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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 22-25 April 2024

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 ongoing 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).



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	9
2.1.	Pre-authorisation procedure oral explanations.....	9
2.1.1.	FRUZAQLA - Fruquintinib - EMEA/H/C/005979	9
2.1.2.	Omecamtiv mecarbil - EMEA/H/C/006112	9
2.2.	Re-examination procedure oral explanations	9
2.3.	Post-authorisation procedure oral explanations	9
2.3.1.	SCENESSE - Afamelanotide - Orphan - EMEA/H/C/002548/II/0044	9
2.4.	Referral procedure oral explanations	10
3.	Initial applications	10
3.1.	Initial applications; Opinions	10
3.1.1.	ALTUVOCT - Efanesoctocog alfa - Orphan - EMEA/H/C/005968	10
3.1.2.	Eribulin Baxter - Eribulin - EMEA/H/C/006191	11
3.1.3.	FRUZAQLA - Fruquintinib - EMEA/H/C/005979	11
3.1.4.	JERAYGO - Aprocitentan - EMEA/H/C/006080	12
3.1.5.	Obgemsa - Vibegron - EMEA/H/C/005957	12
3.1.6.	Tofidence - Tocilizumab - EMEA/H/C/005984	13
3.1.7.	Truqap - Capivasertib - EMEA/H/C/006017	13
3.1.8.	WEZENLA - Ustekinumab - EMEA/H/C/006132	14
3.2.	Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)	14
3.2.1.	Polihexanide - Orphan - EMEA/H/C/005858	14
3.2.2.	Axitinib - EMEA/H/C/006206	14
3.2.3.	Erdafitinib - EMEA/H/C/006050.....	15
3.2.4.	Enzalutamide - EMEA/H/C/006299	15
3.2.5.	Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - PRIME – OPEN - EMEA/H/C/005797	15
3.2.6.	Donanemab - EMEA/H/C/006024	15
3.2.7.	Catumaxomab - EMEA/H/C/005697	16
3.2.8.	Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278	16
3.2.9.	Nilotinib - EMEA/H/C/006315	16
3.2.10.	Odronextamab - Orphan - EMEA/H/C/006215	16

3.2.11.	Crovalimab - EMEA/H/C/006061	17
3.2.12.	Pomalidomide - EMEA/H/C/006273	17
3.2.13.	Pomalidomide - EMEA/H/C/006314	17
3.2.14.	Pomalidomide - EMEA/H/C/006294	18
3.2.15.	Sotatercept - PRIME - Orphan - EMEA/H/C/005647.....	18
3.2.16.	Syfovre - Pegcetacoplan - EMEA/H/C/005954	18
3.2.17.	Macitentan / Tadalafil - EMEA/H/C/005001	19
3.3.	Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)	19
3.3.1.	Repotrectinib - EMEA/H/C/006005.....	19
3.3.2.	Aflibercept - EMEA/H/C/005980	19
3.3.3.	Eltrombopag - EMEA/H/C/006417	19
3.3.4.	Aflibercept - EMEA/H/C/005899	20
3.3.5.	Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594	20
3.3.6.	Govorestat - Orphan - EMEA/H/C/006270	20
3.3.7.	Odevixibat - EMEA/H/C/006462	20
3.3.8.	Vorasidenib - Orphan - EMEA/H/C/006284	21
3.3.9.	Belzutifan - EMEA/H/C/005636	21
3.3.10.	Filgrastim - EMEA/H/C/006400	21
3.4.	Update on on-going initial applications for Centralised procedure.....	22
3.4.1.	rituximab - EMEA/H/C/006224.....	22
3.4.2.	Pomalidomide - EMEA/H/C/006302	22
3.4.3.	Aumolertinib - EMEA/H/C/006069	22
3.4.4.	Ustekinumab - EMEA/H/C/005918.....	22
3.5.	Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004	23
3.5.1.	Nezglyal - Ieriglitzzone - Orphan - EMEA/H/C/005757	23
3.6.	Initial applications in the decision-making phase.....	23
3.6.1.	Qalsody - Tofersen - Orphan - EMEA/H/C/005493	23
3.7.	Withdrawals of initial marketing authorisation application	24
3.7.1.	germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165	24
3.7.2.	Ustekinumab - EMEA/H/C/006415.....	24

4.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	24
-----------	---	-----------

4.1.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion	24
4.1.1.	Mektovi - Binimetinib - EMEA/H/C/004579/X/0029	24
4.1.2.	Ocrevus - Ocrelizumab - EMEA/H/C/004043/X/0039	25
4.1.3.	Ozempic - Semaglutide - EMEA/H/C/004174/X/0043	25

4.1.4.	Rozlytrek - Entrectinib - EMEA/H/C/004936/X/0017/G	25
4.1.5.	Wegovy - Semaglutide - EMEA/H/C/005422/X/0016	26
4.2.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues	27
4.2.1.	Bimzelx - Bimekizumab - EMEA/H/C/005316/X/0021	27
4.2.2.	Cresemba - Isavuconazole - Orphan - EMEA/H/C/002734/X/0042/G	27
4.2.3.	Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038	28
4.2.4.	Skyrizi - Risankizumab - EMEA/H/C/004759/X/0043/G	28
4.3.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question	28
4.3.1.	Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G	28
4.3.2.	Jakavi - Ruxolitinib - EMEA/H/C/002464/X/0070/G	29
4.3.3.	Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G	30
4.4.	Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008	30
4.5.	Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	30

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

30

5.1.	Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information.....	30
5.1.1.	Alecensa - Alectinib - EMEA/H/C/004164/II/0047	30
5.1.2.	Amyvid - Florbetapir (18F) - EMEA/H/C/002422/II/0046	31
5.1.3.	AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0008	31
5.1.4.	Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005	32
5.1.5.	BUCCOLAM - Midazolam - EMEA/H/C/002267/II/0061	32
5.1.6.	Inaqovi - Decitabine / Cedazuridine - EMEA/H/C/005823/II/0002	33
5.1.7.	Infanrix hexa - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/000296/II/0340/G	33
5.1.8.	Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150	34
5.1.9.	Kinpeygo - Budesonide - Orphan - EMEA/H/C/005653/II/0008	34
5.1.10.	LIVMARLI - Maralixibat - Orphan - EMEA/H/C/005857/II/0003/G	34
5.1.11.	OPDIVO - Nivolumab - EMEA/H/C/003985/II/0137	35
5.1.12.	OPDIVO - Nivolumab - EMEA/H/C/003985/II/0140	35
5.1.13.	Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0013	36
5.1.14.	Pemazyre - Pemigatinib - Orphan - EMEA/H/C/005266/II/0015	36
5.1.15.	RYBREVANT - Amivantamab - EMEA/H/C/005454/II/0010	37
5.1.16.	SIRTURO - Bedaquiline - Orphan - EMEA/H/C/002614/II/0056	38

5.1.17.	TAGRISSO - Osimertinib - EMEA/H/C/004124/II/0053	38
5.1.18.	Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0082	39
5.1.19.	Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0003	39
5.1.20.	Triumeq - Dolutegravir / Abacavir / Lamivudine - EMEA/H/C/002754/II/0116	40
5.1.21.	Wegovy - Semaglutide - EMEA/H/C/005422/II/0017	40
5.1.22.	Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027/II/0035	41
5.1.23.	WS2463 Imfinzi - Durvalumab - EMEA/H/C/004771/WS2463/0063 Lynparza - Olaparib - EMEA/H/C/003726/WS2463/0066	41
5.2.	Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	42
5.2.1.	WS2551 Kalfrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/WS2551/0043 Kalydeco - Ivacaftor - EMEA/H/C/002494/WS2551/0121	42
5.2.2.	Kisqali - Ribociclib - EMEA/H/C/004213/II/0045	42
5.3.	Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	43

6. Medical devices 43

6.1.	Ancillary medicinal substances - initial consultation	43
6.2.	Ancillary medicinal substances – post-consultation update	43
6.3.	Companion diagnostics - initial consultation	43
6.4.	Companion diagnostics – follow-up consultation	43
6.4.1.	In vitro diagnostic medical device - EMEA/H/D/006470	43

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 44

7.1.	Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)	44
-------------	--	-----------

8. Pre-submission issues 44

8.1.	Pre-submission issue	44
8.1.1.	Levacetylleucine - Orphan - H0006327	44
8.1.2.	Inavolisib - H0006353	44
8.1.3.	Pridopidine - H0006261	44
8.1.4.	Zanidatamab - Orphan - H0006380	45
8.2.	Priority Medicines (PRIME)	45

9. Post-authorisation issues 45

9.1.	Post-authorisation issues	45
9.1.1.	LUMYKRAS - Sotorasib - EMEA/H/C/005522/II/0010/G	45
9.1.2.	Ofev - nintedanib - EMEA/H/C/003821/X/0052/G	46
9.1.3.	Ozempic - Semaglutide - EMEA/H/C/004174/II/0044/G	46
9.1.4.	Remsuma - Infliximab - EMEA/H/C/002576/II/0133/G	46
9.1.5.	Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0015	47

9.1.6.	SCENESSE - Afamelanotide - Orphan - EMEA/H/C/002548/II/0044	47
9.1.7.	Wegovy - Semaglutide - EMEA/H/C/005422/II/0020/G	48

10. Referral procedures 48

10.1.	Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004	48
10.1.1.	Ocaliva - obeticholic acid - EMEA/H/A-20/1531	48
10.1.2.	Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065	49
10.2.	Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 .	50
10.3.	Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004	50
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	50
10.5.	Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC....	50
10.6.	Community Interests - Referral under Article 31 of Directive 2001/83/EC	50
10.6.1.	Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/153250	
10.7.	Re-examination Procedure under Article 32(4) of Directive 2001/83/EC.....	51
10.8.	Procedure under Article 107(2) of Directive 2001/83/EC	51
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	51
10.10.	Procedure under Article 29 of Regulation (EC) 1901/2006.....	51
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	51

11. Pharmacovigilance issue 52

11.1.	Early Notification System	52
--------------	--	-----------

12. Inspections 52

12.1.	GMP inspections	52
12.2.	GCP inspections.....	52
12.3.	Pharmacovigilance inspections.....	52
12.4.	GLP inspections	52

13. Innovation Task Force 52

13.1.	Minutes of Innovation Task Force.....	52
13.2.	Innovation Task Force briefing meetings.....	52
13.3.	Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004	53
13.4.	Nanomedicines activities	53

14.	Organisational, regulatory and methodological matters	53
14.1.	Mandate and organisation of the CHMP	53
14.2.	Coordination with EMA Scientific Committees.....	53
14.2.1.	Pharmacovigilance Risk Assessment Committee (PRAC)	53
14.2.2.	Paediatric Committee (PDCO)	53
14.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	53
14.3.1.	Biologics Working Party (BWP).....	53
14.3.2.	Election of Vice-Chair – Biologics Working Party (BWP).....	54
14.3.3.	Name Review Group (NRG)	54
14.3.4.	Scientific Advice Working Party (SAWP)	54
14.4.	Cooperation within the EU regulatory network.....	54
14.5.	Cooperation with International Regulators.....	54
14.6.	Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee	54
14.7.	CHMP work plan	54
14.8.	Planning and reporting	55
14.8.1.	H-MAAs 3-year forecast report (March 2024 - December 2026)	55
14.9.	Others	55
14.9.1.	CHMP Learnings	55
15.	Any other business	55
15.1.	AOB topic.....	55
16.	List of participants	56
Explanatory notes		62

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

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

1.2. Adoption of agenda

CHMP agenda for 22-25 April 2024

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 19-21 March 2024.

The CHMP adopted the minutes for the 19-21 March 2024 plenary.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 15 April 2024.

The CHMP adopted the minutes from the PROM meeting held on 11 March 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. FRUZAQLA - Fruquintinib - EMEA/H/C/005979

Takeda Pharmaceuticals International AG Ireland Branch; as monotherapy is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib.

Scope: Oral explanation

Action: Oral explanation to be held on 24 April 2024 at 16:00

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

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 12.10.2023.

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

See 3.1.

2.1.2. Omecamtiv mecarbil - EMEA/H/C/006112

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

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2024 at 11:00

List of Outstanding Issues adopted on 21.03.2024, 14.12.2023. List of Questions adopted on 26.04.2023.

An oral explanation was held on 23 April 2024. The presentation by the applicant focused on the clinical data in support of the application.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. 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."

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2024 at 09:00

Participation of patient representatives

Request for Supplementary Information adopted on 14.12.2023, 25.05.2023.

An oral explanation was held on 23 April 2024.

The presentation by the applicant focused on the clinical data in support of the application.

See 9.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. ALTUVOCT - Efanesoctocog alfa - Orphan - EMEA/H/C/005968

Swedish Orphan Biovitrum AB (publ); Treatment and prophylaxis of bleeding in patients with haemophilia A

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.03.2024, 25.01.2024. List of Questions 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 recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.2. Eribulin Baxter - Eribulin - EMEA/H/C/006191

Baxter Holding B.V.; 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 22.02.2024. List of Questions 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 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.

3.1.3. FRUZAQLA - Fruquintinib - EMEA/H/C/005979

Takeda Pharmaceuticals International AG Ireland Branch; as monotherapy is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 12.10.2023.

See 2.1

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

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

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

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

The legal status was agreed as medicinal product subject to restricted medical prescription.
The summary of opinion was circulated for information.
The CHMP noted the letter of recommendation dated 23 April 2024.

3.1.4. JERAYGO - Aprocitentan - EMEA/H/C/006080

Idorsia Pharmaceuticals Deutschland GmbH; treatment of resistant hypertension

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.03.2024, 14.12.2023. List of Questions adopted on 22.06.2023.

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

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

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 24 April 2024.

3.1.5. Obgemsa - Vibegron - EMEA/H/C/005957

Pierre Fabre Medicament; symptomatic treatment of adult patients with overactive bladder (OAB) syndrome.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 22.02.2024. List of Questions 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 recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

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

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

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 24 April 2024.

3.1.6. Tofidence - Tocilizumab - EMEA/H/C/005984

Biogen Netherlands B.V.; treatment of rheumatoid arthritis (RA), coronavirus disease 2019 (COVID-19), polyarticular juvenile idiopathic arthritis (pJIA), and systemic juvenile idiopathic arthritis (sJIA)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.05.2023. 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 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 noted the letter of recommendation dated 22 April 2024.

3.1.7. Truqap - Capivasertib - EMEA/H/C/006017

AstraZeneca AB; treatment of locally advanced or metastatic breast cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 22.02.2024. List of Questions 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 recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

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

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

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 22 April 2024.

3.1.8. WEZENLA - Ustekinumab - EMEA/H/C/006132

Amgen Technology (Ireland) Unlimited Company; treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults, Crohn's Disease

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 22.02.2024. List of Questions 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 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.

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

3.2.1. Polihexanide - Orphan - EMEA/H/C/005858

SIFI SPA; treatment of acanthamoeba keratitis

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 15.09.2022.

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

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

3.2.2. Axitinib - EMEA/H/C/006206

treatment of adult patients with advanced renal cell carcinoma (RCC)

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. Erdafitinib - EMEA/H/C/006050

treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

3.2.4. Enzalutamide - EMEA/H/C/006299

treatment of prostate cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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. Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - PRIME – OPEN - EMEA/H/C/005797

Accelerated assessment

prevention of disease caused by chikungunya (CHIKV) virus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.02.2024.

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

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

3.2.6. Donanemab - EMEA/H/C/006024

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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.

The CHMP agreed to consult the SAG Neurology and adopted a list of questions to the experts.

3.2.7. Catumaxomab - EMEA/H/C/005697

indicated for the treatment of malignant ascites

Scope: List of outstanding issues

Action: adoption

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

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

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

3.2.8. Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278

Prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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. Nilotinib - EMEA/H/C/006315

treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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. 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 outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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. Crovalimab - EMEA/H/C/006061

treatment of paroxysmal nocturnal haemoglobinuria

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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. Pomalidomide - EMEA/H/C/006273

treatment of adult patients with multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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. Pomalidomide - EMEA/H/C/006314

treatment of multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

3.2.14. Pomalidomide - EMEA/H/C/006294

treatment of adults with multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

3.2.15. Sotatercept - PRIME - Orphan - EMEA/H/C/005647

Merck Sharp & Dohme B.V.; treatment of pulmonary arterial hypertension in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.01.2024.

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

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

3.2.16. Syfovre - Pegcetacoplan - EMEA/H/C/005954

Apellis Netherlands B.V.; Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: List of outstanding issues; third party intervention

The European Medicines Agency has decided to reset the evaluation procedure for Syfovre to day 180 of the initial assessment procedure and convene a new ad-hoc expert group (AHEG). This decision follows the appellate judgment in Case C-291/22 P published on 14 March 2024 by the Court of Justice which had implications for EMA's organisation of Scientific Advisory Groups and AHEGs.

Further information is available in the March and April CHMP meeting highlights.

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 25.05.2023.

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.

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

3.2.17. Macitentan / Tadalafil - EMEA/H/C/005001

treatment of pulmonary arterial hypertension (PAH) in adults patients

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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. Repotrectinib - EMEA/H/C/006005

Treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) and for solid tumours

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application

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

3.3.2. Aflibercept - EMEA/H/C/005980

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

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. Eltrombopag - EMEA/H/C/006417

treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA)

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. Afibercept - EMEA/H/C/005899

treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)

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 by the applicant for an extension to the clock stop to respond to the list of questions.

3.3.5. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594

repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: List of questions

Action: For information

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

The CHMP was updated on discussions at the CAT.

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

3.3.6. Govorestat - Orphan - EMEA/H/C/006270

Advanz Pharma Limited; treatment of adults and children aged 2 years and older with a confirmed diagnosis of classic galactosemia

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 by the applicant for an extension to the clock stop to respond to the list of questions.

3.3.7. Odevixibat - EMEA/H/C/006462

treatment of cholestatic pruritus in Alagille syndrome (ALGS)

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. Vorasidenib - Orphan - EMEA/H/C/006284

Les Laboratoires Servier; treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a IDH1 R132 mutation or IDH2 R172 mutation
treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a IDH1 R132 mutation or IDH2 R172 mutation

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. Belzutifan - EMEA/H/C/005636

treatment of adult patients with advanced renal cell carcinoma (RCC) and treatment of adult patients with von Hippel-Lindau (VHL) disease

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application

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

3.3.10. Filgrastim - EMEA/H/C/006400

for the reduction in the duration of neutropenia and the incidence of febrile neutropenia

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. rituximab - EMEA/H/C/006224

treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis

Scope: Letter by the applicant dated 19.04.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in March 2024.

Action: For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 14.09.2024.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in March 2024.

3.4.2. Pomalidomide - EMEA/H/C/006302

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

Scope: Letter by the applicant dated 19.04.2024 requesting an extension to the clock stop to respond to the list of questions adopted in January 2024.

Action: For adoption

List of Questions adopted on 25.01.2024.

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 January 2024.

3.4.3. Aumolertinib - EMEA/H/C/006069

treatment of non-small cell lung cancer

Scope: Letter by the applicant dated 22.04.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in December 2023.

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 30.03.2023.

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 December 2023.

3.4.4. Ustekinumab - EMEA/H/C/005918

treatment of adult patients with moderately to severely active Crohn's disease, plaque psoriasis, paediatric plaque psoriasis and Psoriatic arthritis (PsA)

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in March 2024.

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 12.10.2023.

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 March 2024.

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

3.5.1. Nezglyal - Ieriglitazone - Orphan - EMEA/H/C/005757

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

Scope: appointment of re-examination rapporteurs via written procedure on 15 March 2024.

Action: For information

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

Opinion adopted on 25.01.2023. List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 15.12.2022.

The CHMP noted that the re-examination rapporteurs were appointed via written procedure on 15 March 2024.

3.6. Initial applications in the decision-making phase

3.6.1. Qalsody - Tofersen - Orphan - EMEA/H/C/005493

Biogen Netherlands B.V.; treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

Scope: Request from the European Commission for clarification in relation to the Opinion adopted by the CHMP for Qalsody at its February meeting, adoption of revised opinion via written procedure on 19 April 2024.

Action: for information

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

Opinion adopted on 22.02.2024. List of Outstanding Issues adopted on 09.11.2023, 14.09.2023. List of Questions adopted on 30.03.2023.

The Committee addressed the request from the European Commission for clarification in relation to the CHMP Opinion adopted at its February meeting.

The CHMP adopted the revised positive opinion for Qalsody via written procedure by majority (23 out of 29 votes).

The divergent positions (Peter Mol, Paolo Gasparini, Kristina Dunder, Carolina Prieto Fernandez, Outi Maki-Ikola, Sol Ruiz) were appended to the opinion.

3.7. Withdrawals of initial marketing authorisation application

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

indicated for in vitro labelling of kits for radiopharmaceutical preparation

Scope: Withdrawal of marketing authorisation application

Action: For information

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

The CHMP noted the withdrawal of the marketing authorisation application.

3.7.2. Ustekinumab - EMEA/H/C/006415

treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults and Crohn's Disease

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Outstanding issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

The CHMP noted the withdrawal of the marketing authorisation application.

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

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

4.1.1. Mektovi - Binimetinib - EMEA/H/C/004579/X/0029

Pierre Fabre Medicament

Rapporteur: Janet Koenig

Scope: "Extension application to add a new strength of 45 mg (film-coated tablets)."

Action: For adoption

List of Questions adopted on 25.01.2024.

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. Ocrevus - Ocrelizumab - EMEA/H/C/004043/X/0039

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (920 mg) and new route of administration (subcutaneous use). The RMP (version 9.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

4.1.3. Ozempic - Semaglutide - EMEA/H/C/004174/X/0043

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

List of Questions adopted on 22.02.2024.

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.

4.1.4. Rozlytrek - Entrectinib - EMEA/H/C/004936/X/0017/G

Roche Registration GmbH

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to:

1) Introduce a new pharmaceutical form (coated granules) associated with a new strength (50 mg).

2) Introduce a new route of administration (gastroenteric use) for the already authorised 100 mg and 200 mg hard capsules presentations.

The above two line extensions are grouped with 3 type II variations:

- C.I.6.a - To extend the currently approved indication in solid tumours with NTRK gene fusion to patients from birth to 12 years of age (both for the coated granules and already approved hard capsules presentations).

- C.I.6.a - To add a new paediatric indication from birth to 18 years of age for patients with solid tumours with a ROS1 gene fusion (both for the coated granules and already approved hard capsules presentations).

Based on final results from studies CO40778 (STARTRK-NG), GO40782 (STARTRK-2) and

BO41932 (TAPISTRY). Study CO40778 is a Phase I/II open-label, dose-escalation and expansion study of entrectinib in paediatrics with locally advanced or metastatic solid or primary CNS tumours and/or who have no satisfactory treatment options; Study GO40782 is an open-label, multicentre, global Phase II basket study of entrectinib for the treatment of patients with solid tumours that harbour an NTRK1/2/3, ROS1, or ALK gene rearrangement (fusion), and Study BO41932 is a Phase II, global, multicentre, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in participants with unresectable, locally advanced or metastatic solid tumours determined to harbour specific oncogenic genomic alterations or who are tumour mutational burden (TMB)-high as identified by a validated next-generation sequencing (NGS) assay.

As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated accordingly. The Package Leaflet and Labelling are updated in accordance.

- C.I.4 - To add wording regarding the option of suspension in water of the content of the capsules to be used orally or via the e.g., gastric or nasogastric tube (in sections 4.2 and 5.2 of the SmPC). The RMP (version 5) is updated in accordance. The MAH took the opportunity to introduce minor editorial changes to the PI and to update Annex II of the SmPC."

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions 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.

4.1.5. Wegovy - Semaglutide - EMEA/H/C/005422/X/0016

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

List of Questions adopted on 22.02.2024.

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. Bimzelx - Bimekizumab - EMEA/H/C/005316/X/0021

UCB Pharma S.A.

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to add a new strength of 320 mg (160 mg/ml) for bimekizumab solution for injection in pre-filled syringe or pre-filled pen, for subcutaneous (SC) administration."

Action: For adoption

List of Questions adopted on 25.01.2024.

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 outstanding issues and a specific timetable.

4.2.2. Cresemba - Isavuconazole - Orphan - EMEA/H/C/002734/X/0042/G

Basilea Pharmaceutica Deutschland GmbH

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 40 mg hard capsule to be used in paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and older for CRESEMBA 200 mg powder, based on final results from studies 9766-CL-0107 and 9766-CL-0046. Study 9766-CL-0046 is a Phase 1, open-label, multicentre study to evaluate the PK, safety and tolerability of intravenous and oral isavuconazonium sulfate in paediatric patients. This study was conducted in two sequential parts: Part 1 with three intravenous dosing cohorts, and Part 2 with two oral dosing cohorts. Study 9766-CL-0107 is a Phase 2, open-label, non-comparative, multicentre study to evaluate the safety and tolerability, efficacy, and PK of isavuconazole for the treatment of invasive aspergillosis or mucormycosis in paediatric patients aged 1 to < 18 years.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

4.2.3. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: "Extension application to introduce three new strengths of tablets (1.5 mg, 4 mg and 9 mg) for semaglutide."

Action: For adoption

List of Questions adopted on 22.02.2024.

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

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

4.2.4. Skyrizi - Risankizumab - EMEA/H/C/004759/X/0043/G

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to a new strength of 180 mg of risankizumab (solution for injection in cartridge) grouped with a type II variation extension of indication (C.I.6.a) to include treatment of adult patients with moderately to severely active ulcerative colitis, for SKYRIZI, based on final results from studies M16-067 substudy 2: a phase 2b/3 multicentre, randomised, double-blind, placebo-controlled induction study to evaluate the efficacy and safety of risankizumab in subjects with moderately to severely active ulcerative colitis, and M16-066 substudy 1: a multicentre, randomized, double-blind, placebo controlled 52-week maintenance and an open-label extension study of the efficacy and safety of risankizumab in subjects with ulcerative colitis, as well as DDI study M19-974. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC for the Skyrizi 600 mg concentrate for solution for infusion, and sections 1, 2, 4.1, 4.2, 4.8, 5.1, 5.2, 5.3, 6.5 and 6.6 of the SmPC for the Skyrizi 360 mg solution for injection in cartridge are updated. The Annex II, Labelling and Package Leaflets are updated in accordance. Version 5.0 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

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

4.3.1. Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G

Sanofi B.V.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to introduce a new strength (21 mg capsule, hard) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who have been previously treated with enzyme replacement therapy (ERT), and who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs) for Cerdelga, based on interim results from study EFC13738 (Open label, two cohort (with and without imiglucerase), multicentre study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in paediatric patients with Gaucher disease type 1 and type 3). 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. The RMP version 8.0 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

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. [Jakavi - Ruxolitinib - EMEA/H/C/002464/X/0070/G](#)

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg/ml oral solution) and a new route of administration (gastric use), indicated for the treatment of Graft versus host disease (GvHD) in patients aged 28 days or older.

The above line extension is grouped with a type II variation:

- C.I.6.a - To include treatment of paediatric patients aged 28 days to less than 18 years old in acute and chronic Graft versus Host Disease for JAKAVI, based on final results from studies REACH4 (CINC424F12201) and REACH5 (Study CINC424G12201). REACH4 is a Phase I/II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in paediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation; while REACH5 is a Phase II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in paediatric subjects with moderate and severe chronic graft vs. host disease after allogeneic stem cell transplantation (both for oral solution and already approved tablets presentations). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.

The RMP (version 16) is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to implement editorial changes to Annex II."

Action: For adoption

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

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

4.3.3. Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an extension of indication to include treatment of active polyarticular-course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older for KEVZARA, based on results from study DRI13925; this is a multinational, multi-center, open-label, 2 phase, 3 portions study to describe the PK profile as well as safety and efficacy of sarilumab. 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. Version 3.0 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 the CHMP recommendation and scientific discussion together with the list of questions.

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

No items

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

No items

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

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

5.1.1. Alecensa - Alectinib - EMEA/H/C/004164/II/0047

Roche Registration GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Jana Lukacisinova

Scope: "Extension of indication to include the use of Alecensa as monotherapy in adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as adjuvant treatment following tumour resection, based on final results from study BO40336 (ALINA), a randomized, active controlled, multicentre, open-label, Phase III

study designed to evaluate the efficacy and safety of alectinib compared with platinum-based chemotherapy in the adjuvant setting in patients with completely resected Stage IB (tumours 4 cm) to Stage IIIA ALK positive NSCLC. 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 4.2 of the RMP has also been agreed. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Furthermore, the CHMP reviewed the data submitted by the marketing authorisation holder, taking into account the provisions of Article 14(11) of Regulation (EC) No 726/2004 and considers by consensus that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies, as set out in Annex IV."

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

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

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

The summary of opinion was circulated for information.

5.1.2. [Amyvid - Flortetapir \(18F\) - EMEA/H/C/002422/II/0046](#)

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include monitoring response to therapy for AMYVID, based on supporting literature. As a consequence, sections 4.1 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.8 of the SmPC to reflect the current clinical trial exposures to align it with the updated RMP."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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.

5.1.3. [AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0008](#)

GlaxoSmithkline Biologicals S.A.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of adults 50-59 years of age who are at increased risk for RSV disease for AREXVY, based on results from study 219238 (RSV OA=ADJ-018); this is a phase 3, observer-blind, placebo-controlled, randomized, multi-country, multi-center, non-inferiority study with 2 cohorts to evaluate immunogenicity, reactogenicity and safety of a single dose of RSVPreF3 OA in adults 50-59 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.3, 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.", 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.

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

5.1.4. [Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005](#)

Sanofi Winthrop Industrie

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of children up to 24 months of age who remain vulnerable to severe Respiratory Syncytial Virus (RSV) disease through their second RSV season for BEYFORTUS, based on interim results from studies D5290C00005 and D5290C00008.

Study D5290C00005 (MEDLEY) is a Phase II/III, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus in high-risk children. Study D5290C00008 (MUSIC) is a Phase II, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetics, and occurrence of antidrug antibody for Beyfortus in immunocompromised children ≤ 24 Months of Age.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 2.1 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

Request for Supplementary Information adopted on 25.01.2024, 12.10.2023, 20.07.2023.

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.

5.1.5. [BUCCOLAM - Midazolam - EMEA/H/C/002267/II/0061](#)

Neuraxpharm Pharmaceuticals S.L.

Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include treatment of adults to Buccolam 10 mg, based on the results from study 2023-504903-10-00; this is an Interventional Study, Relative Bioavailability to investigate the pharmacokinetics of a single dose of midazolam oromucosal solution (Buccolam) compared to midazolam solution for intramuscular injection (Hypnovel) in healthy volunteers under fasting conditions. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 8.1 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.

5.1.6. [Inaqovi - Decitabine / Cedazuridine - EMEA/H/C/005823/II/0002](#)

Otsuka Pharmaceutical Netherlands B.V.

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

Scope: "Grouped application consisting of:

C.I.6: Extension of indication to include treatment of adult patients with myelodysplastic syndromes (MDS) for INAQOVI.

C.I.6: Extension of indication to include treatment of adult patients with chronic myelomonocytic leukaemia (CMML) for INAQOVI.

Based on final results from studies ASTX727-01, ASTX727-02, ASTX727-04, E7727-01, and E7727-02. 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. Version 1.1 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 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

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.

5.1.7. [Infanrix hexa - Diphtheria, tetanus, pertussis \(acellular, component\), hepatitis B \(rDNA\), poliomyelitis \(inact.\) and haemophilus type B conjugate vaccine \(adsorbed\) - EMEA/H/C/000296/II/0340/G](#)

GlaxoSmithkline Biologicals SA

Rapporteur: Christophe Focke

Scope: "A grouped application consisting of two type II variations, as follows:

C.I.6.a: To modify the approved therapeutic indication to include treatment from the age of 6 weeks for the administration of the primary vaccination, section 4.1 of the SmPC is updated accordingly.

C.I.4: Update of section 4.2 of the SmPC for the use of mixed hexavalent/pentavalent primary vaccination schedule and vaccine interchangeability. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and 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.

5.1.8. [Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150](#)

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with enfortumab vedotin, the first-line treatment of locally advanced or metastatic urothelial carcinoma in adults, based on the final results from KEYNOTE-A39/EV-302: "An open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)"; 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 45.1 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.

5.1.9. [Kinpeygo - Budesonide - Orphan - EMEA/H/C/005653/II/0008](#)

STADA Arzneimittel AG

Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II; this is a Phase 3, randomized, double-blind, placebo-controlled, multicentre study to evaluate the efficacy, safety, and tolerability of oral Nefecon compared to matching placebo in patients with primary IgAN on a background of optimized RAS inhibitor therapy. 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 1.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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.

5.1.10. [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 Quality variation and:

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, multicentre, 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.

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023, 20.07.2023.

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.

5.1.11. OPDIVO - Nivolumab - EMEA/H/C/003985/II/0137

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include OPDIVO in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma, based on interim results from study CA209901 (CheckMate901). This is a Phase 3, open-label, randomised study of nivolumab combined with ipilimumab, or with standard of care chemotherapy, versus standard of care chemotherapy in participants with previously untreated unresectable or metastatic urothelial cancer. 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 35.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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.

5.1.12. OPDIVO - Nivolumab - EMEA/H/C/003985/II/0140

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include OPDIVO for the treatment of patients with resectable stage II-IIIB non-small cell lung cancer, based on results from study

CA209977T; a phase 3, randomised, double-blind study of neoadjuvant chemotherapy plus nivolumab versus neoadjuvant chemotherapy plus placebo, followed by surgical resection and adjuvant treatment with nivolumab or placebo for participants with resectable stage II-IIIB non-small cell lung cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 36.0 of the RMP has also been submitted.”

Action: For adoption

The Committee discussed the issues identified in this application, relating to clinical aspects.
The Committee adopted a request for supplementary information with a specific timetable.

5.1.13. Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0013

Astellas Pharma Europe B.V.

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová

Scope: “Extension of indication to include in combination with pembrolizumab, the first-line treatment of adult patients with locally advanced or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy for PADCEV, based on the final results from study KEYNOTE-A39/EV-302: “An open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)”; As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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.

5.1.14. Pemazyre - Pemigatinib - Orphan - EMEA/H/C/005266/II/0015

Incyte Biosciences Distribution B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: “Extension of indication to include treatment of adults with myeloid/lymphoid neoplasms (MLNs) with Fibroblast Growth Factor Receptor1 (FGFR1) rearrangement for PEMAZYRE, based on final results from study INCB 54828-203 (FIGHT-203); this is a phase 2, open-label, monotherapy, multicentre study to evaluate the efficacy and safety of INCB054828 in subjects with myeloid/lymphoid neoplasms with FGFR1 rearrangement. 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. In addition, the MAH took the opportunity to introduce minor changes to 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

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. RYBREVANT - Amivantamab - EMEA/H/C/005454/II/0010

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations for RYBREVANT, based on the final results from study 61186372NSC3001 listed as a Specific Obligation in the Annex II of the Product Information; this is a global, open-label, randomized Phase 3 study of ACP compared to CP alone in participants with newly diagnosed, locally advanced or metastatic NSCLC characterized by EGFR exon 20ins. The primary objective of the PAPILLON study is to compare efficacy, as demonstrated by PFS, in participants treated with ACP versus CP alone. As a consequence, sections 4.1, 4.2, 4.8, 4.9, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has been agreed. In addition, the MAH took the opportunity to update Annex II and Annex IV of the PI. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation given the fulfilment of the SOB. As part of the application, the MAH also requested an extension of the market protection by one additional year.

The CHMP, having considered the application as set out in the appended assessment report and having reviewed the data submitted by the marketing authorisation holder including the evidence concerning compliance with specific obligations, is of the opinion that the risk-benefit balance of the above mentioned medicinal product remains favourable, that all specific obligations laid down in Annex II have been fulfilled and that comprehensive data supports a favourable benefit-risk balance of the above mentioned medicinal product. Therefore, pursuant to Article 14-a(8) of Regulation (EC) No 726/2004, the CHMP recommends by consensus the granting of a marketing authorisation in accordance with Article 14(1) of Regulation (EC) No 726/2004 for the above mentioned medicinal product for which the draft Summary of Product Characteristics is set out in Annex I.

Furthermore, the CHMP reviewed the data submitted by the marketing authorisation holder, taking into account the provisions of Article 14(11) of Regulation (EC) No 726/2004 and considers by consensus that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies, as set out in Annex IV.

The CHMP members of Iceland and Norway agree with the above-mentioned recommendation of the CHMP on granting of a Marketing Authorisation in accordance with Article 14(1) of Regulation (EC) No 726/2004 and the variation(s) to the terms of the marketing authorisation and the additional year of market/data exclusivity."

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

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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.

5.1.16. SIRTURO - Bedaquiline - Orphan - EMEA/H/C/002614/II/0056

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication (by removing the restriction limiting the use of Sirturo for patients for whom an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability) based on final results from study STREAM Stage 2; a multicentre, open-label, parallel-group, randomised, 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). Submission of the study fulfils SOB 007. As a consequence, 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. The Labelling and Package Leaflet are updated in accordance. A revised RMP version 10.2 has been approved. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024.

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. 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

Request for Supplementary Information adopted on 14.12.2023.

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.

5.1.18. 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

Request for Supplementary Information adopted on 14.12.2023.

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.

5.1.19. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0003

Beigene Ireland Limited

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder

Scope: “Extension of indication to include in combination with platinum-based chemotherapy the first-line treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (OSCC) for TEVIMBRA, based on results from study BGB-A317-306; this is a multi-regional, randomized, placebo-controlled, double-blind phase 3 study evaluating the efficacy and safety of tislelizumab in combination with chemotherapy compared to placebo in combination with chemotherapy as first-line treatment in patients with unresectable or locally advanced recurrent or metastatic OSCC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the 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.

5.1.20. Triumeq - Dolutegravir / Abacavir / Lamivudine - EMEA/H/C/002754/II/0116

ViiV Healthcare B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: “Extension of indication to include treatment of paediatric patients from 3 months of age and weighting at least 6 kg to less than 25 kg for Triumeq Dispersible Tablets, based on PK, safety, and efficacy data observed in the final results of study 205860 (IMPAACT 2019). As a consequence of this new indication, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 22.0 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.

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

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 25.01.2024.

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.

5.1.21. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: “Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and BMI ≥ 27 kg/m² for WEGOVY, based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. 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 25.01.2024.

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.

5.1.22. [Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027/II/0035](#)

Pfizer Ireland Pharmaceuticals

Rapporteur: Ingrid Wang, Co-Rapporteur: Larisa Gorobets, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include treatment of paediatric patients from birth to less than 3-months of age in the following infections: complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI), including pyelonephritis, hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) and in the treatment of infections due to aerobic Gram-negative organisms in patients with limited treatment options, for ZAVICEFTA, based on final results from study C3591024 and the population PK modelling/simulation analyses. Study C3591024 is a Phase 2a, 2-part, open-label, non-randomized, multicentre, single and multiple dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in neonates and infants from birth to less than 3 months of age with suspected or confirmed infections due to gram-negative pathogens requiring intravenous antibiotic treatment. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 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.

5.1.23. [WS2463](#) [Imfinzi - Durvalumab - EMEA/H/C/004771/WS2463/0063](#) [Lynparza - Olaparib - EMEA/H/C/003726/WS2463/0066](#)

AstraZeneca AB

Lead Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication for Lynparza in combination with Imfinzi for the maintenance treatment of adult patients with newly diagnosed advanced or recurrent endometrial cancer following treatment with Imfinzi and platinum-based chemotherapy, based on results from pivotal Phase III study, D9311C00001 (DUO-E). This was a phase III, randomised, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of durvalumab in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance durvalumab with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 30 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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.

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

5.2.1. WS2551

Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/WS2551/0043
Kalydeco - Ivacaftor - EMEA/H/C/002494/WS2551/0121

Vertex Pharmaceuticals (Ireland) Limited

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "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."

Update on the procedure; intervention by a third party

Action: For information

Request for Supplementary Information adopted on 22.02.2024.

The CHMP noted the update on the procedure.

5.2.2. 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, multicentre, 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, .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."

Letter by the applicant dated 19.04.2024 requesting an extension to the clock stop to respond to the RSI adopted in March 2024.

Action: For information

Request for Supplementary Information adopted on 21.03.2024 and 14.12.2023.

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

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

No items

6.4. Companion diagnostics – follow-up consultation

6.4.1. In vitro diagnostic medical device - EMEA/H/D/006470

to detect amplification of the HER2/neu gene via quantitative fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer

Scope: Opinion

Action: For adoption

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

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

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. Levacetylleucine - Orphan - H0006327

Intrabio Ireland Limited; Niemann-Pick disease type C (NPC)

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. Inavolisib - H0006353

Inavolisib in combination with palbociclib and fulvestrant, is indicated for the treatment of adult patients with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer (LA/mBC), following recurrence on or within 12 months of completing adjuvant endocrine treatment

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. Pridopidine - H0006261

Treatment of Huntington's disease (HD)

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. Zanidatamab - Orphan - H0006380

Jazz Pharmaceuticals Ireland Limited; Zanidatamab is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive biliary tract cancer (BTC)

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.

8.2. 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. 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 Multicentre, Randomised, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumours With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023 and 25.05.2023.

The Committee discussed the issues identified in this application.

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

9.1.2. Ofev - nintedanib - EMEA/H/C/003821/X/0052/G

Boehringer Ingelheim International GmbH

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: AHEG meeting nomination of experts

Action: For adoption

The CHMP adopted the list of experts for the AHEG.

9.1.3. Ozempic - Semaglutide - EMEA/H/C/004174/II/0044/G

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

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

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

The summary of opinion was circulated for information.

9.1.4. Remsima - Infliximab - EMEA/H/C/002576/II/0133/G

Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Grouped application comprising of three type II variations (C.I.4) as follows:

- Update of section 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information based on Week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (crohn's disease), listed as a category 3 study in the RMP; Study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease.
- Update of section 4.2 and 5.2 of the SmPC in order to add subcutaneous induction

posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.

- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study). The RMP version 16.1 has also been submitted. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI.”

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 09.11.2023.

The Committee discussed the issues identified in this application.

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

9.1.5. Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0015

Roche Registration GmbH

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga

Scope: “Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive analysis of the results from the drug pregnancy registry cohort (PDC study GV44373), listed as a category 3 PASS in the RMP, as well as data from clinical studies and post-marketing surveillance. The RMP version 3.0 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.”

Action: For adoption

Request for Supplementary Information adopted on 07.03.2024.

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

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

The summary of opinion was circulated for information.

9.1.6. 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.”

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2024 at 09:00

Participation of patient representatives

Request for Supplementary Information adopted on 14.12.2023, 25.05.2023.

See 2.3

An oral explanation was held on 23 April 2024.

The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the withdrawal of extension of indication application.

9.1.7. [Wegovy - Semaglutide - EMEA/H/C/005422/II/0020/G](#)

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

Request for Supplementary Information adopted on 07.03.2024.

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.

10. Referral procedures

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

10.1.1. [Ocaliva - obeticholic acid - EMEA/H/A-20/1531](#)

Advanz Pharma Limited

Referral Rapporteur: Carolina Prieto Fernandez, Referral Co-Rapporteur: Paolo Gasparini

Scope: List of outstanding issues / opinion; intervention by a third party

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 Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in

the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed.

List of outstanding issues adopted on 25.01.2024. List of Questions adopted on 12.10.2023.

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

Submission of responses: 28 May 2024

Re-start of the procedure: 30 May 2024

Ad-hoc expert group meeting (AHEG): TBD

Rapporteur/co-rapporteur JAR to CHMP: 11 June 2024

Comments: 17 June 2024

Updated rapporteur/co-rapporteur JAR to CHMP: 19 June 2024

CHMP opinion: June 2024 CHMP

10.1.2. [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 Philadelphia

Scope: List of outstanding issues / opinion

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.

CHMP list of outstanding issues adopted on 14.12.2023. List of Questions adopted on 14.09.2023.

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

The CHMP adopted a revised list of questions to the SAG Cardiovascular.

The CHMP agreed to consult the PRAC and adopted a list of questions to this Committee.

Submission of responses: 24 May 2024

Re-start of the procedure: 30 May 2024

Scientific Advisory Group meeting: TBD

Rapporteur/co-rapporteur JAR to PRAC and CHMP: 07 June 2024

PRAC advice: 13 June 2024

Comments: 13 June 2024

Updated rapporteur/co-rapporteur JAR to CHMP: 19 June 2024

CHMP list of outstanding issues or CHMP opinion: June 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

No items

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

No items

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

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

MAH various (NAPs only)

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Antonio Gómez Outes

Scope: List of outstanding issues

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.

List of Questions adopted on 09 November 2023.

The CHMP agreed to consult the IDWP and adopted a list of questions to the working party.

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

CHMP list of outstanding issues and CHMP list of questions to IDWP: April 2024 CHMP

Submission of responses: 29 August 2024

PRAC advice to CHMP: 05 September 2024

Re-start of the procedure: 19 September 2024

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 26 September 2024

Comments: 03 October 2024

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 09 October 2024

CHMP list of outstanding issues /CHMP opinion: October 2024 CHMP

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

April 2024 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for April 2024

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Agenda of the April 2024 PDCO plenary meeting.

Action: For information

The CHMP noted the PDCO agenda.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry

Reports from the BWP meeting for CHMP adoption

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Election of Vice-Chair – Biologics Working Party (BWP)

Following the call for nominations launched in March, CHMP to elect the Vice-Chair from the candidates who submitted nominations.

Nomination(s) received

Action: For election

The CHMP elected Andreea Barbu (SE), as vice-chairperson of the Biologics Working Party.

14.3.3. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 16-17 April 2024.

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 15-18 April 2024. Table of conclusions

Action: For information

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

The CHMP noted the update.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. H-MAAs 3-year forecast report (March 2024 - December 2026)

3-year forecast report of initial marketing authorisations, Type II Variations and Line Extension applications planned for the next three years (March 2024 - December 2026).

Action: For information

The CHMP noted the 3-year forecast report.

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 learnings identified during the April plenary meeting.

15. Any other business

15.1. AOB topic

No items

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 22-25 April 2024 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 Philadelphia	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 interests declared	
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:	4.1.3. Ozempic - Semaglutide - EMEA/H/C/004174 /X/0043 4.1.5. Rybelsus - Semaglutide - EMEA/H/C/004953 /X/0038 4.1.6. Wegovy - Semaglutide - EMEA/H/C/005422 /X/0016 5.1.22. Wegovy - Semaglutide - EMEA/H/C/005422 /II/0017 9.1.4. Ozempic - Semaglutide - EMEA/H/C/004174 /II/0044/G 9.1.7. Wegovy - Semaglutide - EMEA/H/C/005422 /II/0020/G
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No participation in discussion, final deliberations and voting on:	2.1.2. Omecamtiv mecarbil - EMEA/H/C/006112
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
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	
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	4.3.1. Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G 4.3.3. Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G 5.1.4. Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
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	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Simona Badoi	Member	Romania	No interests declared	
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 participation in final deliberations and voting on:	3.2.13. Pomalidomide - EMEA/H/C/006314 10.6.1. Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/1532
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	Spain	No interests declared	
Antonio Gomez-Outes	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 interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Lenka Králová	Expert	Czech Republic	No interests declared	
Michaela Dlouhá	Expert	Czech Republic	No interests declared	
Lenka Králová	Expert	Czech Republic	No interests declared	
Jana Žižkovská	Expert	Czech Republic	No interests declared	
Michaela Dlouhá	Expert	Czech Republic	No interests declared	
Jitka Soukupová	Expert	Czech Republic	No interests declared	
Jiří Haman	Expert	Czech Republic	No interests declared	
Mária Kováčová	Expert	Czech Republic	No interests declared	
Heidi Mestl	Expert	Norway	No interests declared	
Veronica Krogstad	Expert	Norway	No interests declared	
Lars Peter Engeset Austdal	Expert	Norway	No interests declared	
Anne-Berit Erdal	Expert	Norway	No interests declared	
Martin Walter	Expert	Austria	No interests declared	
Susanne Urach	Expert	Austria	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lisa Nika	Expert	Austria	No restrictions applicable to this meeting	
Mair Powell	Expert	Ireland	No interests declared	
Ailise Carleton	Expert	Ireland	No interests declared	
Brian Aylward	Expert	Ireland	No interests declared	
Juta Kraav	Expert	Estonia	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Joerg Zinserling	Expert	Germany	No interests declared	
Elina Rönnemaa	Expert	Sweden	No interests declared	
André Elferink	Expert	Netherlands	No interests declared	
Sabrina Jenull	Expert	Austria	No restrictions applicable to this meeting	
Ingrid Bourges	Expert	Belgium	No interests declared	
Edwige Haelterman	Expert	Belgium	No interests declared	
Marta Romano	Expert	Belgium	No interests declared	
Violette Dirix	Expert	Belgium	No interests declared	
Filip Van Nuffel	Expert	Belgium	No interests declared	
Alexandru-Mihail Simion	Expert	Belgium	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Maija Tarkkanen	Expert	Finland	No interests declared	
Karin Krogars	Expert	Finland	No interests declared	
Maria Paile-Hyvärinen	Expert	Finland	No interests declared	
Michal Zwiewka	Expert	Germany	No interests declared	
Irene Nowotny	Expert	Germany	No interests declared	
Benjamin Hofner	Expert	Germany	No restrictions applicable to this meeting	
Katja Findeisen	Expert	Germany	No restrictions applicable to this meeting	
Poleta Luga	Expert	Germany	No interests declared	
Niklas Walther	Expert	Germany	No restrictions applicable to this meeting	
Julia Katharina Maier	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Sara Tognarelli	Expert	Germany	No restrictions applicable to this meeting	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Mogens Westergaard	Expert	Denmark	No interests declared	
Veronica Krogstad	Expert	Norway	No interests declared	
Gro Dahlseng Håkonsen	Expert	Norway	No interests declared	
Astrid Doutreluingne	Expert	France	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Miki Hew	Expert	Netherlands	No interests declared	
Esther Broekman	Expert	Netherlands	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Frank Holtkamp	Expert	Netherlands	No interests declared	
Richard Ijzerman	Expert	Netherlands	No restrictions applicable to this meeting	
Adrian Post	Expert	Netherlands	No interests declared	
Marc Maliepaard	Expert	Netherlands	No interests declared	
Lieke Sandberg-Smiths	Expert	Netherlands	No interests declared	
Esther Brandon	Expert	Netherlands	No interests declared	
Karijn Pijnenburg-Kleizen	Expert	Netherlands	No interests declared	
Johannes Petrus Theodorus Span	Expert	Netherlands	No interests declared	
Peter van de Ven	Expert	Netherlands	No participation in final deliberations and voting on:	5.1.11. OPDIVO - Nivolumab - EMEA/H/C/003985/II/0137 5.1.24. WS2463 Imfinzi - Durvalumab - EMEA/H/C/004771/WS2463/0063 Lynparza - Olaparib - EMEA/H/C/003726/WS2463/0066 3.2.15. Sotatercept - PRIME - Orphan - EMEA/H/C/005647 3.3.9. Belzutifan - EMEA/H/C/005636 5.1.8. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150
Laura Rodwell	Expert	Netherlands	No interests declared	
Chantal van de Schootbrugge	Expert	Netherlands	No interests declared	
Eleonora Wijnans	Expert	Netherlands	No interests declared	
Illiana Meurs	Expert	Netherlands	No interests declared	
Bernice Aronsson	Expert	Sweden	No interests declared	
Per Albertsson	Expert	Sweden	No restrictions applicable to this meeting	
Klara Hammarström	Expert	Sweden	No interests declared	
Karin Fjordén	Expert	Sweden	No participation in final deliberations and voting on:	5.1.8. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150
Jolanta Gulbinovic	Expert	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jenny-Maria Jönsson	Expert	Sweden	No participation in final deliberations and voting on:	5.1.8. Keytruda - Pembrolizumab - EMEA/H/C/003820 /II/0150 5.1.19. Tecentriq - Atezolizumab - EMEA/H/C/004143 /II/0082 5.1.11. OPDIVO - Nivolumab - EMEA/H/C/003985 /II/0137 5.1.12. OPDIVO - Nivolumab - EMEA/H/C/003985 /II/0140
Asimina Zisi	Expert	Sweden	No interests declared	
Jacqueline van Kuijk	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Friederike Marei Feldmann	Expert	Germany	No interests declared	
Irene Bachmann	Expert	Germany	No interests declared	
Nils Lilienthal	Expert	Germany	No interests declared	
Ulrike Hermes	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Martin Mengel	Expert	Germany	No interests declared	
Sofia Kapanadze	Expert	Germany	No restrictions applicable to this meeting	
Miriam Fürst-Wilmes	Expert	Germany	No interests declared	
Andreea Barbu	Expert	Sweden	No interests declared	
Barbora Ladinova	Expert	Czech Republic	No interests declared	
Rutger van den Bor	Expert	Netherlands	No restrictions applicable to this meeting	
Sara Galluzzo	Expert	Italy	No interests declared	
Angelo Molinaro	Expert	Italy	No interests declared	
Gunnar Thor Gunnarsson	Expert	Iceland	No interests declared	
Sylvie Benchetrit	Expert	France	No interests declared	
Anissa Benlazar	Expert	Spain	No interests declared	
Thurid Buch	Expert	Germany	No interests declared	
Michael Schramm	Expert	Germany	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with the help of EMA staff.				

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

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

Explanatory notes

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

Oral explanations (section 2)

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

Initial applications (section 3)

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

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

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



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

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

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

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

Extensions of marketing authorisations are applications for the change or addition of new strengths,

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

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

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

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

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

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

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

Re-examination procedures *(section 5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found [here](#).

Pharmacovigilance issues (section 11)

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

Inspections Issues (section 12)

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

Innovation task force (section 13)

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

Scientific advice working party (SAWP) (section 14.3.1)

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

Satellite groups / other committees (section 14.2)

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

Invented name issues (section 14.3)

This section lists 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

07 August 2024
EMA/CHMP/180369/2024

Annex to 22-25 April 2024 CHMP Summary of Outcome

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	3
B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal	3
B.2.2. Renewals of Marketing Authorisations for unlimited validity	3
B.2.3. Renewals of Conditional Marketing Authorisations	4
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES	5
B.4. EPARs / WPARs	10
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	20
B.5.3. CHMP-PRAC assessed procedures.....	34
B.5.4. PRAC assessed procedures.....	44
B.5.5. CHMP-CAT assessed procedures	52
B.5.6. CHMP-PRAC-CAT assessed procedures	53
B.5.7. PRAC assessed ATMP procedures	54
B.5.8. Unclassified procedures and worksharing procedures of type I variations	54
B.5.9. Information on withdrawn type II variation / WS procedure	57
B.5.10. Information on type II variation / WS procedure with revised timetable	57
B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION	58
B.6.1. Start of procedure for New Applications: timetables for information	58
B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information	59



B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information	61
B.6.4. Annual Re-assessments: timetables for adoption.....	64
B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed	64
B.6.6. VARIATIONS – START OF THE PROCEDURE	65
B.6.7. Type II Variations scope of the Variations: Extension of indication	65
B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects	68
B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects.....	70
B.6.10. CHMP-PRAC assessed procedures.....	79
B.6.11. PRAC assessed procedures	83
B.6.12. CHMP-CAT assessed procedures.....	86
B.6.13. CHMP-PRAC-CAT assessed procedures	87
B.6.14. PRAC assessed ATMP procedures.....	87
B.6.15. Unclassified procedures and worksharing procedures of type I variations	87
B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY	89
B.7.1. Yearly Line listing for Type I and II variations	89
B.7.2. Monthly Line listing for Type I variations	89
B.7.3. Opinion on Marketing Authorisation transfer (MMD only)	89
B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)	89
B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)	89
B.7.6. Notifications of Type I Variations (MMD only).....	89
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)	89
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)	89
E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES	89
E.1. PMF Certification Dossiers:.....	89
E.1.1. Annual Update	89
E.1.2. Variations:.....	89
E.1.3. Initial PMF Certification:.....	89
E.2. Time Tables – starting & ongoing procedures: For information	89
F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver	90
G. ANNEX G	90
G.1. Final Scientific Advice (Reports and Scientific Advice letters):	90
G.2. PRIME	90
H. ANNEX H - Product Shared Mailboxes – e-mail address	90

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for April 2024: For adoption	Adopted
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A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for April 2024: For adoption	Adopted
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A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Ceplene - Histamine dihydrochloride - EMEA/H/C/000796/S/0048

Laboratoires Delbert, Rapporteur: Jayne Crowe,
PRAC Rapporteur: Eamon O Murchu
Request for Supplementary Information adopted
on 25.04.2024.

LIVMARLI - Maralixibat - EMEA/H/C/005857/S/0012, Orphan Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
--	---

SCENESSE - Afamelanotide - EMEA/H/C/002548/S/0050, Orphan Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
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B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Epidyolex - Cannabidiol -	Request for supplementary information adopted
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EMEA/H/C/004675/R/0031, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, Co- Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins Request for Supplementary Information adopted on 25.04.2024.	with a specific timetable.
Inbrija - Levodopa - EMEA/H/C/004786/R/0022 Acorda Therapeutics Ireland Limited, Rapporteur: Peter Mol, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Barbara Kovacic Bytyqi	Positive Opinion adopted by consensus together with the CHMP assessment report. 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.
XOSPATA - Gilteritinib - EMEA/H/C/004752/R/0017, Orphan Astellas Pharma Europe B.V., Rapporteur: Ingrid Wang, Co-Rapporteur: Elita Poplavska, PRAC Rapporteur: Martin Huber	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.
Zydelig - Idelalisib - EMEA/H/C/003843/R/0059 Gilead Sciences Ireland UC, Rapporteur: Filip Josephson, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 22.02.2024.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
B.2.3. Renewals of Conditional Marketing Authorisations	
Kinpeygo - Budesonide - EMEA/H/C/005653/R/0010, Orphan STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen	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.
TALVEY - Talquetamab - EMEA/H/C/005864/R/0005, Orphan Janssen-Cilag International N.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Barbara Kovacic Bytyqi	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.
Tecvayli - Teclistamab - EMEA/H/C/005865/R/0010 Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuori, Co-Rapporteur: Paolo	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

Gasparini, PRAC Rapporteur: Jana Lukacisinova	be granted. The Marketing Authorisation remains conditional.
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B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 08-11 April 2024
PRAC:

Signal of serious Cutaneous Adverse Reactions	Adopted
--	---------

Adagrasib – KRAZATI

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

PRAC recommendation on a variation

Action: For adoption

Signal of coeliac disease	Adopted
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Atezolizumab; aveluma; cemiplima;
dostarlimab; durvalumab; ipilimumab;
nivolumab; nivolumab, relatlimab;
pembrolizumab; tislelizumab; tremelimumab -
TECENTRIQ; BAVENCIO; LIBTAYO; JEMPERLI;
IMFINZI; YERVOY; OPDIVO; OPDUALAG;
KEYTRUDA; TEVIMBRA; IMJUDO (CAP)

Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Bianca Mulder

PRAC recommendation on a variation

Action: For adoption

Signal of pancreatic failure	Adopted
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Atezolizumab; aveluma; cemiplima;
dostarlimab; durvalumab; ipilimumab;
nivolumab; nivolumab, relatlimab;
pembrolizumab; tislelizumab; tremelimumab -
TECENTRIQ; BAVENCIO; LIBTAYO; JEMPERLI;
IMFINZI; YERVOY; OPDIVO; OPDUALAG;
KEYTRUDA; TEVIMBRA; IMJUDO (CAP)

Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Martin Huber

PRAC recommendation on a variation

Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its April 2024 meeting:

EMA/H/C/PSUSA/00001187/202308

(duloxetine)

CAPS:

Cymbalta (EMA/H/C/000572) (Duloxetine), Eli Lilly Nederland B.V., Rapporteur: Antonio Gomez-Outes

Duloxetine Lilly (EMA/H/C/004000)

(Duloxetine), Eli Lilly Nederland B.V.,

Rapporteur: Antonio Gomez-Outes

Yentreve (EMA/H/C/000545) (Duloxetine), Eli Lilly Nederland B.V., Rapporteur: Antonio Gomez-Outes

NAPS:

NAPs - EU PRAC Rapporteur: Maria del Pilar Rayon, "03/08/2020 To: 03/08/2023"

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(s), concerning the following change(s):

Update of section 4.4 of the SmPC to amend the information about serotoninergic syndrome and to add information about the neuroleptic malignant syndrome.

Update of section 4.8 of the SmPC to include stress cardiomyopathy (Takotsubo cardiomyopathy) under SOC "Cardiac disorders" with frequency not known.

EMA/H/C/PSUSA/00001988/202309

(mercaptopurine)

CAPS:

Xaluprine (EMA/H/C/002022)

(Mercaptopurine), Nova Laboratories Ireland Limited, Rapporteur: Filip Josephson

NAPS:

NAPs - EU, PRAC Rapporteur: Ulla Wändel Liminga, "02/09/2021 To: 01/09/2023"

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(s), concerning the following change(s):

Update of section 4.8 of the SmPC to add the adverse reaction stomatitis, cheilitis, mucosal inflammation and coagulation factors decreased with a frequency not known. Update of sections 4.4 and 4.8 of the SmPC to add a warning/precaution regarding pellagra and the adverse reaction pellagra with a frequency not known. Update of section 4.6 of the SmPC regarding cholestasis of pregnancy. Update of section 4.5 of the SmPC to add interactions regarding infliximab and methotrexate. The package leaflet is updated accordingly.

EMA/H/C/PSUSA/00003149/202308

(zoledronic acid (indicated for cancer and fractures))

CAPS:

Zoledronic acid Hospira (SRD)

(EMA/H/C/002365) (Zoledronic acid), Pfizer

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

<p>Europe MA EEIG, Rapporteur: Kristina Dunder Zoledronic acid medac (EMA/H/C/002359) (Zoledronic acid), medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Alar Irs Zometa (EMA/H/C/000336) (Zoledronic acid), Phoenix Labs Unlimited Company, Rapporteur: Thalia Marie Estrup Blicher NAPS: NAPS - EUR, PRAC Rapporteur: Karin Erneholm, "01/09/2020 To: 31/08/2023"</p>	<p>terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction 'Tubulointerstitial nephritis' with a frequency 'not known'. The package leaflet is updated accordingly.</p>
<p>EMA/H/C/PSUSA/00009142/202308 (emtricitabine / rilpivirine / tenofovir disoproxil) CAPS: Eviplera (EMA/H/C/002312) (Emtricitabine / Rilpivirine / Tenofovir disoproxil), Gilead Sciences Ireland UC, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan, "11/08/2020 To: 10/08/2023"</p>	<p>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.</p>
<p>EMA/H/C/PSUSA/00010082/202308 (cobicistat / elvitegravir / emtricitabine / tenofovir disoproxil) CAPS: Stribild (EMA/H/C/002574) (Elvitegravir / Cobicistat / Emtricitabine / Tenofovir disoproxil), Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, "27/08/2020 To: 26/08/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product, concerning the following change(s): Update of section 4.4 of the SmPC to 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.</p>
<p>EMA/H/C/PSUSA/00010095/202308 (enzalutamide) CAPS: Xtandi (EMA/H/C/002639) (Enzalutamide), Astellas Pharma Europe B.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Maria del Pilar Rayon, "31/08/2020 To: 30/08/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning/precaution regarding severe cutaneous</p>

	<p>adverse reactions, and update of section 4.8 of the SmPC to add the following adverse drug reactions: Stevens-Johnson syndrome with a frequency not known and Hepatic enzymes increased with a frequency uncommon. The package leaflet is updated accordingly.</p>
<p>EMA/H/C/PSUSA/00010456/202309 (mepolizumab) CAPS: Nucala (EMA/H/C/003860) (Mepolizumab), GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer, "24/03/2023 To: 23/09/2023"</p>	<p>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):</p> <p>Update of section 4.8 of the SmPC to add the adverse reactions Herpes Zoster with the frequency "uncommon" and arthralgia with the frequency "common". The package leaflet is updated accordingly. In addition, the MAH took the opportunity to make editorial changes and update the local representative details.</p>
<p>EMA/H/C/PSUSA/00010718/202308 (eravacycline) CAPS: Xerava (EMA/H/C/004237) (Eravacycline), Paion Deutschland GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "26/08/2022 To: 26/08/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product, concerning the following change(s):</p> <p>Update of sections 4.4 of the SmPC to add a warning/precaution regarding coagulopathy. Hypofibrinogenaemia with frequency common, Increased international normalised ratio (INR) with frequency common, Prolonged activated partial thromboplastin time (aPTT) with frequency common and Prolonged prothrombin time (PT) with frequency common were added to Section 4.8 under the SOC Blood and lymphatic system disorders. Section 2 of the Package leaflet was updated accordingly. The MAH took the opportunity to update the list of local representatives in the package Leaflet.</p>
<p>EMA/H/C/PSUSA/00010724/202309 (abemaciclib) CAPS: Verzenios (EMA/H/C/004302) (Abemaciclib), Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Carla Torre,</p>	<p>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),</p>

<p>"29/09/2022 To: 28/09/2023"</p>	<p>concerning the following change(s): Update of section(s) 4.8 of the SmPC to add the adverse reaction Photopsia with a frequency uncommon. The package leaflet is updated accordingly.</p>
<p>EMEA/H/C/PSUSA/00010857/202309 (ebola vaccine (rDNA, replication-incompetent)) CAPS: MVABEA (EMEA/H/C/005343) (Ebola vaccine (rDNA, replication-incompetent)), Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt ZABDENO (EMEA/H/C/005337) (Ebola vaccine (rDNA, replication-incompetent)), Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "27/09/2022 To: 26/09/2023"</p>	<p>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 maintenance of the terms of the marketing authorisation for Mvabea and the variation to the terms of the marketing authorisation(s) for Zabdeno, concerning the following change(s): Update of section 4.4 of the SmPC to add a warning/precaution regarding Thrombosis with Thrombocytopenia Syndrome. The package leaflet is updated accordingly.</p>
<p>EMEA/H/C/PSUSA/00010927/202309 (ofatumumab) CAPS: Kesimpta (EMEA/H/C/005410) (Ofatumumab), Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli, "26/03/2023 To: 25/09/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section(s) 4.4 and 4.8 of the SmPC to amend a warning regarding injection-related reactions and to add nausea and vomiting with a frequency common. The package leaflet is updated accordingly.</p>
<p>EMEA/H/C/PSUSA/00010952/202308 (vosoritide) CAPS: Voxzogo (EMEA/H/C/005475) (Vosoritide), BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Zane Neikena, "26/02/2023 To: 25/08/2023"</p>	<p>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 Hypertrichosis with a frequency uncommon. The package leaflet is updated accordingly.</p>
<p>EMEA/H/C/PSUSA/00010954/202309 (idecabtagene vicleucel) CAPS: Abecma (EMEA/H/C/004662) (Idcabtagene vicleucel), Bristol-Myers Squibb Pharma EEIG,</p>	<p>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</p>

Rapporteur: Rune Kjekken, PRAC Rapporteur:
Ulla Wändel Liminga, "24/03/2023 To:
24/09/2023"

terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of section(s) 4.4, 4.8 of the SmPC, Annex II and package leaflet to include information in regard to immune effector cell-associated neurotoxicity syndrome (ICANs). In addition, some adjustments have been included in the package leaflet for the general presentation of serious ADRs and their frequency and to align the PI to QRD and to previous procedures.

EMEA/H/C/PSUSA/00010967/202309
(avacopan)

CAPS:

TAVNEOS (EMEA/H/C/005523) (Avacopan),
Vifor Fresenius Medical Care Renal Pharma
France, Rapporteur: Kristina Dunder, PRAC
Rapporteur: Liana Martirosyan, "26/03/2023 To:
26/09/2023"

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 4.4 and 4.8 of the SmPC to add the adverse reactions Drug-induced liver injury (DILI) and Vanishing bile duct syndrome (VBDS), both with a frequency 'not known'. The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00011032/202309
(maralixibat)

CAPS:

LIVMARLI (EMEA/H/C/005857) (Maralixibat),
Mirum Pharmaceuticals International B.V.,
Rapporteur: Martina Weise, PRAC Rapporteur:
Adam Przybylkowski, "28/03/2023 To:
28/09/2023"

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 4.4 and 4.8 of the SmPC to add the adverse reaction ALT increased and AST increased with a frequency common and a warning regarding increased ALT and AST activity. The package leaflet is updated accordingly.

B.4. EPARs / WPARs

**AGILUS - Dantrolene sodium,
hemiheptahydrate - EMEA/H/C/006009,
Orphan**

Norgine B.V., treatment of malignant
hyperthermia (including suspected cases),
Hybrid application (Article 10(3) of Directive No
2001/83/EC)

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

<p>Awigli - Insulin icodec - EMEA/H/C/005978</p> <p>Novo Nordisk A/S, treatment of diabetes mellitus in adults, New active substance (Article 8(3) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Dimethyl fumarate Accord - Dimethyl fumarate - EMEA/H/C/006471</p> <p>Accord Healthcare, treatment of multiple sclerosis, Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Dimethyl fumarate Mylan - Dimethyl fumarate - EMEA/H/C/006397</p> <p>Mylan Ireland Limited, for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS), Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Dimethyl fumarate Neuraxpharm - Dimethyl fumarate - EMEA/H/C/006500</p> <p>Neuraxpharm Pharmaceuticals S.L., treatment of multiple sclerosis, Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Emblaveo - Aztreonam / Avibactam - EMEA/H/C/006113</p> <p>Pfizer Europe Ma EEIG, 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, New active substance (Article 8(3) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Fabhalta - Iptacopan - EMEA/H/C/005764, Orphan</p> <p>Novartis Europharm Limited, treatment of paroxysmal nocturnal haemoglobinuria, New active substance (Article 8(3) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Jubbonti - Denosumab - EMEA/H/C/005964</p> <p>Sandoz GmbH, treatment of osteoporosis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>

Lytenava - Bevacizumab - EMEA/H/C/005723 Outlook Therapeutics Limited, Treatment of neovascular (wet) age-related macular degeneration (nAMD)., 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.
Neotricon - Dopamine hydrochloride - EMEA/H/C/006044, PUMA BrePco Biopharma Limited, Treatment of hypotension in neonates, infants and children, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Omlyclo - Omalizumab - EMEA/H/C/005958 Celltrion Healthcare Hungary Kft., treatment of asthma, chronic rhinosinusitis with nasal polyps and chronic spontaneous urticaria, treatment of asthma and chronic rhinosinusitis with nasal polyps, 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.
UPSTELDA (WD) - Ustekinumab - EMEA/H/C/006415 Amgen Technology (Ireland) Unlimited Company, treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults and Crohn's Disease, treatment of Crohn's Disease, , Similar biological application (Article 10(4) of Directive No 2001/83/EC) WPAR	For information only. Comments can be sent to the PL in case necessary.
Wyost - Denosumab - EMEA/H/C/006378 Sandoz GmbH, prevention of skeletal related events with advanced malignancies , 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

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0015 LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 11.04.2024. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 11.04.2024.
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on 01.02.2024.

**Adtralza - Tralokinumab -
EMA/H/C/005255/II/0018**

LEO Pharma A/S, Rapporteur: Jayne Crowe
Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on
11.04.2024.

**Advate - Octocog alfa -
EMA/H/C/000520/II/0122/G**

Takeda Manufacturing Austria AG, Rapporteur:
Jan Mueller-Berghaus
Request for Supplementary Information adopted
on 04.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Aimovig - Erenumab -
EMA/H/C/004447/II/0030**

Novartis Europharm Limited, Rapporteur:
Kristina Dunder
Opinion adopted on 18.04.2024.

Positive Opinion adopted by consensus on
18.04.2024.

**AQUIPTA - Atogepant -
EMA/H/C/005871/II/0001/G**

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Janet Koenig
Request for Supplementary Information adopted
on 04.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Atosiban SUN – Atosiban -
EMA/VR/0000167976**

Sun Pharmaceutical Industries (Europe) B.V.,
Rapporteur: John Joseph Borg

**Buvidal - Buprenorphine -
EMA/H/C/004651/II/0025**

Camurus AB, Rapporteur: Finbarr Leacy
Request for Supplementary Information adopted
on 25.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Cancidas - Caspofungin -
EMA/H/C/000379/II/0083/G**

Merck Sharp & Dohme B.V., Rapporteur:
Christophe Focke
Request for Supplementary Information adopted
on 04.04.2024, 11.01.2024.

Request for supplementary information adopted
with a specific timetable.

**Cetrotide - Cetrorelix -
EMA/H/C/000233/II/0090**

Merck Europe B.V., Rapporteur: Martina Weise
Opinion adopted on 25.04.2024.
Request for Supplementary Information adopted
on 01.02.2024, 29.06.2023.

Positive Opinion adopted by consensus on
25.04.2024.

**Dovprela - Pretomanid -
EMA/H/C/005167/II/0020, Orphan**

Mylan IRE Healthcare Limited, Rapporteur: Filip

Positive Opinion adopted by consensus on
11.04.2024.

Josephson Opinion adopted on 11.04.2024. Request for Supplementary Information adopted on 07.03.2024.	
Ebixa - Memantine / Memantine hydrochloride - EMEA/H/C/000463/II/0101 H. Lundbeck A/S, Duplicate of Axura, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 25.04.2024, 11.01.2024.	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 Opinion adopted on 04.04.2024. Request for Supplementary Information adopted on 14.12.2023, 31.08.2023, 25.05.2023.	Positive Opinion adopted by consensus on 04.04.2024.
Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0004/G Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 04.04.2024.	Request for supplementary information adopted with a specific timetable.
Enhertu - Trastuzumab - EMEA/H/C/005124/II/0043/G Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 15.02.2024.	Positive Opinion adopted by consensus on 18.04.2024.
Ervebo - Recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0035 Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke Opinion adopted on 25.04.2024.	Positive Opinion adopted by consensus on 25.04.2024.
Eylea - Aflibercept - EMEA/H/C/002392/II/0088 Bayer AG, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 04.04.2024.	Request for supplementary information adopted with a specific timetable.
Gilenya - Fingolimod - EMEA/H/C/002202/II/0088 Novartis Europharm Limited, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 25.04.2024.

**GONAL-f - Follitropin alfa -
EMA/H/C/000071/II/0168/G**

Merck Europe B.V., Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted
on 18.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Herzuma - Trastuzumab -
EMA/H/C/002575/II/0061/G**

Celltrion Healthcare Hungary Kft., Rapporteur:
Jan Mueller-Berghaus
Request for Supplementary Information adopted
on 11.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Hizentra - Human normal immunoglobulin -
EMA/H/C/002127/II/0151/G**

CSL Behring GmbH, Rapporteur: Jan Mueller-
Berghaus
Request for Supplementary Information adopted
on 18.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Ibandronic Acid Teva - Ibandronic acid -
EMA/H/C/001195/II/0021**

Teva B.V., Generic of Bondronat, Bonviva,
Rapporteur: Hrefna Gudmundsdottir
Request for Supplementary Information adopted
on 11.04.2024, 29.02.2024, 16.11.2023.

Request for supplementary information adopted
with a specific timetable.

**Insuman - Insulin human -
EMA/H/C/000201/II/0146**

Sanofi-Aventis Deutschland GmbH, Rapporteur:
Karin Janssen van Doorn
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted
on 15.02.2024.

Positive Opinion adopted by consensus on
11.04.2024.

**Jivi - Damoctocog alfa pegol -
EMA/H/C/004054/II/0031/G**

Bayer AG, Rapporteur: Thalia Marie Estrup
Blicher
Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on
11.04.2024.

**Latuda - Lurasidone -
EMA/H/C/002713/II/0041**

Aziende Chimiche Riunite Angelini Francesco
A.C.R.A.F. S.p.A., Rapporteur: Filip Josephson
Opinion adopted on 04.04.2024.
Request for Supplementary Information adopted
on 08.02.2024.

Positive Opinion adopted by consensus on
04.04.2024.

**NUVAXOVID - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0063/G**

Request for supplementary information adopted
with a specific timetable.

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted
on 25.04.2024.

Ogivri - Trastuzumab - EMA/H/C/004916/II/0060 Biosimilar Collaborations Ireland Limited, Rapporteur: Karin Janssen van Doorn Opinion adopted on 04.04.2024.	Positive Opinion adopted by consensus on 04.04.2024.
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Origio A.R.T. Media - Gentamicin sulfate / Insulin human / Sargramostim / Heparin sodium / Insulin human - EMA/H/D/006090/II/0002 Coopersurgical Inc., Rapporteur: Jayne Crowe Opinion adopted on 11.04.2024.	Positive Opinion adopted by consensus on 11.04.2024.
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Ovaleap - Follitropin alfa - EMA/H/C/002608/II/0039 Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 11.04.2024, 07.12.2023.	Request for supplementary information adopted with a specific timetable.
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Ozempic - Semaglutide - EMA/H/C/004174/II/0044/G Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 25.04.2024.	Positive Opinion adopted by consensus on 25.04.2024. See 9.1
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Posaconazole Accord - Posaconazole - EMA/H/C/005005/II/0012/G Accord Healthcare S.L.U., Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 18.04.2024.
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PREVYMIS - Letermovir - EMA/H/C/004536/II/0036, Orphan Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.	Request for supplementary information adopted with a specific timetable.
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Privigen - Human normal immunoglobulin - EMA/H/C/000831/II/0202/G CSL Behring GmbH, Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 18.04.2024.	Request for supplementary information adopted with a specific timetable.
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Reblozyl - Luspatercept - EMA/H/C/004444/II/0027, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur:	Positive Opinion adopted by consensus on 11.04.2024.
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Daniela Philadelphy
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted
on 15.02.2024.

**Ruxience - Rituximab -
EMA/H/C/004696/II/0015**

Pfizer Europe MA EEIG, Rapporteur: Peter Mol
Request for Supplementary Information adopted
on 04.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Saxenda - Liraglutide -
EMA/H/C/003780/II/0038**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted
on 11.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Skyrizi - Risankizumab -
EMA/H/C/004759/II/0046/G**

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Finbarr Leacy
Opinion adopted on 18.04.2024.
Request for Supplementary Information adopted
on 08.02.2024.

Positive Opinion adopted by consensus on
18.04.2024.

**Skytrofa - Lonapegsomatropin -
EMA/H/C/005367/II/0025/G, Orphan**

Ascendis Pharma Endocrinology Division A/S,
Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted
on 04.04.2024, 08.02.2024.

Request for supplementary information adopted
with a specific timetable.

**Spectrila - Asparaginase -
EMA/H/C/002661/II/0036**

medac Gesellschaft für klinische
Spezialpräparate mbH, Rapporteur: Christian
Gartner
Opinion adopted on 04.04.2024.
Request for Supplementary Information adopted
on 22.02.2024.

Positive Opinion adopted by consensus on
04.04.2024.

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0123/G**

Moderna Biotech Spain S.L., Rapporteur: Jan
Mueller-Berghaus
Request for Supplementary Information adopted
on 25.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Sugammadex Mylan - Sugammadex -
EMA/H/C/005403/II/0010/G**

Mylan Ireland Limited, Generic of Bridion,
Rapporteur: Hrefna Gudmundsdottir
Opinion adopted on 18.04.2024.
Request for Supplementary Information adopted

Positive Opinion adopted by consensus on
18.04.2024.

on 22.02.2024.	
TEPADINA - Thiotepa - EMA/H/C/001046/II/0050/G ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 04.04.2024.	Request for supplementary information adopted with a specific timetable.
TRODELVY - Sacituzumab govitecan - EMA/H/C/005182/II/0032 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.04.2024.	Positive Opinion adopted by consensus on 25.04.2024.
Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMA/H/C/004051/II/0050/G Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt Opinion adopted on 25.04.2024. Request for Supplementary Information adopted on 22.02.2024, 14.12.2023.	Positive Opinion adopted by consensus on 25.04.2024.
Vazkepa - Icosapent ethyl - EMA/H/C/005398/II/0023/G Amarin Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise Request for Supplementary Information adopted on 25.04.2024.	Request for supplementary information adopted with a specific timetable.
Vyvgart - Efgartigimod alfa - EMA/H/C/005849/II/0016, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 04.04.2024.	Request for supplementary information adopted with a specific timetable.
Wegovy - Semaglutide - EMA/H/C/005422/II/0020/G Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 25.04.2024.	Positive Opinion adopted by consensus on 25.04.2024. 9.1
Yuflyma - Adalimumab - EMA/H/C/005188/II/0035/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 25.04.2024.	Request for supplementary information adopted with a specific timetable.
WS2608/G Apretude- EMA/H/C/005756/WS2608/0001/G Vocabria- EMA/H/C/004976/WS2608/0020/G	Positive Opinion adopted by consensus on 18.04.2024.

ViiV Healthcare B.V., Duplicate of Vocabria,
Lead Rapporteur: Bruno Sepodes
Opinion adopted on 18.04.2024.
Request for Supplementary Information adopted
on 08.02.2024.

WS2630 Hefiya-EMA/H/C/004865/WS2630/0052 Hyrmoz- EMA/H/C/004320/WS2630/0051 Sandoz GmbH, Lead Rapporteur: Christian Gartner Opinion adopted on 11.04.2024. Request for Supplementary Information adopted on 07.03.2024.	Positive Opinion adopted by consensus on 11.04.2024.
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WS2634 Hexacima- EMA/H/C/002702/WS2634/0154 Hexyon- EMA/H/C/002796/WS2634/0158 Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 04.04.2024.	Request for supplementary information adopted with a specific timetable.
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WS2651 Nilemdo- EMA/H/C/004958/WS2651/0036 Nustendi- EMA/H/C/004959/WS2651/0041 Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 11.04.2024.	Positive Opinion adopted by consensus on 11.04.2024.
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WS2655/G GONAL-f- EMA/H/C/000071/WS2655/0167/G Pergoveris- EMA/H/C/000714/WS2655/0091/G Merck Europe B.V., Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 11.04.2024.	Positive Opinion adopted by consensus on 11.04.2024.
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WS2659/G Riarify- EMA/H/C/004836/WS2659/0032/G Trimbow- EMA/H/C/004257/WS2659/0039/G Trydonis- EMA/H/C/004702/WS2659/0036/G Chiesi Farmaceutici S.p.A., Informed Consent of	Request for supplementary information adopted with a specific timetable.
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Trimbow, Lead Rapporteur: Janet Koenig
Request for Supplementary Information adopted
on 25.04.2024.

B.5.2. 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 -**

EMA/H/C/006054/II/0002/G

GlaxoSmithkline Biologicals S.A., Rapporteur:
Patrick Vrijlandt, "Update of section 4.5 of the
SmPC in order to update information on the co-
administration with inactivated seasonal
quadrivalent influenza vaccines: with a high
dose unadjuvanted influenza vaccine (FLU HD)
and a standard dose adjuvanted influenza
vaccine (FLU aQIV) based on final results from
studies RSV OA=ADJ-008 and RSV OA=ADJ-
017. These are Phase III studies intended to
evaluate the immune response, safety and
reactogenicity of Arexvy when co-administered
with a high dose unadjuvanted influenza vaccine
(FLU HD) and a standard dose adjuvanted
influenza vaccine (FLU aQIV), respectively."
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted
on 07.03.2024, 09.11.2023.

Positive Opinion adopted by consensus on
11.04.2024.

**AREXVY - Respiratory syncytial virus,
glycoprotein F, recombinant, stabilised in
the pre-fusion conformation, adjuvanted
with AS01E - EMA/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

Request for supplementary information adopted
with a specific timetable.

revaccination schedules in adults aged 60 years and above)."

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

Biktarvy - Bictegravir / Emtricitabine / Tenofovir alafenamide -

EMA/H/C/004449/II/0059

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, "Update of sections 4.4, 4.5, 4.6, 5.1 and 5.2 of the SmPC in order to update information on pregnancy and update the dosing recommendations with polyvalent caution-containing products for pregnant patients based on final results from GS-US-380-5310; A Phase 1b, Open-label study to Evaluate the Pharmacokinetics (PK), Safety and Efficacy of B/F/TAF in HIV-1 infected, Virologically Suppressed, Pregnant Women in their Second and Third Trimesters; study GS-US-380-3909 and the Antiretroviral Pregnancy Registry. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes."

Request for Supplementary Information adopted on 25.04.2024.

Request for supplementary information adopted with a specific timetable.

CAMZYOS - Mavacamten -

EMA/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."

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

Request for supplementary information adopted with a specific timetable.

Cetrotide - Cetrorelix -

EMA/H/C/000233/II/0091

Merck Europe B.V., Rapporteur: Martina Weise, "Type II C.I.4 To update section 6.6 of the SmPC to amend the administered dose of cetrorelix from 'dose of at least 0.23 mg' to

Request for supplementary information adopted with a specific timetable.

'dose of 0.21 mg' based on the representative dose study conducted to evaluate the administered dose after reconstitution."
Request for Supplementary Information adopted on 25.04.2024.

Cresemba - Isavuconazole -
EMA/H/C/002734/II/0045, Orphan
Basilea Pharmaceutica Deutschland GmbH,
Rapporteur: Patrick Vrijlandt, "Update of section 4.5 of the SmPC in order to revise the interactions table to improve guidance for health care professionals in relation to the co-administration of cyclophosphamide with isavuconazole based on literature and postmarketing data. In addition, the MAH took the opportunity to correct a mistake in section 4.5 of the SmPC."
Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Cuprior - Trientine -
EMA/H/C/004005/II/0028
Orphalan, Rapporteur: Jayne Crowe,
"Submission of the final report from study TRIUMPH-2: Trientine dihydrochloride (Syprine capsules) vs. tetrahydrochloride (tablets): a Phase 1, single centre, randomised, interventional, open-label, 4-way crossover study in adult healthy male and female subjects to evaluate the pharmacokinetics and the safety and tolerability of 2 different oral formulations."
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

Drovelis - Drospirenone / Estetrol -
EMA/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."
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted on 14.12.2023.

Positive Opinion adopted by consensus on 11.04.2024.

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

Request for supplementary information adopted with a specific timetable.

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."

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

**Erleada - Apalutamide -
EMA/H/C/004452/II/0036**

Positive Opinion adopted by consensus on 25.04.2024.

Janssen-Cilag International N.V., Rapporteur:

Carolina Prieto Fernandez, "- to update the method of administration for Erleada 60 mg film-coated tablets provided in the SmPC Section 4.2 (and related Section of the PL) to allow patients to take tablets with non-fizzy beverage or soft food, or by a nasogastric feeding tube; hence, aligning the vehicles for administration between the two Erleada strengths (i.e. 60 mg and 240 mg).

The MAH took the opportunity to introduce the following editorial changes:

- Irish country code has been added in the contact information of the local representative;
- New link for reporting of adverse events in Section 4.8 of SmPC and Section 4 of PL has been provided."

Opinion adopted on 25.04.2024.

**Glyxambi - Empagliflozin / Linagliptin -
EMA/H/C/003833/II/0057**

Positive Opinion adopted by consensus on 11.04.2024.

Boehringer Ingelheim International GmbH, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the information on paediatric population based on final results from study DINAMO 1218-0091 - A double-blind, randomised, placebo-controlled, parallel group

trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Opinion adopted on 11.04.2024.

Kisqali - Ribociclib -

EMA/H/C/004213/II/0049

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.2 and 4.4 of the SmPC in order to update the ECG monitoring recommendations in patients with advanced or metastatic breast cancer (aBC) treated with ribociclib based on the continuing and comprehensive assessments of QT/QTcF effects in patients with cancer from studies A2301 (MONALEESA-2), E2301 (MONALEESA-7) and F2301 (MONALEESA-3). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes."

Request for Supplementary Information adopted on 25.04.2024.

Request for supplementary information adopted with a specific timetable.

Lydisilka - Drospirenone / Estetrol -

EMA/H/C/005382/II/0021

Estetra SRL, 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."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 14.12.2023.

Positive Opinion adopted by consensus on 11.04.2024.

Lysodren - Mitotane -

EMA/H/C/000521/II/0029/G

HRA Pharma Rare Diseases, Rapporteur: Carolina Prieto Fernandez, "A grouped application consisting of two Type II variations: Update of sections 4.4, 4.5, 4.6, 4.8 and 4.9 of the SmPC in order to update the special warnings information and to update the

Request for supplementary information adopted with a specific timetable.

pregnancy information, as well as, to add "Corticosteroid binding globulin increased" and "Thyroxin binding globulin increased" to the list of adverse drug reactions (ADRs) with frequency 'Not Known'; based on clinical practice guidance and post-marketing data.

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3, and to implement editorial changes to the SmPC."

Request for Supplementary Information adopted on 18.04.2024.

MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0030

Sanofi Pasteur, Rapporteur: Daniela

Philadelphia, "Update of sections 4.5 and 5.1 of the SmPC in order to update immunogenicity and safety information based on final results from study MEQ00071; this is a parallel, multi-center, multinational, randomized, active-controlled phase 3b immunogenicity and safety study of a quadrivalent meningococcal conjugate vaccine versus Nimenrix, and when administered alone or concomitantly with 9vHPV and Tdap-IPV vaccines in healthy adolescents aged 10 to 17 years. 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."

Request for Supplementary Information adopted on 04.04.2024.

Request for supplementary information adopted with a specific timetable.

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

Sanofi B.V., Rapporteur: Christian Gartner,

"Update of section 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

Positive Opinion adopted by consensus on 04.04.2024.

local representatives in the Package Leaflet.”
Opinion adopted on 04.04.2024.
Request for Supplementary Information adopted
on 08.02.2024.

**NUVAXOVID - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0062**

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt,
“Submission of the final report from clinical
study 2019nCoV-505 listed as a category 3
study in the RMP. This is a Phase 2,
Randomized, Observer-Blinded Study to
Evaluate the Safety and Immunogenicity of a
SARS CoV-2 Recombinant Spike Protein
Nanoparticle Vaccine (SARS-CoV-2 rS) with
Matrix M Adjuvant in People Living with HIV.”
Request for Supplementary Information adopted
on 11.04.2024.

Request for supplementary information adopted
with a specific timetable.

**Olumiant - Baricitinib -
EMA/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.”
Request for Supplementary Information adopted
on 04.04.2024, 08.02.2024.

Request for supplementary information adopted
with a specific timetable.

**Pombiliti - Cipaglucosidase alfa -
EMA/H/C/005703/II/0010**

Amicus Therapeutics Europe Limited,
Rapporteur: Patrick Vrijlandt, “Update of
sections 4.6 and 5.3 of the SmPC in order to
provide information regarding pre-implantation
loss based on the reassessment of non-clinical
data. In addition, the MAH took the opportunity
to bring the PI in line with the latest QRD
template version 10.3 and to introduce editorial
changes.”
Request for Supplementary Information adopted
on 18.04.2024.

Request for supplementary information adopted
with a specific timetable.

**PONVORY - Ponesimod -
EMA/H/C/005163/II/0013**

Request for supplementary information adopted
with a specific timetable.

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."
Request for Supplementary Information adopted
on 11.04.2024, 25.01.2024.

**QUVIVIQ - Daridorexant -
EMA/H/C/005634/II/0013/G**

Positive Opinion adopted by consensus on
11.04.2024.

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 apnoea;
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."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted
on 07.03.2024, 01.02.2024.

**Reagila - Cariprazine -
EMA/H/C/002770/II/0034**

Positive Opinion adopted by consensus on
11.04.2024.

Gedeon Richter Plc., Rapporteur: Kristina
Dunder, PRAC Rapporteur: Ana Sofia Diniz
Martins, "Update of sections 4.3, 4.4 and 4.5 of
the SmPC in order to update an existing
contraindication and update drug-drug
interaction information with CYP3A4 inhibitors,
based on final results from study RGH-188-301
(CYPRESS) listed as a category 3 study in the
RMP; this is an open-label, single-arm, fixed-

sequence study to investigate the effect of erythromycin, a moderate CYP3A4 inhibitor on the pharmacokinetics of cariprazine in male patients with schizophrenia. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 08.02.2024, 26.10.2023.

**REKAMBYS - Rilpivirine -
EMA/H/C/005060/II/0020**

Positive Opinion adopted by consensus on 11.04.2024.

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, “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.”
Opinion adopted on 11.04.2024.

**Remsima - Infliximab -
EMA/H/C/002576/II/0133/G**

Request for supplementary information adopted with a specific timetable.

Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, “Grouped application comprising three type II variations (C.I.4) as follows:
- Update of section 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information based on Week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (Crohn’s disease), listed as a category 3 study in the RMP; Study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn’s Disease.
- Update of section 4.2 and 5.2 of the SmPC in

See 9.1

order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.

- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study).

The RMP version 16.1 has also been submitted. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI."

Request for Supplementary Information adopted on 25.04.2024, 21.03.2024, 09.11.2023.

**Revestive - Teduglutide -
EMA/H/C/002345/II/0064, Orphan**

Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to add the recommendation of upper GI endoscopy or other imaging before and during the treatment with teduglutide per clinical discretion as a precaution to 'Gastrointestinal neoplasia including hepatobiliary tract' based on the cumulative review of literature. In addition, the MAH took the opportunity to introduce minor editorial changes and to bring the PI in line with the latest QRD template."

Request for Supplementary Information adopted on 25.04.2024.

Request for supplementary information adopted with a specific timetable.

**Reyataz - Atazanavir -
EMA/H/C/000494/II/0139**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.3 and 4.5 of the SmPC in order to reclassify the drug-drug-interaction information to a contraindication for the co-administration with antineoplastic agents (encorafenib and ivosidenib), as well as, for the co-administration with the anticonvulsant agents (carbamazepine, phenobarbital, and phenytoin); based on post-marketing data and literature. The Package Leaflet is updated accordingly."

Opinion adopted on 25.04.2024.

Positive Opinion adopted by consensus on 25.04.2024.

**RINVOQ - Upadacitinib -
EMA/H/C/004760/II/0050**

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to include long term efficacy and safety information (up to week 104 data) from study M19-944 (Study 1); this is a phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult subjects with axial spondyloarthritis followed by a remission-withdrawal period."

Request for Supplementary Information adopted on 04.04.2024.

Request for supplementary information adopted with a specific timetable.

**SARCLISA - Isatuximab -
EMA/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, multicentre 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."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 25.01.2024.

Positive Opinion adopted by consensus on 11.04.2024.

**SARCLISA - Isatuximab -
EMA/H/C/004977/II/0028**

Sanofi Winthrop Industrie, Rapporteur: Peter Mol, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study ACT15378 (ISAKIDS). This was a Phase 2, single-arm, multicentre, open-label study evaluating the antitumor activity, safety, and PK of isatuximab in combination with standard salvage chemotherapies in paediatric participants with R/R ALL (including both T-ALL and B-ALL) and AML conducted in 3 separate cohorts. Male and female children from 28 days to less than 18 years of age with R/R T-ALL, B-

Positive Opinion adopted by consensus on 04.04.2024.

ALL, or AML in first or second relapse were eligible. Participants under 2 years of age could only be enrolled after the dose reassessment is completed on the first 20 participants who were 2 to less than 18 years of age.

The Package Leaflet is updated accordingly."

Opinion adopted on 04.04.2024.

**Skilarence - Dimethyl fumarate -
EMA/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 25.04.2024, 14.12.2023.

Request for supplementary information adopted with a specific timetable.

**Sunlenca - Lenacapavir -
EMA/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 introduce minor editorial changes to the PI."

Request for Supplementary Information adopted on 11.04.2024, 18.01.2024.

Request for supplementary information adopted with a specific timetable.

**Tecentriq - Atezolizumab -
EMA/H/C/004143/II/0084**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Update of section 4.8 of the SmPC in order to add 'hypophysitis' to the list of adverse drug reactions (ADRs) with frequency 'uncommon' based on interim results from study WO39391 (IMpassion030). This is a Phase III, randomized, open label study comparing atezolizumab in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple-negative breast cancer; the package leaflet is updated accordingly. In

Positive Opinion adopted by consensus on 11.04.2024.

addition, the MAH took the opportunity to implement editorial changes to the SmPC, labelling and package leaflet.”

Opinion adopted on 11.04.2024.

**TEPMETKO - Tepotinib -
EMA/H/C/005524/II/0011**

Positive Opinion adopted by consensus on 18.04.2024.

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.”
Opinion adopted on 18.04.2024.

Request for Supplementary Information adopted on 22.02.2024.

**Ultomiris - Ravulizumab -
EMA/H/C/004954/II/0041**

Request for supplementary information adopted with a specific timetable.

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, “Update of section 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.”

Request for Supplementary Information adopted on 25.04.2024, 11.01.2024.

**Veltassa - Patiomer -
EMA/H/C/004180/II/0034/G**

Positive Opinion adopted by consensus on 25.04.2024.

Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Jayne Crowe, “Update of sections 4.4 and 4.8 the SmPC in order to update safety information based on a pooled safety database. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.

Update of section 4.8 of the SmPC in order to add “Hypersensitivity” to the list of adverse drug reactions (ADRs) with frequency “not

known”, based on post-marketing data. The Package Leaflet is updated accordingly.”
Opinion adopted on 25.04.2024.
Request for Supplementary Information adopted on 25.01.2024, 14.09.2023.

**Verzenio - Abemaciclib -
EMA/H/C/004302/II/0033**

Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, “Update of section 5.1 of the SmPC in order to include the final OS data based on final results from study MONARCH3 (I3Y-MC-JPBM). This is a randomized, double-blind, placebo-controlled, phase 3 trial of nonsteroidal aromatase inhibitors (anastrozole or letrozole) plus LY2835219, a CDK4/6 Inhibitor, or placebo in postmenopausal women with hormone receptor-positive, HER2-Negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting.”
Request for Supplementary Information adopted on 25.04.2024.

Request for supplementary information adopted with a specific timetable.

**Wegovy - Semaglutide -
EMA/H/C/005422/II/0019**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, “Update of sections 4.1, 4.4, 4.8 and 5.1 in order to include information in patients with obesity-related HFpEF, with and without type 2 diabetes based on the final reports from studies EX9536-4665 STEP-HFpEF, EX9536-4773 STEP HFpEF-DM and EX9536-4388 SELECT. In addition, the MAH took this opportunity to introduce editorial changes to the PI.”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

**Xevudy - Sotrovimab -
EMA/H/C/005676/II/0027**

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, “Update of section 5.1 of the SmPC with data on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron HV.1 and BA.2.86 spike variants (PC-23-0165) and the Omicron HK.3 spike variant (PC-23-0179) as well as data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-COV-2 EG.5.1 variant (PC-23-0176) based on the relevant pharmacology study reports.”

Positive Opinion adopted by consensus on 18.04.2024.

Opinion adopted on 18.04.2024.

**XGEVA - Denosumab -
EMA/H/C/002173/II/0084**

Amgen Europe B.V., Rapporteur: Kristina Dunder, "Submission of the final report from study 20140114, listed as a category 3 study in the RMP. This is a long-term safety follow up study, that was conducted to continue to follow subjects with GCTB who were treated in Study 20062004 for an additional 5 or more years of long-term safety follow up and to further evaluate denosumab treatment in subjects with GCTB."

Request for Supplementary Information adopted on 04.04.2024.

Request for supplementary information adopted with a specific timetable.

**WS2612
Finlee-EMA/H/C/005885/WS2612/0003
Mekinist-
EMA/H/C/002643/WS2612/0062
Spexotras-
EMA/H/C/005886/WS2612/0001
Tafinlar-
EMA/H/C/002604/WS2612/0065**

Novartis Europharm Limited, Lead Rapporteur: Peter Mol, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Tumour lysis syndrome and add Tumour lysis syndrome to the list of adverse drug reactions (ADRs) with frequency Not known based on the review of MAH global database, clinical trials database and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and to introduce editorial changes."

Opinion adopted on 25.04.2024.

Positive Opinion adopted by consensus on 25.04.2024.

**WS2650
Imfinzi-EMA/H/C/004771/WS2650/0065
IMJUDO-
EMA/H/C/006016/WS2650/0006**

AstraZeneca AB, Lead Rapporteur: Aaron Sosa Mejia, "Update of section 4.2 and 4.4 of the SmPC in order to simplify current dosing recommendations."

Opinion adopted on 25.04.2024.

Positive Opinion adopted by consensus on 25.04.2024.

B.5.3. CHMP-PRAC assessed procedures

Beyfortus - Nirsevimab -

Positive Opinion adopted by consensus on

EMA/H/C/005304/II/0018/G

25.04.2024.

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."

Opinion adopted on 25.04.2024.

Request for Supplementary Information adopted on 07.03.2024, 08.02.2024.

BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMA/H/C/006058/II/0010

Positive Opinion adopted by consensus on 11.04.2024.

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 1.4 has also been submitted."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 11.01.2024.

Ilumetri - Tildrakizumab - EMA/H/C/004514/II/0055

Request for supplementary information adopted with a specific timetable.

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

Request for Supplementary Information adopted on 11.04.2024.

Inrebic - Fedratinib -

Request for supplementary information adopted

EMA/H/C/005026/II/0020, Orphan

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Peter Mol, PRAC Rapporteur: Sonja Hrabcik,

"Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information regarding thiamine levels based on a review of the primary results of the study FEDR-MF-002. This is a Phase 3, multicentre, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared with BAT in subjects with DIPSS intermediate-2 or high-risk primary MF, post-PV MF, or post-ET MF and previously treated with ruxolitinib. The RMP version 3 has also been submitted."

Request for Supplementary Information adopted on 25.04.2024.

with a specific timetable.

JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) -**EMA/H/C/005737/II/0076**

Janssen-Cilag International N.V., Rapporteur:

Christophe Focke, PRAC Rapporteur: Ulla

Wändel Liminga, "Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to update

information regarding the co-administration of JCOVDEN with influenza vaccine based on the final report from study VAC31518COV3005

listed as a category 3 study in the RMP; this is a randomized, double-blind, Phase 3 study to evaluate safety, reactogenicity, and

immunogenicity of co-administration of Ad26.COV2.S and influenza vaccines in healthy adults 18 years of age and older. The Package Leaflet is updated accordingly. Version 8.1 of the RMP has also been submitted."

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

Juluca - Dolutegravir / Rilpivirine -**EMA/H/C/004427/II/0057/G**

ViiV Healthcare B.V., Rapporteur: Janet Koenig,

PRAC Rapporteur: Nathalie Gault, "Grouped application comprising two type II variations as follows:

C.I.13: Submission of the final report from study 201636 (SWORD 1) listed as a category 3 study in the RMP. This is a phase III, randomized, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine from current INI-, NNRTI-, or PI-

Positive Opinion adopted by consensus on 18.04.2024.

based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed.

C.I.13: Submission of the final report from study 201637 (SWORD 2) listed as a category 3 study in the RMP. This is a phase III, randomized, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine from current INI-, NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed.

The RMP version 7.0 has also been submitted.”

Opinion adopted on 18.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Jyseleca - Filgotinib -

EMA/H/C/005113/II/0031/G

Galapagos N.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, “Grouped application comprising two variations as follows:

Type II (C.I.4): Update of sections 4.8 and 5.1 of the SmPC to update the safety mean duration exposure and efficacy information based on final results (up to Week 432) from study GLPG0634-CL-205 (DARWIN 3) listed as a category 3 study in the RMP (MEA/009); this is a phase II, open-label, long-term follow-up safety and efficacy study to evaluate the long-term safety and tolerability of filgotinib for the treatment of Rheumatoid Arthritis in patients who received treatment in their parent studies. The RMP version 6.1 has also been submitted.

Type IA (A.6): To change the ATC code for Janus-associated kinase (JAK) inhibitor from L04AA45 filgotinib to L04AF04 filgotinib.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Leqvio - Inclisiran -

EMA/H/C/005333/II/0021

Novartis Europharm Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Kimmo Jaakkola, “Submission of the final report from study ORION-8 - A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high

Request for supplementary information adopted with a specific timetable.

cardiovascular risk and elevated LDL-C, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted.”

Request for Supplementary Information adopted on 11.04.2024.

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

Request for Supplementary Information adopted on 25.04.2024, 14.12.2023, 25.05.2023.

Request for supplementary information adopted with a specific timetable.

**Lupkynis - Voclosporin -
EMA/H/C/005256/II/0013**

Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski, “Update of section 4.6 of the SmPC in order to updated breast-feeding information based on final results from study AUR-VCS-2021-04. This study is a single-center, open-label, Phase 1, lactation study to investigate the amount of voclosporin excreted in breast milk following a single oral dose of 23.7 mg voclosporin in healthy, lactating,

Request for supplementary information adopted with a specific timetable.

female volunteers. The Package Leaflet is updated accordingly. The updated RMP version 5.0 has also been submitted.”
Request for Supplementary Information adopted on 11.04.2024.

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

Positive Opinion adopted by consensus on 11.04.2024.

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, randomised, parallel-group, active-controlled, multi-centre 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 2.0 has also been submitted.”
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted on 11.01.2024.

Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0023/G

Request for supplementary information adopted with a specific timetable.

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Gabriele Maurer, “A grouped application comprised of 2 Type II variations and 1 Type IA variation, as follows:

Type II variation (C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information, based on the final report from study WO40324 (FeDeriCa) listed as a category 3 study in the RMP. This is a phase 3, randomized, multicentre, open-label, two-arm study to evaluate the pharmacokinetics, efficacy, and safety of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in combination with chemotherapy in patients with HER2-positive early breast cancer.

Type II variation (C.I.4): Update of section 4.8 of the SmPC in order to only present specific Phesgo safety data by updating the summary of

safety profile and the tabulated list of adverse reactions to reflect this information. The Package Leaflet is updated accordingly.

Type IA variation (A.6): To change the ATC code of pertuzumab and trastuzumab from L01XY02 to L01FY01.

The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to update the list of local representatives in the Package Leaflet.” Request for Supplementary Information adopted on 25.04.2024.

Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) -	Positive Opinion adopted by consensus on 11.04.2024.
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EMA/H/C/005451/II/0023

Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphia, PRAC Rapporteur: Jean-Michel Dogné, “Submission of the final current B7471015 study protocol, the Statistical Analysis Plan (SAP) and the final country feasibility assessment report for Apexxnar. The RMP (version 5.0) is updated accordingly.” Opinion adopted on 11.04.2024.

Ronapreve - Casirivimab / Imdevimab -	Positive Opinion adopted by consensus on 25.04.2024.
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EMA/H/C/005814/II/0015

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, “Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive analysis of the results from the drug pregnancy registry cohort (PDC study GV44373), listed as a category 3 PASS in the RMP, as well as data from clinical studies and post-marketing surveillance. The RMP version 3.0 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.” Opinion adopted on 25.04.2024. Request for Supplementary Information adopted on 07.03.2024.

See 9.1

Spikevax - COVID-19 mRNA vaccine -	Positive Opinion adopted by consensus on 11.04.2024.
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EMA/H/C/005791/II/0120

Moderna Biotech Spain S.L., Rapporteur: Jan

Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Submission of the final report from study mRNA-1273-P301; this is a Phase 3, randomised, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of Spikevax in adults aged 18 years and older, listed as a category 3 study in the RMP. The RMP version 8.2 has also been approved."

Opinion adopted on 11.04.2024.

**Spravato - Esketamine -
EMA/H/C/004535/II/0020**

Positive Opinion adopted by consensus on 11.04.2024.

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 multicentre, 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."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 11.01.2024.

**TAKHZYRO - Lanadelumab -
EMA/H/C/004806/II/0040, Orphan**

Request for supplementary information adopted with a specific timetable.

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, "Update of section 4.4 of the SmPC in order to remove the information related to non-availability of clinical data on the use of lanadelumab in HAE patients with normal C1-INH activity, based on results from studies CASPIAN (SHP643-303) and CASPIAN OLE (TAK-743-3001). CASPIAN (SHP643-303) is a Phase 3, multicentre, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of lanadelumab for prevention against acute attacks of NONHISTAMINERGIC ANGIOEDEMA

with Normal C1 Inhibitor (C1-INH); and CASPIAN OLE (TAK-743-3001) is an open-label study to evaluate the long term safety and efficacy of lanadelumab for prevention against acute attacks of Nonhistaminergic Angioedema with Normal C1-Inhibitor (C1-INH).

The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the Package Leaflet.”

Request for Supplementary Information adopted on 11.04.2024.

**Tecvayli - Teclistamab -
EMA/H/C/005865/II/0009**

Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuori, PRAC Rapporteur: Jana Lukacisinova, “Update of section 4.4 of the SmPC in order to update the warning on Progressive Multifocal Leukoencephalopathy (PML) based on a cumulative safety review. The Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted. 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.”

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

**VPRIV - Velaglucerase alfa -
EMA/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-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 25.04.2024, 14.12.2023.

Request for supplementary information adopted with a specific timetable.

**Vyvgart - Efgartigimod alfa -
EMA/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

Positive Opinion adopted by consensus on 11.04.2024.

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, multicentre, phase 3 follow-on study of ARGX-113-1704 to evaluate the safety and tolerability of ARGX-113 in patients with myasthenia gravis having generalized muscle weakness. The Applicant took advantage to update the PI with relevant information about sodium content as requested during the post-linguistic review of procedure II-06, to update the PI on some information about additional suppliers in the important instructions for use in line with the input received from one Member State reporting the unavailability of some suppliers in the country and to update the list of local representatives of the Marketing Authorisation Holder. The RMP has been updated to RMP version 2.4.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024, 11.01.2024.

**ZTALMY - Ganaxolone -
EMA/H/C/005825/II/0004/G, Orphan**

Marinus Pharmaceuticals Emerald Limited,
Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, “A grouped application comprised of 8 Type II variations as follows: The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC.”

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

**ZTALMY - Ganaxolone -
EMA/H/C/005825/II/0006, Orphan**

Marinus Pharmaceuticals Emerald Limited,
Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, “Update of section 5.1 of the SmPC in order to update open-label data based on the final report from study 1042-CDD-3001 OLE listed as a category 3 study in the RMP. This was the open-label portion of the pivotal study 1042-CDD-3001; a double-blind, randomized, placebo-controlled trial of adjunctive ganaxolone treatment in children and

Request for supplementary information adopted with a specific timetable.

young adults with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) followed by long-term open-label treatment. The RMP version 1.4 has also been submitted.”
Request for Supplementary Information adopted on 11.04.2024.

WS2619/G

Invokana-

EMA/H/C/002649/WS2619/0066/G

Vokanamet-

EMA/H/C/002656/WS2619/0073/G

Janssen-Cilag International N.V., Lead Rapporteur: Martina Weise, Lead PRAC Rapporteur: Martin Huber, “A grouped application consisting of two Type II variations, as follows:

C.I.4: Update of section 4.4 of the SmPC in order to amend an existing warning on Diabetic Ketoacidosis based on literature. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy based on literature.

The RMP version 11.1 has also been submitted.”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

WS2670

Finlee-EMA/H/C/005885/WS2670/0004

Spexotras-

EMA/H/C/005886/WS2670/0003

Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ulla Wändel Liminga, “To include into the product information for dabrafenib and trametinib to include the signal “peripheral neuropathy” in line with the PRAC recommended wording from EMA/PRAC/289010/2023, EPITT No. 19947.”
Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on 11.04.2024.

B.5.4. PRAC assessed procedures

PRAC Led

AJOVY - Fremanezumab -

EMA/H/C/004833/II/0047

TEVA GmbH, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, “Submission of the final report from the PASS study TV48125-MH-50039 listed as a category 3 study in the RMP. This is a long-term,

Positive Opinion adopted by consensus on 11.04.2024.

prospective, observational study to evaluate the safety, including cardiovascular safety, of fremanezumab in patients with migraine in routine clinical practice. The RMP version 6.0 has also been submitted.”

Opinion adopted on 11.04.2024

PRAC Led

Bavencio - Avelumab -

EMA/H/C/004338/II/0044/G

Merck Europe B.V., PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, “Grouped application comprising four variations as follows:

Type II (C.I.11.b): To update Annex II and the RMP version 7.1 for Bavencio to change the classification of “safety in patients with autoimmune disease” to the important identified risk “other immune mediated adverse reactions” along with removal of the patient information brochure from the educational material, following the PRAC assessment report PSUSA/00010635/202303.

Type IA (A.6): To change ATC level name from Other antineoplastic agents, monoclonal antibodies to Antineoplastic agents, monoclonal antibodies, PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors in Section 5.1 of the Summary of Product Characteristics (SmPC). The ATC code remains unchanged.

Type IA (C.I.z): To update the statement for “infusion-related reactions” in section 4.4 of the SmPC and to align terminology with the RMP for the term “immune-related” versus “immune-mediated”.

Type IAIN (C.I.12): To remove from the Product Information the black symbol and explanatory statements for medicinal products subject to additional monitoring.

In addition, the MAH took this opportunity to introduce editorial changes and to bring the PI in line with the latest QRD template version 10.3.”

Request for Supplementary Information adopted on 11.04.2024”

Request for supplementary information adopted with a specific timetable.

PRAC Led

Benlysta - Belimumab -

EMA/H/C/002015/II/0116

GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP

Positive Opinion adopted by consensus on 11.04.2024.

liaison: Kristina Dunder, "Submission of the final report for the Belimumab Pregnancy registry (BEL114256) listed as a category 3 study in the RMP. This is a non-interventional study to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months preconception and/or during pregnancy. In addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with SLE and SABLE (Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus) protocol who were not exposed to belimumab and enrolled in BPR. As a result, Section 4.6 of the SmPC was updated. In addition, RMP version 45.0 has been submitted."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 26.10.2023.

PRAC Led

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

EMA/H/C/005735/II/0206/G

BioNTech Manufacturing GmbH, PRAC

Rapporteur: Liana Martirosyan, PRAC-CHMP

liaison: Patrick Vrijlandt, "A grouped application comprised of 3 Type II variations as follows:

Request for supplementary information adopted with a specific timetable.

C.I.13: Submission of the final report from study C4591012 listed as a category 3 study in the RMP. This is a non-interventional Post-Emergency Use Authorization active safety surveillance study among individuals in the Veteran's Affairs health system receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. The RMP version 11.2 has also been submitted.

C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591052 protocol amendments 1 & 2) in the RMP, where there is an impact on the description of the study.

C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591021

protocol amendment 4) in the RMP, where there is an impact on the description of the study.

In addition, the MAH took the opportunity to update the milestones for the two studies C4591022 and C4591051 in the RMP.”

Request for Supplementary Information adopted on 11.04.2024.

PRAC Led

**DaTSCAN - Ioflupane (123I) -
EMA/H/C/000266/II/0067**

GE Healthcare B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, “To update sections 4.4 and 4.5 of the SmPC and section 2 of the Package Leaflet to implement the recommendation of the PRAC following the PSUSA procedure

(EMA/H/C/PSUSA/00001767/202207). In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Enbrel - Etanercept -
EMA/H/C/000262/II/0254**

Pfizer Europe MA EEIG, Rapporteur: Antonio Gómez Outes, PRAC Rapporteur: Monica Martínez Redondo, PRAC-CHMP liaison: Antonio Gómez Outes, “Update of section 4.8 of the SmPC in order to update the frequency of Adverse Drug Reaction (ADR)

‘Glomerulonephritis’ from ‘Not Known’ to ‘Rare’ following PSUSA/00010795/202302 procedure, based on available evidence from clinical trials, literature, and post-marketing data. The Package Leaflet is updated accordingly. Minor editorial changes have also been introduced.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

PRAC Led

**Flixabi - Infliximab -
EMA/H/C/004020/II/0084/G**

Samsung Bioepis NL B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “A grouped application comprised of

Positive Opinion adopted by consensus on 11.04.2024.

two Type II variations as follows:

C.I.13: Submission of the final report from study CEDUR listed as a category 3 study in the RMP. This is a nationwide German IBD registry to describe the long-term effectiveness of treatment with IBD therapies such as drug survival, effectiveness, side effects of treatment combination, and disease activity achieved.

C.I.13: Submission of the final report from study CREDIT listed as a category 3 study in the RMP. This is a Czech Register of IBD Patients on Biological Therapy to monitor effectiveness of total population of IBD patients on biological medication in the Czech Republic and regular analytical evaluation of the effectiveness.

The RMP version 13.0 has also been submitted.”
Opinion adopted on 11.04.2024.

PRAC Led

**Humira - Adalimumab -
EMA/H/C/000481/II/0218**

AbbVie Deutschland GmbH & Co. KG, PRAC
Rapporteur: Mari Thorn, PRAC-CHMP liaison:
Kristina Dunder, “Submission of the final report
for study P10-023 listed as a category 3 study
in the RMP. This is a 10-year, post marketing,
observational registry to assess long term safety
of Humira (adalimumab) in adult patients with
chronic plaque psoriasis (Ps).”
Request for Supplementary Information adopted
on 11.04.2024.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

**MenQuadfi - Meningococcal Group A, C, W
and Y conjugate vaccine -
EMA/H/C/005084/II/0031**

Sanofi Pasteur, PRAC Rapporteur: Jean-Michel
Dogné, PRAC-CHMP liaison: Karin Janssen van
Doorn, “Update of section 4.8 of the SmPC in
order to add ‘Hypersensitivity including
anaphylaxis’ to the list of adverse drug reactions
(ADRs) with frequency not known, based on a
cumulative review of cases of
hypersensitivity/allergic reaction (including
anaphylaxis) following the request by PRAC in
the Assessment Report for
PSUSA/00010044/202304. The Package Leaflet
is updated accordingly.”

Request for supplementary information adopted
with a specific timetable.

Request for Supplementary Information adopted on 11.04.2024.

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 study, 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."
Request for Supplementary Information adopted on 11.04.2024, 11.01.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led
NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0060
Novavax CZ, a.s., PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 4.3 after approval of adapted COVID-19 vaccine by new strain, Omicron XBB.1.5."
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

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."
Request for Supplementary Information adopted

Request for supplementary information adopted with a specific timetable.

on 11.04.2024, 11.01.2024.

PRAC Led

**RAYVOW - Lasmiditan -
EMA/H/C/005332/II/0007**

Eli Lilly Nederland B.V., PRAC Rapporteur: Anna Mareková, PRAC-CHMP liaison: Frantisek Drafi, "Submission of the final report from study H8H-MC-B005, listed as a category 3 study in the RMP (MEA/003). This is a Real-World Observational Study to Assess Drug Utilisation Patterns in the US Among Migraine Patients Treated with Lasmiditan. The RMP version 2.1 is submitted alongside the final study report."

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**SARCLISA - Isatuximab -
EMA/H/C/004977/II/0027**

Sanofi Winthrop Industrie, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Update of section 4.8 of the SmPC in order to add 'Thrombocytopenia' and 'Anaemia' to the list of adverse drug reactions (ADRs) and to amend the frequency of all remaining ADRs with their appropriate frequencies, following PRAC request in the outcome of the PSUSA procedure PSUSA/00010851/202303."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

PRAC Led

**SCENESSE - Afamelanotide -
EMA/H/C/002548/II/0049, Orphan**

Clinuvel Europe Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "To remove 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 9.11) are updated accordingly."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted

Positive Opinion adopted by consensus on 11.04.2024.

on 08.02.2024.

PRAC Led

Sprycel - Dasatinib -

EMA/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 11.04.2024, 30.11.2023.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

VEYVONDI - Vonicog alfa -

EMA/H/C/004454/II/0033

Baxalta Innovations GmbH, PRAC Rapporteur:

Mari Thorn, PRAC-CHMP liaison: Kristina

Dunder, "Submission of the final report from

study TAK-577-4005 listed as a category 3

PASS in the RMP. This is a non-interventional

retrospective cohort study that evaluated the

safety of VEYVONDI in real-world clinical

practice. The RMP version 5.0 has also been

submitted."

Request for Supplementary Information adopted

on 11.04.2024.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

Vyndaqel - Tafamidis -

EMA/H/C/002294/II/0091/G, Orphan

Pfizer Europe MA EEIG, PRAC Rapporteur:

Tiphaine Vaillant, PRAC-CHMP liaison: Jean-

Michel Race, "A grouped application comprised

of two Type II Variations, as follows:

C.I.4: Update of the Annex II based on final
results from study B3461001 (THAOS) listed as
a category 3 study in the RMP. This is a global,
multi-center, longitudinal, observational survey
of patients with documented transthyretin gene
mutations or wild-type transthyretin
amyloidosis.

C.I.13: Submission of the final report from
study B3461042 listed as a category 3 study in
the RMP. This is a post-marketing safety
surveillance study in Japanese patients with

Request for supplementary information adopted
with a specific timetable.

AATR-PN.

The RMP version 10.0 has also been submitted.
In addition, the MAH took the opportunity to
provide B3461028 Clinical Study Report (CSR)
Errata.”

Request for Supplementary Information adopted
on 11.04.2024.

PRAC Led
WS2519/G
Advagraf-
EMA/H/C/000712/WS2519/0071/G
Modigraf-
EMA/H/C/000954/WS2519/0046/G

Request for supplementary information adopted
with a specific timetable.

Astellas Pharma Europe B.V., Lead PRAC
Rapporteur: Eamon O Murchu, PRAC-CHMP
liaison: Jayne Crowe, “A grouped application
consisting of:

Type II (C.I.13): Submission of the final report
from study F506-PV-0001 listed as a category 3
study in the RMP for Advagraf and Modigraf.
This is a non-interventional post-authorization
safety study (NI-PASS) of outcomes associated
with the use of tacrolimus around conception, or
during pregnancy or lactation using data from
Transplant Pregnancy Registry International
(TPRI). The RMP version 5.0 has also been
submitted.

Type IB (C.I.11.z): To include the feasibility
assessment of using alternative secondary-use
data sources to replicate the Transplant
Pregnancy Registry International (TPRI) study
as a category 3 additional pharmacovigilance
activity in the RMP, including the milestones for
the progress report and the final report of the
feasibility assessment, related to
EMA/H/C/000712/MEA/032 and
EMA/H/C/000954/MEA/024.”
Request for Supplementary Information adopted
on 11.04.2024, 26.10.2023.

B.5.5. CHMP-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel -
EMA/H/C/005095/II/0023, Orphan,
ATMP

Positive Opinion adopted by consensus on
25.04.2024.

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

Opinion adopted on 25.04.2024, 19.04.2024.
Request for Supplementary Information adopted
on 19.01.2024, 06.10.2023.

ROCTAVIAN - Valoctocogene roxaparvovec Positive Opinion adopted by consensus on
- EMEA/H/C/005830/II/0010, Orphan, 25.04.2024.
ATMP

BioMarin International Limited, Rapporteur:
Violaine Closso Carella, CHMP Coordinator:
Jean-Michel Race, "Submission of the final
report from study BMN270-302 listed as a
category 3 study in the RMP (phase 3 open-
label, single-arm study to evaluate the efficacy
and safety of BMN 270, an adeno-associated
virus vector-mediated gene transfer of human
factor VIII at a dose of 4x10¹³ vg/kg in
haemophilia A patients with residual FVIII levels
≤ 1 IU/dL receiving prophylactic FVIII
infusions)."

Opinion adopted on 25.04.2024, 19.04.2024.

WS2607 Positive Opinion adopted by consensus on
Tecartus- 25.04.2024.
EMA/H/C/005102/WS2607/0039

Yescarta-
EMA/H/C/004480/WS2607/0067

Kite Pharma EU B.V., Lead Rapporteur: Jan
Mueller-Berghaus

Opinion adopted on 25.04.2024, 19.04.2024.

Request for Supplementary Information adopted
on 19.01.2024.

WS2646 Positive Opinion adopted by consensus on
Tecartus- 04.04.2024.
EMA/H/C/005102/WS2646/0042

Yescarta-
EMA/H/C/004480/WS2646/0073

Kite Pharma EU B.V., Lead Rapporteur: Jan
Mueller-Berghaus, Quality Variation

Furthermore, that MAH has taken the
opportunity to introduce editorial changes as
listed in the application form, present and
proposed table."

Opinion adopted on 04.04.2024.

B.5.6. CHMP-PRAC-CAT assessed procedures

WS2632 Positive Opinion adopted by consensus on
Tecartus- 25.04.2024.
EMA/H/C/005102/WS2632/0041

Yescarta-
EMA/H/C/004480/WS2632/0072

Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2 and 5.1 of the SmPC in order to update the safety monitoring timelines based on data from clinical studies, post marketing studies, and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to sections 2.2, 6.3 and 6.6 and to update sections 4.4 and 4.5 of the SmPC to align the language across both products."

Opinion adopted on 25.04.2024, 19.04.2024.

B.5.7. PRAC assessed ATMP procedures

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

WS2618 Dengue Tetravalent Vaccine (Live, Attenuated) Takeda- EMA/H/W/005362/WS2618/0013 Qdenga- EMA/H/C/005155/WS2618/0014 Takeda GmbH, Lead Rapporteur: Sol Ruiz Quality Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 15.02.2024.	Positive Opinion adopted by consensus on 18.04.2024.
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WS2629/G Eviplera- EMA/H/C/002312/WS2629/0115/G Stribild- EMA/H/C/002574/WS2629/0122/G Truvada- EMA/H/C/000594/WS2629/0180/G Viread- EMA/H/C/000419/WS2629/0211/G Gilead Sciences Ireland UC, Lead Rapporteur: Jean-Michel Race, Quality Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 04.04.2024.
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WS2633/G Hexacima- Hexyon- Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Quality Opinion adopted on 18.04.2024.	Positive Opinion adopted by consensus on 18.04.2024.
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WS2639 Glyxambi- EMA/H/C/003833/WS2639/0059 Jentaducto- EMA/H/C/002279/WS2639/0072 Trajenta- EMA/H/C/002110/WS2639/0054 Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt Quality Opinion adopted on 18.04.2024.	Positive Opinion adopted by consensus on 18.04.2024.
WS2640 Infanrix hexa- EMA/H/C/000296/WS2640/0343 GlaxoSmithKline Biologicals SA, Lead Rapporteur: Christophe Focke Quality	Positive Opinion adopted by consensus on 04.04.2024.
WS2645/G Avamys- EMA/H/C/000770/WS2645/0052/G Elebrato Ellipta- EMA/H/C/004781/WS2645/0039/G Relvar Ellipta- EMA/H/C/002673/WS2645/0066/G Revinty Ellipta- EMA/H/C/002745/WS2645/0063/G Trelegy Ellipta- EMA/H/C/004363/WS2645/0036/G GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy Quality Request for Supplementary Information adopted on 11.04.2024.	Request for supplementary information adopted with a specific timetable.
WS2648/G Mircera- EMA/H/C/000739/WS2648/0098/G NeoRecormon- EMA/H/C/000116/WS2648/0123/G Roche Registration GmbH, Lead Rapporteur: Martina Weise, Quality " Furthermore, the MAH has taken the opportunity to implement editorial changes, to rearrange information regarding the PEG Reagent." Opinion adopted on 04.04.2024.	Positive Opinion adopted by consensus on 04.04.2024.
WS2654 Aerius-EMA/H/C/000313/WS2654/0106 Azomyr- EMA/H/C/000310/WS2654/0110 Neoclarityn- EMA/H/C/000314/WS2654/0104	Request for supplementary information adopted with a specific timetable.

Organon N.V., Duplicate, Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke Quality

In addition, the MAH has taken the opportunity to update section 4.8 of the SmPC and section 4 of the package leaflet to correct the link to QRD Appendix V for the national reporting system. Furthermore, the MAH has taken the opportunity to update the package leaflet with details of the local representative for Austria. Lastly, the MAH has taken the opportunity to introduce minor editorial corrections to the PI in the following language: CS.”

Request for Supplementary Information adopted on 04.04.2024.

WS2657

HyQvia-EMEA/H/C/002491/WS2657/0097

Kiovig-EMEA/H/C/000628/WS2657/0127

Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Quality

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

WS2660/G

Entresto-

EMEA/H/C/004062/WS2660/0059/G

Neparvis-

EMEA/H/C/004343/WS2660/0057/G

Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Quality
Opinion adopted on 04.04.2024.

Positive Opinion adopted by consensus on 04.04.2024.

WS2661

Mirapexin-

EMEA/H/C/000134/WS2661/0108

Sifrol-EMEA/H/C/000133/WS2661/0099

Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher, Quality
Opinion adopted on 18.04.2024.

Request for Supplementary Information adopted on 29.02.2024.

Positive Opinion adopted by consensus on 18.04.2024.

WS2662/G

Edistride-

EMEA/H/C/004161/WS2662/0066/G

Forxiga-

EMEA/H/C/002322/WS2662/0087/G

AstraZeneca AB, Lead Rapporteur: Kristina DunderQuality

WS2674

Nuwiq-EMEA/H/C/002813/WS2674/0060

Positive Opinion adopted by consensus on

Vihuma- EMA/H/C/004459/WS2674/0042 Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 04.04.2024.	04.04.2024.
WS2675 Hefiya-EMA/H/C/004865/WS2675/0053 Hyrimoz- EMA/H/C/004320/WS2675/0052 Sandoz GmbH, Duplicate of Hyrimoz, Lead Rapporteur: Christian Gartner, Quality " Opinion adopted on 04.04.2024.	Positive Opinion adopted by consensus on 04.04.2024.

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

BUCCOLAM - Midazolam - EMA/H/C/002267/II/0062/G Neuraxpharm Pharmaceuticals S.L., Rapporteur: Peter Mol Withdrawal request submitted on 18.04.2024.	The MAH withdrew the procedure on 18.04.2024.
Bylvay - Odevixibat - EMA/H/C/004691/II/0020, Orphan Ipsen Pharma, Rapporteur: Patrick Vrijlandt Withdrawal request submitted on 11.04.2024.	The MAH withdrew the procedure on 11.04.2024.
Clopidogrel Zentiva - Clopidogrel - EMA/H/C/000975/II/0089 Zentiva k.s., Duplicate of Clopidogrel BMS (SRD), Informed Consent of Iscover, Rapporteur: Bruno Sepodes Withdrawal request submitted on 03.04.2024.	The MAH withdrew the procedure on 03.04.2024.

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

Cablivi - Caplacizumab - EMA/H/C/004426/II/0048, Orphan Ablynx NV, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information on paediatric patients based on results from study OBS17325 - Retrospective Data Collection of Pediatric Patients with Immune Thrombotic Thrombocytopenic Purpura (iTTP) Treated with Caplacizumab. The primary objective of this study was to describe the effectiveness and safety of caplacizumab in pediatric patients with iTTP." Request for Supplementary Information adopted on 14.03.2024.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in March 2024.
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B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Obecabtagene autoleucel -

EMA/H/C/005907, Orphan, ATMP

Autolus GmbH, treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)

Deutetrabenazine - EMA/H/C/006371

treatment of tardive dyskinesia

Ferric citrate coordination complex -

EMA/H/C/006402

treatment of iron deficiency anaemia in adult chronic kidney disease (CKD) patients with elevated serum phosphorus levels

Human normal immunoglobulin -

EMA/H/C/006423

replacement therapy (primary immunodeficiency syndromes and secondary hypogammaglobulinemia), immunomodulation (in primary immune thrombocytopenic purpura, Guillain Barré syndrome, Kawasaki disease and Multifocal Motor Neuropathy).

Eltrombopag - EMA/H/C/006459

treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA)

Mozafancogene autotemcel -

EMA/H/C/005537, Orphan, ATMP

Rocket Pharmaceuticals B.V., treatment of paediatric patients with Fanconi Anaemia Type A

Influenza vaccine (live attenuated, nasal) -

EMA/H/C/006514

Prophylaxis of influenza

Denosumab - EMA/H/C/006398

prevention of skeletal related events with advanced malignancies

Denosumab - EMA/H/C/006424

treatment of osteoporosis and bone loss

In vitro diagnostic medical device -

EMA/H/D/006530

to detect somatic alterations in human DNA and RNA isolated from formalin-fixed, paraffin-embedded (FFPE) solid tumour samples.

Denosumab - EMEA/H/C/006157

prevention of skeletal related events with advanced malignancies

Denosumab - EMEA/H/C/006399

treatment of osteoporosis and bone loss

Ustekinumab - EMEA/H/C/006544

treatment of Crohn's Disease and Ulcerative colitis, treatment of moderate to severe plaque psoriasis, active psoriatic arthritis

Pneumococcal polysaccharide conjugate vaccine (21-valent) - EMEA/H/C/006267

for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae*

Denosumab - EMEA/H/C/006156

treatment of osteoporosis and bone loss

Atropine sulfate - EMEA/H/C/006324

treatment of progression of myopia in children aged 3 to 18 years

Sargramostim - EMEA/H/C/006411**Accelerated review**

treatment for exposure to myelosuppressive doses of radiation

Aflibercept - EMEA/H/C/006192

treatment of age-related macular degeneration (AMD) and visual impairment, treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)

Denosumab - EMEA/H/C/006468

prevention of skeletal related events with advanced malignancies and treatment of giant cell tumour of bone

Tegomil fumarate - EMEA/H/C/006427

treatment of multiple sclerosis

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

Bosulif - Bosutinib -**EMEA/H/C/002373/X/0058/G**

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Extension application to introduce a new pharmaceutical form (100 mg hard capsules) associated with a new strength (50 mg hard capsules) grouped with an extension of

indication (C.I.6.a) to include treatment of paediatric patients greater than or equal to 1 year of age with newly-diagnosed (ND) chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML) for BOSULIF, based on interim results from study ITCC-054/AAML1921 (BCHILD); this is a phase 1/2, multicentre, international, single-arm, open-label study of bosutinib in paediatric patients with newly diagnosed chronic phase or resistant/intolerant Ph+ chronic myeloid leukaemia. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information.”

PREVYMIS - Letermovir -

EMA/H/C/004536/X/0037/G, Orphan

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Kirsti Villikka, “Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment of paediatric patients from birth up to 18 years old based on the final results from studies P030 and P031.

Study P030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety, and tolerability of LET when used for CMV prophylaxis in paediatric participants from birth to <18 years of age who are at risk of developing CS-CMV following an allogeneic HSCT.

Study P031 was an open-label, single-dose, four-period, seven-treatment, crossover study designed to evaluate the bioavailability of 2 paediatric formulations of MK-8228 (Formulations A and B) administered alone or in soft food (applesauce and vanilla pudding) compared to a currently marketed tablet formulation.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 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 and to introduce editorial changes.”

**Retsevmo - Selpercatinib -
EMA/H/C/005375/X/0031**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, “Extension application to introduce a new pharmaceutical form (film-coated tablets) associated with new strengths (40 mg, 80 mg, 120 mg and 160 mg). The RMP (version 7.1) is updated in accordance.”

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

Delgocitinib - EMA/H/C/006109

treatment of moderate to severe chronic hand eczema (CHE)
List of Questions adopted on 14.12.2023.

**Edurant - Rilpivirine -
EMA/H/C/002264/X/0042/G**

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan, “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 studies 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.”
List of Questions adopted on 14.12.2023.

**Eliquis - Apixaban -
EMA/H/C/002148/X/0089/G**

Bristol-Myers Squibb / Pfizer EEIG, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Bianca Mulder,
“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.”
List of Questions adopted on 14.12.2023.

Ustekinumab - EMA/H/C/005805

treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Crohn’s Disease and Ulcerative colitis
List of Questions adopted on 25.01.2024.

Trastuzumab - EMA/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)

List of Questions adopted on 14.12.2023.

Elafibranor - EMEA/H/C/006231, Orphan

Ipsen Pharma, treatment of primary biliary cholangitis (PBC)

List of Questions adopted on 22.02.2024.

Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - EMEA/H/C/005797

prevention of disease caused by chikungunya (CHIKV) virus

List of Questions adopted on 20.02.2024.

Avacincaptad pegol - EMEA/H/C/006153

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

List of Questions adopted on 14.12.2023.

Zapomeran - EMEA/H/C/006207

active immunisation to prevent COVID-19

List of Questions adopted on 14.12.2023.

In vitro diagnostic medical device - EMEA/H/D/006470

to detect amplification of the HER2/neu gene via quantitative fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer and adenocarcinomas of the stomach (including gastroesophageal junction) tissue specimens

Request for Supplementary Information adopted on 21.03.2024.

Rybelsus - Semaglutide - EMEA/H/C/004953/X/0039

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Extension application to add two new strengths (25 mg and 50 mg) tablets."

List of Questions adopted on 22.02.2024.

Lutetium (177Lu) chloride - EMEA/H/C/005882

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

List of Questions adopted on 14.12.2023.

Ciclosporin - EMEA/H/C/006250

Treatment of dry eye disease in adult patients

List of Questions adopted on 14.12.2023.

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

Evoltra - Clofarabine -

EMA/H/C/000613/S/0081

Sanofi B.V., Rapporteur: Alexandre Moreau,
PRAC Rapporteur: Tiphaine Vaillant

Lamzede - Velmanase alfa -

EMA/H/C/003922/S/0035, Orphan

Chiesi Farmaceutici S.p.A., Rapporteur: Patrick
Vrijlandt, PRAC Rapporteur: Jan Neuhauser

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

AYVAKYT - Avapritinib -

EMA/H/C/005208/R/0034, Orphan

Blueprint Medicines (Netherlands) B.V.,
Rapporteur: Carolina Prieto Fernandez, PRAC
Rapporteur: Bianca Mulder

BAQSIMI - Glucagon -

EMA/H/C/003848/R/0015

Amphastar France Pharmaceuticals, Rapporteur:
Karin Janssen van Doorn, Co-Rapporteur:
Martina Weise, PRAC Rapporteur: Eamon O
Murchu

Cegfila - Pegfilgrastim -

EMA/H/C/005312/R/0020

Mundipharma Corporation (Ireland) Limited,
Duplicate, Duplicate of Pelmeg, Rapporteur:
Karin Janssen van Doorn, Co-Rapporteur:
Christian Gartner, PRAC Rapporteur: Bianca
Mulder

Clopidogrel/Acetylsalicylic acid Viatris -

Clopidogrel / Acetylsalicylic acid -

EMA/H/C/004996/R/0012

Mylan Pharmaceuticals Limited, Generic,
Generic of DuoPlavin, Rapporteur: Kristina
Nadrah, PRAC Rapporteur: Carla Torre

Evenity - Romosozumab -

EMA/H/C/004465/R/0025

UCB Pharma S.A., Rapporteur: Kristina Dunder,
PRAC Rapporteur: Tiphaine Vaillant

Idefirix - Imlifidase -

EMA/H/C/004849/R/0020, Orphan

Hansa Biopharma AB, Rapporteur: Martina
Weise, Co-Rapporteur: Kristina Dunder, PRAC
Rapporteur: Bianca Mulder

MINJUVI - Tafasitamab -
EMA/H/C/005436/R/0015, Orphan

Incyte Biosciences Distribution B.V.,
Rapporteur: Aaron Sosa Mejia, PRAC
Rapporteur: Ulla Wändel Liminga

Quofenix - Delafloxacin -
EMA/H/C/004860/R/0026

A. Menarini Industrie Farmaceutiche Riunite
s.r.l., Rapporteur: Janet Koenig, PRAC
Rapporteur: Petar Mas

Rhokiinsa - Netarsudil -
EMA/H/C/004583/R/0022

Santen Oy, Rapporteur: Jayne Crowe, Co-
Rapporteur: Ewa Balkowiec Iskra, PRAC
Rapporteur: Maria del Pilar Rayon

ROCTAVIAN - Valoctocogene roxaparvovec
- EMA/H/C/005830/R/0011, Orphan,
ATMP

BioMarin International Limited, Rapporteur:
Violaine Closson Carella, Co-Rapporteur: Silke
Dorner, CHMP Coordinator: Jean-Michel Race,
PRAC Rapporteur: Bianca Mulder

Spravato - Esketamine -
EMA/H/C/004535/R/0023

Janssen-Cilag International N.V., Rapporteur:
Martina Weise, PRAC Rapporteur: Kirsti Villikka

Tepkinly - Epcoritamab -
EMA/H/C/005985/R/0004, Orphan

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Peter Mol, PRAC Rapporteur:
Monica Martinez Redondo

VITRAKVI - Larotrectinib -
EMA/H/C/004919/R/0035

Bayer AG, Rapporteur: Filip Josephson, PRAC
Rapporteur: Rugile Pilviniene

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

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

Darzalex - Daratumumab -
EMA/H/C/004077/II/0072, Orphan

Janssen-Cilag International N.V., Rapporteur:
Aaron Sosa Mejia, PRAC Rapporteur: Carla
Torre, "Extension of indication to include, in
combination with bortezomib, lenalidomide and

dexamethasone, the treatment of adult patients with newly diagnosed multiple myeloma, who are eligible for autologous stem cell transplant for Darzalex, based on the primary analysis results from the pivotal study

54767414MMY3014 (PERSEUS) and the results from study 54767414MMY2004 (GRIFFIN) and the D-VRd cohort of study 54767414MMY2040 (PLEIADES).

MMY3014 (PERSEUS) is a randomised, open-label, active-controlled, multicentre phase 3 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy (as required for autologous stem cell transplant). The primary objective is to compare the efficacy of (subcutaneous) daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd) in terms of progression free survival (PFS).

MMY2004 (GRIFFIN) is a randomised, open-label, active controlled, multicentre phase 2 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy and autologous stem cell transplant. The primary objective is to compare the efficacy of daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd), in terms of stringent complete response (sCR) rate.

MMY2040 (PLEIADES) is a randomised, open-label, multicentre phase 2 study to evaluate subcutaneous daratumumab in combination with standard multiple myeloma treatment regimens. The D-VRd cohort included adult subjects with newly diagnosed multiple myeloma, who were evaluated for clinical benefit in terms of very good partial response or better (VGPR) rate. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 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."

**Esperoct - Turoctocog alfa pegol -
EMA/H/C/004883/II/0023**

Novo Nordisk A/S, Rapporteur: Daniela Philadelphia, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include children below 12 years of age for treatment and prophylaxis of bleeding with haemophilia A for Esperoct, including previously untreated patients (PUPs) based on the final results from studies 3776, 4410, 3908, 3859, 3885, 3860, 4033 and 4595. As a consequence, section 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

**Jaypirca - Pirtobrutinib -
EMA/H/C/005863/II/0002**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection." Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)

**Keytruda - Pembrolizumab -
EMA/H/C/003820/II/0153**

Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "Extension of indication for KEYTRUDA in combination with carboplatin and paclitaxel to include first-line treatment of primary advanced or recurrent endometrial carcinoma in adults, based on final results from study KEYNOTE-868.

This is a randomized Phase 3, placebo-controlled, double-blind study of pembrolizumab vs placebo in combination with chemotherapy (paclitaxel plus carboplatin) for newly diagnosed Stage III/Stage IVA, Stage IVB, or recurrent endometrial cancer.

As a consequence, sections 4.1 and 5.1 of the SmPC are updated. Version 46.1 of the RMP has also been submitted.”

**Tevimbra - Tislelizumab -
EMA/H/C/005919/II/0008**

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, “Extension of indication to include treatment of adult patients with non-small cell lung cancer (NSCLC) in combination and as monotherapy for TEVIMBRA, based on results from studies BGB-A317-303, BGB-A317-304, BGB-A317-307 and BGB A317-206. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information.”

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

**Besremi - Ropeginterferon alfa-2b -
EMA/H/C/004128/II/0033/G**

AOP Orphan Pharmaceuticals GmbH,
Rapporteur: Janet Koenig

**Cosentyx - Secukinumab -
EMA/H/C/003729/II/0116**

Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola

**Darzalex - Daratumumab -
EMA/H/C/004077/II/0073/G, Orphan**

Janssen-Cilag International N.V., Rapporteur:
Aaron Sosa Mejia

**Erbitux - Cetuximab -
EMA/H/C/000558/II/0098/G**

Merck Europe B.V., Rapporteur: Filip Josephson

**Flixabi - Infliximab -
EMA/H/C/004020/II/0086**

Samsung Bioepis NL B.V., Rapporteur: Jan

Mueller-Berghaus

**Hizentra - Human normal immunoglobulin -
EMA/H/C/002127/II/0155**

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

**Inhixa - Enoxaparin sodium -
EMA/H/C/004264/II/0109**

Techdow Pharma Netherlands B.V., Duplicate of
Thorinane (EXP), Rapporteur: Christian Gartner

**Kengrexal - Cangrelor -
EMA/H/C/003773/II/0033**

Chiesi Farmaceutici S.p.A., Rapporteur: Patrick
Vrijlandt

**Leqvio - Inclisiran -
EMA/H/C/005333/II/0027/G**

Novartis Europharm Limited, Rapporteur:
Martina Weise

**Mounjaro - Tirzepatide -
EMA/H/C/005620/II/0022**

Eli Lilly Nederland B.V., Rapporteur: Martina
Weise

**NexoBrid - Concentrate of proteolytic
enzymes enriched in bromelain -
EMA/H/C/002246/II/0068**

MediWound Germany GmbH, Rapporteur: Janet
Koenig

**NUVAXOVID - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0070/G**

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt

**Pelgraz - Pegfilgrastim -
EMA/H/C/003961/II/0052/G**

Accord Healthcare S.L.U., Rapporteur: Sol Ruiz

**Skyclarys - Omaveloxolone -
EMA/H/C/006084/II/0003/G, Orphan**

Reata Ireland Limited, Rapporteur: Thalia Marie
Estrup Blicher

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0132/G**

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

**Steen Solution - Human albumin solution -
EMA/H/D/000002/II/0005**

XVIVO Perfusion AB, Rapporteur: Filip

Josephson

Tysabri - Natalizumab -

EMA/H/C/000603/II/0143/G

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

**Vaxelis - Diphtheria, tetanus, pertussis
(acellular, component), hepatitis B (rDNA),
poliomyelitis (inact.) and haemophilus type
B conjugate vaccine (adsorbed) -
EMA/H/C/003982/II/0141**

MCM Vaccine B.V., Rapporteur: Christophe
Focke

**Vaxneuvance - Pneumococcal
polysaccharide conjugate vaccine (15
valent, adsorbed) -
EMA/H/C/005477/II/0020**

Merck Sharp & Dohme B.V., Rapporteur: Patrick
Vrijlandt

**Xenpozyme - Olipudase alfa -
EMA/H/C/004850/II/0009, Orphan**

Sanofi B.V., Rapporteur: Patrick Vrijlandt

**Ximluci - Ranibizumab -
EMA/H/C/005617/II/0010**

STADA Arzneimittel AG, Rapporteur: Jayne
Crowe

**Zilbrysq - Zilucoplan -
EMA/H/C/005450/II/0002**

UCB Pharma S.A., Rapporteur: Kristina Dunder

**WS2663/G
Infanrix hexa-
EMA/H/C/000296/WS2663/0344/G**

GlaxoSmithKline Biologicals SA, Lead
Rapporteur: Christophe Focke

**WS2684
Nuwiq-EMA/H/C/002813/WS2684/0061
Vihuma-
EMA/H/C/004459/WS2684/0043**

Octapharma AB, Lead Rapporteur: Jan Mueller-
Berghaus

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

**Arixtra - Fondaparinux sodium -
EMA/H/C/000403/II/0092**

Viatis Healthcare Limited, Rapporteur: Kristina
Dunder, "Update of sections 5.1 and 5.2 of the

SmPC in order to update efficacy and pharmacokinetic information based on final results from study FDPX-IJS-7001; this is a retrospective cohort study to evaluate long-term dosing, efficacy, and safety of fondaparinux for treatment of venous thromboembolism in paediatric patients. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.”

**Cimzia - Certolizumab pegol -
EMA/H/C/001037/II/0110**

UCB Pharma S.A., Rapporteur: Kristina Dunder, “Update of sections 4.2 and 4.6 of the SmPC in order to update information on pregnancy based on final results from study UP0085, OTIS Phase I report and post marketing data. UP0085 is a Phase 1b, prospective, longitudinal, interventional, open-label study evaluating the impact of pregnancy on the PK of CZP. OTIS Phase I report presents the formal analysis of pregnancy outcome and infant and child follow-up data from the OTIS CZP Pregnancy Registry (RA0023). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.”

**Clopidogrel Zentiva - Clopidogrel -
EMA/H/C/000975/II/0091**

Zentiva k.s., Duplicate of Clopidogrel BMS (SRD), Informed Consent of Iscover, Rapporteur: Bruno Sepodes, “Update of section 4.4 and 4.8 of the SmPC in order to update an existing warning on ‘Bleeding and haematological disorders’ by adding a statement on triple antiplatelet therapy (clopidogrel + aspirin + dipyridamole) for stroke secondary prevention based on the cumulative review of the MAH global safety database and scientific 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 to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes.”

Constella - Linaclotide -

EMA/H/C/002490/II/0063

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the statement relating to guanylate cyclase-C (GCC) receptor expression in the paediatric population to reflect current clinical data, including final results from study MCP-103-311; this is a non-interventional clinical research study to characterize GCC mRNA expression in duodenal and colonic mucosal biopsies in children aged 0 to 17 years. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to bring it in line with the latest QRD template."

Erleada - Apalutamide -**EMA/H/C/004452/II/0037**

Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, "Update of section 5.1 of the SmPC in order to include information on Prostate Specific Antigen (PSA) reduction to undetectable levels, based on results from the TITAN (56021927PCR3002) and SPARTAN (ARN-509-003) studies. TITAN is a Phase 3 randomized, placebo-controlled, double-blind study of Apalutamide Plus Androgen Deprivation Therapy (ADT) versus ADT in subjects with Metastatic Hormone-sensitive Prostate Cancer (mHSPC). SPARTAN is a Phase 3, randomized, double-blind, placebo-controlled study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer."

Evrysdi - Risdiplam -**EMA/H/C/005145/II/0022**

Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Submission of the final report from study 'BP39055 (SUNFISH)' listed as a category 3 study in the RMP; this is a Two-Part Seamless, Multi-Center Randomized, Placebo-Controlled, Double-blind Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of RO7034067 in Type 2 and 3 Spinal Muscular Atrophy Patients."

EVUSHELD - Tixagevimab / Cilgavimab -**EMA/H/C/005788/II/0018**

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the warning"

on antiviral resistance, based on the latest neutralisation data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the Product Information.”

**Helicobacter Test INFAI - 13C-Urea -
EMA/H/C/000140/II/0028**

INFAI GmbH, Rapporteur: Christian Gartner,
“Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC.”

**Imfinzi - Durvalumab -
EMA/H/C/004771/II/0066**

AstraZeneca AB, Rapporteur: Aaron Sosa Mejia,
“Update of sections 4.2, 4.4, and 4.8 of the SmPC in order to include rhabdomyolysis as an extension of the myositis and polymyositis medical concept based on post marketing data and literature.”

**JEMPERLI - Dostarlimab -
EMA/H/C/005204/II/0031**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, “Type II (C.I.4) - To update section 6.6 of the SmPC for the addition of a maximum dilution volume for infusion solution for the 500 mg and 1000 mg doses and to update the corresponding minimum concentration for the 1000 mg dose (from 2 mg/mL to 4mg/mL). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information.”

**KIMMTRAK - Tebentafusp -
EMA/H/C/004929/II/0005, Orphan**

Immunocore Ireland Limited, Rapporteur: Aaron Sosa Mejia, “Update of section 5.1 of the SmPC in order to include the updated Overall Survival (OS) data based on results from study IMCgp100-202; this is a phase III randomized,

open-label, multi-center study of the safety and efficacy of IMCgp100 compared with investigator's choice in HLA-A*0201 positive patients with previously untreated advanced uveal melanoma."

**LIBTAYO - Cemiplimab -
EMA/H/C/004844/II/0043**

Regeneron Ireland Designated Activity Company, Rapporteur: Aaron Sosa Mejia, "Update of section 4.8 of the SmPC in order to add 'uveitis' to the list of adverse drug reactions (ADRs) with frequency rare, based on a safety evaluation report. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor corrections to the efficacy data in section 5.1 of the SmPC based on an erratum for the interim report for study R2810-ONC-1620, as well as to introduce minor editorial and formatting changes to the PI and to update the list of local representatives in the Package Leaflet."

**Mounjaro - Tirzepatide -
EMA/H/C/005620/II/0021/G**

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, "A grouped application consisting of two Type II variations, as follows:
C.I.4: Update of sections 4.6, 4.8 and 5.1 of the SmPC in order to include information on weight management (WM) based on final results from Phase 3 interventional WM studies (SURMOUNT-2, -3, and -4) and Phase 1 mechanism of action studies (GPGU and GPHH studies). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity implement editorial changes to the SmPC.
C.I.4: Update of section 5.1 of the SmPC in order to update the mechanism of action based on final results from in vitro studies ENDO123, QSB24, ENDO187, ENDO188 and ENDO190. The Package Leaflet is updated accordingly."

**NUVAXOVID - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0069**

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from study 2019nCoV-311 Part 1 listed as a category 3 study in the RMP. This is a 2-part, phase 3, randomized, observer blinded study to evaluate the safety and immunogenicity of Omicron

subvariant and bivalent SARS-CoV-2 rS vaccines in adults previously vaccinated with other COVID-19 vaccines.”

Ocrevus - Ocrelizumab -

EMA/H/C/004043/II/0040/G

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, “A grouped application comprised of three Type II Variations and one Type IA Variation, as follows:

3 Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to update clinical safety information based on final results from the three studies: study WA21092 (OPERA I), study WA21093 (OPERA II) and study WA25046 (ORATORIO). Study WA21092 (OPERA I) and study WA21093 (OPERA II) are randomized, double-blind, double-dummy, parallel-group studies to evaluate the efficacy and safety of ocrelizumab in comparison to interferon beta-1a (Rebif) in patients with relapsing multiple sclerosis (RMS), while study WA25046 (ORATORIO) is a phase 3, multicentre, randomized, parallel-group, double blinded, placebo controlled study to evaluate the efficacy and safety of ocrelizumab in adults with primary progressive multiple sclerosis (PPMS). In addition, the MAH took the opportunity to introduce minor editorial change to the Product Information.

Type IA (A.6): Change the ATC Code of ocrelizumab from L04AA36 to L04AG08.”

Orgovyx - Relugolix -

EMA/H/C/005353/II/0020

Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt, “Update of sections 4.2 and 4.5 of the SmPC in order to add information on “Combination with other medicines for advanced hormone-sensitive prostate cancer” based on clinical studies and literature. In addition, the MAH took the opportunity to update section 5.1 of the SmPC.”

OZAWADE - Pitolisant -

EMA/H/C/005117/II/0010

Bioprojet Pharma, Rapporteur: Peter Mol, “Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen, change posology recommendations for

patients with renal and hepatic impairment and to update the list of adverse drug reactions (ADRs) as well as efficacy information, based on the final results from study P15-13 (HAROSA III); this is a prospective, multicentre, randomized, double blind, placebo-controlled phase 3 study of the efficacy and safety of pitolisant in the treatment of excessive daytime sleepiness in patients with obstructive sleep apnoea (OSA). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information, to bring it in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.”

Rystiggo - Rozanolixizumab -

EMA/H/C/005824/II/0002, Orphan

UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher, “Update of sections 4.4 and 4.8 of the SmPC in order to add ‘aseptic meningitis’ to the list of adverse drug reactions (ADRs) with frequency ‘not known’ based on post-marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.”

Sivextro - Tedizolid phosphate -

EMA/H/C/002846/II/0053

Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, “Update of section 5.1 of the SmPC in order to implement the revised EUCAST MIC breakpoints of tedizolid. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

Spikevax - COVID-19 mRNA vaccine -

EMA/H/C/005791/II/0130

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, “To delete the following presentations (EU/1/20/1507/001; EU/1/20/1507/002; EU/1/20/1507/003; EU/1/20/1507/004; EU/1/20/1507/005; EU/1/20/1507/006; EU/1/20/1507/007; EU/1/20/1507/008; EU/1/20/1507/009; EU/1/20/1507/010) from the Spikevax marketing authorization. The SmPC, Package Leaflet and Labelling section of the Product Information are updated accordingly.”

Spravato - Esketamine -
EMA/H/C/004535/II/0024

Janssen-Cilag International N.V., Rapporteur:
Martina Weise, "Update of section 4.8 of the SmPC in order to add 'hypotension' to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI."

TAVNEOS - Avacopan -
EMA/H/C/005523/II/0013, Orphan

Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, "Submission of the analysis of 2 selected pharmacodynamic (PD) markers in the avacopan clinical studies CL003_168 and CL010_168: serum anti-proteinase 3 antibody (anti-PR3) titres and serum anti-myeloperoxidase antibody (anti-MPO) titres."

Tevimbra - Tislelizumab -
EMA/H/C/005919/II/0009

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to update efficacy information based on the overall survival (OS) final analyses for study BGB-A317-302; this is a randomized, controlled, open-label, global phase 3 study comparing the efficacy of the anti-PD-1 antibody tislelizumab (BGB-A317) versus chemotherapy as second line treatment in patients with advanced unresectable/metastatic oesophageal squamous cell carcinoma."

Ultomiris - Ravulizumab -
EMA/H/C/004954/II/0045

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, "Update of sections 4.8 and 5.1 of the SmPC in order to update the summary of safety profile and information in adult patients with Generalised Myasthenia Gravis based on final results from study ALXN1210-MG-306; this is a Phase 3, randomized, double-blind, parallel-group, placebo-controlled, multi-center study with an ongoing Open-Label Extension Period of up to 2 years in adult patients with gMG who were naïve to complement inhibitor treatment. In addition, the MAH took the opportunity to

introduce minor editorial changes to the PI.”

VANFLYTA - Quizartinib -

EMA/H/C/005910/II/0002

Daiichi Sankyo Europe GmbH, Rapporteur: Peter Mol, “To update section 5.2 of the SmPC in order to add information on interaction with Breast cancer resistant protein (BCRP) substrates based on results from study GE-2161 – Inhibitory Effects of Quizartinib on the Transport Activity of BCRP (REC). In addition, the MAH is taking this opportunity to introduce editorial changes to the PI.”

Wegovy - Semaglutide -

EMA/H/C/005422/II/0021

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, “Update of section 5.1 of the SmPC in order to include new data generated in patients with knee osteoarthritis (OA), based on final results from study NN9536-4578 (STEP 9); this is a phase 3b randomised, two-arm, double-blinded, multi-centre clinical trial comparing semaglutide s.c. 2.4 mg once-weekly with semaglutide placebo in subjects with moderate OA of one or both knees, pain due to knee OA, and obesity.”

Xevudy - Sotrovimab -

EMA/H/C/005676/II/0028

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, “Update of section 5.1 of the SmPC with data on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron XBB.1.16.6 and FL.1.5.1 spike variants (PC-23-0155), and the Omicron JN.1(PC-24-0103) spike variant; data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-CoV-2 XBB.2.3 variant (PC-23-0154), FL.1.5.1 and BA.2.86 variants (PC-23-0180); data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-CoV-2 XBB.2.3 variant (PC-23-0154), FL.1.5.1 and BA.2.86 variants (PC-23-0180) and data on the epitope conservation and sotrovimab activity against pseudotyped virus encoding epitope variants (PC-7831-0143v21) based on the relevant pharmacology study reports.”

WS2658

Braftovi-

EMA/H/C/004580/WS2658/0039

Mektovi-**EMA/H/C/004579/WS2658/0031**

Pierre Fabre Medicament, Lead Rapporteur:
Janet Koenig, "Update of sections 5.1 of the SmPC in order to update efficacy and safety information following the outcome of procedures 004579/0000 and R/0024 based on final results from study C4221004 (CMEK162B2301). This was a 2-part, multi-center, randomized, open label, Phase III study comparing the efficacy and safety of encorafenib plus binimetinib to vemurafenib and encorafenib monotherapy in participants with locally advanced unresectable or metastatic melanoma with BRAF V600 mutation. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

WS2683**Relvar Ellipta-****EMA/H/C/002673/WS2683/0068****Revinty Ellipta-****EMA/H/C/002745/WS2683/0065**

GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Antonio Gómez Outes, "Update of section 5.1 of the SmPC in order to update the results of study HZA107116 - A randomised, double-blind, parallel group, multicentre, stratified, study evaluating the efficacy and safety of once daily fluticasone furoate/vilanterol inhalation powder compared to once daily fluticasone furoate inhalation powder in the treatment of asthma in participants aged 5 to 17 years old (inclusive) currently uncontrolled on inhaled corticosteroids."

B.6.10. CHMP-PRAC assessed procedures

Beovu - Brolucizumab -**EMA/H/C/004913/II/0029**

Novartis Europharm Limited, Rapporteur:
Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 5.1 of the SmPC in order to include information on maintenance treatment and to update efficacy and safety information based on final results from studies CRTH258A2303 (TALON) and CRTH258A2303E1 (TALON Extension). TALON is a 64-week, two-arm, randomized, double-masked, phase IIIb study assessing the efficacy

and safety of brolucizumab 6 mg compared to aflibercept 2 mg in a treat-to-control regimen in patients with neovascular age-related macular degeneration. TALON Extension is a 56-week phase IIIb/IV, open-label, one-arm extension study to assess the efficacy and safety of brolucizumab 6 mg in a Treat-to-Control regimen with maximum treatment intervals up to 20 weeks for the treatment of subjects with neovascular age-related macular degeneration who have completed the CRTH258A2303 (TALON) study.

The Package Leaflet is updated accordingly. The RMP version 12.0 has also been submitted.”

**Byooviz - Ranibizumab -
EMA/H/C/005545/II/0016/G**

Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, PRAC Rapporteur: Ulla Wändel Liminga

**Dapivirine Vaginal Ring 25 mg - Dapivirine
- EMA/H/W/002168/II/0025/G**

International Partnership for Microbicides
Belgium AISBL, Rapporteur: Patrick Vrijlandt,
PRAC Rapporteur: Jan Neuhauser, “A grouped application consisting of:
Type II (C.I.4): Update of section 4.6 of the SmPC in order to update information on breastfeeding based on final results from study MTN-043 (B-PROTECTED) listed as a category 3 study in the RMP (MEA/009). MTN-043 is a Phase 3b, randomized, open-label, safety, and drug detection study of dapivirine vaginal ring and oral Truvada in breastfeeding mother-infant pairs. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI.

Type IB (C.I.11.z): Submission of an updated RMP version 1.4 in order to request a change on the due date for the MTN-034 (REACH) study.”

**Kalydeco - Ivacaftor -
EMA/H/C/002494/II/0126**

Vertex Pharmaceuticals (Ireland) Limited,
Rapporteur: Antonio Gómez Outes, PRAC
Rapporteur: Monica Martinez Redondo,
“Submission of the final report from study VX15-770-126 (study 126) listed as a category 3 study in the RMP; this is a phase 3, 2-arm, multicentre open-label study to evaluate the

safety and pharmacodynamics of long-term ivacaftor treatment in subjects with cystic fibrosis who are less than 24 months of age at treatment initiation and have an approved ivacaftor-responsive mutation. The RMP version 16.0 has also been submitted.”

**Loargys - Pegzilarginase -
EMA/H/C/005484/II/0002/G, Orphan**

Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, “Grouped application comprising two type II variations as follows:

C.I.4 – 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 CAEB1102-300A (SOB 003), listed as a specific obligation in Annex II. Study 300A was a Phase 3, randomized, double blind, placebo-controlled study of the efficacy and safety of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).

C.I.4 – Update of section 4.8 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-102A (SOB 004), listed as a specific obligation in Annex II.

Study 102A was an open label extension study to evaluate the long-term safety, tolerability, and efficacy of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).

The Package Leaflet and Annex II are updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes.”

**RINVOQ - Upadacitinib -
EMA/H/C/004760/II/0052**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, “Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to change posology recommendations in adolescents with atopic dermatitis to include the 30mg dose option based on results from studies M16-045, M16-047 and M18-891 (pivotal phase 3 studies with adolescent sub studies). The Package Leaflet is updated accordingly. The RMP version 14.0 has

also been submitted.”

SCENESSE - Afamelanotide -

EMA/H/C/002548/II/0052, Orphan

Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, “Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information.”

Tecvayli - Teclistamab -

EMA/H/C/005865/II/0012

Janssen-Cilag International N.V., Rapporteur: Johanna Lähtenvuo, PRAC Rapporteur: Jana Lukacisinova, “Update of sections 4.2, 4.8, 5.1 of the SmPC in order to amend the recommendations for dose delays, as well as, to update safety and efficacy information based on final results from study 64007957MMY1001 listed as a specific obligation in the Annex II (SOB/005); this is a phase 1/2, first in human, open label, dose escalation study of teclistamab in subjects with relapsed or refractory multiple myeloma. The Package Leaflet is updated accordingly. The RMP version 4.2 has also been submitted. In addition, the MAH took the opportunity to update Annex II and Annex IV of the PI.”

VELSIPITY - Etrasimod -

EMA/H/C/006007/II/0001

Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, “Update of section 4.4 to modify the macular oedema warning based on the evaluation of the cases of MO/cystoid MO reported in the etrasimod clinical studies and other S1P labels in the EU. The Package Leaflet and Annex II are updated in accordance. RMP version 1.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI.”

Zeposia - Ozanimod -

EMA/H/C/004835/II/0024/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Bruno Sepodes, PRAC Rapporteur: Maria del
Pilar Rayon, "Grouped application comprising
two variations as follows:

Type II (C.I.4) – Update of sections 4.4 and 4.8
the SmPC in order to add a new warning on
liver injury, to add Liver injury to the list of
adverse drug reactions (ADRs) with frequency
rare based on the cumulative review of the MAH
safety database, clinical trials and literature
search. The RMP version 8.0 also been
submitted.

Type IA (A.6) – To change the ATC code from
L04AA38 to L04AE02."

WS2664

Ebymect-

EMA/H/C/004162/WS2664/0066

Qtern-EMA/H/C/004057/WS2664/0043

Xigduo-EMA/H/C/002672/WS2664/0076

AstraZeneca AB, Lead Rapporteur: Kristina
Dunder, Lead PRAC Rapporteur: Bianca Mulder,
"Update of sections 4.2, 4.4, 4.5, 4.8, 5.1 and
6.1 of the SmPC in order to align dapagliflozin
related information in Fixed Dose Combination
with Forxiga. The Package Leaflet is updated
accordingly. The RMPs version 15.1 (Xigduo and
Wbymect) and 9.1 (Qtern) has also been
submitted. In addition, the MAH took the
opportunity to introduce editorial changes to the
PI."

B.6.11. PRAC assessed procedures

PRAC Led

BESPONSA - Inotuzumab ozogamicin -

EMA/H/C/004119/II/0028, Orphan

Pfizer Europe MA EEIG, PRAC Rapporteur:
Gabriele Maurer, PRAC-CHMP liaison: Jan
Mueller-Berghaus, "Submission of the final
report from study B1931028; this is a non-
interventional post-authorization safety study
(PASS) of inotuzumab ozogamicin to
characterize complications post-hematopoietic
stem cell transplantation (HSCT) following
inotuzumab ozogamicin treatment in adult and
paediatric patients with B-cell precursor acute
lymphoblastic leukaemia (ALL). The RMP version
3.0 has also been submitted."

PRAC Led

CAMZYOS - Mavacamten -
EMA/H/C/005457/II/0008

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Patrick Vrijlandt, PRAC Rapporteur: Kimmo
Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola,
"Submission of an updated RMP version 3.0 in
order to revise the number of patients planned
to be enrolled in DISCOVER-HCM US-registry
study CV027012 (MEA 005). In addition, the
MAH took this opportunity to update protocol
title for MAVEL-HCM study (CV027013) and
include reference to study protocol in Annex 3 of
the RMP, following the assessment of PAM
procedure MEA 001."

PRAC Led

Gilenya - Fingolimod -
EMA/H/C/002202/II/0090/G

Novartis Europharm Limited, PRAC Rapporteur:
Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre
Moreau, "Grouped application comprising two
variations as follows:

Type II (C.I.3.b) - Update of sections 4.3 and
4.4 of the SmPC in order to add history of
progressive multifocal leukoencephalopathy
(PML) as a new contraindication and to amend
an existing warning on PML and to update the
educational material to improve the general
readability of these documents and better
address key messages and recommendations
for healthcare professionals following the
assessment of procedure

PSUSA/00001393/202302. The Package Leaflet
and Annex II are updated accordingly. The RMP
version 20.0 has also been submitted.

Type IA (A.6) - To change the ATC Code of
Fingolimod from L04AA27 to L04AE01."

PRAC Led

Olumiant - Baricitinib -
EMA/H/C/004085/II/0047

Eli Lilly Nederland B.V., PRAC Rapporteur: Adam
Przybylkowski, PRAC-CHMP liaison: Ewa
Balkowiec Iskra, "Submission of the final report
from non-interventional Study I4V-MC-B012
listed as a category 3 study in the RMP. This is a
post-marketing safety surveillance of baricitinib
in three European registries. The RMP version
23.1 has also been submitted."

PRAC Led

Reyataz - Atazanavir -

EMA/H/C/000494/II/0140

Bristol-Myers Squibb Pharma EEIG, PRAC

Rapporteur: Nathalie Gault, PRAC-CHMP liaison:

Jean-Michel Race, "Update of section 4.4 of the SmPC in order to clarify and update the warning regarding dyslipidaemia in relation to other comparators, following PRAC's recommendation in the outcome of procedure

PSUSA/00000258/202106. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

PRAC Led

Spikevax - COVID-19 mRNA vaccine -**EMA/H/C/005791/II/0131**

Moderna Biotech Spain S.L., PRAC Rapporteur:

Marie Louise Schougaard Christiansen, PRAC-

CHMP liaison: Thalia Marie Estrup Blicher,

"Submission of the final report from study mRNA-1273-919 - An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to Spikevax During Pregnancy, listed as a category 3 study in the RMP."

PRAC Led

Uptravi - Selexipag -**EMA/H/C/003774/II/0045**

Janssen-Cilag International N.V., PRAC

Rapporteur: Nathalie Gault, PRAC-CHMP liaison:

Alexandre Moreau, "Submission of the final report from study 67896049PAH0002

(EXTRACT) and interim report for study AC-065A401 (EXPOSURE), listed as a category 3 study in the RMP. EXTRACT is a Retrospective Medical Chart Review of Patients with PAH newly treated with either Uptravi (selexipag) or any other PAH-specific therapy. EXPOSURE is an observational cohort study of PAH patients newly treated with either Uptravi (selexipag) or any other PAH-specific therapy, in clinical practice."

PRAC Led

Xeljanz - Tofacitinib -**EMA/H/C/004214/II/0062**

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana

Martirosyan, PRAC-CHMP liaison: Peter Mol,

"Submission of the final report from study

A3921203 (Tofacitinib Pregnancy Exposure Registry OTIS Autoimmune Diseases in Pregnancy Project) listed as a category 3 study in the RMP; this is a prospective, observational

cohort study of pregnancy outcomes in women with a disease for which tofacitinib had an approved indication.”

PRAC Led

Xeljanz - Tofacitinib -

EMA/H/C/004214/II/0063

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol, “Submission of an updated RMP version 32.0 in order to propose the removal of category 3 study A3921329 (A Long-Term, Observational Study within the CorEvitas [formerly Corrona] Inflammatory Bowel Disease (IBD) Registry to Characterize the Safety of Tofacitinib in Patients with Ulcerative Colitis in the Post-Approval Setting). In addition, the MAH took the opportunity to update the RMP with some other minor updates.”

B.6.12. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel -

EMA/H/C/004662/II/0047, Orphan, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang”- To update section 6.6 of the SmPC - “Special precautions for disposal and other handling”, and corresponding section of the Package Leaflet, to clarify dose preparation and administration instructions of the thawed finished product (IV administration set fitted with a non-leukodepleting in-line filter which can be used to reduce visible cellular aggregates that do not disperse after gentle manual mixing).”

CARVYKTI - Ciltacabtagene autoleucel -

EMA/H/C/005095/II/0027/G, Orphan, ATMP

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

Libmeldy - Atidarsagene autotemcel -

EMA/H/C/005321/II/0025, Orphan, ATMP

Orchard Therapeutics (Netherlands) B.V., Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol

Upstaza - Eladocagene exuparvovec -

**EMA/H/C/005352/II/0021, Orphan,
ATMP**

PTC Therapeutics International Limited,
Rapporteur: Joseph DeCoursey, CHMP
Coordinator: Finbarr Leacy

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

WS2656/G

Copalia HCT-

EMA/H/C/001159/WS2656/0112/G

Dafiro HCT-

EMA/H/C/001160/WS2656/0114/G

Exforge HCT-

EMA/H/C/001068/WS2656/0111/G

Novartis Europharm Limited, Lead Rapporteur:
Thalia Marie Estrup Blicher

WS2662/G

Edistride-

EMA/H/C/004161/WS2662/0066/G

Forxiga-

EMA/H/C/002322/WS2662/0087/G

AstraZeneca AB, Lead Rapporteur: Kristina
Dunder

WS2665

Mircera-EMA/H/C/000739/WS2665/0101

NeoRecormon-

EMA/H/C/000116/WS2665/0125

Roche Registration GmbH, Lead Rapporteur:
Antonio Gomez-Outes, "

WS2669

HyQvia-EMA/H/C/002491/WS2669/0098

Kiovig-EMA/H/C/000628/WS2669/0128

Baxalta Innovations GmbH, Lead Rapporteur:
Jan Mueller-Berghaus,

WS2677

Mircera-EMA/H/C/000739/WS2677/0100

NeoRecormon-

EMA/H/C/000116/WS2677/0124

Roche Registration GmbH, Lead Rapporteur:
Martina Weise

WS2678

Incresync-

EMA/H/C/002178/WS2678/0048

Vipdomet-

EMA/H/C/002654/WS2678/0047

Vipidia-EMA/H/C/002182/WS2678/0037

Takeda Pharma A/S, Lead Rapporteur: Patrick

Vrijlandt,

WS2685

Mekinist-

EMA/H/C/002643/WS2685/0065

Tafinlar-

EMA/H/C/002604/WS2685/0070

Novartis Europharm Limited, Lead Rapporteur:

Filip Josephson, "To update the product information section 4.2 with the pharmaceutical form capsule and tablets, respectively and section 5.2 with pharmacokinetic exposure at weight adjusted dosage for adolescents."

WS2687

Eucreas-

EMA/H/C/000807/WS2687/0109

Icandra-

EMA/H/C/001050/WS2687/0114

Zomarist-

EMA/H/C/001049/WS2687/0111

Novartis Europharm Limited, Lead Rapporteur:

Kristina Dunder, "Change in the specification parameters of an active substance Metformin hydrochloride to delete the Footnote 2 for the test identity by IR(ATR), Loss on drying and Assay by titration have been removed to rectify a typographical error. As a consequence the other footnotes have been re-numbered for the tests 2-Propanol, Dimethylformamide and Di-n-butylether under Residual solvents by GC."

WS2704

Filgrastim Hexal-

EMA/H/C/000918/WS2704/0077

Zarzio-EMA/H/C/000917/WS2704/0078

Sandoz GmbH, Lead Rapporteur: Peter Mol, "To

update section 4.8 of the SmPC to add "extramedullary haematopoiesis" as adverse a reaction with frequency "rare", following assessment of the same change in the reference product, Neupogen. The Package Leaflet (section 4) has been updated accordingly.

Furthermore, the Marketing Authorisation Holder has taken the opportunity to update the

local representative details for Cyprus.”

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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