



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2025
EMA/CHMP/112185/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 22-25 April 2025

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

22 April 2025, 09:00 – 19:30, virtual meeting/room 1C

23 April 2025, 08:30 – 19:30, virtual meeting/room 1C

24 April 2025, 08:30 – 19:30, virtual meeting/room 1C

25 April 2025, 08:30 – 15:00, virtual meeting/room 1C

Disclaimers

Some of the information contained in this agenda 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, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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.	Atropine - PUMA - EMEA/H/C/006385.....	8
2.1.2.	Inavolisib - EMEA/H/C/006353	8
2.1.3.	Nirogacestat - Orphan - EMEA/H/C/006071.....	9
2.1.4.	Teriparatide - EMEA/H/C/005687.....	9
2.2.	Re-examination procedure oral explanations	9
2.3.	Post-authorisation procedure oral explanations	9
2.4.	Referral procedure oral explanations	9
3.	Initial applications	9
3.1.	Initial applications; Opinions.....	9
3.1.1.	Deutivacaftor / Tezacaftor / Vanzacaftor - Orphan - EMEA/H/C/006382.....	9
3.1.2.	L-Acetylleucine - Orphan - EMEA/H/C/006327	10
3.1.3.	Trastuzumab - EMEA/H/C/006219	10
3.1.4.	Denosumab - EMEA/H/C/006199	10
3.1.5.	Denosumab - EMEA/H/C/006526	10
3.1.6.	Diflunisal - Orphan - EMEA/H/C/006248	10
3.1.7.	Givinostat - Orphan - EMEA/H/C/006079	11
3.1.8.	Denosumab - EMEA/H/C/006376	11
3.1.9.	Denosumab - EMEA/H/C/006152	11
3.1.10.	Denosumab - EMEA/H/C/006436	11
3.1.11.	Resminostat - Orphan - EMEA/H/C/006259.....	11
3.1.12.	Octreotide - Orphan - EMEA/H/C/006322.....	12
3.1.13.	Sepiapterin - Orphan - EMEA/H/C/006331	12
3.1.14.	Teprotumumab - EMEA/H/C/006396	12
3.1.15.	Denosumab - EMEA/H/C/006534	12
3.1.16.	Clascoterone - EMEA/H/C/006138.....	12
3.1.17.	Denosumab - EMEA/H/C/006437	13
3.1.18.	Denosumab - EMEA/H/C/006377	13
3.1.19.	Zanidatamab - Orphan - EMEA/H/C/006380.....	13
3.2.	Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)	13

3.2.1.	Aflibercept - EMEA/H/C/006438.....	13
3.2.2.	Aflibercept - EMEA/H/C/006761.....	13
3.2.3.	Belantamab mafodotin - Orphan - EMEA/H/C/006511	14
3.2.4.	Delandistrogene moxeparvovec - Orphan - ATMP - EMEA/H/C/005293	14
3.2.5.	Emtricitabine / Rilpivirine / Tenofovir alafenamide - EMEA/H/C/006491	14
3.2.6.	Aflibercept - EMEA/H/C/006282.....	14
3.2.7.	Mirdametinib - Orphan - EMEA/H/C/006460.....	14
3.2.8.	Ustekinumab - EMEA/H/C/006467	14
3.2.9.	Macitentan - EMEA/H/C/006524	15
3.2.10.	Macitentan - EMEA/H/C/006523	15
3.2.11.	Nintedanib - EMEA/H/C/006486.....	15
3.2.12.	Vimseltinib - Orphan - EMEA/H/C/006363.....	15
3.3.	Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)	15
3.3.1.	Nadofaragene firadenovec - ATMP - EMEA/H/C/005856	15
3.3.2.	Blarcamesine - EMEA/H/C/006475.....	16
3.3.3.	Donidalorsen - Orphan - EMEA/H/C/006554.....	16
3.3.4.	Iloperidone - EMEA/H/C/006561.....	16
3.3.5.	Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA/H/C/006639.....	16
3.3.6.	Eflornithine - Orphan - EMEA/H/C/006067	16
3.3.7.	Imlunestrant - EMEA/H/C/006184.....	16
3.3.8.	mRNA-1283 - EMEA/H/C/006428.....	17
3.3.9.	Aficamten - EMEA/H/C/006228.....	17
3.3.10.	Denosumab - EMEA/H/C/006492	17
3.3.11.	Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - Orphan - ATMP - EMEA/H/C/006525	17
3.4.	Update on on-going initial applications for Centralised procedure.....	17
3.4.1.	ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304.....	17
3.5.	Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004	18
3.5.1.	Kisunla - Donanemab - EMEA/H/C/006024	18
3.6.	Initial applications in the decision-making phase.....	18
3.7.	Withdrawals of initial marketing authorisation application	18

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 18

4.1.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion	18
4.1.1.	Adempas - Riociguat - EMEA/H/C/002737/X/0041	18
4.1.2.	Brukinsa - Zanubrutinib - EMEA/H/C/004978/X/0023.....	18
4.1.3.	Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/X/0033/G	19

4.1.4.	Talzenna - Talazoparib - EMEA/H/C/004674/X/0022	19
4.2.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues	19
4.3.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question	19
4.3.1.	Koselugo - Selumetinib - Orphan - EMEA/H/C/005244/X/0018/G.....	19
4.3.2.	Lunsumio - Mosunetuzumab - Orphan - EMEA/H/C/005680/X/0015	20
4.3.3.	Remsima - Infliximab - EMEA/H/C/002576/X/0149	20
4.3.4.	Spinraza - Nusinersen - Orphan - EMEA/H/C/004312/X/0038.....	20
4.4.	Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008	20
4.5.	Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	21

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

21

5.1.	Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information.....	21
5.1.1.	ADCETRIS - Brentuximab vedotin - EMEA/H/C/002455/II/0111	21
5.1.2.	Alhemo - Concizumab - EMA/VR/0000244862.....	21
5.1.3.	Amvuttra - Vutrisiran - Orphan - EMEA/H/C/005852/II/0015	22
5.1.4.	BAQSIMI - Glucagon - EMA/VR/0000244909	22
5.1.5.	Calquence - Acalabrutinib - EMEA/H/C/005299/II/0028	22
5.1.6.	Clopidogrel Zentiva - Clopidogrel - EMEA/H/C/000975/II/0092.....	23
5.1.7.	Cystadrops - Mercaptamine - Orphan - EMEA/H/C/003769/II/0032.....	23
5.1.8.	Gazyvaro - Obinutuzumab - EMA/VR/0000244907.....	23
5.1.9.	Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040	24
5.1.10.	Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0092	24
5.1.11.	Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/II/0034	24
5.1.12.	Keytruda - Pembrolizumab - EMA/VR/0000245108.....	25
5.1.13.	Koselugo - Selumetinib - EMA/VR/0000245231	25
5.1.14.	Neuraceq - Florbetaben (18F) - EMA/VR/0000227744	26
5.1.15.	Norvir - Ritonavir - EMA/VR/0000249795	26
5.1.16.	Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0061/G	26
5.1.17.	Revolade - Eltrombopag - EMEA/H/C/001110/II/0077	27
5.1.18.	Simponi - Golimumab - EMEA/H/C/000992/II/0121	27
5.1.19.	TEZSPIRE - Tezepelumab - EMA/VR/0000245013.....	27
5.1.20.	Veklury - Remdesivir - EMEA/H/C/005622/II/0053/G	28
5.1.21.	Vyvgart - Efgartigimod alfa - Orphan - EMEA/H/C/005849/II/0020	28
5.1.22.	Xofluza - Baloxavir marboxil - EMEA/H/C/004974/II/0021	29

5.1.23.	Zoonotic Influenza Vaccine Seqirus - Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted) - EMA/VR/0000249071.....	29
5.2.	Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	29
5.3.	Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	29

6. Medical devices 30

6.1.	Ancillary medicinal substances - initial consultation	30
6.1.1.	Human albumin solution - EMEA/H/D/006540	30
6.2.	Ancillary medicinal substances – post-consultation update.....	30
6.3.	Companion diagnostics - initial consultation	30
6.4.	Companion diagnostics – follow-up consultation.....	30

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 30

7.1.	Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)	30
-------------	--	-----------

8. Pre-submission issues 30

8.1.	Pre-submission issue.....	30
8.1.1.	Lurbinectedin – H0006673.....	30
8.1.2.	Nerandomilast – H0006405.....	31
8.2.	Priority Medicines (PRIME).....	31

9. Post-authorisation issues 31

9.1.	Post-authorisation issues	31
9.1.1.	Extavia (SRD) - Interferon beta-1B – EMEA/H/C/000933.....	31
9.1.2.	Eylea – Aflibercept - EMA/VR/0000249440.....	31
9.1.3.	Kymriah – Tisagenlecleucel - EMA/VR/0000248534.....	32
9.1.4.	Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/S/0019	32
9.1.5.	Omidria - Phenylephrine / Ketorolac - EMEA/H/C/003702/R/0030.....	32
9.1.6.	Pemazyre - Pemigatinib – Orphan – EMEA/H/C/005266/R/0019	32
9.1.7.	Regkirona – Regdanvimab – EMEA/H/C/005854	32
9.1.8.	Trixeo Aerosphere - Formoterol / Glycopyrronium bromide / Budesonide - EMA/R/0000245136	33
9.1.9.	Zostavax - shingles (herpes zoster) vaccine (live) EMEA/H/C/000674	33

10. Referral procedures 33

10.1.	Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004	33
10.2.	Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 .	33
10.3.	Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004	33

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	33
10.5.	Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC....	34
10.6.	Community Interests - Referral under Article 31 of Directive 2001/83/EC	34
10.7.	Re-examination Procedure under Article 32(4) of Directive 2001/83/EC.....	34
10.8.	Procedure under Article 107(2) of Directive 2001/83/EC	34
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	34
10.10.	Procedure under Article 29 of Regulation (EC) 1901/2006.....	34
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	34
11.	Pharmacovigilance issue	34
11.1.	Early Notification System	34
12.	Inspections	35
12.1.	GMP inspections	35
12.2.	GCP inspections.....	35
12.3.	Pharmacovigilance inspections.....	35
12.4.	GLP inspections	35
13.	Innovation Task Force	35
13.1.	Minutes of Innovation Task Force.....	35
13.2.	Innovation Task Force briefing meetings.....	35
13.3.	Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004	35
13.4.	Nanomedicines activities	35
14.	Organisational, regulatory and methodological matters	36
14.1.	Mandate and organisation of the CHMP	36
14.1.1.	Vote by Proxy	36
14.1.2.	CHMP membership.....	36
14.1.3.	Strategic Review and Learning Meeting	36
14.2.	Coordination with EMA Scientific Committees.....	36
14.2.1.	Pharmacovigilance Risk Assessment Committee (PRAC)	36
14.2.2.	Paediatric Committee (PDCO).....	36
14.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	36
14.3.1.	Biologics Working Party (BWP)	36
14.3.2.	Name Review Group (NRG).....	37
14.3.3.	Scientific Advice Working Party (SAWP).....	37

14.3.4.	Election of a new Non-Clinical Working Party (NcWP) Chair and Vice-Chair	37
14.3.5.	Election of a new Central Nervous System Working Party (CNSWP) Chair	37
14.3.6.	Election of a new Vaccines Working Party (VWP) Chair	37
14.3.7.	Election of a new Cardiovascular Working Party (CVSWP) Chair	37
14.3.8.	Election of a new Infectious Disease Working Party (IDWP) Chair	38
14.4.	Cooperation within the EU regulatory network.....	38
14.5.	Cooperation with International Regulators.....	38
14.6.	Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee.....	38
14.7.	CHMP work plan	38
14.8.	Planning and reporting	38
14.9.	Others	38
15.	Any other business	38
15.1.	AOB topic.....	38
15.1.1.	GIREX rules	38
Explanatory notes		39

1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 22-25 April 2025. See April 2025 CHMP minutes (to be published post May 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 22-25 April 2025

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 14 April 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

treatment of myopia in children aged 3 years and older

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2025 at 16:00

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

2.1.2. 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: Oral explanation

Action: Oral explanation to be held on 24 April 2025 at 16:00

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

2.1.3. Nirogacestat - Orphan - EMEA/H/C/006071

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: Oral explanation

Action: Oral explanation to be held on 22 April 2025 at 16:00

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 27.06.2024.

2.1.4. Teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2025 at 11:00

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 09.11.2023.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 17.10.2024.

3.1.3. Trastuzumab - EMEA/H/C/006219

treatment of metastatic and early breast cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 30.05.2024.

3.1.4. Denosumab - EMEA/H/C/006199

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.5. Denosumab - EMEA/H/C/006526

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 12.12.2024.

3.1.6. Diflunisal - Orphan - EMEA/H/C/006248

AO Pharma AB; Treatment of ATTR amyloidosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 30.05.2024.

3.1.7. Givinostat - Orphan - EMEA/H/C/006079

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024, 19.09.2024. List of Questions adopted on 14.12.2023.

3.1.8. Denosumab - EMEA/H/C/006376

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.9. Denosumab - EMEA/H/C/006152

for the treatment of osteoporosis and bone loss.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.10. Denosumab - EMEA/H/C/006436

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Questions adopted on 14.11.2024.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 27.06.2024.

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

Camurus AB; treatment of acromegaly

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.14. Teprotumumab - EMEA/H/C/006396

treatment of moderate to severe Thyroid Eye Disease (TED)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.15. Denosumab - EMEA/H/C/006534

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 12.12.2024.

3.1.16. Clascoterone - EMEA/H/C/006138

indicated for the topical treatment of acne vulgaris in adults and adolescents

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025, 12.12.2024, 17.10.2024. List of Questions adopted on 22.02.2024.

3.1.17. Denosumab - EMEA/H/C/006437

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: Opinion

Action: For adoption

List of Questions adopted on 14.11.2024.

3.1.18. Denosumab - EMEA/H/C/006377

for the treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

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

Jazz Pharmaceuticals Ireland Limited; Treatment of biliary tract cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 17.10.2024.

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

3.2.1. Aflibercept - EMEA/H/C/006438

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2024.

3.2.2. Aflibercept - EMEA/H/C/006761

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

Scope: List of outstanding issues

Action: For adoption

3.2.3. [Belantamab mafodotin - Orphan - EMEA/H/C/006511](#)

Glaxosmithkline Trading Services Limited; treatment of multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

3.2.4. [Delandistrogene moxeparvovec - Orphan - ATMP - EMEA/H/C/005293](#)

Roche Registration GmbH; treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

Scope: List of outstanding issues

Action: For information

List of Outstanding Issues adopted on 16.04.2025. List of Questions adopted on 11.10.2024.

3.2.5. [Emtricitabine / Rilpivirine / Tenofovir alafenamide - EMEA/H/C/006491](#)

treatment of HIV-1

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

3.2.6. [Aflibercept - EMEA/H/C/006282](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

3.2.7. [Mirdametinib - Orphan - EMEA/H/C/006460](#)

Springworks Therapeutics Ireland Limited; treatment of neurofibromatosis type 1

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2024.

3.2.8. [Ustekinumab - EMEA/H/C/006467](#)

treatment of plaque psoriasis, arthritis psoriatic, Crohn's Disease and ulcerative colitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

3.2.9. Macitentan - EMEA/H/C/006524

treatment of pulmonary arterial hypertension (PAH)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.10. Macitentan - EMEA/H/C/006523

treatment of pulmonary arterial hypertension (PAH)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.11. Nintedanib - EMEA/H/C/006486

treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

3.2.12. Vimseltinib - Orphan - EMEA/H/C/006363

Deciphera Pharmaceuticals (Netherlands) B.V.; Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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

3.3.1. Nadofaragene firadenovec - ATMP - EMEA/H/C/005856

treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

Scope: List of questions

Action: For adoption

3.3.2. [Blarcamesine - EMEA/H/C/006475](#)

treatment of Alzheimer's disease and dementia

Scope: List of questions

Action: For adoption

3.3.3. [Donidalorsen - Orphan - EMEA/H/C/006554](#)

Otsuka Pharmaceutical Netherlands B.V.; for routine prevention of recurrent attacks of hereditary angioedema (HAE)

Scope: List of questions

Action: For adoption

3.3.4. [Iloperidone - EMEA/H/C/006561](#)

treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder

Scope: List of questions

Action: For adoption

3.3.5. [Germanium \(68Ge\) chloride / Gallium \(68Ga\) chloride - EMEA/H/C/006639](#)

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

Scope: List of questions

Action: For adoption

3.3.6. [Eflornithine - Orphan - EMEA/H/C/006067](#)

Norgine B.V.; treatment of high-risk neuroblastoma responsive to prior multiagent, multimodality therapy

Scope: List of questions

Action: For adoption

3.3.7. [Imlunestrant - EMEA/H/C/006184](#)

treatment of adult patients with advanced or metastatic breast cancer

Scope: List of questions

Action: For adoption

3.3.8. mRNA-1283 - EMEA/H/C/006428

Active immunisation to prevent COVID 19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Scope: List of questions

Action: For adoption

3.3.9. Aficamten - EMEA/H/C/006228

treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adult patients

Scope: List of questions

Action: For adoption

3.3.10. Denosumab - EMEA/H/C/006492

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients.

Scope: List of questions

Action: For adoption

3.3.11. Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - Orphan - ATMP - EMEA/H/C/006525

Fondazione Telethon Ets; treatment of patients with Wiskott-Aldrich Syndrome (WAS)

Scope: List of questions

Action: For information

3.4. Update on on-going initial applications for Centralised procedure

3.4.1. ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304

indicated as active booster immunization against pertussis of persons aged 11 years onwards and passive protection against pertussis in early infancy following maternal immunization during pregnancy

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

Action: For adoption

List of Questions adopted on 14.11.2024.

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

3.5.1. Kisunla - Donanemab - EMEA/H/C/006024

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

Scope: Appointment of re-examination rapporteurs.

Action: For adoption

Opinion adopted on 27.03.2025. List of Outstanding Issues adopted on 12.12.2024, 25.04.2024. List of Questions adopted on 14.12.2023.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. 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 Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 17.10.2024.

4.1.2. Brukinsa - Zanubrutinib - EMEA/H/C/004978/X/0023

BeiGene Ireland Ltd;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (160 mg film-coated tablets)."

Action: For adoption

List of Questions adopted on 14.11.2024.

4.1.3. Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/X/0033/G

Bayer AG;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to add a new strength of Jivi 4000 UI powder and solvent for solution for injection for treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency).

Version 3.1 of the RMP has also been submitted.

In addition, the MAH has taken the opportunity to align the product information with the pre-specified language from the updated EC Excipient Guideline.

Action: For adoption

List of Questions adopted on 30.01.2025.

4.1.4. 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

List of Questions adopted on 27.02.2025.

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

No items

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. Koselugo - Selumetinib - Orphan - EMEA/H/C/005244/X/0018/G

AstraZeneca AB;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new pharmaceutical form (Granules in capsules for opening) associated with new strengths (5 mg and 7.5 mg capsule) grouped with a Type II variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to align the SmPC and labelling of Koselugo capsules and Koselugo granules in capsules for opening. The Package Leaflet and Labelling are updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

4.3.2. Lunsumio - Mosunetuzumab - Orphan - EMEA/H/C/005680/X/0015

Roche Registration GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (5 mg and 45 mg) and new route of administration (subcutaneous use).

The RMP (version 3.0) is updated in accordance."

Action: For adoption

4.3.3. Remsima - Infliximab - EMEA/H/C/002576/X/0149

Celltrion Healthcare Hungary Kft.;

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

Scope: "Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion) associated with a new strength (40 mg/ml)."

Action: For adoption

4.3.4. Spinraza - Nusinersen - Orphan - EMEA/H/C/004312/X/0038

Biogen Netherlands B.V.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Karin Bolin

Scope: "Extension application to add a new strength of 28 mg and 50 mg.

The RMP (version 12.x) is updated in accordance (version 12.2 is under assessment in procedure EMEA/H/C/004312/II/0034/G)."

Action: For adoption

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. ADCETRIS - Brentuximab vedotin - EMEA/H/C/002455/II/0111

Takeda Pharma A/S;

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

Scope: "Extension of indication for ADCETRIS to include treatment for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD), based on final results from phase 3 study HD21 (NCT02661503). This study is titled Treatment Optimization Trial in the First-Line Treatment of Advanced-Stage Hodgkin Lymphoma; Comparison of 4-6 Cycles of Escalated BEACOPP With 4-6 Cycles of BrECADD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 20.0 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 and to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 25.07.2024.

5.1.2. Alhemo – Concizumab - EMA/VR/0000244862

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt; Co-Rapporteur: Daniela Philadelphia

Scope: Extension of indication to include treatment of haemophilia A without inhibitors and haemophilia B without inhibitors for ALHEMO based on final results from study NN7415-4307; this is an interventional study to investigate efficacy and safety of concizumab prophylaxis in patients with haemophilia A or B without inhibitors. 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 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.

Action: For adoption

5.1.3. Amvuttra - Vutrisiran - Orphan - EMEA/H/C/005852/II/0015

Alnylam Netherlands B.V.;

Rapporteur: Janet Koenig, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include treatment of wild-type or hereditary transthyretin-mediated amyloidosis in adult patients with cardiomyopathy (ATTR-CM), based on primary analysis results from study HELIOS-B (ALN-TTRSC02-003); a Phase 3, Randomized, Double-blind, Placebo-controlled, Multicentre Study to Evaluate the Efficacy and Safety of Vutrisiran in Patients With Transthyretin Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. An updated version 1.3 of the RMP has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004).

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

5.1.4. BAQSIMI – Glucagon - EMA/VR/0000244909

Amphastar France Pharmaceuticals;

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Eamon O Murchu

Scope: Extension of indication to include treatment of severe hypoglycaemia in paediatric patients aged 1 and over with diabetes mellitus for BAQSIMI, based on final results from study I8R-MC-IGBO; this is an Open-Label, Multi-Centre, Single-Dose Study to Assess the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of Nasal Glucagon in Paediatric Patients with Type 1 Diabetes Aged 1 to <4 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 1.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce a correction in the Package Leaflet.

Action: For adoption

5.1.5. Calquence - Acalabrutinib - EMEA/H/C/005299/II/0028

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include CALQUENCE in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL), based on interim results from study AMPLIFY (D8221C00001). This is a Randomized, Multicentre, Open-Label, Phase 3 Study to Compare the Efficacy and Safety of Acalabrutinib in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukaemia Without del(17p) or TP53 Mutation

(AMPLIFY). 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 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

5.1.6. Clopidogrel Zentiva - Clopidogrel - EMEA/H/C/000975/II/0092

Zentiva k.s.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Carla Torre

Scope: “Extension of indication to include, in combination with acetylsalicylic acid (ASA), patients with ST segment elevation acute myocardial infarction (STEMI) who are undergoing percutaneous coronary intervention (PCI) for CLOPIDOGREL ZENTIVA. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. Version 0.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, introduce minor editorial changes to the PI and bring it in line with the latest QRD template version 10.4.”

Action: For adoption

5.1.7. Cystadrops - Mercaptamine - Orphan - EMEA/H/C/003769/II/0032

Recordati Rare Diseases;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon

Scope: “Extension of indication to include treatment of children from 6 months of age for CYSTADROPS, based on final results from study CYT-C2-001. This is an Open-label, Single-arm, Multicentre Study to Assess the Safety of Cystadrops in Paediatric Cystinosis Patients from 6 Months to Less Than 2 Years Old. 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 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI and the list of local representatives in the Package Leaflet.”

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

5.1.8. Gazyvaro – Obinutuzumab - EMA/VR/0000244907

Roche Registration GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with active lupus nephritis who are receiving standard therapy for GAZYVARO, based on results from study Regency (CA41705). This is an ongoing, Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of obinutuzumab administered at standard infusion rates in patients with ISN/RPS 2003 Class III or IV lupus nephritis treated with standard-of-care therapy.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 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.

Action: For adoption

5.1.9. [Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040](#)

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought 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

Request for Supplementary Information adopted on 30.01.2025.

5.1.10. [Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0092](#)

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include IMBRUVICA in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for autologous stem cell transplantation (ASCT), based on results from study MCL3003. This is a randomized, 3-arm, parallel-group, open-label, international, multicentre Phase 3 study. The purpose of Study MCL3003 is to compare 3 alternating courses of R CHOP/R-DHAP followed by ASCT (control Arm A), versus the combination with ibrutinib in induction and maintenance (experimental Arm A+I), or the experimental arm without ASCT (experimental Arm I) in participants with previously untreated MCL who are eligible for ASCT. Consequently, 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 update the list of local representatives in the Package Leaflet. Version 23.1 of the RMP has also been submitted."

Action: For adoption

5.1.11. [Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/II/0034](#)

Bayer AG;

Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment and prophylaxis of bleeding in previously treated patients ≥ 7 years of age with haemophilia A for JIVI, based on integrated analysis results from Part A of the Alfa-PROTECT study (21824) and PROTECT Kids main study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe haemophilia A. PROTECT Kids is a multi-centre, Phase 3, non-controlled, open-label trial to evaluate the pharmacokinetics, safety, and efficacy of BAY 94-9027 for prophylaxis and treatment of bleeding in previously treated children (age <12 years) with severe haemophilia A. 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 3.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

5.1.12. Keytruda – Pembrolizumab - EMA/VR/0000245108

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, KEYTRUDA as monotherapy, for the treatment of resectable locally advanced head and neck squamous cell carcinoma (HNSCC) as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without platinum-containing chemotherapy and then as monotherapy in adults, based on the results of study P689V01MK3475 (KEYNOTE-689); this is a Phase 3, randomised, open-label study evaluating pembrolizumab as neoadjuvant therapy and in combination with standard of care as adjuvant therapy for stage III or IVA, resectable, locoregionally advanced head and neck squamous cell carcinoma. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 48.1 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the PI.

Action: For adoption

5.1.13. Koselugo – Selumetinib - EMA/VR/0000245231

AstraZeneca AB;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication for KOSELUGO to include treatment of adults based on results from study D134BC00001 (KOMET). This is a phase III, multicentre, international study with a parallel, randomised, double-blind, placebo-controlled, 2 arm design that assesses efficacy and safety of selumetinib in adult participants with NF1 who have Symptomatic Inoperable Plexiform Neurofibromas.

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 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.14. Neuraceq - Florbetaben (18F) - EMA/VR/0000227744

Life Molecular Imaging GmbH;

Rapporteur: Antonio Gomez-Outes; PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include monitoring of the biological treatment response to pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet (PL) is updated in accordance. Version 6.91 of the RMP has also been submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package.

Action: For adoption

5.1.15. Norvir – Ritonavir - EMA/VR/0000249795

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Patrick Vrijlandt; PRAC Rapporteur: Liana Martirosyan

Scope: Type II (C.I.6.a): To modify the approved therapeutic indication to reflect current clinical use as a pharmacokinetic enhancer of other antiretroviral products only. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8 and 5.1 of the SmPC. The Package Leaflet is updated accordingly. The updated RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.1.16. Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0061/G

Pfizer Europe MA EEIG;

Rapporteur: Jean-Michel Race (FR) (MNAT with DE-BfArM for Quality), Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Martin Huber

Scope: "A grouped application comprised of a Type II Variation and a Type IB Variation, as follows:

Type II (C.I.6.a): Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 years of age and older weighing at least 20 kg for PAXLOVID, based on the final analysis of Cohorts 1 and 2 from pivotal Study C4671026; this is a Phase 2/3, Interventional Safety, Pharmacokinetics, and Efficacy, Open-Label, Multi-Centre, Single-Arm Study to Investigate Orally Administered PF 07321332 (Nirmatrelvir)/Ritonavir in Nonhospitalized Symptomatic Paediatric Participants With COVID-19 Who Are at Risk of Progression to Severe 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 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation

holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Type IB (B.II.e.5.a.2): To add a new pack-size specific to paediatric patients 6 years and older weighing 20 kg to less than 40 kg and moderate renal impaired patients (EU/1/22/1625/003); the Package Leaflet and Labelling are updated accordingly.”

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

Action: For adoption

5.1.17. Revolade - Eltrombopag - EMEA/H/C/001110/II/0077

Novartis Europharm Limited;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo

Scope: “Extension of indication to include second-line treatment of paediatric patients aged 2 years and above with acquired severe aplastic anaemia (SAA) for REVOLADE based on the ETB115E2201 (E2201) study primary analysis results; this is a paediatric phase II, open-label, uncontrolled, intra-patient dose escalation study to characterise the pharmacokinetics after oral administration of eltrombopag in paediatric patients with refractory, relapsed severe aplastic anaemia or recurrent aplastic anaemia. 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 56.0 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 12.12.2024.

5.1.18. Simponi - Golimumab - EMEA/H/C/000992/II/0121

Janssen Biologics B.V.;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin

Scope: “Extension of indication to include treatment of paediatric ulcerative colitis for SIMPONI, based on results from study CNTO148UCO3003; this is a Phase 3 Randomized, Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Golimumab Treatment, a Human anti-TNF α Monoclonal Antibody, Administered Subcutaneously in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. Version 28.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is updated in accordance with the latest EMA excipients guideline and aligned with the latest QRD template version 10.4.”

Action: For adoption

5.1.19. TEZSPIRE – Tezepelumab - EMA/VR/0000245013

AstraZeneca AB;

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

Scope: Extension of indication to include treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Tezspire, based on results from study WAYPOINT (D5242C00001); this is a global, multicentre, randomised, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy and safety of tezepelumab compared with placebo in the treatment of CRSwNP. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI and the Package Leaflet in accordance with the latest EMA excipients guideline.

Action: For adoption

5.1.20. Veklury - Remdesivir - EMEA/H/C/005622/II/0053/G

Gilead Sciences Ireland UC;

Rapporteur: Janet Koenig (DE) (MNAT with AT for Quality), PRAC Rapporteur: Eva Jirsová

Scope: "Grouped application comprising two extensions of indication to include treatment of paediatric patients weighing at least 1.5 kg for VEKLURY, based on final results from study GS-US-540-5823; this is a Phase 2/3 single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of remdesivir in participants from birth to < 18 years of age with COVID-19; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 21.03.2024.

5.1.21. Vyvgart - Efgartigimod alfa - Orphan - EMEA/H/C/005849/II/0020

Argenx;

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

Scope: "Extension of indication to include the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) with active disease despite treatment with corticosteroids or immunoglobulins for VYVGART, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP); and based on interim results from study ARGX-113-1902; this is an open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with (CIDP). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC has been updated. The Package Leaflet has been updated in accordance with the SmPC. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 19.09.2024.

5.1.22. 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 27.02.2025, 17.10.2024.

5.1.23. Zoonotic Influenza Vaccine Seqirus - Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted) - EMA/VR/0000249071

Seqirus S.r.l.;

Rapporteur: Maria Grazia Evandri, PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of individuals 6 months of age and above for Zoonotic Influenza Vaccine Seqirus based on final results from study V87_30. This is a Phase 2, Randomized, Observer-Blind, Multicentre Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Paediatric Subjects 6 Months to < 9 Years of Age. As a consequence, sections 4.1, 4.2, 4.6, 4.7, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the PI.

Action: For adoption

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

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

Ex vivo heart perfusion

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 14.11.2024.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Lurbinectedin – H0006673

Lurbinectedin, in combination with atezolizumab, is indicated for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab, carboplatin and

etoposide.

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

Action: For adoption

8.1.2. Nerandomilast – H0006405

is indicated for the treatment of adult patients with Idiopathic Pulmonary Fibrosis (IPF) and for the treatment of adult patients with Progressive Pulmonary Fibrosis (PPF).

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

Action: For adoption

8.2. Priority Medicines (PRIME)

Information related to priority medicines cannot be released at present time as these contain commercially confidential information.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Extavia (SRD) - Interferon beta-1B – EMEA/H/C/000933

Novartis Europharm Limited; treatment of single demyelinating events and multiple sclerosis

Rapporteur: Janet Koenig, Co-Rapporteur: Elita Poplavska

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.2. Eylea – Aflibercept - EMA/VR/0000249440

Bayer AG;

Rapporteur: Jean-Michel Race

Scope: Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update the posology recommendations for indications nAMD and DME and update clinical information based on the final week 156 results from studies PULSAR and PHOTON. PULSAR (20968) was a pivotal Phase 3 study to investigate the efficacy and safety of high dose aflibercept in patients with neovascular age-related macular degeneration (nAMD). PHOTON (21091) was a pivotal Phase 2/3 study to investigate the efficacy and safety of high dose aflibercept in patients with Diabetic Macular Edema (DME). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI.

Action: For adoption

9.1.3. Kymriah – Tisagenlecleucel - EMA/VR/0000248534

Novartis Europharm Limited;

CAT Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Submission of the interim report from study CCTL019H2301 / BELINDA, including final overall survival results, listed as an obligation in the Annex II of the Product Information. This is an open label, phase III PAES of Kymriah versus standard of care in adult patients with relapsed or refractory aggressive B cell non-Hodgkin lymphoma. The Annex II is updated accordingly.

Action: For adoption

9.1.4. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/S/0019

Mirum Pharmaceuticals International B.V.,

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment for products authorised under exceptional circumstances

Action: For adoption

9.1.5. Omidria - Phenylephrine / Ketorolac - EMEA/H/C/003702/R/0030

Rayner Surgical (Ireland) Limited

Rapporteur: Jayne Crowe, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Jan Neuhauser

Scope: Renewal of marketing authorisation for unlimited validity

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025.

9.1.6. 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.

9.1.7. Regkirona – Regdanvimab – EMEA/H/C/005854

Celltrion Healthcare Hungary Kft.; treatment of Covid 19

Rapporteur: Filip Josephson, Co-Rapporteur: Jan Mueller-Berghaus

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.8. [Trixeo Aerosphere - Formoterol / Glycopyrronium bromide / Budesonide - EMA/R/0000245136](#)

AstraZeneca AB;

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

Scope: Renewal of marketing authorisation for unlimited validity

Action: For adoption

9.1.9. [Zostavax - shingles \(herpes zoster\) vaccine \(live\) EMEA/H/C/000674](#)

Merck Sharp & Dohme B.V.; prevention of herpes zoster and herpes zoster-related post-herpetic neuralgia (PHN)

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Outi Mäki-Ikola

Scope: Withdrawal of marketing authorisation

Action: For information

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

April 2025 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For 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

14.1.3. Strategic Review and Learning Meeting

Agenda of the upcoming SRLM meeting in Poland.

CHMP: Ewa Balkowiec Iskra

Action: For information

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for April 2025.

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at April 2025 PDCO.

Action: For information

Agenda of the PDCO meeting held on 22-25 April 2025.

Action: For 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

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 08-09 April 2025.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 07-10 April 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.

14.3.4. Election of a new Non-Clinical Working Party (NcWP) Chair and Vice-Chair

Election of new NcWP Chair and Vice-Chair. The mandate of the NcWP Chair Susanne Brendler-Schwaab expires on 21 April 2025. The mandate of the NcWP Vice-Chair Karen van Malderen expires on 21 April 2025.

Action: For election

Nomination(s) received for the Chair position

Nomination(s) received for the Vice-Chair position

14.3.5. Election of a new Central Nervous System Working Party (CNSWP) Chair

Election of new CNSWP Chair. The mandate of the CNSWP Chair Andre Elferink will expire on 21 April 2025.

Action: For election

Nomination(s) received

14.3.6. Election of a new Vaccines Working Party (VWP) Chair

Election of new VWP Chair. The mandate of the VWP Chair Mair Powell will expire on 21 April 2025.

Action: For election

Nomination(s) received

14.3.7. Election of a new Cardiovascular Working Party (CVSWP) Chair

Election of new CVSWP Chair and Vice-Chair. The mandate of the CVSWP Chair Alar Irs will expire on 22 April 2025 and the mandate of the vice-chair Patrick Vrijlandt will expire on 19 May 2025.

Action: For election

Nomination(s) received

14.3.8. Election of a new Infectious Disease Working Party (IDWP) Chair

Election of new IDWP Chair. The mandate of the IDWP Chair Maria Jesus Fernandez Cortizo will expire on 18 May 2025.

Action: For election

Nomination(s) received

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

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Analysis of requests for clock-stop extensions and feedback from GIREX.

Action: For discussion

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/



22 April 2025
EMA/CHMP/115343/2025

Annex to 22-25 April 2025 CHMP Agenda

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.....	3
B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal	3
B.2.2. Renewals of Marketing Authorisations for unlimited validity.....	3
B.2.3. Renewals of Conditional Marketing Authorisations.....	4
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES.....	4
B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES	6
B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects	6
B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects.....	9
B.5.3. CHMP-PRAC assessed procedures	14
B.5.4. PRAC assessed procedures.....	17
B.5.5. CHMP-CAT assessed procedures	21
B.5.6. CHMP-PRAC-CAT assessed procedures	21
B.5.7. PRAC assessed ATMP procedures	21
B.5.8. Unclassified procedures and worksharing procedures of type I variations.....	22
B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION	22
D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given	



month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)	22
E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES	22
E.1. PMF Certification Dossiers	22
E.2. Time Tables – starting & ongoing procedures: For information	22
F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver	22
G. ANNEX G	22
G.1. Final Scientific Advice (Reports and Scientific Advice letters):	22
G.2. PRIME.....	22

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for
April 2025: **For adoption**

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

Final Outcome of Rapporteurship allocation for
April 2025: **For adoption**

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Ceplene - Histamine dihydrochloride - EMA/H/C/000796/S/0049

Laboratoires Delbert, Rapporteur: Jayne Crowe,
PRAC Rapporteur: Eamon O Murchu

Livmarli - Maralixibat - See 9.1 EMA/H/C/005857/S/0019, Orphan

Mirum Pharmaceuticals International B.V.,
Rapporteur: Janet Koenig, PRAC Rapporteur:
Adam Przybylkowski

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

Aybintio - Bevacizumab - EMA/H/C/005106/R/0022

Samsung Bioepis NL B.V., Rapporteur: Christian
Gartner, Co-Rapporteur: Beata Maria Jakline
Ullrich, PRAC Rapporteur: Karin Ernehalm
Request for Supplementary Information adopted
on 27.02.2025.

Omidria - Phenylephrine / Ketorolac - See 9.1 EMA/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.

**Raxone - Idebenone -
EMA/H/C/003834/R/0043, Orphan**

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

B.2.3. Renewals of Conditional Marketing Authorisations

Pemazyre - Pemigatinib - See 9.1
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 12.12.2024.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at
the PRAC meeting held on 07-10 April 2025
PRAC:

**Signal of hyperammonaemia,
hyperammonaemic encephalopathy**

Regorafenib – STIVARGA (CAP)

Rapporteur: Peter Mol, Co-Rapporteur: Paolo
Gasparini, PRAC Rapporteur: Bianca Mulder
PRAC recommendation for variation

Action: For adoption

PSUR procedures for which PRAC adopted a
recommendation for variation of the terms of
the MA at its April 2025 meeting:

EMA/H/C/PSUSA/00000107/202409

(epcoritamab)

CAPS:

Topkinly (EMA/H/C/005985) (Epcoritamab),
AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Peter Mol, PRAC Rapporteur: Monica
Martinez Redondo, "22/03/2024 To:
21/09/2024"

EMA/H/C/PSUSA/00001936/202409

(measles / mumps / rubella / varicella vaccines
(live))

CAPS:

ProQuad (EMA/H/C/000622) (Measles,
mumps, rubella and varicella vaccine (live)),
Merck Sharp & Dohme B.V., Rapporteur: Jan

Mueller-Berghaus

NAPS:

NAPS - Europa

PRAC Rapporteur: Gabriele Maurer, "05/09/2021

To: 05/09/2024"

EMA/H/C/PSUSA/00010113/202408

(loxapine (pre-dispensed inhalation powder))

CAPS:

Adasuve (EMA/H/C/002400) (Loxapine),
Ferrer Internacional s.a., Rapporteur: Peter Mol,
PRAC Rapporteur: Liana Martirosyan,
"20/08/2021 To: 20/08/2024"

EMA/H/C/PSUSA/00010366/202409

(naltrexone / bupropion)

CAPS:

Mysimba (EMA/H/C/003687) (Naltrexone
hydrochloride / Bupropion hydrochloride),
Orexigen Therapeutics Ireland Limited,
Rapporteur: Kristina Dunder, PRAC Rapporteur:
Martin Huber, "09/09/2023 To: 09/09/2024"

EMA/H/C/PSUSA/00010403/202409

(pembrolizumab)

CAPS:

Keytruda (EMA/H/C/003820)
(Pembrolizumab), Merck Sharp & Dohme B.V.,
Rapporteur: Paolo Gasparini, PRAC Rapporteur:
Bianca Mulder, "03/09/2023 To: 03/09/2024"

EMA/H/C/PSUSA/00010426/202409

(isavuconazole)

CAPS:

Cresemba (EMA/H/C/002734)
(Isavuconazole), Basilea Pharmaceutica
Deutschland GmbH, Rapporteur: Patrick
Vrijlandt, PRAC Rapporteur: Adam
Przybylkowski, "06/09/2021 To: 06/09/2024"

EMA/H/C/PSUSA/00010920/202408

(somapacitan)

CAPS:

Sogroya (EMA/H/C/005030) (Somapacitan),
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,
PRAC Rapporteur: Martin Huber, "01/09/2023
To: 31/08/2024"

EMA/H/C/PSUSA/00010976/202409

(abrocitinib)

CAPS:

Cibinqo (EMA/H/C/005452) (Abrocitinib),
Pfizer Europe MA EEIG, Rapporteur: Kristina

Dunder, PRAC Rapporteur: Petar Mas,
"08/03/2024 To: 07/09/2024"

EMA/H/C/PSUSA/00011018/202409

(nivolumab / relatlimab)

CAPS:

Opdualag (EMA/H/C/005481) (Nivolumab /
Relatlimab), Bristol-Myers Squibb Pharma EEIG,
Rapporteur: Peter Mol, PRAC Rapporteur:
Gabriele Maurer, "18/03/2024 To: 17/09/2024"

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

Advate - Octocog alfa -

EMA/H/C/000520/II/0124

Takeda Manufacturing Austria AG, Rapporteur:
Jan Mueller-Berghaus

Opinion adopted on 03.04.2025.

Request for Supplementary Information adopted
on 13.02.2025.

Positive Opinion adopted by consensus on
03.04.2025.

Alprolix - Eftrenonacog alfa -

EMA/H/C/004142/II/0048, Orphan

Swedish Orphan Biovitrum AB (publ),

Rapporteur: Daniela Philadelphly

Request for Supplementary Information adopted
on 23.01.2025.

**CooperSurgical Inc ART Media - Human
albumin solution -**

EMA/H/D/002307/II/0012

Coopersurgical Inc., Rapporteur: Kristina
Dunder

Request for Supplementary Information adopted
on 20.02.2025.

GONAL-f - Follitropin alfa -

EMA/H/C/000071/II/0177/G

Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Request for Supplementary Information adopted
on 20.02.2025.

Hizentra - Human normal immunoglobulin -

EMA/H/C/002127/II/0163

CSL Behring GmbH, Rapporteur: Jan Mueller-
Berghaus

Request for Supplementary Information adopted

on 13.02.2025.

**HyQvia - Human normal immunoglobulin -
EMA/H/C/002491/II/0101**

Baxalta Innovations GmbH, Rapporteur: Jan
Mueller-Berghaus

Opinion adopted on 03.04.2025.

Request for Supplementary Information adopted
on 10.10.2024.

Positive Opinion adopted by consensus on
03.04.2025.

**KIMMTRAK - Tebentafusp -
EMA/H/C/004929/II/0009/G, Orphan**

Immunocore Ireland Limited, Rapporteur: Boje
Kvorning Pires Ehmsen

Opinion adopted on 03.04.2025.

Request for Supplementary Information adopted
on 19.12.2024.

Positive Opinion adopted by consensus on
03.04.2025.

**Lamzede - Velmanase alfa -
EMA/H/C/003922/II/0040/G, Orphan**

Chiesi Farmaceutici S.p.A., Rapporteur: Patrick
Vrijlandt

Opinion adopted on 10.04.2025.

Request for Supplementary Information adopted
on 20.02.2025.

Positive Opinion adopted by consensus on
10.04.2025.

**LifeGlobal Media - Human albumin solution
- EMA/H/D/004287/II/0009**

Coopersurgical Inc., Rapporteur: Maria Grazia
Evandri

Request for Supplementary Information adopted
on 20.02.2025.

**Origio - Human albumin solution -
EMA/H/D/000830/II/0021**

Coopersurgical Inc., Rapporteur: Jayne Crowe

Request for Supplementary Information adopted
on 20.02.2025.

**Otulfi - Ustekinumab -
EMA/H/C/006544/II/0001/G**

Fresenius Kabi Deutschland GmbH, Duplicate of
Fymaska, Rapporteur: Jayne Crowe, PRAC

Rapporteur: Rhea Fitzgerald

Opinion adopted on 10.04.2025.

Request for Supplementary Information adopted
on 16.01.2025.

Positive Opinion adopted by consensus on
10.04.2025.

**Ozempic - Semaglutide -
EMA/H/C/004174/II/0051**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

Opinion adopted on 10.04.2025.

Request for Supplementary Information adopted

Positive Opinion adopted by consensus on
10.04.2025.

on 13.02.2025.

**Pombiliti - Cipaglucosidase alfa -
EMA/H/C/005703/II/0019**

Amicus Therapeutics Europe Limited,
Rapporteur: Patrick Vrijlandt

**Prevenar 20 - Pneumococcal
polysaccharide conjugate vaccine (20-
valent, adsorbed) -**

EMA/H/C/005451/II/0031/G

Pfizer Europe MA EEIG, Rapporteur: Daniela
Philadelphia

Request for Supplementary Information adopted
on 16.01.2025.

**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.

**Roclanda - Latanoprost / Netarsudil -
EMA/H/C/005107/II/0031/G**

Santen Oy, Rapporteur: Jayne Crowe

Request for Supplementary Information adopted
on 03.04.2025, 13.02.2025.

Request for supplementary information adopted
with a specific timetable.

Skyrizi - Risankizumab -

EMA/H/C/004759/II/0052/G

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Finbarr Leacy

Request for Supplementary Information adopted
on 30.01.2025.

Sondelbay - Teriparatide -

EMA/H/C/005827/II/0008

Accord Healthcare S.L.U., Rapporteur: Finbarr
Leacy

Opinion adopted on 10.04.2025.

Request for Supplementary Information adopted
on 13.02.2025.

Positive Opinion adopted by consensus on
10.04.2025.

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0148/G**

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

Opinion adopted on 03.04.2025.

Request for Supplementary Information adopted
on 23.01.2025.

Positive Opinion adopted by consensus on
03.04.2025.

Tevimbra - Tislelizumab -

EMA/H/C/005919/II/0019/G

Positive Opinion adopted by consensus on
10.04.2025.

Beigene Ireland Limited, Rapporteur: Jan
Mueller-Berghaus
Opinion adopted on 10.04.2025.

**Vazkepa - Icosapent ethyl -
EMA/H/C/005398/II/0028/G**

Amarin Pharmaceuticals Ireland Limited,
Rapporteur: Janet Koenig
Request for Supplementary Information adopted
on 30.01.2025.

**Wegovy - Semaglutide -
EMA/H/C/005422/II/0027**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted
on 13.02.2025.

Positive Opinion adopted by consensus on
10.04.2025.

WS2747/G

**Nuwiq-
EMA/H/C/002813/WS2747/0063/G
Vihuma-
EMA/H/C/004459/WS2747/0045/G**

Octapharma AB, Lead Rapporteur: Jan Mueller-
Berghaus
Request for Supplementary Information adopted
on 23.01.2025, 31.10.2024.

**WS2756
Hexacima-
EMA/H/C/002702/WS2756/0160
Hexyon-
EMA/H/C/002796/WS2756/0164**

Sanofi Winthrop Industrie, Duplicate of
Hexacima, Lead Rapporteur: Jan Mueller-
Berghaus
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted
on 05.12.2024.

Positive Opinion adopted by consensus on
10.04.2025.

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, randomised, double-
blind, placebo-controlled study to evaluate
safety, immunogenicity and efficacy of Abrysvo

Positive Opinion adopted by consensus on
10.04.2025.

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 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 final clinical study report C3671008, which was already submitted under Article 46, and to update the list of local representatives in the Package Leaflet.”

Opinion adopted on 10.04.2025.

Request for Supplementary Information adopted on 27.02.2025, 21.11.2024.

**Beyfortus - Nirsevimab -
EMA/H/C/005304/II/0028**

Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, “Update of sections 4.8 and 5.1 based on primary analysis and first-year analysis results from study VAS00006 (HARMONIE). This is an ongoing phase IIIb randomized open-label study of nirsevimab (versus no intervention) in preventing hospitalizations due to respiratory syncytial virus in infants (under 12 months) in order to determine the efficacy and safety of a single intramuscular (IM) dose of nirsevimab. In addition, the MAH took the opportunity to introduce minor formatting changes.”

Request for Supplementary Information adopted on 30.01.2025.

**Braftovi - Encorafenib -
EMA/H/C/004580/II/0041**

Pierre Fabre Medicament, Rapporteur: Janet Koenig, “Update of sections 4.2, 4.4 and 5.2 of the SmPC to include a dose recommendation for patients with moderate hepatic impairment based on the results of a modelling and simulation study and post-marketing data The Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 12.12.2024.

**Enhertu - Trastuzumab deruxtecan -
EMA/H/C/005124/II/0054**

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

multicentre, 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.”
Request for Supplementary Information adopted on 13.02.2025.

**Fexinidazole Winthrop - Fexinidazole -
EMA/H/W/002320/II/0021**

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 *T.b. gambiense* at any stage.”
Request for Supplementary Information adopted on 27.02.2025.

**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.”
Opinion adopted on 03.04.2025.
Request for Supplementary Information adopted on 27.02.2025.

Positive Opinion adopted by consensus on 03.04.2025.

**Inrebic - Fedratinib -
EMA/H/C/005026/II/0026, Orphan**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, “Update of sections 4.4 and 4.8 of the SmPC in order to add 'Uveitis' to the list of adverse drug reactions (ADRs) with frequency 'common' based on a cumulative safety review. 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 23.01.2025.

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

GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, “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 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**

Positive Opinion adopted by consensus on 03.04.2025.

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 from the multicentre randomised study MK-7264-043 in patients with refractory or unexplained chronic cough and add 'headache' to the list of adverse drug reactions (ADRs) with frequency common. 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."

Opinion adopted on 03.04.2025.

Request for Supplementary Information adopted on 20.02.2025, 05.12.2024, 12.09.2024.

**Mektovi - Binimetinib -
EMA/H/C/004579/II/0034**

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 5.2 of the SmPC to include a dose recommendation for patients with moderate hepatic impairment based on the results of a modelling and simulation study and post-marketing data. The Package Leaflet is updated accordingly."

Request for Supplementary Information adopted on 12.12.2024.

**Phesgo - Pertuzumab / Trastuzumab -
EMA/H/C/005386/II/0027**

Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Update of sections 4.2 and 4.4 of the SmPC in order to update administration instructions based on final results from studies AL42478 and WP42873.

AL42478 is an Expanded Access, Single-Arm, Multicentre Study to Provide At Home Subcutaneous Administration of Pertuzumab and Trastuzumab Fixed-Dose Combination (PH FDC SC) for Patients with HER2-positive Breast

Cancer During the COVID-19 Pandemic.
WP42873 is a randomized, open-label, 2-arm, parallel group, single dose, multi-centre study in healthy male subjects to investigate the comparability of pharmacokinetics of the fixed-dose combination of pertuzumab and trastuzumab administered subcutaneously using a handheld syringe or using the on-body delivery system.

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

Request for Supplementary Information adopted on 30.01.2025.

Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0210

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, “Update of section 4.4 of the SmPC in order to update the existing warning on ‘Aseptic Meningitis Syndrome (AMS)’ to add a class monitoring precaution for recurrent AMS, associated with IVIg treatment, potentially progressing to brain oedema (cerebral oedema). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 16.01.2025.

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0147

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, “Submission of the final report from study mRNA-1273-P205 listed as a category 3 study in the RMP. This is a Phase 2/3 study to evaluate the immunogenicity and safety of Spikevax vaccine boosters for SARS-CoV-2 Variants.”

Opinion adopted on 10.04.2025.

Request for Supplementary Information adopted on 16.01.2025.

Positive Opinion adopted by consensus on 10.04.2025.

Trodelyv - Sacituzumab govitecan - EMEA/H/C/005182/II/0037

Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus, “Update of sections 4.2, 4.4 and 6.6 of the SmPC in order to add information on the timing of fatal infections as well as recommendations on the use of primary

prophylaxis with G-CSF in patients who are at high risk for neutropenia, based on clinical trials data, post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”
Request for Supplementary Information adopted on 30.01.2025.

B.5.3. CHMP-PRAC assessed procedures

Epruvy - Ranibizumab - EMA/H/C/006528/II/0002/G

MIDAS Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted on 16.01.2025.

Positive Opinion adopted by consensus on 10.04.2025.

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

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

Nyxoid - Naloxone - EMA/H/C/004325/II/0019

Mundipharma Corporation (Ireland) Limited, Rapporteur: Paulo Paixão, PRAC Rapporteur: Liana Martirosyan, “Submission of the interim report from the PAES MR903-9501 listed as an obligation in the Annex II, supported by Real World Evidence from literature and European Take-Home Naloxone programs (THN) demonstrating the effectiveness of Nyxoid in a real-world setting. Study MR903-9501 is a non-interventional multi-national, prospective, mixed methods study of the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. The Annex II and the RMP version 3.0 are updated accordingly. In addition, the MAH took the opportunity to introduce minor administrative changes to the Package Leaflet.”
Request for Supplementary Information adopted on 12.12.2024, 25.07.2024.

Ranivisio - Ranibizumab - EMA/H/C/005019/II/0017/G

Midas Pharma GmbH, Rapporteur: Jan Mueller-

Positive Opinion adopted by consensus on 10.04.2025.

Berghaus, PRAC Rapporteur: Karin Bolin
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted
on 16.01.2025.

**Sunlenca - Lenacapavir -
EMA/H/C/005638/II/0022/G**

Gilead Sciences Ireland Unlimited Company,
Rapporteur: Filip Josephson, PRAC Rapporteur:
Ana Sofia Diniz Martins, "Grouping of two type
II variations:

- Update of section 5.1 of the SmPC to include
efficacy and resistance data based on week 156
interim data from Study GS-US-200-4625; a
phase 2/3 study to evaluate the safety and
efficacy of long-acting capsid inhibitor GS-6207
in combination with an optimized background
regimen in heavily treatment experienced
people living with HIV-1 infection with multidrug
resistance (category 3 study in the RMP).
Additionally, upon request by the CHMP
following the assessment of II/0013, the MAH
proposes to update section 4.8 of the SmPC to
include information related to injection site
nodules and induration that were non-resolved
at the end of follow-up.

- Provision of the final study report of Study GS-
US-200-4334: a phase 2 randomized, open
label, active controlled study evaluating the
safety and efficacy of long-acting capsid
inhibitor GS-6207 in combination with other
antiretroviral agents in people living with HIV
(category 3 study in the RMP).

An updated RMP version 2.1 was included as
part of the application."

Request for Supplementary Information adopted
on 10.04.2025, 13.03.2025, 16.01.2025.

Request for supplementary information adopted
with a specific timetable.

**TAKHZYRO - Lanadelumab -
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.

**XALKORI - Crizotinib -
EMA/H/C/002489/II/0084**

Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Submission of the final report from study CRZ-NBALCL listed as a category 3 study in the RMP. This is a phase I/II study to evaluate the adverse effects of ocular toxicity and bone toxicity and impaired bone growth associated with crizotinib in paediatric and young adult patients with recurrent/refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma or neuroblastoma. The RMP version 9.2 is updated accordingly."

Request for Supplementary Information adopted on 10.04.2025, 16.01.2025.

Request for supplementary information adopted with a specific timetable.

**Xenpozyme - Olipudase alfa -
EMA/H/C/004850/II/0012/G, Orphan**

Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "A grouped application consisting of:

C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study DFI12712 ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicentre, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy, safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC.

Request for supplementary information adopted with a specific timetable.

C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted.”
Request for Supplementary Information adopted on 10.04.2025, 16.01.2025, 31.10.2024.

B.5.4. PRAC assessed procedures

PRAC Led

Enbrel - Etanercept -

EMA/H/C/000262/II/0255

Pfizer Europe MA EEIG, PRAC Rapporteur:
Monica Martinez Redondo, PRAC-CHMP liaison:
Antonio Gomez-Outes, “Update of sections 4.2 and 4.4 of the SmPC in order to remove information regarding the Patient Card, based on final results from study B1801309 (BSR Register of Anti-TNF Treated Patients and Prospective Surveillance Study for Adverse Events: Enbrel). This is a non-interventional PASS study listed as a category 3 study in the RMP. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.7 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4.”

Request for Supplementary Information adopted on 10.04.2025, 16.01.2025.

Request for supplementary information adopted with a specific timetable.

PRAC Led

EXJADE - Deferasirox -

EMA/H/C/000670/II/0090

Novartis Europharm Limited, PRAC Rapporteur:
Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, “Update of section 4.2 of the SmPC in order to update information on posology based on the non-interventional study C1CL670A2429 listed as a category 3 study in the RMP. This is a survey to assess physicians’ knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials (EMs).”

Request for Supplementary Information adopted

Request for supplementary information adopted with a specific timetable.

on 10.04.2025, 28.11.2024.

PRAC Led

**Fintepla - Fenfluramine -
EMA/H/C/003933/II/0028, Orphan**

UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of a revised protocol for study EP0218 listed as an obligation in the Annex II of the Product Information. This is a Long-term Registry in approved indications for fenfluramine, with a specific focus on cardiovascular events and growth retardation. The RMP version 4.0 is updated accordingly. In addition, the MAH introduced minor amendments in the targeted follow-up questionnaire for cardiovascular adverse events."

Request for Supplementary Information adopted on 30.01.2025.

PRAC Led

Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) -

EMA/H/W/002300/II/0085/G

GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "A grouped application comprised of two type II variations, as follows:

C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to remove a warning and precaution regarding meningitis and to add effectiveness data based on EPI-MAL-003 study, listed as a category 3 study in the RMP. This is a prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa countries. The Package Leaflet is updated accordingly.

The RMP version 6.1 has been agreed.

C.I.13: Submission of the final report from study MVPE (Malaria Vaccine Pilot Evaluation) listed as a category 3 study in the RMP. This is a observational study in the context of a cluster-randomized pilot implementation in order to assess the feasibility of delivery, safety, and impact on mortality of the RTS,S/AS01E malaria vaccine delivered through the routine

Positive Opinion adopted by consensus on 10.04.2025.

immunization services in Kenya, Malawi, and Ghana over 4 years.”
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted on 13.03.2025, 28.11.2024.

PRAC Led
Nucala - Mepolizumab - EMEA/H/C/003860/II/0071
GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, “Submission of the final report of the Mepolizumab (Nucala) Pregnancy Exposure Study 200870: a “Vaccines and Medications in Pregnancy Safety Studies” (VAMPSS) post marketing surveillance study of Mepolizumab safety in pregnancy, listed as a category 3 study in the RMP. This is a non-interventional study to monitor planned and unplanned pregnancies exposed to mepolizumab and to evaluate the possible teratogenic effect of this medication relative to the pregnancy outcomes of major birth defects, preterm delivery, small for gestational age infants and spontaneous abortion or stillbirth. The RMP version 13.0 has been approved.”
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted on 28.11.2024.

Positive Opinion adopted by consensus on 10.04.2025.

PRAC Led
POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0026, Orphan
Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, “Update of section 4.8 of the SmPC in order to add 'granuloma' to the list of adverse drug reactions (ADRs) with frequency 'unknown', based on post marketing data; the Package Leaflet is updated accordingly.”
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted on 16.01.2025.

Positive Opinion adopted by consensus on 10.04.2025.

PRAC Led
Supemtek Tetra - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0020
Sanofi Winthrop Industrie, PRAC Rapporteur: Zoubida Amimour, PRAC-CHMP liaison: Alexandre Moreau, “Update of section 4.6 of the

Positive Opinion adopted by consensus on 10.04.2025.

SmPC in order to update pregnancy information based on final results from study VAP00007 (non-interventional PASS); this is a Phase IV, observational retrospective post-authorisation, descriptive, safety surveillance study to evaluate the safety of Supemtek Tetra in pregnant women and their offspring exposed during pregnancy or up to 28 days preceding the estimated date of conception and birth and neonatal/infant outcomes in their infants.”
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted on 05.09.2024.

PRAC Led

**Trulicity - Dulaglutide -
EMA/H/C/002825/II/0071**

Eli Lilly Nederland B.V., PRAC Rapporteur:
Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, “Submission of an updated RMP version 8.2 in order to add a medullary thyroid cancer (MTC) database linkage study (Study I8F-MC-B014) as an additional pharmacovigilance activity to evaluate the important potential risk of MTC in patients exposed to long-acting glucagon-like peptide-1 receptor agonist (GLP-1 RA) therapies. In addition, the MAH took the opportunity to include an amendment to Study H9X-MC-B013 due to the removal of the United States data source.”
Opinion adopted on 10.04.2025.
Request for Supplementary Information adopted on 05.09.2024.

Positive Opinion adopted by consensus on 10.04.2025.

PRAC Led

**Zometa - Zoledronic acid -
EMA/H/C/000336/II/0104**

Phoenix Labs Unlimited Company, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, “Submission of an updated RMP version 12.1 in order to update the list of safety concerns and missing information as per the guidance provided in the GVP V-Rev.2 and PSUSA/3149/202308.”
Request for Supplementary Information adopted on 10.04.2025.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**WS2125
Soliris-EMA/H/C/000791/WS2125/0133
Ultomiris-**

EMA/H/C/004954/WS2125/0047

Alexion Europe SAS, Lead PRAC Rapporteur:
Monica Martinez Redondo, PRAC-CHMP liaison:
Antonio Gomez-Outes, "Submission of an updated RMP version 21.0 for SOLIRIS and RMP version 9.0 for ULTOMIRIS in order to revise the controlled distribution additional risk minimisation measures and to add a new post-authorisation safety study (PASS) intended to evaluate the effectiveness of the revised additional risk minimisation measures for minimising the risk of meningococcal infections in the EU, following the PRAC outcome for PSUSA/00001198/202310 for SOLIRIS. The Annex II is updated accordingly. In addition, the MAH introduced minor updates to the SmPC to align the wording with the updated Annex II."
Request for Supplementary Information adopted on 28.11.2024.

B.5.5. CHMP-CAT assessed procedures

**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.

B.5.6. CHMP-PRAC-CAT assessed procedures**B.5.7. PRAC assessed ATMP procedures**

PRAC Led

**CARVYKTI - Ciltacabtagene autoleucel -
EMA/H/C/005095/II/0034, Orphan,
ATMP**

Janssen-Cilag International NV, PRAC
Rapporteur: Jo Robays, PRAC-CHMP liaison:
Karin Janssen van Doorn, "Submission of an updated RMP version 5.2 in order to add a new important identified risk of "Secondary malignancy of T-cell origin", to change the important potential risk of "Second primary malignancies" to "Second primary malignancy except secondary malignancy of T-cell origin", and to include an additional pharmacovigilance activity for testing of secondary malignancies of

T-cell origin, following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040).” Request for Supplementary Information adopted on 24.01.2025.

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

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.

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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