



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/CHMP/91836/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 24-27 February 2025

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

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	8
2.1.	Pre-authorisation procedure oral explanations.....	8
2.1.1.	Insulin human - EMEA/H/C/006011.....	8
2.1.2.	Kisunla - Donanemab - EMEA/H/C/006024	9
2.1.3.	Atropine - EMEA/H/C/006324.....	9
2.2.	Re-examination procedure oral explanations	9
2.2.1.	CINAINU - Liquid ethanolic extract 30 per cent (W/W) of <i>Allium cepa</i> fresh bulb and <i>Citrus limon</i> fresh fruit / Dry aqueous extract of <i>paullinia cupana</i> seed / Dry hydroethanolic extract of <i>theobroma cacao</i> seed - EMEA/H/C/004155	9
2.2.2.	Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0154	10
2.2.3.	Kizfizo - Temozolomide - Orphan - EMEA/H/C/006169.....	10
2.3.	Post-authorisation procedure oral explanations	10
2.3.1.	Calquence - Acalabrutinib - EMEA/H/C/005299/II/0026	10
2.3.2.	PREVMIS - Letermovir - Orphan - EMEA/H/C/004536/X/0037/G	11
2.4.	Referral procedure oral explanations	11
3.	Initial applications	11
3.1.	Initial applications; Opinions.....	11
3.1.1.	Deqsig - Human normal immunoglobulin - EMEA/H/C/006423	11
3.1.2.	LYNOZYFIC - Linvoseltamab - EMEA/H/C/006370	12
3.1.3.	Trabectedin Accord - Trabectedin - EMEA/H/C/006433	12
3.1.4.	Vyjuvek - Beremagene geperpavec - PRIME - Orphan - ATMP - EMEA/H/C/006330	13
3.2.	Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)	13
3.2.1.	Deutivacaftor / Tezacaftor / Vanzacaftor - Orphan - EMEA/H/C/006382	13
3.2.2.	L-Acetyl-leucine - Orphan - EMEA/H/C/006327	13
3.2.3.	Atropine - PUMA - EMEA/H/C/006385.....	14
3.2.4.	Deutetrabenazine - EMEA/H/C/006371	14
3.2.5.	Denosumab - EMEA/H/C/006434	14
3.2.6.	Denosumab - EMEA/H/C/006435	15
3.2.7.	Denosumab - EMEA/H/C/006199	15
3.2.8.	Denosumab - EMEA/H/C/006376	15
3.2.9.	Inavolisib - EMEA/H/C/006353	15

3.2.10.	Denosumab - EMEA/H/C/006152	16
3.2.11.	Resminostat - Orphan - EMEA/H/C/006259	16
3.2.12.	Octreotide - Orphan - EMEA/H/C/006322	16
3.2.13.	Atropine - EMEA/H/C/006324	17
3.2.14.	Sepiapterin - Orphan - EMEA/H/C/006331	17
3.2.15.	Teprotumumab - EMEA/H/C/006396	17
3.2.16.	Teriparatide - EMEA/H/C/005687	17
3.2.17.	Denosumab - EMEA/H/C/006377	18
3.2.18.	Zanidatamab - Orphan - EMEA/H/C/006380	18
3.3.	Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)	18
3.3.1.	Enzalutamide - EMEA/H/C/006612	18
3.3.2.	Golimumab - EMEA/H/C/006560	18
3.3.3.	Insulin icodec / Semaglutide - EMEA/H/C/006279	19
3.3.4.	Elinzanetant - EMEA/H/C/006298	19
3.3.5.	Rivaroxaban - EMEA/H/C/006643	19
3.3.6.	Teduglutide - EMEA/H/C/006564	19
3.3.7.	Rilzabrutinib - Orphan - EMEA/H/C/006425	20
3.4.	Update on on-going initial applications for Centralised procedure	20
3.4.1.	Troriluzole - Orphan - EMEA/H/C/006068	20
3.4.2.	Bifikafusp alfa / Onfekafusp alfa - EMEA/H/C/005651	20
3.4.3.	Pridopidine - EMEA/H/C/006261	20
3.4.4.	Mozafancogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005537	21
3.5.	Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004	21
3.5.1.	Kizfizo - Temozolomide - Orphan - EMEA/H/C/006169	21
3.6.	Initial applications in the decision-making phase	21
3.6.1.	LEQEMBI - Lecanemab - EMEA/H/C/005966	21
3.7.	Withdrawals of initial marketing authorisation application	22
3.7.1.	CINAINU - Liquid ethanolic extract 30 per cent (W/W) of <i>Allium cepa</i> fresh bulb and <i>Citrus limon</i> fresh fruit / Dry aqueous extract of <i>paullinia cupana</i> seed / Dry hydroethanolic extract of <i>theobroma cacao</i> seed - EMEA/H/C/004155	22
3.7.2.	Pegfilgrastim - PUMA - EMEA/H/C/006348	22
3.7.3.	Riloncept - Orphan - EMEA/H/C/006537	22
4.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	23
4.1.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion	23
4.1.1.	Aqumeldi - Enalapril maleate - EMEA/H/C/005731/X/0001/G	23
4.1.2.	Lyrice - Pregabalin - EMEA/H/C/000546/X/0127	23

4.1.3.	PREVYMIS - Letemovir - Orphan - EMEA/H/C/004536/X/0037/G	24
4.1.4.	Retsevmo - Selpercatinib - EMEA/H/C/005375/X/0031	24
4.1.5.	Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/X/0140	25
4.1.6.	Tremfya - Guselkumab - EMEA/H/C/004271/X/0043/G.....	25
4.2.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues	26
4.2.1.	Adempas - Riociguat - EMEA/H/C/002737/X/0041	26
4.3.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question	26
4.3.1.	Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039	26
4.3.2.	Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0015	27
4.3.3.	Pyzchiva - Ustekinumab - EMEA/H/C/006183/X/0006.....	27
4.3.4.	Spevigo - Spesolimab - EMEA/H/C/005874/X/0011.....	27
4.3.5.	Talzenna - Talazoparib - EMEA/H/C/004674/X/0022	27
4.4.	Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008	28
4.5.	Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	28

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.....	28
5.1.1.	Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0007.....	28
5.1.2.	Calquence - Acalabrutinib - EMEA/H/C/005299/II/0026	29
5.1.3.	Columvi - Glofitamab - Orphan - EMEA/H/C/005751/II/0005	29
5.1.4.	Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0076.....	30
5.1.5.	Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0077	31
5.1.6.	Enhertu - Trastuzumab deruxtecan - EMEA/H/C/005124/II/0048.....	31
5.1.7.	FABHALTA - Iptacopan - Orphan - EMEA/H/C/005764/II/0001	32
5.1.8.	Imfinzi - Durvalumab - EMEA/H/C/004771/II/0064.....	32
5.1.9.	IXCHIQ - Chikungunya virus, strain delta5nsP3, live attenuated - EMEA/H/C/005797/II/0001	33
5.1.10.	Jaypirca - Pirtobrutinib - EMEA/H/C/005863/II/0002.....	33
5.1.11.	LUTATHERA - Lutetium (177Lu) oxodotreotide - Orphan - EMEA/H/C/004123/II/0052.....	34
5.1.12.	Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0038	35
5.1.13.	RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0056.....	35
5.1.14.	Saxenda - Liraglutide - EMEA/H/C/003780/II/0042.....	35
5.1.15.	Stelara - Ustekinumab - EMEA/H/C/000958/II/0108	36

5.1.16.	Supemtek Tetra - Quadrivalent influenza vaccine (recombinant, prepared in cell culture) - EMEA/H/C/005159/II/0021/G	36
5.1.17.	Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0017	37
5.1.18.	Uplizna - Inebilizumab - EMEA/H/C/005818/II/0012	37
5.1.19.	Xofluza - Baloxavir marboxil - EMEA/H/C/004974/II/0021	38
5.1.20.	WS2551 Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/WS2551/0043 Kalydeco - Ivacaftor - EMEA/H/C/002494/WS2551/0121	38
5.2.	Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	39
5.2.1.	Amyvid - Florbetapir (18F) - EMEA/H/C/002422/II/0046	39
5.3.	Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	39
5.3.1.	Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0154	39

6. Medical devices 40

6.1.	Ancillary medicinal substances - initial consultation	40
6.1.1.	Human albumin solution - EMEA/H/D/006540	40
6.2.	Ancillary medicinal substances – post-consultation update	40
6.3.	Companion diagnostics - initial consultation	40
6.3.1.	In vitro diagnostic medical device - EMEA/H/D/006648	40
6.3.2.	In vitro diagnostic medical device - EMEA/H/D/006668	41
6.3.3.	In vitro diagnostic medical device - EMEA/H/D/006656	41
6.4.	Companion diagnostics – follow-up consultation	41

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 41

7.1.	Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)41
-------------	--

8. Pre-submission issues 42

8.1.	Pre-submission issue	42
8.1.1.	Diazoxide choline – H0006576	42
8.1.2.	Brensocatib - H0005820	42
8.1.3.	apitegromab - H0005909	42
8.2.	Priority Medicines (PRIME)	42

9. Post-authorisation issues 43

9.1.	Post-authorisation issues	43
9.1.1.	BIMERVAX - SARS-CoV-2, variant JN.1, spike protein, receptor binding domain fusion homodimer - EMEA/H/C/006058/II/0016	43
9.1.2.	FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan	43
9.1.3.	Fluenz - Influenza vaccine (live, nasal) - EMEA/H/C/006514/II/0002	43
9.1.4.	Cablivi - Caplacizumab - EMEA/H/C/004426/II/0048, Orphan	44

9.1.5.	Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044.....	44
9.1.6.	Champix - Varenicline - EMEA/H/C/000699/II/0085/G	45
9.1.7.	Pemazyre - Pemigatinib – Orphan - EMEA/H/C/005266/R/0019	45
9.1.8.	Ontilyv – Opicapone – EMEA/H/C/005782.....	45
9.1.9.	Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028	45
9.1.10.	Dupixent - Dupilumab - EMEA/H/C/004390/II/0083	46
9.1.11.	Emblaveo - Avibactam sodium, Aztreonam – OPEN – H0006113.....	46

10. Referral procedures 46

10.1.	Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004	46
10.2.	Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 .	46
10.3.	Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004	46
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	46
10.5.	Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC....	47
10.6.	Community Interests - Referral under Article 31 of Directive 2001/83/EC	47
10.6.1.	Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/153247	
10.7.	Re-examination Procedure under Article 32(4) of Directive 2001/83/EC.....	47
10.8.	Procedure under Article 107(2) of Directive 2001/83/EC	48
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	48
10.10.	Procedure under Article 29 of Regulation (EC) 1901/2006.....	48
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	48

11. Pharmacovigilance issue 48

11.1.	Early Notification System	48
--------------	--	-----------

12. Inspections 48

12.1.	GMP inspections	48
12.2.	GCP inspections	48
12.3.	Pharmacovigilance inspections.....	48
12.4.	GLP inspections	49

13. Innovation Task Force 49

13.1.	Minutes of Innovation Task Force.....	49
13.2.	Innovation Task Force briefing meetings.....	49
13.3.	Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004	49

13.4.	Nanomedicines activities	49
14.	Organisational, regulatory and methodological matters	49
14.1.	Mandate and organisation of the CHMP	49
14.1.1.	Vote by Proxy	49
14.1.2.	CHMP membership.....	49
14.2.	Coordination with EMA Scientific Committees.....	50
14.2.1.	Pharmacovigilance Risk Assessment Committee (PRAC)	50
14.2.2.	Paediatric Committee (PDCO).....	50
14.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	50
14.3.1.	Biologics Working Party (BWP)	50
14.3.2.	Name Review Group (NRG).....	50
14.3.3.	Scientific Advice Working Party (SAWP)	50
14.3.4.	Election of new Scientific Advice Working Party (SAWP) Chair	51
14.3.5.	Scientific Advice Group (SAG) mandate renewal and (re)nominations.....	51
14.4.	Cooperation within the EU regulatory network.....	51
14.5.	Cooperation with International Regulators.....	51
14.6.	Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee.....	51
14.7.	CHMP work plan	51
14.8.	Planning and reporting	51
14.9.	Others	52
14.9.1.	CHMP Learnings	52
15.	Any other business	52
15.1.	AOB topic.....	52
15.1.1.	GIREX rules	52
16.	List of participants	53
Explanatory notes		58

1. Introduction

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

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

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

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

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

1.2. Adoption of agenda

CHMP agenda for 24-27 February 2025

The CHMP adopted the agenda.

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 17 February 2025.

The CHMP adopted the minutes from the PROM meeting held on 17 February 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Insulin human - EMEA/H/C/006011

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 February 2025 at 14:00

List of Outstanding Issues adopted on 12.12.2024, 19.09.2024. List of Questions adopted on 25.05.2023.

An oral explanation was held on 24 February 2025. The presentation by the applicant focused on the clinical data in support of the application.

2.1.2. [Kisunla - Donanemab - EMEA/H/C/006024](#)

Eli Lilly Nederland B.V.; to slow disease progression in adult patients with Alzheimer's disease (AD).

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 14:00

Third-party intervention

List of Outstanding Issues adopted on 12.12.2024, 25.04.2024. List of Questions adopted on 14.12.2023.

An oral explanation was held on 26 February 2025. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the third-party intervention.

2.1.3. [Atropine - EMEA/H/C/006324](#)

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

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 09:00

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

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

See 3.2

2.2. **Re-examination procedure oral explanations**

2.2.1. [CINAINU - Liquid ethanolic extract 30 per cent \(W/W\) of *Allium cepa* fresh bulb and *Citrus limon* fresh fruit / Dry aqueous extract of *paullinia cupana* seed / Dry hydroethanolic extract of *theobroma cacao* seed - EMEA/H/C/004155](#)

Legacy Healthcare (France) S.A.S.; treatment of alopecia areata in children and adolescents

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2025 at 14:00

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

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 12.10.2023.

An oral explanation was held on 25 February 2025. The presentation by the applicant focused on the quality, non-clinical and clinical data in support of the application.

See 3.7

2.2.2. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0154

Merck Sharp & Dohme B.V.

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 16:00

Opinion adopted on 14.11.2024.

An oral explanation was held on 26 February 2025. The presentation by the MAH focused on the clinical data in support of the application.

See 5.3

2.2.3. Kizfizo - Temozolomide - Orphan - EMEA/H/C/006169

Orphelia Pharma; treatment of neuroblastoma

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2025 at 11:00

Third-party intervention

Participation of patient representative

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

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 14.12.2023.

An oral explanation was held on 25 February 2025. The presentation by the applicant focused on the clinical data in support of the application.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Calquence - Acalabrutinib - EMEA/H/C/005299/II/0026

AstraZeneca AB

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2025 at 09:00

Request for Supplementary Information adopted on 12.12.2024.

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

See 5.1

2.3.2. PREVMIS - Letermovir - Orphan - EMEA/H/C/004536/X/0037/G

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Terhi Lehtinen

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 11:00

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

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

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Deqsig - Human normal immunoglobulin - EMEA/H/C/006423

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

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.2. LYNZOYFIC - Linvoseltamab - EMEA/H/C/006370

Regeneron Ireland Designated Activity Company; monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

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

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

Furthermore, the CHMP considered that Linvoseltamab 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 recommendations dated 17 February 2025.

The CHMP adopted the similarity assessment report

3.1.3. Trabectedin Accord - Trabectedin - EMEA/H/C/006433

Accord Healthcare S.L.U.; treatment of soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 30.05.2024.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.4. Vyjuvek - Beremagene geperpavec - PRIME - Orphan - ATMP - EMEA/H/C/006330

Krystal Biotech Netherlands B.V.; treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 06.12.2024, 11.10.2024. List of Questions adopted on 15.03.2024.

The CHMP was updated on discussions at the CAT.

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

Based on the draft opinion prepared by the CAT, the CHMP 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 beremagene geperpavec 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

The CHMP endorsed the EMA press release.

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

3.2.1. Deutivacaftor / Tezacaftor / Vanzacaftor - Orphan - EMEA/H/C/006382

Vertex Pharmaceuticals (Ireland) Limited; indicated for the treatment of cystic fibrosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

3.2.2. L-Acetylleucine - Orphan - EMEA/H/C/006327

Intrabio Ireland Limited; is indicated in adults and children from birth for chronic treatment of Niemann-Pick Type C (NPC).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

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.

3.2.3. Atropine - PUMA - EMEA/H/C/006385

treatment of myopia progression in children

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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. Deutetrabenazine - EMEA/H/C/006371

treatment of tardive dyskinesia in adults

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues to be adopted in February 2025

Action: For adoption

List of Questions adopted on 25.07.2024.

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.

The CHMP agreed to the request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in February 2025.

3.2.5. Denosumab - EMEA/H/C/006434

treatment of osteoporosis and bone loss

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues to be adopted in February 2025

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

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

respond to the list of outstanding issues adopted in February 2025.

3.2.6. Denosumab - EMEA/H/C/006435

prevention of skeletal related events with advanced malignancies

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues to be adopted in February 2025.

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

The CHMP agreed to the request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in February 2025.

3.2.7. Denosumab - EMEA/H/C/006199

prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

3.2.8. Denosumab - EMEA/H/C/006376

prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

3.2.9. Inavolisib - EMEA/H/C/006353

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

3.2.10. Denosumab - EMEA/H/C/006152

for the treatment of osteoporosis and bone loss.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

3.2.11. Resminostat - Orphan - EMEA/H/C/006259

4Sc AG; treatment of patients with advanced stage mycosis fungoides (MF) and Sézary syndrome (SS)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

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.

3.2.12. Octreotide - Orphan - EMEA/H/C/006322

Camurus AB; treatment of acromegaly

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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. Atropine - EMEA/H/C/006324

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

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

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

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

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

See 2.1

3.2.14. Sepiapterin - Orphan - EMEA/H/C/006331

PTC Therapeutics International Limited; treatment of hyperphenylalaninemia (HPA) in adult and paediatric patients with phenylketonuria (PKU)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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. Teprotumumab - EMEA/H/C/006396

treatment of moderate to severe Thyroid Eye Disease (TED).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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. Teriparatide - EMEA/H/C/005687

treatment of osteoporosis

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.

3.2.17. Denosumab - EMEA/H/C/006377

for the treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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.

3.2.18. Zanidatamab - Orphan - EMEA/H/C/006380

Jazz Pharmaceuticals Ireland Limited; Treatment of biliary tract cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

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.

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

3.3.1. Enzalutamide - EMEA/H/C/006612

treatment of prostate cancer

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.2. Golimumab - EMEA/H/C/006560

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis

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. [Insulin icodec / Semaglutide - EMEA/H/C/006279](#)

treatment of adults with type 2 diabetes mellitus insufficiently controlled on basal insulin or glucagon-like peptide 1 (GLP-1) receptor agonists

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. [Elinzanetant - EMEA/H/C/006298](#)

for the treatment of moderate to severe vasomotor symptoms (VMS)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.5. [Rivaroxaban - EMEA/H/C/006643](#)

prevention of atherothrombotic events

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.6. [Teduglutide - EMEA/H/C/006564](#)

treatment of Short Bowel Syndrome

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.7. Rilzabrutinib - Orphan - EMEA/H/C/006425

Sanofi B.V.; for the treatment of persistent or chronic immune thrombocytopenia (ITP)

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. Troriluzole - Orphan - EMEA/H/C/006068

Biohaven Bioscience Ireland Limited; is indicated for the treatment of adult patients with spinocerebellar ataxia genotype 3 (SCA3)

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in January 2025

Third-party intervention

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 22.02.2024
The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in January 2025.

The CHMP noted the third-party intervention.

3.4.2. Bifikafusp alfa / Onfekafusp alfa - EMEA/H/C/005651

neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma.

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in October 2024.

Action: For adoption

List of Questions adopted on 17.10.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in October 2024.

3.4.3. Pridopidine - EMEA/H/C/006261

treatment of Huntington's disease

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in December 2024.

Action: For adoption

List of Questions adopted on 12.12.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in December 2024.

3.4.4. [Mozafancogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005537](#)

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

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in July 2024.

Action: For adoption

List of Questions adopted on 15.07.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in July 2024.

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

3.5.1. [Kizfizo - Temozolomide - Orphan - EMEA/H/C/006169](#)

Orphelia Pharma; treatment of neuroblastoma

Scope: Opinion, third party intervention

Action: For adoption

Participation of patient representative

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

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 14.12.2023.

An oral explanation was held on 25 February 2025. The presentation by the applicant focused on the clinical data in support of the application.

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

The question-and-answer document was circulated for information.

The CHMP noted the third-party intervention.

See 2.2

3.6. **Initial applications in the decision-making phase**

3.6.1. [LEQEMBI - Lecanemab - EMEA/H/C/005966](#)

Eisai GmbH; treatment of early Alzheimer's disease in apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes.

Scope: CHMP Response to the EC question

Action: For discussion

As part of its decision-making process, the European Commission has asked the CHMP to consider information on the safety of Leqembi that became available after the adoption of the CHMP opinion in November 2024 and whether this may require an update of the opinion. The EC also asked the CHMP to consider whether the wording of the risk minimisation measures in Annex II of the opinion is clear enough to ensure correct implementation.

The CHMP has now considered this request and concluded that its November opinion recommending the marketing authorisation of Leqembi does not need to be updated. EMA has provided a response to the European Commission which will now resume the decision-making process for Leqembi's marketing authorisation.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. CINAINU - Liquid ethanolic extract 30 per cent (W/W) of *Allium cepa* fresh bulb and *Citrus limon* fresh fruit / Dry aqueous extract of *paullinia cupana* seed / Dry hydroethanolic extract of *theobroma cacao* seed - EMEA/H/C/004155

Legacy Healthcare (France) S.A.S.; treatment of alopecia areata in children and adolescents

Scope: Withdrawal of marketing authorisation application

Action: For information

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

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 12.10.2023.

An oral explanation was held on 25 February 2025. The presentation by the applicant focused on the quality, non-clinical and clinical data in support of the application.

The CHMP noted the withdrawal of the marketing authorisation application.

See 2.2

3.7.2. Pegfilgrastim - PUMA - EMEA/H/C/006348

treatment of neutropenia in paediatric patients

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 12.12.2024, 17.10.2024. List of Questions adopted on 30.05.2024.

The CHMP noted the withdrawal of the marketing authorisation application.

3.7.3. Riloncept - Orphan - EMEA/H/C/006537

FGK Representative Service GmbH; treatment of idiopathic pericarditis

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Questions adopted on 30.01.2025.

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. Aqumeldi - Enalapril maleate - EMEA/H/C/005731/X/0001/G

Proveca Pharma Limited

Rapporteur: John Joseph Borg, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to add a new strength of 1 mg orodispersible tablet grouped with a type IB variation (C.I.z) to correct the SmPC to remove the recommended dose of epinephrine from Section 4.4. The RMP (version 1.1.) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

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. Lyrica - Pregabalin - EMEA/H/C/000546/X/0127

Upjohn EESV

Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 30.05.2024.

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. PREVMIS - Letermovir - Orphan - EMEA/H/C/004536/X/0037/G

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Terhi Lehtinen

Scope: "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 mg and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment in paediatric allogeneic haematopoietic stem cell transplant patients weighing at least 5 kg (concentrate for solution for infusion and granules in sachet) or 15 kg (film-coated tablets), and in paediatric kidney transplant patients weighing at least 40 kg (all pharmaceutical forms) based on the final results from studies MK-8228-030 and MK-8228-031.

Study MK-8228-030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety, and tolerability of letermovir when used for cytomegalovirus (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 MK-8228-031 was an open-label, single-dose, four-period, seven-treatment, crossover study designed to evaluate the bioavailability of 2 paediatric formulations of letermovir (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 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.0 of the RMP has also been approved. In addition, the MAH took the opportunity to introduce editorial updates throughout the Product Information and to update the list of local representatives in the Package Leaflet."

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

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 by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

See 2.3

4.1.4. Retsevmo - Selpercatinib - EMEA/H/C/005375/X/0031

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: "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."

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

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 CHMP adopted the similarity assessment report

4.1.5. Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/X/0140

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus

Scope: "Extension application to add a new strength of 25 µg, XBB.1.5, Dispersion for injection."

Action: For adoption

List of Questions adopted on 14.11.2024.

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.

4.1.6. Tremfya - Guselkumab - EMEA/H/C/004271/X/0043/G

Janssen-Cilag International N.V.

Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to add a new pharmaceutical form (concentrate for solution for infusion), a new strength (200 mg) and a new route of administration (intravenous use) and to add a new strength of 200 mg for solution for injection (in pre-filled syringe / pre-filled pen) for subcutaneous use in the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biologic treatment.

This application is grouped with a type II variation (C.I.6.a) to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biologic treatment. As a consequence, sections 4.1, 4.2, 4.5, 4.6, 4.8, 5.1, 5.2 and 5.3 of the SmPC of the existing form 100 mg solution for injection are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.4 of the RMP is adopted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to align the PI with QRD template version 10.4 and to introduce editorial changes to the PI."

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 19.09.2024.

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.

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. Adempas - Riociguat - EMEA/H/C/002737/X/0041

Bayer AG

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension (PAH) paediatric indication. As a consequence, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated."

Action: For adoption

List of Questions adopted on 17.10.2024.

The Committee discussed the issues identified in this application.

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. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance."

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 .

4.3.2. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0015

Mirum Pharmaceuticals International B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new pharmaceutical form (tablet) associated with new strengths 10 mg, 15mg, 20 mg and 30 mg.

The RMP (version 5.0) is updated in accordance."

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 .

4.3.3. Pyzchiva - Ustekinumab - EMEA/H/C/006183/X/0006

Samsung Bioepis NL B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new strength (45 mg solution for injection in a vial) for partial use in paediatric patients."

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 .

4.3.4. Spevigo - Spesolimab - EMEA/H/C/005874/X/0011

Boehringer Ingelheim International GmbH

Rapporteur: Kristina Dunder, PRAC Rapporteur: Zoubida Amimour

Scope: "Extension application to add a new strength of 300 mg (150 mg/ml) for solution for injection in a pre-filled syringe.

The RMP (version 3.0) is updated in accordance.

In addition, the applicant has updated SmPC (Annex I) and Package Leaflet (Annex IIIB) for both 450 mg concentrate for solution for infusion and 150 mg and 300 mg solution for injection in line with the new excipient guideline."

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 .

4.3.5. Talzenna - Talazoparib - EMEA/H/C/004674/X/0022

Pfizer Europe MA EEIG

Rapporteur: Filip Josephson

Scope: "Extension application to add new strengths of 0.35 mg and 0.5 mg hard capsules. Furthermore, the PI is being brought in line with the QRD template version 10.4."

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

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. Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0007

Pfizer Europe Ma EEIG

Rapporteur: Jayne Crowe, Co-Rapporteur: Daniela Philadelphia, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include active immunization of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Sub study A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥ 18 to < 60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. 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 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, 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 30.01.2025, 12.12.2024, 19.09.2024.

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. Calquence - Acalabrutinib - EMEA/H/C/005299/II/0026

AstraZeneca AB

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include CALQUENCE as monotherapy for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy based on final results from study ACE-LY-004 (D8225C00002); this is an open-label, phase 2 study of ACP-196 in subjects with Mantle Cell Lymphoma. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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 by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

See 2.3

5.1.3. Columvi - Glofitamab - Orphan - EMEA/H/C/005751/II/0005

Roche Registration GmbH

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova

Scope: "Extension of indication to include in combination with gemcitabine and oxaliplatin the treatment of adult patients with relapse or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are not candidates for autologous stem cell transplant (ASCT) for COLUMVI, based on results of primary and updated analyses from study GO41944 (STARGLO) listed as a Specific Obligation in the Annex II of the Product Information, as well supportive data from the Phase Ib study GO41943. Study GO41944 (STARGLO) is a Phase III, open-label, multicentre, randomized study of glofitamab in combination with GemOx (Glofit-GemOx) vs. rituximab in combination with GemOx (R-GemOx) in patients with R/R DLBCL. 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 Annex II and Package Leaflet are 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 PI and 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

Request for Supplementary Information adopted on 30.01.2025, 14.11.2024.

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

The Committee adopted a positive opinion by majority (28 out of 32 votes) together with the CHMP assessment report and translation timetable.

The divergent position (Jan Mueller-Berghaus, Thalia Marie Estrup Blicher, Janet Koenig, Peter Mol) was appended to the opinion.

The CHMP noted the letter of recommendations dated 27 February 2025.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

5.1.4. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0076

Janssen-Cilag International N.V.

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre

Scope: “Extension of indication for Darzalex in combination with bortezomib, lenalidomide and dexamethasone for the treatment of newly diagnosed multiple myeloma, to include also adult patients who are not eligible for stem cell transplant (SCT), based on the results of the final PFS analysis from Study CEPHEUS (54767414MMY3019), a randomised, open-label, active-controlled, multicentre phase 3 study in adult participants, comparing the clinical outcome of D-VRd with VRd in participants with untreated multiple myeloma for whom stem cell transplant is not planned as initial therapy, in terms of the primary endpoint of MRD negativity rate in participants with CR or better rate and major secondary endpoints of CR or better rate, PFS and sustained MRD negativity.

As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated and the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the contact details of the local representatives in the Package Leaflet. An updated RMP version 11.1 has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

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

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

The CHMP noted the letter of recommendation dated 18 February 2025.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

5.1.5. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0077

Janssen-Cilag International N.V.

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Antonio Gomez-Outes, PRAC
Rapporteur: Carla Torre

Scope: "Extension of indication to include daratumumab for the treatment of adult patients with smouldering multiple myeloma (SMM) at high risk of developing multiple myeloma based on results from studies 54767414SMM3001 (AQUILA) and 54767414SMM2001 (CENTAURUS). SMM3001 (AQUILA) is a Phase 3 Randomized, Multicentre Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-risk Smouldering Multiple Myeloma. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smouldering Multiple Myeloma. 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 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in accordance with the latest EMA excipients guideline."

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. Enhertu - Trastuzumab deruxtecan - EMEA/H/C/005124/II/0048

Daiichi Sankyo Europe GmbH

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment for ENHERTU, based on results from study D9670C00001 (DESTINY-Breast06); this is a phase 3, randomized, multicentre, open-label study of trastuzumab deruxtecan (DS-8201a) compared with investigator's choice chemotherapy in, hormone receptor-positive, HER2-low and HER2-ultralow BC patients whose disease has progressed on endocrine therapy in the metastatic setting. 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 8.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI, and to update the PI according to the Excipients Guideline. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

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.

5.1.7. **FABHALTA - Iptacopan - Orphan - EMEA/H/C/005764/II/0001**

Novartis Europharm Limited

Rapporteur: Janet Koenig, PRAC Rapporteur: Lina Seibokiene

Scope: "Extension of indication to include, in combination with a renin-angiotensin system (RAS) inhibitor, the treatment of adult patients with complement 3 glomerulopathy (C3G) for FABHALTA, based on interim analysis results from study CLNP023B12301 (APPEAR-C3G) and supported by additional evidence of efficacy and safety data from Phase II study CLNP023X2202 (X2202) and Phase IIIb study CLNP023B12001B (C3G-REP). APPEAR-C3G is a Phase 3, multicentre, randomized, double-blind, parallel arm, placebo-controlled study to evaluate the efficacy and safety of iptacopan in patients with C3G. The study included a 6-month blinded, placebo-controlled period, followed by a 6-month period in which all patients receive open-label iptacopan (total study duration of 12 months). As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8 and 5.1 of the SmPC are being updated. The Annex II and Package Leaflet are 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 PI."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024

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.

5.1.8. **Imfinzi - Durvalumab - EMEA/H/C/004771/II/0064**

AstraZeneca AB

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include IMFINZI in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, for the treatment of adults with resectable (tumours \geq 4 cm and/or node positive) NSCLC and no known EGFR mutations or ALK rearrangements for IMFINZI, based on the interim results from study D9106C00001 (AEGEAN); this is a Phase III, double-blind, placebo-controlled, multi-centre international study of neoadjuvant/adjuvant durvalumab for the treatment of patients with resectable stages II and III non-small cell lung 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 11 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024, 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.

5.1.9. IXCHIQ - Chikungunya virus, strain delta5nsP3, live attenuated - EMEA/H/C/005797/II/0001

Valneva Austria GmbH

Rapporteur: Christophe Focke, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in adolescents 12 years and older for IXCHIQ, based on interim 6 months results from study VLA1553-321; this is a randomized, double-blinded, multicentre study to evaluate the immunogenicity and safety of the adult dose of VLA1553 6 months following vaccination in adolescents from 12 years to less than 18 years of age after a single immunization. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Annex II is updated accordingly. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. The RMP version 2.1 has been agreed."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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.

5.1.10. Jaypirca - Pirtobrutinib - EMEA/H/C/005863/II/0002

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

Scope: " 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, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted."

Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)"

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 27.06.2024.

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.

The CHMP adopted the similarity assessment report.

5.1.11. [LUTATHERA - Lutetium \(177Lu\) oxodotreotide - Orphan - EMEA/H/C/004123/II/0052](#)

Advanced Accelerator Applications

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (G2 and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) adult patients for LUTATHERA, based on primary analysis results from study CAAA601A22301 (NETTER-2); NETTER-2 study is a Phase III, multicentre, stratified, open-label, randomized, comparator-controlled study comparing treatment with Lutathera plus octreotide LAR 30 mg (Lutathera arm) to treatment with high-dose octreotide LAR 60 mg (control arm). The main purpose of the NETTER-2 study was to determine if treatment in the Lutathera arm prolongs PFS in subjects with newly diagnosed SSTR-positive, G2 and G3 advanced GEP-NET when compared with treatment in the control arm. 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes in the SmPC. 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)

Request by the applicant for an extension to the clock-stop to respond to the request for supplementary information to be adopted in February 2025.

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

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

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

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

The CHMP agreed to the request by the applicant for an extension to the clock-stop to respond to the request for supplementary information adopted in February 2025.

5.1.12. Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0038

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicentre, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

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. RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0056

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: "Extension of indication to include the treatment of giant cell arteritis (GCA) in adult patients for RINVOQ based on final results from study M16-852. This is a phase 3, global, multicenter, randomised, double-blind, placebo-controlled study evaluating the efficacy and safety of upadacitinib in subjects with GCA. 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 16.0 of the RMP is agreed. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP)."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024

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.

5.1.14. Saxenda - Liraglutide - EMEA/H/C/003780/II/0042

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include the use of SAXENDA for weight management in children from the age of 6 years to less than 12 years based on results from study NN8022-4392; this is a 56-week, double-blind, randomised, placebo-controlled study investigating

safety and efficacy of liraglutide on weight management in children with obesity aged 6 to <12 years. 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 34.0 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

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.

5.1.15. [Stelara - Ustekinumab - EMEA/H/C/000958/II/0108](#)

Janssen-Cilag International N.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: “Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies for STELARA, based on final results from study CNTO1275CRD3004. This is a Phase 3 Study of the Efficacy, Safety, and Pharmacokinetics of Ustekinumab as Open label Intravenous Induction Treatment Followed by Randomized Double blind Subcutaneous Ustekinumab Maintenance in Paediatric Participants with Moderately to Severely Active Crohn's Disease. 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 29.1 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024.

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. [Supemtek Tetra - Quadrivalent influenza vaccine \(recombinant, prepared in cell culture\) - EMEA/H/C/005159/II/0021/G](#)

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Zoubida Amimour

Scope: “Grouped application comprising two type II variations as follows:
C.I.6.a – Extension of indication to include the active immunisation of children 9 years of age and older for Supemtek Tetra, based on final results from study VAP00027; this is a Phase III, non-randomised, open-label, uncontrolled study to demonstrate the non-inferior HAI immune response of Supemtek Tetra in participants aged 9 to 17 years compared to participants aged 18 to 49 years; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP

has also been approved.

C.I.4 - Update of sections 4.2 and 5.1 of the SmPC in order to update paediatric information of children between 3 to 8 years of age based on final results from study VAP00026; this is a Phase III, randomised, modified double-blind, active-controlled 2-arm to demonstrate the non-inferior HAI immune response of Supemtek Tetra compared to an authorised inactivated tetravalent influenza vaccine.

The MAH also took the opportunity to include editorial updates in the SmPC and Annex II. The group of variations leads to amendments to the Summary of Product Characteristics, Annex II and Package Leaflet and to the Risk Management Plan (RMP)."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

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. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0017

Beigene Ireland Limited

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

Scope: "Extension of indication to include, in combination with gemcitabine and cisplatin, the first-line treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) for TEVIMBRA based on final results from study BGB-A317-309 (study 309). Study 309 was a Phase 3 randomised, double-blind, placebo-controlled, Asia-only study that compared the efficacy and safety of tislelizumab combined with gemcitabine plus cisplatin (GC) versus placebo combined with GC as 1L treatment for recurrent or metastatic NPC. 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 2.6 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI as well as to update the PI in line with the Excipients Guideline."

Action: For adoption

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

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

5.1.18. Uplizna - Inebilizumab - EMEA/H/C/005818/II/0012

Horizon Therapeutics Ireland DAC

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult

subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it in line with the latest QRD template version 10.4. 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.

5.1.19. [Xofluza - Baloxavir marboxil - EMEA/H/C/004974/II/0021](#)

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Sonja Hrabcik

Scope: "Extension of indication to include treatment of patients aged 3 weeks and above for Xofluza, based on final results from study CP40559 (MiniSTONE-1); this was a global Phase 3, multicentre, single-arm, open-label study to assess the safety, PK, and efficacy of baloxavir marboxil in OWH paediatric patients from birth to < 1 year with influenza-like symptoms. 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 Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

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.

5.1.20. [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.”, Third-party intervention

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 30.05.2024, 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.

The CHMP noted the third-party intervention.

The CHMP endorsed the EMA press release.

The CHMP adopted the similarity assessment report.

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. Amyvid - Florbetapir (18F) - EMEA/H/C/002422/II/0046

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: Request by the applicant for an extension to the clock-stop to respond to the request for supplementary information adopted in April 2024.

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the request for supplementary information adopted in April 2024.

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

5.3.1. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0154

Merck Sharp & Dohme B.V.

Scope: "Extension of indication to include in combination with pemetrexed and platinum chemotherapy the first-line treatment of adults with unresectable non-epithelioid malignant pleural mesothelioma for Keytruda, based on final results from study KEYNOTE-483; this is a multicentre, open-label, Phase 2/3 randomized study to evaluate the efficacy and safety of pembrolizumab in combination with pemetrexed/platinum chemotherapy in participants with unresectable advanced or metastatic malignant pleural mesothelioma (MPM). As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is

updated in accordance. Version 45.0 of the RMP has also been submitted.”

Action: For adoption

Opinion adopted on 14.11.2024.

An oral explanation was held on 26 February 2025. The presentation by the MAH focused on the clinical data in support of the application.

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.

See 2.2

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human albumin solution - EMEA/H/D/006540

Ex vivo heart perfusion

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006648

use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) tissue, using EnVision FLEX visualization system on Dako Omnis

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006668

to detect EGFR mutations in FFPE tissue from adult patients diagnosed with non-small cell lung cancer (NSCLC)

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.

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006656

assay to assess the mismatch repair (MMR) proteins (MLH1, PMS2, MSH2, and MSH6) in formalin-fixed, paraffin-embedded (FFPE) colorectal cancer (CRC) tissue using EnVision FLEX visualization system on Dako Omnis automated staining instrument

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.

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Diazoxide choline – H0006576

Treatment of patients ≥ 4 years of age with Prader-Willi syndrome who have hyperphagia

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. Brensocatib - H0005820

Treatment of non-cystic fibrosis bronchiectasis in patients 12 years of age and older with two or more exacerbations in the prior 12 months.

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

Action: For adoption

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

8.1.3. apitegromab - H0005909

Treatment of 5q spinal muscular atrophy (SMA)

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. BIMERVAX - SARS-CoV-2, variant JN.1, spike protein, receptor binding domain fusion homodimer - EMEA/H/C/006058/II/0016

Hipra Human Health S.L.

Rapporteur: Daniela Philadelphia

Scope: Withdrawal of type II variation application

Action: For information

Request for Supplementary Information adopted on 14.11.2024, 19.09.2024, 25.07.2024.

The CHMP noted the withdrawal of type II variation application.

9.1.2. FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan

Vifor France

Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicentre, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024.

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 CHMP noted the letter of recommendations dated 13 February 2025.

9.1.3. Fluenz - Influenza vaccine (live, nasal) - EMEA/H/C/006514/II/0002

AstraZeneca AB

Rapporteur: Christophe Focke

Scope: "Update of sections 4.2 and 4.4 of the SmPC to restrict the 2-dose schedule to

children from 2 to 8 years of age who have not been vaccinated before, instead of children from 2 to 17 years of age who have not been vaccinated before, and to include a warning regarding the postponement of vaccinations in individuals with symptoms of an acute infection and in case of nasal blockage.

In addition, the MAH took the opportunity to implement changes in sections 1, 2, 3, 4.1, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 6.1, 6.3, 6.5, 6.6 and 8 of the SmPC. The labelling and Package Leaflet are updated accordingly.”

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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.

9.1.4. Cablivi - Caplacizumab - EMEA/H/C/004426/II/0048, Orphan

Ablynx NV

Rapporteur: Filip Josephson

Scope: Withdrawal of type II variation application

Action: For information

Request for Supplementary Information adopted on 17.10.2024, 25.07.2024, 14.03.2024.

The CHMP noted the withdrawal of type II variation application.

9.1.5. Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044

AstraZeneca AB

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

Scope: “Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3.”

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 21.03.2024.

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.

9.1.6. [Champix - Varenicline - EMEA/H/C/000699/II/0085/G](#)

Pfizer Europe MA EEIG

Rapporteur: Thalia Marie Estrup Blicher

Scope: Quality changes

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

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.

9.1.7. [Pemazyre - Pemigatinib – Orphan - EMEA/H/C/005266/R/0019](#)

Incyte Biosciences Distribution B.V.

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

Scope: Renewal of conditional marketing authorisation

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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.

9.1.8. [Ontilyv – Opicapone – EMEA/H/C/005782](#)

Bial Portela & Companhia

Rapporteur: Janet Koenig, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: Expiry of marketing authorisation due to Sunset Clause

Action: For information

The CHMP noted the expiry of marketing authorisation.

9.1.9. [Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028](#)

Infai GmbH

Scope: Request for re-examination, appointment of re-examination rapporteur

Action: For adoption

Opinion adopted on 30.01.2024 Request for Supplementary Information adopted on

17.10.2024, 30.05.2024.

The CHMP noted the request for re-examination and appointed a re-examination rapporteur.

9.1.10. Dupixent - Dupilumab - EMEA/H/C/004390/II/0083

Sanofi Winthrop Industrie

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

Scope: Withdrawal of type II variation application

Action: For information

Request for Supplementary Information adopted on 30.01.2025, 19.09.2024, 30.05.2024.

The CHMP noted the withdrawal of type II variation application.

9.1.11. Emblaveo - Avibactam sodium, Aztreonam – OPEN – H0006113

Pfizer Europe MA EEIG

Rapporteur: Filip Josephson, Co-Rapporteur: Jayne Crowe

Scope: DHPC and communication plan

Action: For adoption

The CHMP adopted the DHPC and communication plan.

10. Referral procedures

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

No items

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

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 outstanding issues adopted on 17.10.2024, 25.04.2024.

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

CHMP list of outstanding issues: 27.02.2025

Submission of responses: 03.04.2025

Re-start of the procedure: 26.04.2025

Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 30.04.2025

Ad-hoc expert group meeting (AHEG): Date to be confirmed

Comments: 08.05.2025

Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 14.05.2025

CHMP LoOI or opinion: May, 2025 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

February 2025 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

Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

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 February 2025

Action: For adoption

The CHMP adopted the EURD list for February 2025.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at February 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 25-28 February 2025

Action: For information

The CHMP noted the information.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 11-12 February 2025.

Action: For adoption

The CHMP adopted the Table of Decisions.

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 10-13 February 2025. 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 table of conclusions.

14.3.4. Election of new Scientific Advice Working Party (SAWP) Chair

Election of new SAWP chair. The first mandate of Scientific Advice Working Party Chair Paolo Foggi will expire on 13 March 2025.

Action: For election

Nomination(s) received

The CHMP re-elected Paolo Foggi as SAWP Chair. The mandate starting date is 14 March 2025.

14.3.5. Scientific Advice Group (SAG) mandate renewal and (re)nominations

Update of the renewal of SAG mandate/call for nomination of experts for the 4 therapeutic SAGs (Neurology, Vaccines, Infectious Diseases and Cardiovascular Issues).

Action: For adoption

The CHMP discussed the SAG mandate renewals and (re)nominations.

The CHMP was presented with the Draft List of candidates for the SAGs (SAG Cardiovascular and SAG Neurology) membership nominations.

The CHMP adopted the SAG Neurology and Cardiovascular Issues memberships.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

The CHMP noted the information.

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Analysis of requests for clock-stop extensions by GIREX.

Action: For discussion

The CHMP noted the information.

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 24-27 February 2025 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
Bruno Sepodes	Chair	Portugal	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Member	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	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	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	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Aris Angelis	Member	Greece	No participation in discussion, final deliberations and voting on:	4.3.5. EMA/H/C/004674/X/0022; 5.1.1. EMA/H/C/006027/II/0007; 9.1.6. EMA/H/C/000699/II/0085/G; 2.2.2. EMA/H/C/003820/II/0154; 2.3.2. EMA/H/C/004536/X/0037/G;

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				4.1.3. EMA/H/C/004536/X/0037/G; 9.1.3. EMA/H/C/006514/II/0002; 9.1.5. EMA/H/C/004108/II/0044; 2.3.1. EMA/H/C/005299/II/0026; 5.1.8. EMA/H/C/004771/II/0064; 3.3.4. EMA/H/C/006298; 4.2.1. EMA/H/C/002737/X/0041
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hjalte 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 Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	5.1.16. EMA/H/C/005159/II/0021/G; 3.3.7. EMA/H/C/006425
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	
Grzegorz Cessak	Alternate	Poland	No interests declared	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Paulo Paixão	Alternate	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	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	
Jana Schweigertová	Expert	Slovakia	No interests declared	
Sofia Bosdotter Enroth	Expert	Sweden	No interests declared	
Jeanette McCallion	Expert	Ireland	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No interests declared	
Nicolas Lee	Expert	Ireland	No restrictions applicable to this meeting	
Olive Smyth	Expert	Ireland	No restrictions applicable to this meeting	
Sarah Gilgunn	Expert	Ireland	No interests declared	
Rosemary Maher	Expert	Ireland	No interests declared	
Joseph De Courcey	Expert	Ireland	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Ludivine Martin	Expert	France	No interests declared	
Benedicte Hay	Expert	France	No interests declared	
Christophe Versini	Expert	France	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Cecile Dop	Expert	France	No interests declared	
Stephanie Hueber	Expert	France	No interests declared	
Justina Creppy	Expert	France	No interests declared	
Mona Kassem-Youssef	Expert	France	No interests declared	
Teresa Llacer Delicado	Expert	Spain	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Sara Tognarelli	Expert	Germany	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
Julia Katharina Maier	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Quynh Lan Nguyen	Expert	Germany	No interests declared	
Georgios Aislaitner	Expert	Germany	No interests declared	
Christine Greiner	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Christian Baarlink	Expert	Germany	No interests declared	
Ana Paula Martins	Expert	Portugal	No interests declared	
Mário Miguel Coelho da Silva Rosa	Expert	Portugal	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
Erich Schneider	Expert	Germany	No interests declared	
Anne Isabel Roth	Expert	Germany	No interests declared	
Jörg Zinserling	Expert	Germany	No interests declared	
Sofia Kapanadze	Expert	Germany	No interests declared	
Ulrike Hermes	Expert	Germany	No interests declared	
Gabriella Passacuale	Expert	Italy	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Pinar Kartal	Expert	Netherlands	No interests declared	
Elizabeth van Vlijmen	Expert	Netherlands	No interests declared	
Carlijn Litjens	Expert	Netherlands	No interests declared	
Lieke Sandberg-Smits	Expert	Netherlands	No interests declared	
Sabine van der Putten - de Brouwer	Expert	Netherlands	No restrictions applicable to this meeting	
Peter van de Ven	Expert	Netherlands	No interests declared	
Therese Klamer	Expert	Netherlands	No interests declared	
Inge Zomerdijs	Expert	Netherlands	No interests declared	
Brigitte Duijndam	Expert	Netherlands	No interests declared	
Hinke Johanna van der Woude	Expert	Netherlands	No interests declared	
Anne Torrez Flores-Lexmond	Expert	Netherlands	No interests declared	
Walter Johannes Beiersdorf	Expert	Austria	No restrictions applicable to this meeting	
Tobias Glüxam	Expert	Austria	No interests declared	
Florian Koban	Expert	Austria	No interests declared	
Angelika Geroldinger	Expert	Austria	No interests declared	
Yseult Brun	Expert	France	No interests declared	
Kristian Wennmalm	Expert	Sweden	No interests declared	
Ulla Wändel Liminga	Expert	Sweden	No interests declared	
Eva Jirsová	Expert	Czech Republic	No interests declared	
Michaela Skořepová	Expert	Czech Republic	No interests declared	
Jana Kopecká	Expert	Czech Republic	No interests declared	
Andreas Bonertz	Expert	Germany	No interests declared	
Pierre Demolis	Expert	Iceland	No interests declared	
Kristyna Pruchova	Expert	Czech Republic	No interests declared	

A representative from the European Commission attended the meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
------	------	-----------------------------	---	---

Meeting run with the help of EMA staff.

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

Explanatory notes

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

Oral explanations (section 2)

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

Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section 5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

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

Pharmacovigilance issues (section 11)

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

Inspections Issues (section 12)

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

Innovation task force (section 13)

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

Scientific advice working party (SAWP) (section 14.3.1)

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

Satellite groups / other committees (section 14.2)

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

Invented name issues (section 14.3)

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

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/CHMP/73424/2025

Annex to 24-27 February 2025 CHMP Minutes

Pre-submission and post-authorisations issues

Note: Starting with January 2025, EMA is publishing in Excel format the CHMP agenda annex with the regulatory procedures handled in IRIS. This is a secure online platform for managing product-related scientific and regulatory procedures with EMA. This change follows the transition of the post-authorisation regulatory procedures to IRIS. It is also in the context of the digitalisation of EMA's activities and will help facilitate data analysis.

A. PRE-SUBMISSION ISSUES	3
A.1. ELIGIBILITY REQUESTS.....	3
A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications	3
B. POST-AUTHORISATION PROCEDURES OUTCOMES	3
B.1. Annual re-assessment outcomes	3
B.1.1. Annual reassessment for products authorised under exceptional circumstances	3
B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES.....	4
B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal	4
B.2.2. Renewals of Marketing Authorisations for unlimited validity.....	4
B.2.3. Renewals of Conditional Marketing Authorisations.....	5
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES.....	6
B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES	7
B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects	8
B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects.....	14
B.5.3. CHMP-PRAC assessed procedures	24
B.5.4. PRAC assessed procedures.....	31
B.5.5. CHMP-CAT assessed procedures	36
B.5.6. CHMP-PRAC-CAT assessed procedures	38
B.5.7. PRAC assessed ATMP procedures	39
B.5.8. Unclassified procedures and worksharing procedures of type I variations.....	39
B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION	40

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)	40
E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES	40
E.1. PMF Certification Dossiers:.....	40
E.2. Time Tables – starting & ongoing procedures: For information	40
F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver	41
G. ANNEX G.....	41
G.1. Final Scientific Advice (Reports and Scientific Advice letters):	41
G.2. PRIME.....	41

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for February 2025: For adoption	Adopted
---	---------

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

Final Outcome of Rapporteurship allocation for February 2025: For adoption	Adopted
---	---------

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

NULIBRY - Fosdenopterin - EMEA/H/C/005378/S/0012, Orphan TMC Pharma (EU) Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Martin Huber	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Orphacol - Cholic acid - EMEA/H/C/001250/S/0056 Theravia, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Maria Poulianiti	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Raxone - Idebenone - EMEA/H/C/003834/S/0041, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/S/0025, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Joseph DeCoursey, Co-Rapporteur: Maria Luttgen, CHMP Coordinator: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 06.12.2024.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Vedrop - Tocofersolan - EMEA/H/C/000920/S/0050 Recordati Rare Diseases, Rapporteur: Beata	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.

Maria Jakline Ullrich, PRAC Rapporteur: Melinda Palfi	The Marketing Authorisation remains under exceptional circumstances.
---	--

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Apixaban Accord - Apixaban - EMEA/H/C/005358/R/0012 Accord Healthcare S.L.U., Generic of Eliquis, Rapporteur: Alar Irs, PRAC Rapporteur: Bianca Mulder	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.
Aybintio - Bevacizumab - EMEA/H/C/005106/R/0022 Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Karin Erneholm Request for Supplementary Information adopted on 27.02.2025.	Request for supplementary information adopted with a specific timetable.
Insulin aspart Sanofi - Insulin aspart - EMEA/H/C/005033/R/0020 Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Mari Thorn Request for Supplementary Information adopted on 30.01.2025.	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.
LIVOGIVA - Teriparatide - EMEA/H/C/005087/R/0015 Theramex Ireland Limited, Rapporteur: Christian Gartner, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Tiphaine Vaillant Request for Supplementary Information adopted on 30.01.2025.	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.
Omidria - Phenylephrine / Ketorolac - EMEA/H/C/003702/R/0030 Rayner Surgical (Ireland) Limited, Rapporteur: Jayne Crowe, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 27.02.2025.	Request for supplementary information adopted with a specific timetable.

B.2.3. Renewals of Conditional Marketing Authorisations

Koselugo - Selumetinib - EMA/H/C/005244/R/0019, Orphan AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>
Lorviqua - Lorlatinib - EMA/H/C/004646/R/0040 Pfizer Europe MA EEIG, Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Barbara Kovacic Bytyqi Request for Supplementary Information adopted on 30.01.2025.	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>Based on the review of the available information, the CHMP was of the opinion that the risk-benefit balance remains favourable and that all specific obligations have been fulfilled, therefore the CHMP recommended granting of a Marketing Authorisation not subject to specific obligations.</p>
Lunsumio - Mosunetuzumab - EMA/H/C/005680/R/0014, Orphan Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>
Pemazyre - Pemigatinib - EMA/H/C/005266/R/0019, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 27.02.2025, 12.12.2024.	<p>Request for supplementary adopted with a specific timetable.</p> <p>See 9.1</p>
WAYLIVRA - Volanesorsen - EMA/H/C/004538/R/0029, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 30.01.2025.	<p>Positive Opinion adopted by consensus together with the CHMP assessment report.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 10-13 February 2025
PRAC:

Signal of colitis

The CHMP adopted the PRAC recommendation.

mogamulizumab – POTELIGEO (CAP)

Rapporteur: Peter Mol, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Marie Louise Schougaard Christiansen

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 February 2025 meeting:

EMA/H/C/PSUSA/00009315/202406

(tobramycin (inhalation powder, capsules))
CAPS:

TOBI Podhaler (EMA/H/C/002155)

(Tobramycin), Viatrix Healthcare Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan, "01/07/2021 To: 30/06/2024"

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 amend a warning/precaution regarding nephrotoxicity and to add the adverse reaction acute kidney injury (AKI) with a frequency 'not known'. The Package leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial amendments throughout the product information.

EMA/H/C/PSUSA/00010379/202407

(nivolumab)

CAPS:

OPDIVO (EMA/H/C/003985) (Nivolumab), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele Maurer "04/07/2021 To: 03/07/2024"

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 patients with pre-existing autoimmune disease. Update of section 4.8 of the SmPC to add the adverse reaction Optic neuritis for nivolumab monotherapy, for

	nivolumab in combination with ipilimumab (with or without chemotherapy), and for nivolumab in combination with chemotherapy. The Package leaflet is updated accordingly.
EMA/H/C/PSUSA/00010438/202407 (sacubitril / valsartan) CAPS: Entresto (EMA/H/C/004062) (Sacubitril / Valsartan), Novartis Europharm Limited, Rapporteur: Patrick Vrijlandt Neparvis (EMA/H/C/004343) (Sacubitril / Valsartan), Novartis Europharm Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Karin Erneholm, "01/08/2023 To: 31/07/2024"	<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 4.6 of the SmPC to amend the wording regarding breastfeeding. No update of the package leaflet is considered warranted as the current information is considered sufficient.</p>
EMA/H/C/PSUSA/00010516/202406 (opicapone) CAPS: Ongentys (EMA/H/C/002790) (Opicapone), Bial - Portela & Ca, S.A., Rapporteur: Janet Koenig Ontilyv (EMA/H/C/005782) (Opicapone), Bial Portela & Companhia S.A., Rapporteur: Janet Koenig, PRAC Rapporteur: Maria del Pilar Rayon, "23/06/2021 To: 23/06/2024"	<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 SmPC section 4.8 to add the ADR of confusional state under the SOC Psychiatric disorders with a frequency uncommon. The package leaflet (section 4) is also updated accordingly.</p>
EMA/H/C/PSUSA/00010634/202407 (cladribine (multiple sclerosis)) CAPS: Mavenclad (EMA/H/C/004230) (Cladribine), Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Carla Torre, "07/07/2023 To: 07/07/2024"	<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 4.6 of the SmPC to amend the wording regarding breast-feeding. No update of the Package leaflet is considered warranted as the current information is considered sufficient.</p>

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 - EMA/H/C/005255/II/0023 LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 27.02.2025.	Positive Opinion adopted by consensus on 27.02.2025.
Advate - Octocog alfa - EMA/H/C/000520/II/0124 Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Aptivus - Tipranavir - EMA/H/C/000631/II/0096/G Boehringer Ingelheim International GmbH, Rapporteur: Jean-Michel Race Opinion adopted on 27.02.2025. Request for Supplementary Information adopted on 19.12.2024.	Positive Opinion adopted by consensus on 27.02.2025.
Briumvi - Ublituximab - EMA/H/C/005914/II/0023/G Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 20.02.2025.	Request for supplementary information adopted with a specific timetable.
Ceprothin - Human protein C - EMA/H/C/000334/II/0143/G Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 20.02.2025.	Request for supplementary information adopted with a specific timetable.
CEVENFACTA - Eptacog beta (activated) - EMA/H/C/005655/II/0012 Laboratoire Francais du Fractionnement et des Biotechnologies, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
Champix - Varenicline - EMA/H/C/000699/II/0085/G Pfizer Europe MA EEIG, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 27.02.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 27.02.2025. See 9.1
CooperSurgical Inc ART Media - Human albumin solution -	Request for supplementary information adopted with a specific timetable.

EMEA/H/D/002307/II/0012 Coopersurgical Inc., Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 20.02.2025.	
Cosentyx - Secukinumab - EMEA/H/C/003729/II/0124 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
ELAHERE - Mirvetuximab soravtansine - EMEA/H/C/005036/II/0001/G, Orphan AbbVie Deutschland GmbH & Co. KG, Rapporteur: Johanna Lähtenvuo Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
Entyvio - Vedolizumab - EMEA/H/C/002782/II/0088/G Takeda Pharma A/S, Rapporteur: Paolo Gasparini Opinion adopted on 20.02.2025.	Positive Opinion adopted by consensus on 20.02.2025.
EVRA - Ethinylestradiol / Norelgestromin - EMEA/H/C/000410/II/0054 Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Fintepla - Fenfluramine - EMEA/H/C/003933/II/0029/G, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
Fluad - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006538/II/0001/G Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 20.02.2025.	Positive Opinion adopted by consensus on 20.02.2025.
GIVLAARI - Givosiran - EMEA/H/C/004775/II/0022, Orphan Alnylam Netherlands B.V., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0177/G Merck Europe B.V., Rapporteur: Patrick Vrijlandt	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 20.02.2025.	
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0163 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0164 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
Lamzede - Velmanase alfa - EMEA/H/C/003922/II/0040/G, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt Request for supplementary information adopted on 13.02.2025	Request for supplementary information adopted with a specific timetable.
LifeGlobal Media - Human albumin solution - EMEA/H/D/004287/II/0009 Coopersurgical Inc., Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 20.02.2025.	Request for supplementary information adopted with a specific timetable.
LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0013/G Theramex Ireland Limited, Rapporteur: Christian Gartner Opinion adopted on 27.02.2025. Request for Supplementary Information adopted on 31.10.2024.	Positive Opinion adopted by consensus on 27.02.2025.
OmvoH - Mirikizumab - EMEA/H/C/005122/II/0010/G Eli Lilly Nederland B.V., Rapporteur: Finbarr Leacy Opinion adopted on 27.02.2025. Request for Supplementary Information adopted on 23.01.2025.	Positive Opinion adopted by consensus on 27.02.2025.
Origio - Human albumin solution - EMEA/H/D/000830/II/0021 Coopersurgical Inc., Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 20.02.2025.	Request for supplementary information adopted with a specific timetable.
Ozempic - Semaglutide - EMEA/H/C/004174/II/0051	Request for supplementary information adopted with a specific timetable.

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted
on 13.02.2025.

Praluent - Alirocumab - EMA/H/C/003882/II/0098/G Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
--	---

Privigen - Human normal immunoglobulin - EMA/H/C/000831/II/0213 CSL Behring GmbH, Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
---	---

Privigen - Human normal immunoglobulin - EMA/H/C/000831/II/0214 CSL Behring GmbH, Rapporteur: Jan Mueller- Berghaus Opinion adopted on 20.02.2025.	Positive Opinion adopted by consensus on 20.02.2025.
--	---

Refixia - Nonacog beta pegol - EMA/H/C/004178/II/0040/G Novo Nordisk A/S, Rapporteur: Daniela Philadelphly Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
---	---

Roclanda - Latanoprost / Netarsudil - EMA/H/C/005107/II/0031/G Santen Oy, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
--	---

Semglee - Insulin glargine - EMA/H/C/004280/II/0053 Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig Opinion adopted on 20.02.2025.	Positive Opinion adopted by consensus on 20.02.2025.
--	---

Simulect - Basiliximab - EMA/H/C/000207/II/0123/G Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
---	---

Skyclarys - Omaveloxolone - EMA/H/C/006084/II/0016, Orphan Biogen Netherlands B.V., Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
--	---

Sondelbay - Teriparatide - EMA/H/C/005827/II/0008	Request for supplementary information adopted with a specific timetable.
--	---

Accord Healthcare S.L.U., Rapporteur: Finbarr Leacy
Request for Supplementary Information adopted on 13.02.2025.

Strensiq - Asfotase alfa - EMA/H/C/003794/II/0073/G, Orphan Alexion Europe SAS, Rapporteur: Paolo Gasparini Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
---	--

TAKHZYRO - Lanadelumab - EMA/H/C/004806/II/0043/G, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
--	--

Tyenne - Tocilizumab - EMA/H/C/005781/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
--	--

Ultomiris - Ravulizumab - EMA/H/C/004954/II/0048 Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
--	--

Uzpruvo - Ustekinumab - EMA/H/C/006101/II/0002/G STADA Arzneimittel AG, Rapporteur: Christian Gartner Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 19.12.2024, 11.07.2024.	Positive Opinion adopted by consensus on 13.02.2025.
---	--

Vyloy - Zolbetuximab - EMA/H/C/005868/II/0006/G, Orphan Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
---	--

Wegovy - Semaglutide - EMA/H/C/005422/II/0027 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
---	--

WS2622 HyQvia-EMA/H/C/002491/WS2622/0103 Kiovig-EMA/H/C/000628/WS2622/0130 Takeda Manufacturing Austria AG, Lead	Positive Opinion adopted by consensus on 13.02.2025.
--	--

Rapporteur: Jan Mueller-Berghaus
Opinion adopted on 13.02.2025.

WS2727 Esperoct- EMA/H/C/004883/WS2727/0025 NovoEight- EMA/H/C/002719/WS2727/0044 NovoSeven- EMA/H/C/000074/WS2727/0125 NovoThirteen- EMA/H/C/002284/WS2727/0032 Refixia-EMA/H/C/004178/WS2727/0038 Novo Nordisk A/S, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 27.02.2025. Request for Supplementary Information adopted on 19.12.2024, 05.09.2024.	Positive Opinion adopted by consensus on 27.02.2025.
---	---

WS2770/G Filgrastim Hexal- EMA/H/C/000918/WS2770/0079/G Zarzio- EMA/H/C/000917/WS2770/0080/G Sandoz GmbH, Lead Rapporteur: Peter Mol Request for Supplementary Information adopted on 13.02.2025, 19.12.2024.	Request for supplementary information adopted with a specific timetable.
---	---

WS2789 Ervebo-EMA/H/C/004554/WS2789/0039 Gardasil- EMA/H/C/000703/WS2789/0109 Gardasil 9- EMA/H/C/003852/WS2789/0078 HBVAXPRO- EMA/H/C/000373/WS2789/0082 M-M-RvaxPro- EMA/H/C/000604/WS2789/0130 ProQuad- EMA/H/C/000622/WS2789/0171 Vaxneuvance- EMA/H/C/005477/WS2789/0028 Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
---	---

WS2804/G Aerius- EMA/H/C/000313/WS2804/0108/G Azomyr- EMA/H/C/000310/WS2804/0112/G Neoclarityn-	Positive Opinion adopted by consensus on 13.02.2025.
--	---

EMA/H/C/000314/WS2804/0106/G

Organon N.V., Duplicate of Allex (SRD),
Azomyr, Opulis (SRD), Lead Rapporteur:
Christophe Focke
Opinion adopted on 13.02.2025.

WS2805/G**Celldemic-****EMA/H/C/006052/WS2805/0003/G****Incellipan-****EMA/H/C/006051/WS2805/0003/G**

Seqirus Netherlands B.V., Lead Rapporteur:
Daniela Philadelphia
Request for Supplementary Information adopted
on 20.02.2025.

Request for supplementary information adopted
with a specific timetable.

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

**Abrysvo - Respiratory syncytial virus
vaccine (bivalent, recombinant) -****EMA/H/C/006027/II/0012**

Pfizer Europe Ma EEIG, Rapporteur: Jayne
Crowe, "Update of section 5.1 of the SmPC in
order to update information based on end-of-
season 2 data from clinical study C3671013.
This is an ongoing Phase 3, randomized, double-
blind, placebo controlled to evaluate safety
immunogenicity, and efficacy of Abrysvo in
prevention of lower respiratory tract disease in
adults 60 years of age and older during the first
respiratory syncytial virus (RSV) season and the
long-term immunogenicity and efficacy of
Abrysvo in the second RSV season and across 2
RSV seasons. In addition, the MAH took the
opportunity to introduce minor changes to the
PI based on the already submitted clinical study
report C3671008."

Request for Supplementary Information adopted
on 27.02.2025, 21.11.2024.

Request for supplementary information adopted
with a specific timetable.

**Abrysvo - Respiratory syncytial virus
vaccine (bivalent, recombinant) -****EMA/H/C/006027/II/0014**

Pfizer Europe Ma EEIG, Rapporteur: Jayne
Crowe, "Update of section 4.5 of the SmPC in
order to add information regarding
coadministration of Abrysvo and COVID-19
mRNA vaccines, with or without a high dose
influenza vaccine following Phase 1/2 study
C5481001 Substudy A - a Study to Evaluate the
Safety, Tolerability, and Immunogenicity of

Positive Opinion adopted by consensus on
13.02.2025.

Combined Vaccine Candidate(s) Against Infectious Respiratory Illnesses, Including COVID 19 and RSV, in healthy participants ≥ 65 years of age; the Package Leaflet is updated accordingly.”

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 12.12.2024.

**Amvuttra - Vutrisiran -
EMA/H/C/005852/II/0014, Orphan**

Alnylam Netherlands B.V., Rapporteur: Janet Koenig, “Update of section 4.2 of the SmPC in order to add the option for administration by patient and/or caregiver, based on an updated Notified Body Opinion report. 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 make editorial changes in the PI.”

Opinion adopted on 06.02.2025.

Request for Supplementary Information adopted on 12.12.2024.

Positive Opinion adopted by consensus on 06.02.2025.

**Cerezyme - Imiglucerase -
EMA/H/C/000157/II/0136**

Sanofi B.V., Rapporteur: Patrick Vrijlandt, “Update of sections 4.4 and 4.8 of the SmPC in order to add ‘Transient hypertension’ to the list of adverse drug reactions (ADRs) with frequency not known as well as to reflect the warning on Infusion-associated reactions (IARs), based on a safety review. The Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

**Efmody - Hydrocortisone -
EMA/H/C/005105/II/0013**

Neurocrine Netherlands B.V., Rapporteur: Patrick Vrijlandt, “Update of sections 4.2, 4.4, 4.5, and 4.8 of the SmPC based on the pooled safety analysis of DIUR-006; this is a phase 3 extension study of efficacy, safety and tolerability of Chronocort in the treatment of congenital adrenal hyperplasia. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI.”

Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

Enhertu - Trastuzumab deruxtecan -

Request for supplementary information adopted

<p>EMA/H/C/005124/II/0054</p> <p>Daiichi Sankyo Europe GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Submission of the final report from study DS8201-A-U201 listed as a Recommendation (REC). This is a phase 2 multicenter, open-label efficacy and safety study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for HER2- positive, unresectable and/or metastatic breast cancer subjects previously treated with T-DM1."</p> <p>Request for Supplementary Information adopted on 13.02.2025.</p>	<p>with a specific timetable.</p>
<p>Fexinidazole Winthrop - Fexinidazole - EMA/H/W/002320/II/0021</p> <p>Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Submission of the final report from study DNDi-FEX-09-HAT. This is a phase 3b, open-label study assessing effectiveness, safety and compliance with fexinidazole in patients with human African trypanosomiasis due to <i>T.b. gambiense</i> at any stage."</p> <p>Request for Supplementary Information adopted on 27.02.2025.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Fintepla - Fenfluramine - EMA/H/C/003933/II/0024, Orphan</p> <p>UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.2 of the SmPC in order to include a table correlating volumes and doses for both Dravet syndrome and Lennox-Gastaut syndrome following the outcome of PSUSA/00010907/202306. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."</p> <p>Opinion adopted on 13.02.2025.</p> <p>Request for Supplementary Information adopted on 05.12.2024, 05.09.2024.</p>	<p>Positive Opinion adopted by consensus on 13.02.2025.</p>
<p>Fluenz - Influenza vaccine (live attenuated, nasal) - EMA/H/C/006514/II/0002</p> <p>AstraZeneca AB, Rapporteur: Christophe Focke, "Update of sections 4.2 and 4.4 of the SmPC to restrict the 2-dose schedule to children from 2 to 8 years of age who have not been vaccinated before, instead of children from 2 to 17 years of age who have not been vaccinated before, and to include a warning regarding the postponement of vaccinations in individuals with symptoms of an acute infection and in case of nasal blockage."</p>	<p>Positive Opinion adopted by consensus on 27.02.2025.</p> <p>See 9.1</p>

In addition, the MAH took the opportunity to implement changes in sections 1, 2, 3, 4.1, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 6.1, 6.3, 6.5, 6.6 and 8 of the SmPC. The labelling and Package Leaflet are updated accordingly.”

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 12.12.2024.

HEPLISAV B - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005063/II/0037

Positive Opinion adopted by consensus on 27.02.2025.

Dynavax GmbH, Rapporteur: Filip Josephson

“Update of section 4.9 of the SmPC in order to revise information regarding overdose to indicate "Not Applicable" following review of overall safety data. In addition, the MAH took the opportunity to make some editorial updates to the PI and bring it in line with the latest QRD template.”

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 16.01.2025.

Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0088/G

Positive Opinion adopted by consensus on 20.02.2025.

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, “A grouped application consisting of:

C.I.4: Update of section 5.1 of the SmPC based on results from Study CLL3011 (GLOW study).

This is a Randomized, Open-label, Phase 3 Study of the Combination of Ibrutinib plus Venetoclax versus Chlorambucil plus Obinutuzumab for the First-line Treatment of Subjects with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL).

C.I.4: Update of section 5.1 of the SmPC based on results from Study PCYC-1116-CA. This is an Open-label Extension Study in Patients 65 Years or Older with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) Who Participated in Study PCYC-1115-CA (Ibrutinib versus Chlorambucil).”

Opinion adopted on 20.02.2025.

Request for Supplementary Information adopted on 16.01.2025.

Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0091

Positive Opinion adopted by consensus on 13.02.2025.

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, “Submission of the final report from study PCYC-1142-CA (CAPTIVATE). This is

a Phase 2, international, multicentre study of the combination of ibrutinib plus venetoclax in subjects with treatment-naïve chronic lymphocytic leukaemia (CLL) /small lymphocytic lymphoma(SLL) in order to assess both minimal residual disease (MRD)-guided discontinuation and fixed duration therapy.”

Opinion adopted on 13.02.2025.

**IMCIVREE - Setmelanotide -
EMA/H/C/005089/II/0034, Orphan**

Rhythm Pharmaceuticals Netherlands B.V.,
Rapporteur: Karin Janssen van Doorn, “Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs) based on the availability of new safety data. The Package Leaflet is updated accordingly.”
Request for Supplementary Information adopted on 27.02.2025.

Request for supplementary information adopted with a specific timetable.

**Inrebic - Fedratinib -
EMA/H/C/005026/II/0027, Orphan**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, “Update of sections 4.2 and 5.2 of the SmPC in order to add administration option based on results from clinical trial FEDR-CP-005. This is a phase 1, open-label, single-centre, 2-part crossover study to evaluate the relative bioavailability of fedratinib when administered as contents of capsules dispersed in a nutritional supplement orally or via nasogastric tube or administered orally as divided doses of intact capsules with a nutritional supplement in healthy adult subjects. The Package Leaflet is being updated accordingly. In addition, the MAH took the opportunity to add editorial changes to the PI.”

Request for Supplementary Information adopted on 27.02.2025.

Request for supplementary information adopted with a specific timetable.

**JEMPERLI - Dostarlimab -
EMA/H/C/005204/II/0040**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, “Update of section 4.8 of the SmPC in order to add 'Guillain-Barre syndrome' to the list of adverse drug reactions (ADRs) in patients treated with dostarlimab in combination with chemotherapy with frequency 'uncommon' based on new safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA

Request for supplementary information adopted with a specific timetable.

excipients guideline. Also, the MAH has taken the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes to the PI.”
Request for Supplementary Information adopted on 06.02.2025.

**LYFNUA - Gefapixant -
EMA/H/C/005476/II/0003/G**

Merck Sharp & Dohme B.V., Rapporteur: Peter Mol, “Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information and add ‘headache’ to the list of adverse drug reactions (ADRs) with frequency common, based on final results from studies MK-7264-042 and MK-7264-043; these are multicentre, randomized, double-blind, placebo controlled Phase 3b studies conducted in patients with refractory or unexplained chronic cough. 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 introduce minor editorial changes to the PI.”
Request for Supplementary Information adopted on 20.02.2025, 05.12.2024, 12.09.2024.

Request for supplementary information adopted with a specific timetable.

**Metalyse - Tenecteplase -
EMA/H/C/000306/II/0075/G**

Boehringer Ingelheim International GmbH, Rapporteur: Janet Koenig, “A grouped application comprised of 4 Type II Variations, as follows:

C.I.4: Update of sections 4.3 and 4.4 of the SmPC in order to update the safety information pertaining to the prevention of bleeding risk related to thrombolytic treatment based on a dataset consisting of literature review including published clinical study outcomes. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to update the safety information for patients with body weight < 50 kg based on the dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.3 and 4.4 of the SmPC related to the medical recommendations for prior stroke patients based on a dataset

Request for supplementary information adopted with a specific timetable.

consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to revise the medical recommendation in line with the most current medical knowledge in treatment guidelines. The Package Leaflet is updated accordingly.

In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI, as well as to update the excipient information according to the latest EU Excipients Guideline. Furthermore, the PI is being brought in line with the latest QRD template (version 10.4)."

Request for Supplementary Information adopted on 27.02.2025

**Nexavar - Sorafenib -
EMA/H/C/000690/II/0059**

Positive Opinion adopted by consensus on 13.02.2025.

Bayer AG, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to update preclinical safety data on carcinogenicity studies based on final results from studies T4079666 - Carcinogenicity Study in CD-1 Mice (2 Years Administration by Diet) and T8076320 - Carcinogenicity Study in Wistar Rats (2 Years Administration in the Diet with Dose Adjustment). In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet."

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 07.11.2024, 04.07.2024.

**Nuvaxovid - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0087**

Positive Opinion adopted by consensus on 27.02.2025.

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-311 Part 2 listed as a category 3 study in the RMP. This is a Multi-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."

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 14.11.2024.

Nuvaxovid - Covid-19 Vaccine

(recombinant, adjuvanted) -

EMA/H/C/005808/II/0097/G

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt
"Submission of the final clinical study reports from clinical study 2019nCoV-313 Part 1 and Part 2 listed as a category 3 study in the RMP. This is A 2-Part Phase 2/3 Open-Label Study to Evaluate the Safety and Immunogenicity of an XBB.1.5 (Omicron Subvariant) SARS -CoV-2 rS Vaccine Booster Dose in Previously mRNA COVID-19 Vaccinated and Baseline SARS-CoV-2 Seropositive COVID-19 Vaccine Naïve Participants."

Opinion adopted on 27.02.2025.

Positive Opinion adopted by consensus on 27.02.2025.

Ontozry - Cenobamate -

EMA/H/C/005377/II/0029

Angelini S.p.A., Rapporteur: Paulo Paixão,
"Update of sections 4.2 and 5.2 of the SmPC to include the crushed tablets method of administration and section 4.5 of the SmPC in order to present the existing information on DDI in a tabular format. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction of the contact details of the manufacturer ACRAF SPA in Annex II and Package Leaflet."

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 12.12.2024.

Positive Opinion adopted by consensus on 27.02.2025.

OZAWADE - Pitolisant -

EMA/H/C/005117/II/0012

Bioprojet Pharma, Rapporteur: Peter Mol,
"Submission of the study note PH24048. This is an update of the final PopPK model (PH20043) submitted at initial Marketing Authorization Approval integrating the results of study 15-03 (HAROSA III). In addition, the results of re-estimated model parameters and covariates are provided."

Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

Rezzayo - Rezafungin -

EMA/H/C/005900/II/0007, Orphan

Mundipharma GmbH, Rapporteur: Fátima Ventura, " Update of sections 4.8, and 5.1 of

Positive Opinion adopted by consensus on 27.02.2025.

the SmPC based on final results of China extension part from study ReSTORE; this is a pivotal Phase 3, multicentre, randomised, double-blind study of the efficacy and safety of rezafungin versus the active control caspofungin IV, followed by optional oral fluconazole step-down, in the treatment of subjects with IC; updated population PK modelling was also presented; the Package Leaflet is updated accordingly.”

Opinion adopted on 27.02.2025.

**RINVOQ - Upadacitinib -
EMA/H/C/004760/II/0055**

Positive Opinion adopted by consensus on 27.02.2025.

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, “Update of sections 4.8 and 5.1 of the SmPC in order to include long term efficacy and safety data for ulcerative colitis based on results from study M14-533. This is a phase 3, multicentre, long-term extension study to evaluate the safety and efficacy of upadacitinib in subjects with ulcerative colitis.”

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 12.12.2024, 12.09.2024.

**Samsca - Tolvaptan -
EMA/H/C/000980/II/0051**

Positive Opinion adopted by consensus on 13.02.2025.

Otsuka Pharmaceutical Netherlands B.V.,
Rapporteur: Paolo Gasparini, “Update of section 4.5 of the SmPC in order to add drug-drug interaction information with St John’s wort based on literature and to implement the recommendation from EMA on the risk of drug interactions with Hypericum perforatum (St John’s Wort) and antiretroviral medicinal products. 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 13.02.2025.

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0149**

Positive Opinion adopted by consensus on 06.02.2025.

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, “Submission of the final report from study mRNA-1273-P204 listed as a category 3 study in the RMP; this is interventional Phase 2/3, 3-part, dose-escalation, open-label, age de-escalation and randomised, observer-blind, placebo-controlled

expansion study to evaluate the safety, reactogenicity, and effectiveness of Spikevax (mRNA-1273) in children 6 months through 11 years of age.”
Opinion adopted on 06.02.2025.

Vyloy - Zolbetuximab -
EMA/H/C/005868/II/0005, Orphan
Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus, “Update of section 5.1 of the SmPC in order to update immunogenicity data based on the validation report for the new method (8951-ME-0016) to replace the method originally used to test ADA samples from the pivotal studies SPOTLIGHT and GLOW. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI.”
Request for Supplementary Information adopted on 27.02.2025.

Request for supplementary information adopted with a specific timetable.

Xarelto - Rivaroxaban -
EMA/H/C/000944/II/0113
Bayer AG, Rapporteur: Kristina Dunder, “Update of section 4.8 of the SmPC in order to add ‘splenic rupture’ to the list of adverse drug reactions (ADRs) with frequency ‘very rare’ based on the data from the clinical trials, post-marketing data sources and literature; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity introduce editorial updates as agreed with QRD group.”
Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

Xeljanz - Tofacitinib -
EMA/H/C/004214/II/0068
Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, “Update of section 4.6 of the SmPC in order to update information on breast-feeding section based on literature and post-marketing data. In addition, the MAH took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet.”
Opinion adopted on 13.02.2025.

Positive Opinion adopted by consensus on 13.02.2025.

Xenpozyme - Olipudase alfa -
EMA/H/C/004850/II/0013/G, Orphan
Sanofi B.V., Rapporteur: Patrick Vrijlandt, “A grouped application consisting of:
C.I.4: Update of section 4.2 of the SmPC in order to update the ‘Missed Doses’ section to

Positive Opinion adopted by consensus on 13.02.2025.

facilitate the appropriate clinical management of patients based on pre-existing data from the clinical trials.

C.I.4: Update of section 4.2 of the SmPC in order to include a clarification of the infusion rate during the home infusion based on pre-existing data from the clinical trials.”

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 12.12.2024.

Zejula - Niraparib -

EMA/H/C/004249/II/0057/G, Orphan

GlaxoSmithKline (Ireland) Limited, Rapporteur:

Ingrid Wang, “C.I.4: Update of section 4.5 of the SmPC in order to update information on pharmacokinetic drug-drug interactions based on Physiologically based on results from pharmacokinetic (PBPK) modelling; this is Evaluation of GSK3985771 (Niraparib) Drug-Drug Interaction (DDI) Risk Assessment as a Perpetrator using PBPK Modelling; 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 introduce editorial changes to the PI.

C.I.4: Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on results from Refined PRIMA Model; this is an amendment to addendum to population pharmacokinetic and exposure-response modelling of niraparib in PRIMA study; the Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 27.02.2025.

Request for supplementary information adopted with a specific timetable.

B.5.3. CHMP-PRAC assessed procedures

Bavencio - Avelumab -

EMA/H/C/004338/II/0046/G

Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Erneholm, “A grouped application consisting of:

C.I.4: Update of sections 4.2, 4.4, 4.6 and 4.8 of the SmPC in order to add the immune-mediated adverse reactions sclerosing cholangitis, arthritis, polymyalgia rheumatica, and Sjogren’s syndrome based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version

Positive Opinion adopted by consensus on 13.02.2025.

7.3 has also been submitted.

C.I.4: Update of section 4.8 of the SmPC in order to update the immunogenicity information based on results from studies EMR100070-003, B9991003 and 100/B9991001. Study EMR100070-003 is a Phase 2, single-arm, open label, multicentre study to investigate the clinical activity and safety of avelumab in patients with mMCC. T. Study B9991003 is a Phase 3 multinational, multicentre, randomized (1:1), open-label, parallel 2 - arm study of avelumab in combination with axitinib versus sunitinib monotherapy in the 1L treatment of participants with aRCC. Study 100/B9991001 is a Phase 3, multicentre, multinational, randomized, open-label, parallel-arm efficacy and safety study of avelumab plus best supportive care (BSC) versus BSC alone as a maintenance treatment in adult participants with locally advanced or metastatic UC whose disease did not progress after completion of 1L platinum-containing chemotherapy.”

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 31.10.2024.

**Columvi - Glofitamab -
EMA/H/C/005751/II/0010, Orphan**

Positive Opinion adopted by consensus on 27.02.2025.

Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova, “Submission of the updated 2-year follow-up report from study NP30179 listed as a Specific Obligation in the Annex II of the Product Information. This is a multicentre, open-label Phase I/II study to evaluate the safety, efficacy, tolerability, and pharmacokinetics of escalating doses of glofitamab in patients with relapsed/refractory B-cell Non-Hodgkin’s Lymphoma (NHL). The Annex II and the RMP version 4.0 are updated accordingly. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation.”

Opinion adopted on 27.02.2025.

**FILSPARI - Sparsentan -
EMA/H/C/005783/II/0002, Orphan**

Positive Opinion adopted by consensus on 27.02.2025.

Vifor France, Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber, “Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs)

See 9.1

based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicentre, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation.”

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024.

HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0102

Positive Opinion adopted by consensus on 27.02.2025.

Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, “Update of sections 4.8 and 5.1 of the SmPC to reflect results from the final report from study 161505; this is a Phase 3b, open-label, non-controlled, multicentre study to assess the long-term tolerability and safety of immune globulin infusion 10% (human) with recombinant human hyaluronidase (HyQvia) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). The package leaflet is updated accordingly. In addition, the marketing authorisation holder has taken the opportunity to update the list of local representatives in the PL and implement minor editorial changes in sections 4.1, 4.2, 4.4, 5.2 and 6.4 of the SmPC and PL. The RMP version 16.0 has also been approved.”

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted on 31.10.2024.

Kadcyla - Trastuzumab emtansine - EMEA/H/C/002389/II/0071/G

Positive Opinion adopted by consensus on 20.02.2025.

Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Karin Erneholm, “A grouped application consisting of: C.I.4 (Type II): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study BO27938 (KATHERINE) listed as a PAES in the Annex II and as a category 3 study in the

RMP. This is a Randomized, Multicentre, Open Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer who have Residual Tumour Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy. The Package Leaflet is updated in accordance. The RMP version 16.0 has also been submitted. 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, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI. Furthermore, the MAH took the opportunity to update Annex II-D and to implement editorial changes to the Labelling section. Opinion adopted on 20.02.2025. Request for Supplementary Information adopted on 16.01.2025, 31.10.2024.

**Kayfanda - Odevixibat -
EMA/H/C/006462/II/0001/G**

Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of:
C.I.4: Update of sections 4.4, 4.8, and 5.1 of the SmPC based on results from Study A4250-015 listed as a category 3 study in the RMP; this is a Phase 3, multicentre, open-label extension study to evaluate the long-term safety and efficacy of odevixibat in patients with ALGS. The Package Leaflet is updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

C.I.13: Submission of the 72-week report from study A4250-008. This is a Phase 3, multicentre, open-label extension study to investigate the long-term efficacy and safety of odevixibat in patients with Progressive Familial Intrahepatic Cholestasis Types 1 and 2 (PEDFIC 2)."

Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

**Litfulo - Ritlecitinib -
EMA/H/C/006025/II/0007**

Pfizer Europe MA EEIG, Rapporteur: Peter Mol,

Positive Opinion adopted by consensus on 13.02.2025.

PRAC Rapporteur: Adam Przybylowski, "Update of section 4.8 of the SmPC in order to update the safety information based on interim results from study B7981032 listed as a category 3 study in the RMP; this is a phase 3 open-label, multi-centre, long-term study investigating the safety and efficacy of ritlecitinib in adult and adolescent participants with alopecia areata. The RMP version 2 is acceptable."
Opinion adopted on 13.02.2025.

MVABEA - Ebola vaccine (MVA-BN-Filo [recombinant]) - EMEA/H/C/005343/II/0021

Positive Opinion adopted by consensus on 27.02.2025.

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorization vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."
Request for Supplementary Information adopted on 27.06.2024.
Opinion adopted on 27.02.2025.

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0096/G

Request for supplementary information adopted with a specific timetable.

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Gabriele Maurer
Request for Supplementary Information adopted on 13.02.2025.

Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0041

Positive Opinion adopted by consensus on 13.02.2025.

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.6 and 5.3 of the SmPC in order to amend the recommendations for breast-feeding during ocrelizumab therapy, based on newly available clinical data. The

Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The RMP has been updated to version 10.0.”

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 16.01.2025, 31.10.2024, 11.07.2024.

**Ondexxya - Andexanet alfa -
EMA/H/C/004108/II/0044**

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, “Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3.”

Request for Supplementary Information adopted on 27.02.2025, 19.09.2024, 21.03.2024.

Request for supplementary information adopted with a specific timetable.

See 9.1

**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.”

Request for Supplementary Information adopted on 27.02.2025, 14.11.2024, 30.05.2024.

Request for supplementary information adopted with a specific timetable.

TAKHZYRO - Lanadelumab -

Request for supplementary information adopted

EMA/H/C/004806/II/0040, Orphan

Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Kristina Dunder,
PRAC Rapporteur: Terhi Lehtinen, "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 27.02.2025, 17.10.2024, 11.04.2024.

with a specific timetable.

Vyvgart - Efgartigimod alfa -**EMA/H/C/005849/II/0022/G, Orphan**

Argenx, Rapporteur: Thalia Marie Estrup Blicher,
PRAC Rapporteur: Rhea Fitzgerald

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted
on 31.10.2024.

Positive Opinion adopted by consensus on
13.02.2025.

Yondelis - Trabectedin -**EMA/H/C/000773/II/0070**

Pharma Mar, S.A., Rapporteur: Boje Kvorning
Pires Ehmsen, PRAC Rapporteur: Marie Louise
Schougaard Christiansen, "Update of sections
4.4 and 4.6 of the SmPC in order to update the
contraceptive precautions when receiving
Yondelis, in line with EMA recommendations.
The Package Leaflet is updated accordingly. The
RMP version 11.1 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."

Opinion adopted on 13.02.2025.

Positive Opinion adopted by consensus on
13.02.2025.

Zabdeno - Ebola vaccine (Ad26.ZEBOV-GP

Positive Opinion adopted by consensus on

[recombinant]] -

27.02.2025.

EMA/H/C/005337/II/0019

Janssen-Cilag International N.V., Rapporteur:
Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel
Dogné, "Update of sections 4.6 and 5.1 of the
SmPC in order to update information on
pregnancy based on final results from study
VAC52150EBL3010 listed as a category 3 study
in the RMP as well as study VAC52150EBL3008
and two post-authorisation vaccination
campaigns. Study VAC52150EBL3010 is a phase
3 open-label randomized clinical trial to evaluate
the safety, reactogenicity and immunogenicity
of a 2-dose Ebola vaccine regimen of
Ad26.ZEBOV followed by MVA-BN-Filo in healthy
pregnant women. The Package Leaflet is
updated accordingly. The RMP version 3.3 has
also been submitted. In addition, the MAH took
the opportunity to introduce minor changes to
the Product Information."

Opinion adopted on 27.02.2025.

Request for Supplementary Information adopted
on 27.06.2024.

WS2798

Nilemdo-

EMA/H/C/004958/WS2798/0045

Nustendi-

EMA/H/C/004959/WS2798/0050

Daiichi Sankyo Europe GmbH, Lead Rapporteur:
Patrick Vrijlandt, Lead PRAC Rapporteur: Kimmo
Jaakkola, "Update of sections 4.2, 4.4, and 5.2
of the SmPC in order to amend information
concerning renal impairment based on the final
results from Study 1002-071 listed as a
category 3 study in the RMP; this is a phase 1,
open-label, single-dose study to evaluate the
pharmacokinetics of bempedoic acid in healthy
subjects with normal renal function and subjects
with end-stage renal disease receiving HD; the
Package Leaflet is updated accordingly. The RMP
version 7.0 has also been submitted."

Request for Supplementary Information adopted
on 13.02.2025.

Request for supplementary information adopted
with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led

**Cinryze - C1 ESTERASE INHIBITOR
(HUMAN) - EMA/H/C/001207/II/0104**

Takeda Manufacturing Austria AG, PRAC

Request for supplementary information adopted
with a specific timetable.

Rapporteur: Gabriele Maurer, PRAC-CHMP
liaison: Jan Mueller-Berghaus, "Update of sections 4.6, 5.1 and 5.3 of the SmPC based on final results from the Icatibant Outcome Survey (IOS), listed as an imposed PASS in the Annex II. This is a prospective, observational disease registry. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the product information in line with the latest QRD template version 10.4 and to update Annex II of the PI."
Request for Supplementary Information adopted on 13.02.2025.

PRAC Led	Positive Opinion adopted by consensus on 13.02.2025.
----------	--

**Cosentyx - Secukinumab -
EMA/H/C/003729/II/0127**

Novartis Europharm Limited, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Update of section 4.4 of the SmPC to include recommendations on clinical management of cases of tuberculosis following the PSUSA (PSUSA/00010341/202312) procedure following which cumulative requests were requested to assess the safety topics of tuberculosis and hepatitis C virus with secukinumab. The Package Leaflet is updated accordingly."
Opinion adopted on 13.02.2025.

PRAC Led	Positive Opinion adopted by consensus on 13.02.2025.
----------	--

**Fasenra - Benralizumab -
EMA/H/C/004433/II/0054**

AstraZeneca AB, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Submission of the final report from study D3250R00042 listed as a category 3 study in the RMP. This is a noninterventional, descriptive post authorisation safety study of the incidence of malignancy in severe asthma patients receiving benralizumab and other therapies. The RMP version 7.1 has also been submitted."
Opinion adopted on 13.02.2025.

PRAC Led	Positive Opinion adopted by consensus on 13.02.2025.
----------	--

**Fintepla - Fenfluramine -
EMA/H/C/003933/II/0025, Orphan**

UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig,

"Update of section 4.8 of the SmPC in order to propose a combined Adverse Drug Reaction table for Dravet Syndrome and Lennox-Gastaut syndrome following PSUSA procedure EMEA/H/C/PSUSA/00010907/202306. The package leaflet is updated accordingly."
Opinion adopted on 13.02.2025.
Request for Supplementary Information adopted on 31.10.2024, 05.09.2024.

PRAC Led

Firazyr - Icatibant -

EMA/H/C/000899/II/0061

Takeda Pharmaceuticals International AG
Ireland Branch, PRAC Rapporteur: Mari Thorn,
PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a prospective, observational disease registry. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4."

Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

PRAC Led

Humira - Adalimumab -

EMA/H/C/000481/II/0219

AbbVie Deutschland GmbH & Co. KG, PRAC
Rapporteur: Karin Bolin, PRAC-CHMP liaison:
Kristina Dunder, "Submission of the final report from study P10-262 listed as a category 3 study in the RMP. This is a long-term, multi-centre, longitudinal, post-marketing observational registry to assess long-term safety and effectiveness of Humira (adalimumab) in children with moderately to severely active polyarticular or polyarticular-course juvenile idiopathic arthritis (JIA). The RMP version 16.2 has also been approved."

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 31.10.2024.

Positive Opinion adopted by consensus on 13.02.2025.

PRAC Led

Kaftrio - Ivacaftor / Tezacaftor /

Ellexacaftor -

EMA/H/C/005269/II/0052/G, Orphan

Vertex Pharmaceuticals (Ireland) Limited, PRAC

Positive Opinion adopted by consensus on 13.02.2025.

Rapporteur: Martin Huber, PRAC-CHMP liaison:
Janet Koenig, "Grouped application comprising
two type II variations as follows:

- Type II (C.I.3.b)

- Update of sections 4.4 and 4.8 of the SmPC in order to update information on existing statements related to rash events in adults and add information regarding the paediatric population.
- Update of section 4.8 to add hypersensitivity to the list of adverse drug reactions with frequency "not known".

- Type II (C.I.z) – Update of section 4.6 based on post-marketing breast-feeding case reports. Clarification is provided that the medicinal product has been detected in breastfed newborns/infants of treated women.

The Package Leaflet is updated accordingly."

Opinion adopted on 13.02.2025.

Request for Supplementary Information adopted on 16.01.2025, 05.09.2024.

PRAC Led

**OPDIVO - Nivolumab -
EMA/H/C/003985/II/0149**

Bristol-Myers Squibb Pharma EEIG, PRAC

Rapporteur: Gabriele Maurer, PRAC-CHMP

liaison: Jan Mueller-Berghaus, "Submission of the final clinical study report (CSR) for the PASS study CA209234 listed as a category 3 study in the RMP. This is an observational, multicentre, prospective study in patients treated with nivolumab for melanoma and lung cancer in order assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab (monotherapy or with ipilimumab) in routine oncology care facilities. The RMP version 42.0 has also been submitted."

Request for Supplementary Information adopted on 13.02.2025.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Revlimid - Lenalidomide -
EMA/H/C/000717/II/0130**

Bristol-Myers Squibb Pharma EEIG, PRAC

Rapporteur: Tiphaine Vaillant, PRAC-CHMP

liaison: Alexandre Moreau, "Submission of the final report from study CC-5013-MCL-005 listed as a category 3 study in the RMP. This is a non-interventional, post-authorization safety study

Request for supplementary information adopted with a specific timetable.

of patients with relapsed or refractory mantle cell lymphoma to further investigate and characterize the association of lenalidomide with tumour flare reaction and high tumour burden. The RMP version 42.0 has also been submitted.” Request for Supplementary Information adopted on 13.02.2025.

PRAC Led
WS2802
Entresto-
EMA/H/C/004062/WS2802/0070

Positive Opinion adopted by consensus on 13.02.2025.

Neparvis-
EMA/H/C/004343/WS2802/0067
Novartis Europharm Limited, Lead PRAC
Rapporteur: Karin Erneholm, PRAC-CHMP
liaison: Thalia Marie Estrup Bliche, “Submission of the final report for study CLCZ696B2014 listed as a category 3 study in the RMP; this is a non-interventional post-authorization multi-database safety study to characterize the risk of angioedema and other specific safety events of interest in association with use of Entresto (sacubitril/valsartan) in adult patients with heart failure. The RMP version 9.0 for Entresto and Neparvis has also been submitted.”
Opinion adopted on 13.02.2025.

PRAC Led
WS2803
Entresto-
EMA/H/C/004062/WS2803/0071

Positive Opinion adopted by consensus on 13.02.2025.

Neparvis-
EMA/H/C/004343/WS2803/0068
Novartis Europharm Limited, Lead PRAC
Rapporteur: Karin Erneholm, PRAC-CHMP
liaison: Thalia Marie Estrup Blicher, “Submission of the final report for study CLCZ696B2015 listed as a category 3 study in the RMP for Entresto and Neparvis; this is a non-interventional post-authorization multi-database safety study to assess the risk of myotoxicity, hepatotoxicity and acute pancreatitis in statin-exposed heart failure patients with or without concomitant use of sacubitril/valsartan. The RMP version 9.0 for Entresto and Neparvis has also been submitted.”
Opinion adopted on 13.02.2025.

PRAC Led
WS2819
Ozempic-

Positive Opinion adopted by consensus on 13.02.2025.

EMA/H/C/004174/WS2819/0053

Wegovy-

EMA/H/C/005422/WS2819/0029

Novo Nordisk A/S, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To align the RMPs to the version approved for Rybelsys on 3 October 2024."

Opinion adopted on 13.02.2025.

B.5.5. CHMP-CAT assessed procedures

**Abecma - Idecabtagene vicleucel -
EMA/H/C/004662/II/0058/G, Orphan,
ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang
Request for Supplementary Information adopted on 21.02.2025.

Request for supplementary information adopted with a specific timetable.

**Breyanzi - Lisocabtagene maraleucel /
Lisocabtagene maraleucel -
EMA/H/C/004731/II/0055/G, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini
Request for Supplementary Information adopted on 21.02.2025.

Request for supplementary information adopted with a specific timetable.

**CARVYKTI - Ciltacabtagene autoleucel -
EMA/H/C/005095/II/0037, Orphan,
ATMP**

Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Opinion adopted on 27.02.2025, 21.02.2025.

Positive Opinion adopted by consensus on 27.02.2025.

**Casgevy - Exagamglogene autotemcel -
EMA/H/C/005763/II/0009/G, Orphan,
ATMP**

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Opinion adopted on 27.02.2025, 21.02.2025.
Request for Supplementary Information adopted on 06.12.2024.

Positive Opinion adopted by consensus on 27.02.2025.

**Casgevy - Exagamglogene autotemcel -
EMA/H/C/005763/II/0012/G, Orphan,
ATMP**

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Positive Opinion adopted by consensus on 27.02.2025.

Opinion adopted on 27.02.2025, 21.02.2025.

**Kymriah - Tisagenlecleucel -
EMA/H/C/004090/II/0086/G, Orphan,
ATMP**

Positive Opinion adopted by consensus on
27.02.2025.

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, "A grouped application consisting of:

C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on cytokine release syndrome based on literature.

C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on neurological adverse reaction based on literature. The Package Leaflet is updated accordingly.

C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on hypersensitivity reactions based on post marketing data and literature. The Package Leaflet is updated accordingly.

In addition, a new warning of CD19-negative disease ALL patients has been included in section 4.4 of the SmPC.

The MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the PI."

Opinion adopted on 27.02.2025, 21.02.2025.

Request for Supplementary Information adopted on 06.12.2024, 11.10.2024.

**Libmeldy - Atidarsagene autotemcel -
EMA/H/C/005321/II/0031/G, Orphan,
ATMP**

Positive Opinion adopted by consensus on
27.02.2025.

Orchard Therapeutics (Netherlands) B.V.,
Rapporteur: Emmely de Vries, CHMP

Coordinator: Peter Mol

Opinion adopted on 27.02.2025, 21.02.2025.

Request for Supplementary Information adopted on 08.11.2024.

**Yescarta - Axicabtagene ciloleucel -
EMA/H/C/004480/II/0085, Orphan,
ATMP**

Request for supplementary information adopted
with a specific timetable.

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Submission of the final report from study KT-US-482-0147 (ZUMA-26). This is a Prospective, Noninterventional, Clinical Efficacy Study Investigating and Analyzing the Impact of Tumor Cd19 Antigen Expression and Density on Response to Axicabtagene Ciloleucel

Treatment.”
Request for Supplementary Information adopted
on 21.02.2025.

WS2736
Tecartus-
EMA/H/C/005102/WS2736/0048

Positive Opinion adopted by consensus on
27.02.2025.

Yescarta-
EMA/H/C/004480/WS2736/0080

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

Opinion adopted on 27.02.2025, 21.02.2025.

Request for Supplementary Information adopted
on 06.12.2024, 13.09.2024.

B.5.6. CHMP-PRAC-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel -
EMA/H/C/005095/II/0036, Orphan,
ATMP

Request for supplementary information adopted
with a specific timetable.

Janssen-Cilag International NV, Rapporteur: Jan
Mueller-Berghaus, CHMP Coordinator: Jan
Mueller-Berghaus, PRAC Rapporteur: Jo Robays,
“Update of sections 4.8, and 5.1 of the SmPC in
order to update the list of adverse drug
reactions (ADRs), and update clinical efficacy
and safety information based on second interim
analysis from study 68284528MMY3002
(CARTITUDE-4); this is a phase 3 randomized
study comparing ciltacabtagene autoleucel, a
chimeric antigen receptor T cell (CAR-T) therapy
directed against BCMA, versus Pomalidomide,
Bortezomib and Dexamethasone (PvD) or
Daratumumab, Pomalidomide and
Dexamethasone (DPd) in subjects with relapsed
and lenalidomide-refractory multiple myeloma;
The RMP version 5.3 has also been submitted.
In addition, the MAH took the opportunity to
update the list of local representatives in the
Package Leaflet.”

Request for Supplementary Information adopted
on 21.02.2025.

ROCTAVIAN - Valoctocogene roxaparvovec
- EMA/H/C/005830/II/0014, Orphan,
ATMP

Positive Opinion adopted by consensus on
27.02.2025.

BioMarin International Limited, Rapporteur:
Violaine Closson Carella, CHMP Coordinator:
Jean-Michel Race, PRAC Rapporteur: Bianca
Mulder, “Update of the Annex II in order to

propose changes to the current marketing authorisation obligations for ROCTAVIAN. The RMP version 1.3 has also been submitted.”
Opinion adopted on 27.02.2025, 21.02.2025.
Request for Supplementary Information adopted on 08.11.2024.

B.5.7. PRAC assessed ATMP procedures

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

WS2763/G Trimbow- EMA/H/C/004257/WS2763/0043/G Trydonis- EMA/H/C/004702/WS2763/0040/G Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 12.12.2024.	Positive Opinion adopted by consensus on 13.02.2025.
--	--

WS2774/G Dapagliflozin Viatris- EMA/H/C/006006/WS2774/0005/G Viatris Limited, Generic of Forxiga, Lead Rapporteur: Tomas Radimersky Opinion adopted on 20.02.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 20.02.2025.
---	--

WS2791/G Aflunov- EMA/H/C/002094/WS2791/0091/G Foclivia- EMA/H/C/001208/WS2791/0095/G Zoonotic Influenza Vaccine Seqirus- EMA/H/C/006375/WS2791/0009/G Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 06.02.2025, 19.12.2024.	Request for supplementary information adopted with a specific timetable.
---	--

WS2807 Ebymect- EMA/H/C/004162/WS2807/0068 Xigduo-EMA/H/C/002672/WS2807/0078 AstraZeneca AB, Lead Rapporteur: Kristina Dunder Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
---	--

WS2810/G	Positive Opinion adopted by consensus on
-----------------	--

Copalia- EMA/H/C/000774/WS2810/0138/G Copalia HCT- EMA/H/C/001159/WS2810/0116/G Dafiro- EMA/H/C/000776/WS2810/0142/G Dafiro HCT- EMA/H/C/001160/WS2810/0118/G Exforge- EMA/H/C/000716/WS2810/0137/G Exforge HCT- EMA/H/C/001068/WS2810/0115/G Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 20.02.2025.	20.02.2025.
WS2820 Blitzima- EMA/H/C/004723/WS2820/0081 Truxima- EMA/H/C/004112/WS2820/0084 Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

The information on Marketing authorisation applications under review including a summary of the therapeutic indication applied for by the applicant, will continue be published on the EMA website (under this page). As of February, The EMA will also start publishing on the same EMA webpage information on the start of the procedures for extension applications and for Type II variation that propose an extension of the authorised indication, which have been submitted and started in IRIS in 2025. This information will be published the week following the CHMP plenary.

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

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

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

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

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

G.2. PRIME

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