer patients treated with alpelisib plus endocrine therapy. - Update of section 4.8 of the SmPC in order to add "uveitis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on a cumulative review of the MAH safety database and literature.	Request for supplementary information adopted with a specific timetable.

The Package Leaflet and Annex II are updated accordingly. The RMP version 7.0 has also been submitted." Request for Supplementary Information adopted on 30.11.2023.	
Tegsedi - Inotersen - EMEA/H/C/004782/II/0038, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.8 of the SmPC in order to modify the warning on liver monitoring and drug-induced liver injury and to add 'drug-induced liver injury' to the list of adverse drug reactions (ADRs) with frequency not known, following the request in the Assessment Report for PAM procedure EMEA/H/C/004782/LEG/008. The Annex II and Package Leaflet are updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 28.09.2023.	Positive Opinion adopted by consensus on 30.11.2023.
Tysabri - Natalizumab - EMEA/H/C/000603/II/0136 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 4.4 of the SmPC to modify administration instructions and update educational guidance to enable the subcutaneous formulation to be administered outside a clinical setting by healthcare professionals based on the cumulative review of post-marketing and clinical study data. The Package Leaflet and Annex IID are updated accordingly. The RMP version 29.1 has also been submitted. In addition, the MAH took this opportunity to introduce minor editorial changes." Request for Supplementary Information adopted on 14.12.2023, 09.11.2023, 20.07.2023.	Request for supplementary information adopted with a specific timetable.
VPRIV - Velaglucerase alfa - EMEA/H/C/001249/II/0063 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Update of section 4.2 of the SmPC in order to add information to support at-home self-	Request for supplementary information adopted with a specific timetable.

administration of VPRIV by a trained patient and/or a caregiver based on post-marketing data and literature. The Package Leaflet and Annex IID are updated accordingly. The updated RMP version 13.0 has also been submitted." Request for Supplementary Information adopted on 14.12.2023.	

B.5.4. PRAC assessed procedures

PRAC Led **Caelyx pegylated liposomal - Doxorubicin - EMEA/H/C/000089/II/0107** Baxter Holding B.V., PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "Submission of an updated RMP version 6.1 in order to align to GVP Module V Revision 2 requirements, following a request received within the Assessment Report for procedure EMEA/H/C/PSUSA/00001172/202111." Request for Supplementary Information adopted on 30.11.2023, 28.09.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **HEPLISAV B - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005063/II/0031** Dynavax GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study DV2-HBV-28 - Post-marketing observational surveillance study to evaluate pregnancy outcomes among women who receive HEPLISAV-B or Engerix-B; HBV-28 was conducted using the same patient population as two observational post-marketing surveillance studies designed to evaluate the incidence of AMI (HBV-25) or new-onset immune mediated diseases, herpes zoster, and anaphylaxis (HBV-26) in recipients of HEPLISAV-B compared with recipients of Engerix-B. The primary objective of this study was to describe and compare pregnancy outcomes in recipients of HEPLISAV-B and recipients of Engerix-B. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 30.11.2023.	
PRAC Led **Juluca - Dolutegravir / Rilpivirine - EMEA/H/C/004427/II/0054** ViiV Healthcare B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from non-interventional PASS study COMBINE-2 listed as a category 3 study in the RMP. This is a real-world evidence study to evaluate effectiveness of two drug regimen, antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor. The RMP version 6.1 has also been submitted in order to remove the important identified risk of ''drug resistance''." Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
PRAC Led **Lenvima - Lenvatinib - EMEA/H/C/003727/II/0053** Eisai GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of interim results from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP. This is a non-interventional multicentre, observational, phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. Update of section 4.8 of the SmPC to include 'gastrointestinal perforation' as an adverse drug reaction with frequency 'common'. The package leaflet has been updated accordingly. RMP version 15.2 has also been submitted." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 26.10.2023.	Positive Opinion adopted by consensus on 30.11.2023.
PRAC Led **MabThera - Rituximab - EMEA/H/C/000165/II/0199** Roche Registration GmbH, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa Mejia, "Submission of the final report for study BE29950 (RIVAS), listed as a category 3 study in the RMP. This is a prospective, single center, secondary data use, long-term surveillance, non-interventional PASS with the objective to better characterise the risk profile of MabThera by collecting long-term safety data in patients	Positive Opinion adopted by consensus on 30.11.2023.

with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have been treated with rituximab (MabThera) or other available non-rituximab therapies. The RMP version 24.0 has also been submitted." Opinion adopted on 30.11.2023.	
PRAC Led **Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0127** Pfizer Europe MA EEIG, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Submission of an updated RMP version 9.0 in order to remove the important potential risks 'Change in meningococcal epidemiology/serogroup replacement' and 'Lack of Efficacy' from the list of the safety concerns, to remove 'Long-term persistence of the vaccine response and need for a booster dose' as missing information and to remove 'Use during pregnancy' from the list of safety concerns." Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
PRAC Led **Nivestim - Filgrastim - EMEA/H/C/001142/II/0074/G** Pfizer Europe MA EEIG, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Grouped application consisting of: C.I.13: Submission of the final report from non-interventional PASS study ZOB-NIV-1513/C1121008 listed as a category 3 study in the RMP. This is a multinational, multi-centre, prospective, non-interventional, post-authorisation safety study in Healthy Donors (HDs) exposed to nivestim (biosimilar filgrastim) for Haematopoietic Stem Cell (HSC) Mobilisation (NEST). The RMP version 12 has also been submitted. C.I.11 for RMP: Submission of an updated RMP version 12.0 in order to align it with the reference product, Neupogen, RMP v. 6.3 dated June 2022." Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Olumiant - Baricitinib - EMEA/H/C/004085/II/0043** Eli Lilly Nederland B.V., PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa	Positive Opinion adopted by consensus on 30.11.2023.

Balkowiec Iskra, "Submission of an updated RMP version 22.1, dated 9 June 2023 in order to remove existing additional pharmacovigilance activities (category 3 studies): Study I4V-MC-JAJA (JAJA) and Study I4V-MC-JAJD (JAJD). The RMP version 22.2, dated 26 September 2023, is acceptable." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 31.08.2023.	
PRAC Led **Remicade - Infliximab - EMEA/H/C/000240/II/0241** Janssen Biologics B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report for the PSOLAR (C0168Z03) registry "A Multicenter, Open Registry of Patients with Psoriasis Who Are Candidates for Systemic Therapy Including Biologics: PSOLAR", listed as a category 3 study in the RMP (MEA114). This is an international, multicenter, prospective observational registry for monitoring the long-term safety experience and clinical status of patients ≥18 years of age who are eligible to receive or are actively receiving any systemic therapies for psoriasis, including those currently receiving or planning to receive infliximab. The RMP version 21.1 has also been submitted." Opinion adopted on 30.11.2023. Request for Supplementary Information adopted on 06.07.2023.	Positive Opinion adopted by consensus on 30.11.2023.
PRAC Led **Revatio - Sildenafil - EMEA/H/C/000638/II/0107** Upjohn EESV, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 8.0 in order to remove "Long-term Mortality" as missing information based on the completion of study A1481324 - A multinational, multicentre study to assess the effects of oral sildenafil on mortality in adults with pulmonary arterial hypertension (PAH). In addition, the MAH took the opportunity to reflect the completion of the studies A1481324 and A1481319." Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
PRAC Led **Simponi - Golimumab -**	Positive Opinion adopted by consensus on

EMEA/H/C/000992/II/0117/G Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Grouped application consisting of: C.I.13: Submission of the final report from study UC Nordic (MK-8259-013) listed as a category 3 study in the RMP. This is a Non-interventional Observational Longitudinal Post Authorisation Safety Study (PASS) of SIMPONI in Treatment of Ulcerative Colitis using Nordic National Health Registries. C.I.13: Submission of the final report from study ENEIDA (MK-8259-042) listed as a category 3 study in the RMP. This is a Post-Authorisation Safety Study (PASS) of Golimumab in UC Using the Spanish ENEIDA Registry. The RMP version 27.1 has also been submitted." Opinion adopted on 30.11.2023.	30.11.2023.
PRAC Led **Sprycel - Dasatinib - EMEA/H/C/000709/II/0090** Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Aaron Sosa Mejia, "Submission of an updated RMP version 18.0 in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects." Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Vedrop - Tocofersolan - EMEA/H/C/000920/II/0047** Recordati Rare Diseases, PRAC Rapporteur: Melinda Palfi, PRAC-CHMP liaison: Beata Maria Jakline Ullrich, "Submission of an updated RMP version 10.1 in order to remove all important potential risks and missing information from the list of safety concerns, to align with the new RMP format according to Good Pharmacovigilance Practices Module V Revision 2 and to remove one closed post-authorisation safety study of category 2 (Recordati Rare Diseases's Vedrop registry) from the pharmacovigilance plan."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 30.11.2023.	
PRAC Led **Zaltrap - Aflibercept - EMEA/H/C/002532/II/0071** Sanofi Winthrop Industrie, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 5.0 in order to update the Risk Minimisation Measures and List of Safety Concerns removing "Nephrotic syndrome", "Cardiac failure and ejection fraction decreased", "Posterior reversible encephalopathy syndrome", "Thrombotic microangiopathy" and "Osteonecrosis of jaw" of the important identified risks, "Reproductive and developmental toxicity" as an important potential risk and "Safety in patients with severe hepatic impairment" of the missing information, following the assessment of PSUSA/00010019/202108." Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
PRAC Led **WS2569** **Corlentor-** **EMEA/H/C/000598/WS2569/0059** **Ivabradine Anpharm-** **EMEA/H/C/004187/WS2569/0019** **Procoralan-** **EMEA/H/C/000597/WS2569/0058** Les Laboratoires Servier, Lead PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Patrick Vrijlandt, "C.I.11.z - To update the RMP to delete the obsolete products (Ivabradine Egis and Ivabradine Proterapia) that are still mentioned in the RMP." Opinion adopted on 14.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
PRAC Led **WS2571** **Glyxambi-** **EMEA/H/C/003833/WS2571/0055** **Jardiance-** **EMEA/H/C/002677/WS2571/0082** **Synjardy-** **EMEA/H/C/003770/WS2571/0076** Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Submission of the final report from study 1245-	Request for supplementary information adopted with a specific timetable.

0201. This is an observational post-authorisation safety study (PASS) to assess the risk of acute pancreatitis in type 2 diabetes mellitus (T2DM) patients newly initiating empagliflozin compared to other oral non-incretin/non-sodium glucose co-transporter-2 inhibitors (SGLT2i)-containing glucose lowering drugs. The RMP versions 22.0, 15.0 and 10.0 have also been submitted for Jardiance, Synjardy and Glyxambi, respectively." Request for Supplementary Information adopted on 30.11.2023.	

B.5.5. CHMP-CAT assessed procedures

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0018/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Opinion adopted on 14.12.2023, 08.12.2023. Request for Supplementary Information adopted on 15.06.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0026/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Opinion adopted on 14.12.2023, 08.12.2023. Request for Supplementary Information adopted on 08.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0032, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Request for Supplementary Information adopted on 08.12.2023.	Request for supplementary information adopted with a specific timetable.
Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0009/G, Orphan, ATMP CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy Opinion adopted on 14.12.2023, 08.12.2023. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 14.12.2023.

on 31.10.2023.	
Libmeldy - Atidarsagene autotemcel - EMEA/H/C/005321/II/0021, Orphan, ATMP Orchard Therapeutics (Netherlands) B.V., Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol Opinion adopted on 14.12.2023, 08.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - EMEA/H/C/003854/II/0039, Orphan, ATMP Fondazione Telethon ETS, Rapporteur: Sol Ruiz, CHMP Coordinator: Maria Concepcion Prieto Yerro Opinion adopted on 14.12.2023, 08.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.
Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0065, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC in order to add Infusion Related Reactions to the list of adverse drug reactions (ADRs) with frequency Common, based on a cumulative review of the MAH safety database, clinical trials and post-marketing data. The Package Leaflet is updated accordingly." Opinion adopted on 14.12.2023, 08.12.2023.	Positive Opinion adopted by consensus on 14.12.2023.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

WS2408 Riarify-EMEA/H/C/004836/WS2408/0027 Trydonis-EMEA/H/C/004702/WS2408/0030 Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 12.10.2023.	Positive Opinion adopted by consensus on 14.12.2023.

WS2528/G **Eucreas-** **EMEA/H/C/000807/WS2528/0101/G** **Icandra-** **EMEA/H/C/001050/WS2528/0106/G** **Zomarist-** **EMEA/H/C/001049/WS2528/0103/G** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder, "C.I.z - To provide the Environmental Risk Assessment (ERA) report for vildalgiptin to add data from OECD TG308 and OECD TG218 studies. C.I.z - To provide the Environmental Risk Assessment (ERA) report for metformin to add FOCUS_DEGKINv2 SFO calculated DT50 values." Opinion adopted on 16.11.2023. Request for Supplementary Information adopted on 12.10.2023, 31.08.2023.	Positive Opinion adopted by consensus on 16.11.2023.
WS2540 **Biktarvy-** **EMEA/H/C/004449/WS2540/0057** **Descovy-** **EMEA/H/C/004094/WS2540/0064** **Genvoya-** **EMEA/H/C/004042/WS2540/0088** **Odefsey-** **EMEA/H/C/004156/WS2540/0062** **Vemlidy-** **EMEA/H/C/004169/WS2540/0044** Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes Opinion adopted on 14.12.2023. Request for Supplementary Information adopted on 28.09.2023.	Positive Opinion adopted by consensus on 14.12.2023.
WS2561/G **Olanzapine Glenmark-** **EMEA/H/C/001085/WS2561/0041/G** **Olanzapine Glenmark Europe-** **EMEA/H/C/001086/WS2561/0038/G** **Olazax-** **EMEA/H/C/001087/WS2561/0033/G** **Olazax Disperzi-** **EMEA/H/C/001088/WS2561/0035/G** Glenmark Arzneimittel GmbH, Generic, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau Opinion adopted on 23.11.2023. Request for Supplementary Information adopted on 12.10.2023.	Positive Opinion adopted by consensus on 23.11.2023.

WS2570 **Lantus-EMEA/H/C/000284/WS2570/0131** **Suliqua-EMEA/H/C/004243/WS2570/0036** **Toujeo-EMEA/H/C/000309/WS2570/0126** Sanofi-Aventis Deutschland GmbH, Lead Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 16.11.2023, 05.10.2023.	Request for supplementary information adopted with a specific timetable.
WS2572/G **Herceptin-EMEA/H/C/000278/WS2572/0191/G** **MabThera-EMEA/H/C/000165/WS2572/0200/G** Roche Registration GmbH, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 30.11.2023.	Request for supplementary information adopted with a specific timetable.
WS2581/G **Fluenz Tetra-EMEA/H/C/002617/WS2581/0136/G** **Pandemic influenza vaccine H5N1 AstraZeneca-EMEA/H/C/003963/WS2581/0070/G** AstraZeneca AB, Lead Rapporteur: Christophe Focke Opinion adopted on 30.11.2023.	Positive Opinion adopted by consensus on 30.11.2023.
WS2589 **Ongentys-EMEA/H/C/002790/WS2589/0062** **Ontilyv-EMEA/H/C/005782/WS2589/0017** Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise Opinion adopted on 23.11.2023.	Positive Opinion adopted by consensus on 23.11.2023.
WS2592/G **Nuwiq-EMEA/H/C/002813/WS2592/0056/G** **Vihuma-EMEA/H/C/004459/WS2592/0038/G** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 07.12.2023.	Positive Opinion adopted by consensus on 07.12.2023.
WS2602/G **Eucreas-EMEA/H/C/000807/WS2602/0104/G** **Icandra-EMEA/H/C/001050/WS2602/0109/G** **Zomarist-EMEA/H/C/001049/WS2602/0106/G**	Positive Opinion adopted by consensus on 30.11.2023.

Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder Opinion adopted on 30.11.2023.	
WS2614 **Cegfila-EMEA/H/C/005312/WS2614/0019** **Pelmeg-EMEA/H/C/004700/WS2614/0027** Mundipharma Corporation (Ireland) Limited, Lead Rapporteur: Karin Janssen van Doorn Request for Supplementary Information adopted on 07.12.2023.	Request for supplementary information adopted with a specific timetable.

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

Maviret - Glecaprevir / Pibrentasvir - EMEA/H/C/004430/II/0056 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, "Update of section 5.1 of the SmPC in order to add a statement regarding concordance of SVR4 and SVR12, based on post-hoc analysis of the data from the Phase 2 and 3 clinical trials." Request for Supplementary Information adopted on 23.11.2023.	The MAH withdrew the procedure on 07.12.2023.
Tremelimumab AstraZeneca - Tremelimumab - EMEA/H/C/004650/II/0002 AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the paediatric information based on final results from study D419EC00001; this is a Phase I/II, open-label, multicenter study to evaluate the safety, tolerability, and preliminary efficacy of durvalumab monotherapy or durvalumab in combination with tremelimumab in paediatric patients with advanced solid tumors and haematological malignancies." Withdrawal request submitted on 29.11.2023.	The MAH withdrew the procedure on 29.11.2023.
Zolsketil pegylated liposomal - Doxorubicin - EMEA/H/C/005320/II/0004 Accord Healthcare S.L.U., Rapporteur: Carolina Prieto Fernandez Request for Supplementary Information adopted on 13.07.2023. Withdrawal request submitted on 16.11.2023.	The MAH withdrew the procedure on 16.11.2023.

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Dimethyl fumarate - EMEA/H/C/006397 for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).	
Garadacimab - EMEA/H/C/006116, Orphan CSL Behring GmbH, routine prevention of attacks of hereditary angioedema (HAE)	
Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - EMEA/H/C/005797 prevention of disease caused by chikungunya (CHIKV) virus	**Accelerated review**
Aflibercept - EMEA/H/C/006056 treatment of age-related macular degeneration (AMD) and visual impairment	
Beremagene geperpavec - EMEA/H/C/006330, Orphan, ATMP Krystal Biotech Netherlands B.V., treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene	

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/0199 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Extension application to add a new presentation of Comirnaty Omicron XBB.1.5, 3 micrograms/dose concentrate for dispersion for injection (yellow caps, 3-doses per vial) for infants and children aged 6 months to 4 years."	

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

Abilify Maintena - Aripiprazole - EMEA/H/C/002755/X/0045 Otsuka Pharmaceutical Netherlands B.V.,	

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga, "Extension application to introduce a new pharmaceutical form associated with two new strengths (720 and 960 mg Prolonged-release suspension for injection). The RMP (version 12.1) is updated in accordance."
List of Questions adopted on 09.11.2023.

In vitro diagnostic medical device - EMEA/H/D/006372
next generation sequencing (NGS) assay for tumor mutation profiling
Request for Supplementary Information adopted on 09.11.2023.

Denosumab - EMEA/H/C/005964
treatment of osteoporosis
List of Questions adopted on 14.09.2023.

In vitro diagnostic medical device - EMEA/H/D/006373
detection of PD-L1 protein
Request for Supplementary Information adopted on 09.11.2023, 12.10.2023.

TEPADINA - Thiotepa - EMEA/H/C/001046/X/0049
ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau, "Extension application to add a new strength (200 mg powder and solvent for solution for infusion)."
List of Questions adopted on 09.11.2023.

Denosumab - EMEA/H/C/006378
prevention of skeletal related events with advanced malignancies
List of Questions adopted on 14.09.2023.

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

NULIBRY - Fosdenopterin - EMEA/H/C/005378/S/0006, Orphan
TMC Pharma (EU) Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

NYXTHRACIS - Obiltoxaximab - EMEA/H/C/005169/S/0013, Orphan
SFL Pharmaceuticals Deutschland GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Liana Gross-Martirosyan

Orphacol - Cholic acid - EMEA/H/C/001250/S/0053

Theravia, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Sofia Trantza

Raxone - Idebenone - EMEA/H/C/003834/S/0035, Orphan

Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli

Vedrop - Tocofersolan - EMEA/H/C/000920/S/0049

Recordati Rare Diseases, Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Melinda Palfi

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

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/R/0025, Orphan, ATMP

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

Lacosamide UCB - Lacosamide - EMEA/H/C/005243/R/0020

UCB Pharma S.A., Informed Consent of Vimpat, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Lorviqua - Lorlatinib - EMEA/H/C/004646/R/0031

Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Nikica Mirošević Skvrce

Ondexxya - Andexanet alfa - EMEA/H/C/004108/R/0041

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst

Posaconazole Accord - Posaconazole - EMEA/H/C/005005/R/0014

Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Nathalie Gault

Posaconazole AHCL - Posaconazole - EMEA/H/C/005028/R/0011

Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir,

PRAC Rapporteur: Nathalie Gault

Zydelig - Idelalisib -
EMEA/H/C/003843/R/0059
Gilead Sciences Ireland UC, Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

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

Hepcludex - Bulevirtide -
EMEA/H/C/004854/II/0031, Orphan
Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "Extension of indication to include treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease for Hepcludex, based on a modelling and simulation study and an extrapolation study to evaluate the use of Bulevirtide for the treatment of chronic hepatitis D infection in children from 3 to less than 18 years of age. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 4.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI."

Pegasys - Peginterferon alfa-2a -
EMEA/H/C/000395/II/0119/G
Pharmaand GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Grouped application consisting of:
Extension of indication to include treatment of Polycythaemia Vera (PV) and Essential thrombocytopenia (ET) for PEGASYS, based on published data of clinical studies conducted in support of the efficacy and safety of Pegasys for the treatment of ET and PV. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

SIRTURO - Bedaquiline - EMEA/H/C/002614/II/0056, Orphan

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Extension of indications by removal of the restriction for use of SIRTURO (bedaquiline [BDQ]), based on final results from study STREAM Stage 2; this is an multicenter, open-label, parallel-group, randomized, active-controlled study in participants aged 15 years or older with RR/MDR-TB to evaluate an investigational BDQ-containing, all-oral, 40-week regimen of anti-TB drugs (Regimen C) compared to an injectable-containing 40-week control regimen (Regimen B). As a consequence of the data emerging from the submitted study, sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. In addition, section E of Annex II has also been updated. The Labelling and Package Leaflet are updated in accordance. Version 10.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3. As part of the application, the MAH is requesting the switch from a conditional MA to standard MA."

Tepkinly - Epcoritamab - EMEA/H/C/005985/II/0001, Orphan

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Mol, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Monica Martinez Redondo, "Extension of indication to include treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy for TEPKINLY, based on results from the indolent Non-Hodgkins Lymphoma (iNHL) expansion cohort of study GCT3013-01, the First In Human (FIH) Phase 1/2 study in R/R B-NHL, with key supportive data from the Phase 1b/2 study GCT3013-04 in Japanese subjects. Study GCT3013-01 is an ongoing global, single-arm, Phase 1/2 study designed to evaluate epcoritamab as monotherapy in R/R B-NHL. As a consequence, sections 1, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.4, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes

to the PI."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

WS2551
Kaftrio-EMEA/H/C/005269/WS2551/0043
Kalydeco-EMEA/H/C/002494/WS2551/0121
Vertex Pharmaceuticals (Ireland) Limited, Lead Rapporteur: Peter Mol, Lead PRAC Rapporteur: Martin Huber, "Extension of the indication for Kaftrio (ivacaftor/tezacaftor/elexacaftor) and Kalydeco (ivacaftor) in a combination regimen to include the treatment of patients with cystic fibrosis (CF) aged 2 years and older who do not carry any F508del mutations and have at least one ivacaftor/tezacaftor/elexacaftor-responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene based on study VX21-445-124, study VX21-445-125 and study VX22-CFD-016. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the Kaftrio SmPC are updated; sections 4.1 and 5.1 of the Kalydeco SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Adenuric - Febuxostat - EMEA/H/C/000777/II/0071/G
Menarini International Operations Luxembourg S.A., Rapporteur: Christian Gartner

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0014/G
LEO Pharma A/S, Rapporteur: Jayne Crowe

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0015
LEO Pharma A/S, Rapporteur: Jayne Crowe

Apretude - Cabotegravir - EMEA/H/C/005756/II/0002/G
ViiV Healthcare B.V., Duplicate, Duplicate of Vocabria, Rapporteur: Bruno Sepodes

Artesunate Amivas - Artesunate - EMEA/H/C/005550/II/0011, Orphan
Amivas Ireland Limited, Rapporteur: Jayne

Crowe

ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0015, Orphan
Swedish Orphan Biovitrum AB (publ), Rapporteur: Alexandre Moreau

Aybintio - Bevacizumab - EMEA/H/C/005106/II/0019/G
Samsung Bioepis NL B.V., Rapporteur: Christian Gartner

Benepali - Etanercept - EMEA/H/C/004007/II/0078
Samsung Bioepis NL B.V., Rapporteur: Christian Gartner

Bortezomib SUN - Bortezomib - EMEA/H/C/004076/II/0022
Sun Pharmaceutical Industries Europe B.V., Generic, Generic of VELCADE, Rapporteur: Margareta Bego

Briumvi - Ublituximab - EMEA/H/C/005914/II/0006
Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra

Cablivi - Caplacizumab - EMEA/H/C/004426/II/0047/G, Orphan
Ablynx NV, Rapporteur: Filip Josephson

Cancidas - Caspofungin - EMEA/H/C/000379/II/0083/G
Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke

Cervarix - Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0126/G
GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke

Circadin - Melatonin - EMEA/H/C/000695/II/0071/G
RAD Neurim Pharmaceuticals EEC SARL, Rapporteur: Bruno Sepodes

Clopidogrel Viatris - Clopidogrel - EMEA/H/C/001189/II/0049/G
Viatris Limited, Generic, Duplicate, Generic of Plavix, Duplicate of Grepid, Rapporteur: Kristina Nadrah

COMIRNATY - COVID-19 mRNA vaccine

(nucleoside-modified) - EMEA/H/C/005735/II/0197/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Cosentyx - Secukinumab - EMEA/H/C/003729/II/0110
Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola

Ebixa - Memantine / Memantine hydrochloride - EMEA/H/C/000463/II/0101
H. Lundbeck A/S, Duplicate, Duplicate of Axura, Rapporteur: Maria Concepcion Prieto Yerro

Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0002
Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau

EXPAREL liposomal - Bupivacaine - EMEA/H/C/004586/II/0018
Pacira Ireland Limited, Rapporteur: Elita Poplavska

Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0044
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Foclivia - Pandemic Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/001208/II/0084/G
Seqirus S.r.l, Rapporteur: Maria Grazia Evandri

Gliolan - 5-aminolevulinic acid - EMEA/H/C/000744/II/0026/G
Photonamic GmbH & Co. KG, Rapporteur: Bruno Sepodes

Hetlioz - Tasimelteon - EMEA/H/C/003870/II/0037, Orphan
Vanda Pharmaceuticals Netherlands B.V., Rapporteur: Jayne Crowe

Ixiaro - Japanese encephalitis vaccine (inactivated, adsorbed) - EMEA/H/C/000963/II/0116
Valneva Austria GmbH, Rapporteur: Jan Mueller-Berghaus

Latuda - Lurasidone - EMEA/H/C/002713/II/0041

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Rapporteur: Filip Josephson

MINJUVI - Tafasitamab - EMEA/H/C/005436/II/0014/G, Orphan
Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia

Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0130/G
Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang

Nordimet - Methotrexate - EMEA/H/C/003983/II/0033/G
Nordic Group B.V., Rapporteur: Bruno Sepodes

Nulojix - Belatacept - EMEA/H/C/002098/II/0090/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson

Ontruzant - Trastuzumab - EMEA/H/C/004323/II/0049
Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn

Ovitrelle - Choriogonadotropin alfa - EMEA/H/C/000320/II/0090
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Pedmarqsi - Sodium thiosulfate - EMEA/H/C/005130/II/0002/G
Fennec Pharmaceuticals (EU) Limited, Rapporteur: Elita Poplavska

Pemetrexed Fresenius Kabi - Pemetrexed - EMEA/H/C/003895/II/0035/G
Fresenius Kabi Deutschland GmbH, Generic, Generic of Alimta, Rapporteur: Eva Skovlund

Posaconazole Accord - Posaconazole - EMEA/H/C/005005/II/0012/G
Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir

PREVYMIS - Letermovir - EMEA/H/C/004536/II/0036, Orphan
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson

Refixia - Nonacog beta pegol - EMEA/H/C/004178/II/0036/G
Novo Nordisk A/S, Rapporteur: Daniela

Philadelphy

Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0024, Orphan
Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt

Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0024, Orphan
Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt

Somavert - Pegvisomant - EMEA/H/C/000409/II/0108/G
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race

Sugammadex Piramal - Sugammadex - EMEA/H/C/006083/II/0001
Piramal Critical Care B.V., Generic, Generic of Bridion, Rapporteur: Hrefna Gudmundsdottir

Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0013/G
Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus

Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0015/G
Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus

Tabrecta - Capmatinib - EMEA/H/C/004845/II/0007/G
Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez

TEPMETKO - Tepotinib - EMEA/H/C/005524/II/0012
Merck Europe B.V., Rapporteur: Filip Josephson

Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0136/G
MCM Vaccine B.V., Rapporteur: Christophe Focke

Yellox - Bromfenac - EMEA/H/C/001198/II/0036/G
Bausch + Lomb Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher

Zirabev - Bevacizumab - EMEA/H/C/004697/II/0032

Pfizer Europe MA EEIG, Rapporteur: Eva Skovlund

WS2557/G
Infanrix hexa-EMEA/H/C/000296/WS2557/0337/G
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2590
Eucreas-EMEA/H/C/000807/WS2590/0103
Galvus-EMEA/H/C/000771/WS2590/0081
Icandra-EMEA/H/C/001050/WS2590/0108
Jalra-EMEA/H/C/001048/WS2590/0084
Xiliarx-EMEA/H/C/001051/WS2590/0082
Zomarist-EMEA/H/C/001049/WS2590/0105
Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder

WS2608/G
Apretude-EMEA/H/C/005756/WS2608/0001/G
Vocabria-EMEA/H/C/004976/WS2608/0020/G
ViiV Healthcare B.V., Duplicate, Duplicate of Vocabria, Lead Rapporteur: Bruno Sepodes

WS2625
Hukyndra-EMEA/H/C/005548/WS2625/0020
Libmyris-EMEA/H/C/005947/WS2625/0009
STADA Arzneimittel AG, Lead Rapporteur: Outi Mäki-Ikola

Mosquirix-EMEA/H/W/002300/WS2585/0078
Shingrix-EMEA/H/C/004336/WS2585/0071
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Jan Mueller-Berghaus

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

AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0004
GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, "Update of sections 4.8 and

5.1 of the SmPC in order to include data on persistence of protection over at least 2 RSV seasons following administration of a single dose of Arexvy based on final results from study RSV OA=ADJ-006 (A Phase 3, randomized, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above) and RSV OA=ADJ-004 (A phase 3, randomized, open-label, multi-country study to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above)."	
Benlysta - Belimumab - EMEA/H/C/002015/II/0117 GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, "Update of section 4.4 of the SmPC in order to amend an existing warning and precautions for Progressive multifocal leukoencephalopathy (PML) following the recent review of the wording in the company Core Safety Datasheet."	
Benlysta - Belimumab - EMEA/H/C/002015/II/0118 GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to change the frequency of urticaria and rash from uncommon to common and to change the frequency of diarrhoea and nausea from very common to common and to update the Summary of the safety profile based on a cumulative review of clinical trials. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes."	
Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0025 UCB Pharma S.A., Rapporteur: Finbarr Leacy, "Update of section 5.1 of the SmPC in order to add long-term efficacy data based on the interim results (week 144 data) from study PS0014 listed as a category 3 study in the RMP (MEA/005); this is an ongoing, multicenter, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of	

bimekizumab in adult study participants with moderate to severe plaque PSO who completed 1 of the 3 completed feeder studies (PS0008, PS0009, and PS0013)."

BYANNLI - Paliperidone - EMEA/H/C/005486/II/0005

Janssen-Cilag International N.V., Informed Consent of Xeplion, Rapporteur: Kristina Dunder, "Submission of the Environmental Risk Assessment Report and environmental risk studies (OECD 232, OECD 307 and OECD 308)."

CAMZYOS - Mavacamten - EMEA/H/C/005457/II/0006

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Patrick Vrijlandt, "Update of section 4.9 of the SmPC in order to include information on the management of mavacamten overdose with administration of activated charcoal, based on final results from study CV027043. This is a single-center, open-label, randomized, parallel-group study to evaluate the effects of co-administration of activated charcoal with sorbitol on the single-dose PK of mavacamten in healthy subjects. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the Package Leaflet."

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0194

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Submission of the final report from study C4591014 listed as a category 3 study in the RMP. This is a retrospective database study to evaluate the effectiveness of COVID-19 BNT162b2 vaccine in a real-world setting."

Edarbi - Azilsartan medoxomil - EMEA/H/C/002293/II/0033/G

Takeda Pharma A/S, Rapporteur: Patrick Vrijlandt, "Grouped application comprising two type II variations as follows:
- Update of section 4.8 of the SmPC in order to add rhabdomyolysis to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of MAH safety database and literature.
- Update of section 4.8 of the SmPC in order to

add arthralgia to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of MAH safety database and literature.
The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."

Evrysdi - Risdiplam - EMEA/H/C/005145/II/0021
Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information based on primary analysis results from study BN40703 (RAINBOWFISH); this is an open-label, single-arm, multicenter clinical study to investigate the efficacy, safety, pharmacokinetics, and pharmacodynamics of risdiplam in patients aged from birth to 6 weeks (at first dose) who are genetically diagnosed with SMA (SMN1 deletion and any SMN2 copies) but not yet presenting with symptoms. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the Instructions for Use."

Gardasil 9 - Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0069
Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update long-term effectiveness information based on results from the 4th interim report for study V503-021, listed as a category 3 study in the RMP. This is a registry-based extension of protocol V503-001 in countries with centralised cervical cancer screening infrastructures to evaluate the long-term effectiveness, immunogenicity, and safety of 9vHPV vaccine as administered to 16- to 26-year-old women. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet."

Gazyvaro - Obinutuzumab - EMEA/H/C/002799/II/0054/G, Orphan
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Grouped application comprising

two variations as follows: C.I.4 - Update of section 4.4 of the SmPC in order to amend the cytokine release syndrome (CRS) statement based on the cumulative review of the MAH safety database, clinical trials and literature. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.3. A.6 - To change the ATC Code of Obinutuzumab from L01XC15 to L01FA03."	
Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0083 Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC following the 24-month extended follow up from primary analysis data from study CLL3011. This is a randomized, open-label, Phase 3 study of the combination of Ibrutinib plus Venetoclax versus Chlorambucil plus Obinutuzumab for the First-line Treatment of Subjects with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). In addition, the MAH took the opportunity to add a footnote to the dose modifications table for non-cardiac events in section 4.2 to define the grading systems used for the adverse reactions."	
Instanyl - Fentanyl - EMEA/H/C/000959/II/0081 Takeda Pharma A/S, Rapporteur: Alexandre Moreau, "Update of section 4.9 of the SmPC in order to add Toxic Leukoencephalopathy as a symptom overdose based on the cumulative review of safety databases, clinical trial data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0147 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-B61; this is a Phase 2, Single-arm, Open-label Clinical Trial of Pembrolizumab Plus Lenvatinib in Participants	

with First-line Advanced/Metastatic Non-clear Cell Renal Cell Carcinoma (nccRCC)."

Kineret - Anakinra - EMEA/H/C/000363/II/0092

Swedish Orphan Biovitrum AB (publ), Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add 'Injection site amyloid deposits' to the list of adverse drug reactions (ADRs) with frequency not known, based on a review of the clinical study and post-marketing data to evaluate a possible causal association between anakinra (Kineret) and amyloidosis. The Package Leaflet is updated accordingly."

Kisplyx - Lenvatinib - EMEA/H/C/004224/II/0058

Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-B61; this is a phase 2, single-arm, open-label clinical trial of pembrolizumab plus lenvatinib in participants with first-line advanced/metastatic non-clear cell Renal Cell Carcinoma (nccRCC). In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

LIVMARLI - Maralixibat - EMEA/H/C/005857/II/0009, Orphan

Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise, "Update of section 5.3 of the SmPC in order to update preclinical safety information based on final results from study MRX-NC-006, listed as a category 3 study in the RMP. This is a 104-week oral gavage carcinogenicity study of maralixibat in Sprague Dawley Rats performed to evaluate the toxicity and carcinogenic potential of maralixibat."

Mavenclad - Cladribine - EMEA/H/C/004230/II/0032

Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to update an existing warning on infections. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce an editorial update to the PI."

Nexviadyme - Avalglucosidase alfa - EMEA/H/C/005501/II/0015

Sanofi B.V., Rapporteur: Christian Gartner, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update safety and efficacy information based on final results from study EFC14028 - COMparative Enzyme replacement Trial with neoGAA versus rhGAA (COMET), listed as a category 3 study in the RMP. This is a phase 3 randomized, multicenter, multinational, double-blinded study comparing the efficacy and safety of repeated biweekly infusions of avalglucosidase alfa (neoGAA, GZ402666) and alglucosidase alfa in treatment naive patients with late onset Pompe disease. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet."

Olumiant - Baricitinib - EMEA/H/C/004085/II/0046

Eli Lilly Nederland B.V., Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC in order to add information on JIA-associated uveitis or chronic anterior antibody positive uveitis based on interim results from study I4VMC-JAHW; this is an open-label, active-controlled, safety, and efficacy study of oral baricitinib in patients from 2 years to less than 18 years old with active juvenile idiopathic arthritis-associated uveitis or chronic anterior antinuclear antibody-positive uveitis."

Oxlumo - Lumasiran - EMEA/H/C/005040/II/0017, Orphan

Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Submission of the final report from study ALN-GO1-002 (study 002), listed as a category 3 study in the RMP. This is a phase 2, multicenter, open-label, extension study to evaluate the long-term administration of ALN-GO1 in patients with primary hyperoxaluria type 1."

OZAWADE - Pitolisant - EMEA/H/C/005117/II/0007

Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the final report from study P21-03. This is an open label, single center, drug-drug interaction study to evaluate the effect of a combination of itraconazole and paroxetine treatment on the pitolisant pharmacokinetics at steady-state in eighteen healthy male Caucasian subjects."

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0051/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Grouped application comprising of the following variations:
Type II (C.I.4): Update of section 4.2 of the SmPC in order to add clarifying language to the posology section to distinguish between symptom severity and baseline disease severity.
Type II (C.I.4): Update of section 4.4 of the SmPC in order to add information on severe, life-threatening, and fatal drug reactions associated with DDIs.
Type II (C.I.4): Update of section 4.6 of the SmPC in order to clarify that there is limited human data on the use of Paxlovid during pregnancy.
Type II (C.I.4): Update of section 5.1 of the SmPC in order to update information on antiviral activity."

PONVORY - Ponesimod - EMEA/H/C/005163/II/0013

Janssen-Cilag International N.V., Rapporteur: Peter Mol, "Update of section 4.4 of the SmPC to amend an existing warning on PML-IRIS based on the cumulative review of literature. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to introduce editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.3."

PONVORY - Ponesimod - EMEA/H/C/005163/II/0014

Janssen-Cilag International N.V., Rapporteur: Peter Mol, "Update of section 4.5 of the SmPC to amend an existing interaction wording for carbamazepine under the sub-heading "Effect of other medicinal products on ponesimod" based on study 67896153MSC1001. This is a Phase 1, Open-label, Parallel-group Study to Assess the Effect of Steady-state Carbamazepine on the Pharmacokinetics of Ponesimod in Healthy Adult Participants. In addition, the MAH took the opportunity to update the contact details of local representatives in the Package Leaflet."

Puregon - Follitropin beta - EMEA/H/C/000086/II/0128

Organon N.V., Rapporteur: Finbarr Leacy, "Update of section 4.8 of the SmPC in order to

add "anaphylactic reactions" to the list of adverse drug reactions (ADRs) with frequency not known, based on post-marketing surveillance data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI and to bring it in line with the latest QRD template."

QUVIVIQ - Daridorexant - EMEA/H/C/005634/II/0013/G

Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, "Update of sections 4.4, 4.5 and 5.1 of the SmPC in order to reflect the conclusions of studies ID-075-121, ID-078-122 and ID-078-118, respectively. The Package Leaflet was updated accordingly. Study ID-078-121 is a randomized, double-blind, placebo-controlled, 2-way crossover study to investigate the effects of daridorexant on nighttime respiratory function and sleep in subjects with severe obstructive sleep apnea; study ID-078-122 is a prospective, open-label, single-dose Phase 1 study to measure daridorexant in breast milk of healthy lactating women; and study ID-078-118 is a single-center, randomized, double-blind, single-dose, 3-way crossover study to compare the effects of daridorexant and placebo on postural stability, the auditory awakening threshold, and cognitive function in the middle of the night following evening administration to healthy adult and elderly subjects."

Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0014

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from study R10933-10987-COV-2118 (COV-2118) - A Phase 2 Randomized, Open-Label, Parallel Group Study to Assess the Immunogenicity, Safety, and Tolerability of Moderna mRNA-1273 Vaccine Administered with Casirivimab+ Imdevimab in Healthy Adult Volunteers."

SARCLISA - Isatuximab - EMEA/H/C/004977/II/0025

Sanofi Winthrop Industrie, Rapporteur: Peter Mol, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to amend an existing warning on second primary malignancies and to update

efficacy and safety information based on Overall Survival analysis from study EFC15246 (IKEMA - Randomized, open label, multicenter study assessing the clinical benefit of isatuximab combined with carfilzomib (Kyprolis) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with 1 to 3 prior lines). In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Spinraza - Nusinersen - EMEA/H/C/004312/II/0032, Orphan
Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of section 4.8 of the SmPC in order to add 'Arachnoiditis' to the list of adverse drug reactions (ADRs) with frequency not known, based on post-marketing review. The Package Leaflet is updated accordingly."

Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0013
Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from study TX-200-2046 entitled, "104 Week Subcutaneous Injection Carcinogenicity and Toxicokinetic Study of GS-6207 Administered Every 13 Weeks in Wistar-Han Rats". In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

TAGRISSO - Osimertinib - EMEA/H/C/004124/II/0054
AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, "Update of section 4.8 of the SmPC to add 'Skin Hyperpigmentation' to the list of adverse drug reactions (ADRs) with frequency 'uncommon' based on literature. The package leaflet has been updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

TEPMETKO - Tepotinib - EMEA/H/C/005524/II/0011
Merck Europe B.V., Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to add alternative methods of administration dispersed in water, as oral drinking suspension

or via feeding tubes based on the available physicochemical and clinical pharmacology data. The Package Leaflet is updated accordingly.”	
Ultomiris - Ravulizumab - EMEA/H/C/004954/II/0041 Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, “Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update the frequency of adverse reactions and to update pharmacokinetic, efficacy and safety information on PNH based on final results from studies ALXN1210-PNH-304, ALXN1210-PNH-301 (listed as a category 3 study in the RMP), ALXN1210-PNH-201 and ALXN1210-PNH-103. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to align the warning in Annex II and the PI where male patients should not father a child or donate sperm up to eight months after treatment and to introduce editorial changes.”	
Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0137 MCM Vaccine B.V., Rapporteur: Christophe Focke, “Update of section 5.1 of the SmPC in order to add information on rates of predicted protection against pertussis, based on a validated model that correlates anti-pertussis antibody levels with protection against pertussis; this is a modelling study that applied the validated Storsaeter-Kohberger model to the pertussis pre-vaccination and post-vaccination ELISA outputs from Phase 3 studies V419-007 and V419-008.”	
Venclyxto - Venetoclax - EMEA/H/C/004106/II/0047 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, “Submission of the final report from study GO28667 (MURANO) listed as a category 3 study in the RMP. This is a Multicenter, Phase III, Open-Label, Randomized Study in Relapsed/Refractory Patients with Chronic Lymphocytic Leukaemia to Evaluate the Benefit of GDC-0199 (ABT-199) Plus Rituximab Compared with Bendamustine Plus Rituximab.”	
Vocabria - Cabotegravir -	

EMEA/H/C/004976/II/0019
ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, "Update of section 4.2 of the SmPC in order to update administration instructions to mitigate product leakage related to the correct use of the vial adapter, based on Human Factor studies. The Package Leaflet (Instructions for Use) is updated accordingly."

Volibris - Ambrisentan - EMEA/H/C/000839/II/0067
GlaxoSmithKline (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, "To update sections 4.8 and 5.1 of the SmPC following the assessment of Art 46 procedure (EMEA/H/C/000839) based on final results from study AMB114588; this is an open-label, long-term extension study for treatment of pulmonary arterial hypertension in paediatric patients aged 8 years up to 18 years who have participated in AMB112529 and in whom continued treatment with ambrisentan is desired. In addition, the MAH took the opportunity to implement minor editorial changes to Annex II and to the Package Leaflet."

Wegovy - Semaglutide - EMEA/H/C/005422/II/0018
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to add 'Dysgeusia' to the list of adverse drug reactions (ADRs) with frequency 'Common' based on results from clinical studies, post-marketing data and literature. The Package Leaflet is updated accordingly."

Xevudy - Sotrovimab - EMEA/H/C/005676/II/0024
Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to include virology information based on data from various pharmacology studies on the in vitro activity of sotrovimab in a pseudotyped virus assay against the SARS-CoV-2 Omicron XBB.1.16 and XBB.2.3 spike variants (PC-23-0137), the XBB.1.16.1 and XBB.1.5.10 spike variants (PC-23-0151), and Omicron spike variants encoding epitope substitutions (PC-22-0108), as well as data on the in vitro activity of sotrovimab in an authentic virus assay against

the SARS-CoV-2 XBB.1.16 variant (PC-23-0146), and the SARS-CoV-2 BA.2.75, BA.4.6 and BQ.1.1 variants (PC-23-0139).”
WS2583 **Stayveer-EMEA/H/C/002644/WS2583/0040** **Tracleer-EMEA/H/C/000401/WS2583/0105** Janssen-Cilag International N.V., Lead Rapporteur: Alexandre Moreau, “Update of section 4.4 of the SmPC to update the wording concerning breast feeding based on literature and 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.”
WS2597 **OPDIVO-EMEA/H/C/003985/WS2597/0138** **Yervoy-EMEA/H/C/002213/WS2597/0107** Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Carolina Prieto Fernandez, “Update of section 4.8 of the SmPC in order to add ‘myelitis’ to the list of adverse drug reactions (ADRs) based on post- marketing data and literature; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”
WS2603 **Eucreas-EMEA/H/C/000807/WS2603/0105** **Galvus-EMEA/H/C/000771/WS2603/0082** **Icandra-EMEA/H/C/001050/WS2603/0110** **Jalra-EMEA/H/C/001048/WS2603/0085** **Xiliarx-EMEA/H/C/001051/WS2603/0083** **Zomarist-EMEA/H/C/001049/WS2603/0107** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder, “Update of section 4.8 of the SmPC in order to add ‘Cholecystitis’ to the list of adverse drug reactions (ADRs) with frequency ‘Not known’. The Package Leaflet is updated accordingly.”

B.6.10. CHMP-PRAC assessed procedures

Beyfortus - Nirsevimab -

EMEA/H/C/005304/II/0018/G

Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising two type II variations as follows:
C.I.13: Submission of the final report from study D5290C00004 (MELODY) listed as a category 3 study in the RMP. This is a phase III study, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of MEDI8897, a monoclonal antibody with an extended half-life against respiratory syncytial virus, in healthy late preterm and term infants.
C.I.13: Submission of the final report from study D5290C00005 (MEDLEY) listed as a category 3 study in the RMP. This is a phase II/III study, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus (nirsevimab) in high-risk children.
The RMP version 2.3 has also been submitted."

BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0010

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Zane Neikena, "Submission of the final report from study HIPRA-HH-5, "A phase III, open label, single arm, multi-center, trial to assess the safety and immunogenicity of a booster vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-COV-2, in adults vaccinated against COVID-19". The RMP version 1.3 has also been submitted."

Enhertu - Trastuzumab deruxtecan - EMEA/H/C/005124/II/0040

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of sections 4.2 and 5.2 of the SmPC based on final results from studies DS8201-A-J101, DS8201-A-J102, DS8201-A-A103, DS8201-A-A104, DS8201-A-U201, DS8201-A-J202, DS8201-A-J203, DS8201-A-U204, DS8201-A-U205, DS8201-A-U206, DS8201-A-U207, DS8201-A-U301, DS8201-A-U302, and DS8201-A-U303, listed as category 3 activity in the RMP. The updated RMP version

7.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the SmPC and Annex II.D."

MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0027

Sanofi Pasteur, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final report from study MET52, listed as a category 3 study in the RMP. This was a Phase III, open-label, randomized, parallel-group, active-controlled, multi-center study to evaluate the immunogenicity and describe the safety of MenACYW conjugate vaccine when administered concomitantly with a Meningococcal Group B vaccine and other routine paediatric vaccines as part of the National Immunisation Schedule in healthy infants and toddlers in the United Kingdom. The RMP version 1.3 has also been submitted."

Spravato - Esketamine - EMEA/H/C/004535/II/0020

Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Kirsti Villikka, "Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on severe hepatic impairment and to include the long-term safety information based on final results from study 54135419TRD3008 (An Open-label Long-term Extension Safety Study of Esketamine Nasal Spray in Treatment-resistant Depression), listed as a category 3 study in the RMP; This was a multicenter, open-label, long-term extension safety study to evaluate safety, tolerability, and efficacy of esketamine in participants with TRD. The RMP version 5.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0083/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, "A grouped application comprising of 2 Type II variations, as follows:
C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study IMvigor210 (GO29293)

listed as a PAES in the Annex II; this is a Phase II, multicenter, single-arm study of atezolizumab in patients with locally advanced or metastatic urothelial bladder cancer. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template. C.I.13: Submission of the final report from study SAUL (MO29983) listed as a category 3 study in the RMP. This is an open-label, single arm, multicenter, safety study of atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract. The RMP version 30.0 has also been submitted."	
Vabysmo - Faricimab - EMEA/H/C/005642/II/0009 Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of section 4.8 of the SmPC in order to add 'Retinal Vasculitis' and 'Retinal Occlusive Vasculitis' to the list of adverse drug reactions (ADRs) with frequency not known, based on a drug safety report and post-marketing data; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to add study CR45271 as a category 3 study in the RMP, to introduce minor changes and corrections to the PI and to update the list of local representatives in the Package Leaflet."	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0096 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the SmPC based on final results from study D7220C00001; this is a phase 2/3 partially double-blinded, randomised, multinational, active-controlled study in both previously vaccinated and unvaccinated adults to determine the safety and immunogenicity of AZD2816, a vaccine for the prevention of COVID-19 caused by variant strains of SARS-CoV-2. The RMP version 8 s1 has also been submitted."	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0097	

AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final report from study D8110C00001 listed as a category 3 study in the RMP (SOB/020). This is a phase III, randomised, placebo-controlled study of AZD1222 (Vaxzevria) conducted in the US, Peru and Chile. The purpose of the final CSR addendum is to provide long-term safety data through to study completion and include the second year of follow-up post-first dose and final day 730 visit. The RMP version 8 s2 has also been submitted."

Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0014, Orphan

Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.4 of the SmPC in order to amend an existing warning on infusion reactions and hypersensitivity reactions, and update of section 5.1 of the SmPC to update the mechanism of action of efgartigimod in relation to albumin; based on final results from study ARGX-113-1705 listed a category 3 study in the RMP. This is a long-term, single-arm, open-label, multicenter, phase 3 follow-on study of ARGX-113-1704 to evaluate the safety and tolerability of ARGX-113 in patients with myasthenia gravis having generalised muscle weakness. The RMP version 2.2 has also been submitted."

Xevudy - Sotrovimab - EMEA/H/C/005676/II/0026

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Liana Gross-Martirosyan, "To update sections 4.2, 4.8 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study COMET-PACE (215226), a category 3 study in the RMP; this is an open-label, non-comparator, multicentre study to describe the pharmacokinetics (PK), pharmacodynamics (PD; viral load) and safety following a single intravenous or intramuscular dose of sotrovimab in paediatric participants with mild to moderate COVID-19 at high risk of disease progression. The updated RMP version 1.1 has also been submitted."

Zeposia - Ozanimod - EMEA/H/C/004835/II/0023

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Update of sections 4.4 and 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study RPC01-3001, listed as a category 3 study in the RMP. This is a multi-site, open label extension trial of RPC1063 in relapsing multiple sclerosis. The study's main objectives were to characterise the long-term safety and tolerability, and the long-term efficacy of ozanimod in patients with relapsing multiple sclerosis. The RMP version 7.0 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led

BLINCYTO - Blinatumomab - EMEA/H/C/003731/II/0054, Orphan

Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jana Lukacisinova, PRAC-CHMP liaison: Petr Vrbata, "To update sections 4.2, 4.4 and 4.8 of the SmPC to include Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS); and to update section D of Annex II to remove educational materials for physicians, pharmacists and nurses and to include ICANS within neurologic events in educational material for patient/caregivers and patient alert card following the outcome of PSUR procedure EMEA/H/C/PSUSA/00010460/202212. The Package Leaflet is updated accordingly. The RMP version 17.0 has also been submitted."

PRAC Led

Entyvio - Vedolizumab - EMEA/H/C/002782/II/0081

Takeda Pharma A/S, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study Vedolizumab-5001 (OTIS Entyvio Pregnancy Exposure Registry); this is a non-interventional study to monitor planned and unplanned pregnancies in female patients with ulcerative colitis or Crohn's disease. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes and

corrections to the PI and bring it in line with the latest QRD template."

PRAC Led

Evrysdi - Risdiplam - EMEA/H/C/005145/II/0020

Roche Registration GmbH, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Daniela Philadelphy, "Submission of an updated RMP version 2.0 in order to remove the important potential risk of retinal toxicity with risdiplam due to the absence of evidence of retinal toxicity based on thorough ophthalmological monitoring in clinical studies to date."

PRAC Led

Instanyl - Fentanyl - EMEA/H/C/000959/II/0082

Takeda Pharma A/S, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from study Instanyl-5002 listed as a category 3 study in the RMP. This is a non-interventional PASS study with title "Assessment of the Effectiveness of Updated Educational Materials on Prescribers' Knowledge and Behavior with Respect to Risks Associated with INSTANYL Off-Label Use". The RMP version 20.0 has also been submitted."

PRAC Led

MabThera - Rituximab - EMEA/H/C/000165/II/0201/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa Mejia, "A grouped application comprising of:
Type II (C.I.3.b): Update of sections 4.1, 4.2, 4.3, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC in order to introduce several structural and editorial changes to align with the current SmPC guideline and to remove the educational materials for HCPs and patients, following the request by the PRAC in the AR for the PSUSA procedure EMA/PRAC/257005/2023. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 25.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.
Type I (A.6): To change the ATC Code of

rituximab from L01XC02 to L01FA01."

PRAC Led

Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0077

GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report from study EPI-MALALARIA-002 VS AME (115055). This is a non-interventional study, designed to estimate the incidence of diseases specified as adverse events of special interest, of other adverse events leading to hospitalisation or death, and of meningitis in infants and young children in sub-Saharan Africa."

PRAC Led

Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0066

Orexigen Therapeutics Ireland Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of final report from study NB-453, listed as a category 3 study in the RMP. This is a noninterventional qualitative research using online focus groups to assess understanding, attitude and behaviour for usage of the Mysimba Physician Prescribing Checklist (PPC) among physicians in the European Union (EU), following a previous cross-sectional survey that aimed at evaluating the effectiveness of the same PPC (study NB-452). The RMP version 12.10 has also been submitted."

PRAC Led

Prolia - Denosumab - EMEA/H/C/001120/II/0100

Amgen Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from the post-marketing observational study 20090522, listed as a category 3 study in the RMP. This is a denosumab global safety assessment among women with postmenopausal osteoporosis (PMO), men with osteoporosis, and men and women who receive Prolia with glucocorticoid exposure in multiple observational databases."

PRAC Led

RAYVOW - Lasmiditan -
EMEA/H/C/005332/II/0005
Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Anna Mareková, PRAC-CHMP liaison: Frantisek Drafi, "Submission of an updated RMP version 1.1 in order to include a descriptive interim analysis in the study design of study H8H-MC-B006, listed as a category 3 study in the RMP. This is a non-interventional study titled 'Lasmiditan Use and Motor Vehicle Accidents in Real-World Settings in the US'."

PRAC Led
SARCLISA - Isatuximab -
EMEA/H/C/004977/II/0024
Sanofi Winthrop Industrie, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Submission of the final report from study SARSAC09715, listed as a category 3 study in the RMP. This is a non-interventional survey to evaluate the effectiveness of the isatuximab educational materials to minimise the risk of interference for blood typing (minor antigen) (positive indirect Coombs test). The RMP version 1.3 has also been submitted."

PRAC Led
SCENESSE - Afamelanotide -
EMEA/H/C/002548/II/0049, Orphan
Clinuvel Europe Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of the final report from study CUV-RCR-001 (Scenesse (Afamelanotide 16mg) Retrospective Chart Review) listed as an obligation in the Annex II of the Product Information. This is a retrospective study comparing long-term safety data and outcome endpoints in patients receiving and not receiving Scenesse, or having discontinued Scenesse use. The Annex II and the RMP (version 9.6) are updated accordingly."

PRAC Led
Spravato - Esketamine -
EMEA/H/C/004535/II/0021
Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 5.2 in order to remove "use during pregnancy" as

missing information from the list of safety concerns, with the consequential removal of the associated category 3 additional pharmacovigilance activity, the National Pregnancy Registry for Antidepressants ("Massachusetts General Hospital (MGH) pregnancy registry)."
PRAC Led **Stelara - Ustekinumab - EMEA/H/C/000958/II/0104** Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of the final report from study RRA-20745 listed as a category 3 study in the RMP. This is an observational post-authorisation safety study (PASS) to describe the safety of ustekinumab and other Crohn's disease treatments in a cohort of patients with Crohn's disease. The RMP version 27.2 has also been submitted."
PRAC Led **TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0124** Corza Medical GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 9.1 in order to reflect the extension of indication to include the paediatric population and to update the details of the planned non-interventional post-authorisation safety study: PASS-TachoSil Evaluation (PasTel)."
PRAC Led **Zessly - Infliximab - EMEA/H/C/004647/II/0033** Sandoz GmbH, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 4.0 in order to remove the UKIBD (UK) registry from the additional pharmacovigilance activities."
PRAC Led **WS2577 Kinzalmono- EMEA/H/C/000211/WS2577/0120 Micardis- EMEA/H/C/000209/WS2577/0129 Pritor-EMEA/H/C/000210/WS2577/0133** Boehringer Ingelheim International GmbH, Lead Rapporteur: Paolo Gasparini, Lead PRAC

Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 6.1 in order to implement an overall update regarding safety concerns based on literature and post-marketing data; and to adapt the RMP to the current RMP format (Rev 2.0.1), in line with GVP Module V, Revision 2."

PRAC Led
WS2587
TECFIDERA-
EMEA/H/C/002601/WS2587/0085
Vumerity-
EMEA/H/C/005437/WS2587/0015
Biogen Netherlands B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final report from study 109MS401, a multicenter, global, observational study to collect information on safety and to document the drug utilisation of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category 3 study in the RMP (MEA007.6). The RMPs version 16.1 for Tecfidera and version 2.1 for Vumerity, have also been submitted."

PRAC Led
WS2591/G
Hefiya-
EMEA/H/C/004865/WS2591/0050/G
Hyrimoz-
EMEA/H/C/004320/WS2591/0049/G
Sandoz GmbH, Lead Rapporteur: Christian Gartner, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "C.I.13: Submission of the final report from study RABBIT. This is a German registry for the long-term observation of therapy with biologics in adult patients with rheumatoid arthritis.
C.I.13: Submission of the final report from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR). This is a registry to investigate the long-term safety outcomes of psoriasis patients treated with biologic therapy.
C.I.13: Submission of the final report from the Inflammatory Bowel Disease Registry (UK-IBD). This registry was used to identify adverse reactions to Hyrimoz in a cohort of inflammatory bowel disease patients managed in a real-world

setting.”	
PRAC Led **WS2604** **Riarify-EMEA/H/C/004836/WS2604/0029** **Trydonis-** **EMEA/H/C/004702/WS2604/0034** Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig, Lead PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, “C.I.11.z - To provide a new version of the RMP for Riarifly and Trydonis in order to: - update the post-authorisation exposure data - replace the protocol of the PASS study for study CLI-05993BA1-05 in Annex 3, following its approval via procedure EMEA/H/X/004257/MEA/002.3.”	
PRAC Led **WS2611** **Kinzalkomb-** **EMEA/H/C/000415/WS2611/0123** **MicardisPlus-** **EMEA/H/C/000413/WS2611/0130** **PritorPlus-** **EMEA/H/C/000414/WS2611/0133** Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, “Submission of an updated RMP version 9.1 for MicardisPlus, PritorPlus and Kinzalkomb in order to remove all important identified and potential risks from the list of safety concerns and to adapt the RMP to the current RMP format (Rev 2.0.1), in line with GVP Module V, Revision 2.”	
PRAC Led **WS2615** **Abseamed-** **EMEA/H/C/000727/WS2615/0108** **Binocrit-** **EMEA/H/C/000725/WS2615/0108** **Epoetin alfa Hexal-** **EMEA/H/C/000726/WS2615/0108** Sandoz GmbH, Lead PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, “Submission of the final report from Non-Interventional Post authorisation Safety Study, NI-PASS HX575-507 listed as a category 3 study in the RMP. The non-interventional study (NIS PASS) HX575-507 was conducted to	

address a post-approval requirement (MEA 13.5) to evaluate the safety profile of HX575 administered s.c. in patients with CKD-induced anaemia under real-life conditions, in order to increase confidence on the safe use of s.c. HX575. The RMP version 19.0 has also been submitted."

PRAC Led
WS2620
Dovato-EMEA/H/C/004909/WS2620/0047
Juluca-EMEA/H/C/004427/WS2620/0056
Tivicay-EMEA/H/C/002753/WS2620/0092
Triumeq-
EMEA/H/C/002754/WS2620/0118
ViiV Healthcare B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of section 4.6 of the SmPC in order to update information about the use of DTG-containing regimens in pregnancy and at conception based on final results from non-interventional Tsepamo study and the Eswatini Birth Outcomes Surveillance study. In addition, data from other cohort studies and pregnancy registries, including the APR, DOLOMITE-EPPICC (study 208613) and DOLOMITE-NEAT-ID Network study (study 208759) both listed as category 3 studies in the RMP; and the US Chart Review (study 212976) as well as data from literature are included. DOLOMITE-EPPICC (Study 208613) is a s a non-interventional study to Assess "real-world" maternal and foetal outcomes following DTG use during pregnancy and to describe patterns of DTG utilisation; DOLOMITE NEAT ID Network Study (208759) is a non-interventional, multi-site observational study to define the safety and effectiveness of Dolutegravir use in HIV positive pregnant women. The Package Leaflet is updated accordingly. The RMP version 19 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to sections 4.4 and 4.5 of the SmPC."

B.6.12. CHMP-CAT assessed procedures

Alofisel - Darvadstrocel -
EMEA/H/C/004258/II/0047/G, Orphan, ATMP
Takeda Pharma A/S, Rapporteur: Maria Luttgen,

CHMP Coordinator: Kristina Dunder

WS2607
Tecartus-
EMEA/H/C/005102/WS2607/0039
Yescarta-
EMEA/H/C/004480/WS2607/0067
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2475/G
Revatio-
EMEA/H/C/000638/WS2475/0109/G
Viagra-
EMEA/H/C/000202/WS2475/0121/G
Upjohn EESV, Lead Rapporteur: Patrick Vrijlandt

WS2518/G
Combivir-
EMEA/H/C/000190/WS2518/0110/G
Epivir-
EMEA/H/C/000107/WS2518/0127/G
Kivexa-
EMEA/H/C/000581/WS2518/0097/G
Trizivir-
EMEA/H/C/000338/WS2518/0132/G
ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race

WS2584
HyQvia-EMEA/H/C/002491/WS2584/0094
Kiovig-EMEA/H/C/000628/WS2584/0125
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

WS2601
Nuwiq-EMEA/H/C/002813/WS2601/0057
Vihuma-
EMEA/H/C/004459/WS2601/0039
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS2606/G
M-M-RvaxPro-

EMEA/H/C/000604/WS2606/0122/G
ProQuad-
EMEA/H/C/000622/WS2606/0164/G
Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus

WS2617
Blitzima-
EMEA/H/C/004723/WS2617/0071
Truxima-
EMEA/H/C/004112/WS2617/0074
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

WS2624
Abseamed-
EMEA/H/C/000727/WS2624/0109
Binocrit-
EMEA/H/C/000725/WS2624/0109
Epoetin alfa Hexal-
EMEA/H/C/000726/WS2624/0109
Sandoz GmbH, Lead Rapporteur: Alexandre Moreau

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.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.

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