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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes of the meeting on 06-09 November 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in these minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the [CHMP meeting highlights](#) once the procedures are finalised and start of referrals will also be available.

Of note, this set of minutes 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 minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



Table of contents

1.	Introduction	8
1.1.	Welcome and declarations of interest of members, alternates and experts.....	8
1.2.	Adoption of agenda	8
1.3.	Adoption of the minutes	8
2.	Oral Explanations	9
2.1.	Pre-authorisation procedure oral explanations.....	9
2.1.1.	tofersen - Orphan - EMEA/H/C/005493.....	9
2.2.	Re-examination procedure oral explanations	9
2.2.1.	Krazati - adagrasib - EMEA/H/C/006013	9
2.3.	Post-authorisation procedure oral explanations	9
2.3.1.	Veltassa - patiromer - EMEA/H/C/004180/X/0031/G	9
2.4.	Referral procedure oral explanations	10
3.	Initial applications	10
3.1.	Initial applications; Opinions.....	10
3.1.1.	Azacidine Kabi - azacidine - EMEA/H/C/006154.....	10
3.1.2.	Naveruclif - paclitaxel - EMEA/H/C/006173	10
3.1.3.	Omjjara - momelotinib - Orphan - EMEA/H/C/005768	11
3.1.4.	Rimmyrah - ranibizumab - EMEA/H/C/006055.....	11
3.1.5.	Rystiggo - rozanolixizumab - Orphan - EMEA/H/C/005824	12
3.1.6.	Spexotras - trametinib - Orphan - EMEA/H/C/005886	12
3.1.7.	Uzpruvo - ustekinumab - EMEA/H/C/006101	13
3.2.	Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)	13
3.2.1.	polihexanide - Orphan - EMEA/H/C/005858	13
3.2.2.	exagamglogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005763.....	14
3.2.3.	Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006052	14
3.2.4.	cefepime / enmetazobactam - EMEA/H/C/005431.....	14
3.2.5.	Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006051	15
3.2.6.	leniolisib - Orphan - EMEA/H/C/005927	15
3.2.7.	catumaxomab - EMEA/H/C/005697.....	15
3.2.8.	lecanemab - EMEA/H/C/005966	15
3.2.9.	bevacizumab - EMEA/H/C/005723	16
3.2.10.	paliperidone - EMEA/H/C/006185	16
3.2.11.	pomalidomide - EMEA/H/C/006195.....	16

3.2.12.	tofersen - Orphan - EMEA/H/C/005493.....	16
3.2.13.	danicopan - PRIME - Orphan - EMEA/H/C/005517.....	17
3.3.	Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)	17
3.3.1.	dasiglucagon - EMEA/H/C/006214	17
3.3.2.	levetiracetam - EMEA/H/C/006186.....	17
3.3.3.	ustekinumab - EMEA/H/C/006221.....	18
3.3.4.	nilotinib - EMEA/H/C/006315	18
3.3.5.	crovalimab - EMEA/H/C/006061	18
3.3.6.	Respiratory syncytial virus mRNA vaccine – OPEN – EMEA/H/C/006278.....	18
3.3.7.	teriparatide - EMEA/H/C/005687	19
3.3.8.	zolbetuximab - Orphan - EMEA/H/C/005868	19
3.3.9.	macitentan / tadalafil - EMEA/H/C/005001.....	19
3.4.	Update on on-going initial applications for Centralised procedure.....	19
3.4.1.	apadamtase alfa - Orphan - EMEA/H/C/006198	19
3.4.2.	dantrolene sodium, hemiheptahydrate - Orphan - EMEA/H/C/006009.....	20
3.4.3.	ustekinumab - EMEA/H/C/006183.....	20
3.4.4.	omalizumab - EMEA/H/C/005958.....	20
3.5.	Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004	20
3.5.1.	Krazati - adagrasib - EMEA/H/C/006013	20
3.6.	Initial applications in the decision-making phase.....	21
3.7.	Withdrawals of initial marketing authorisation application	21
3.7.1.	Vijoice - alpelisib - Orphan - EMEA/H/C/005468	21

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 21

4.1.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion	21
4.1.1.	Eylea - aflibercept - EMEA/H/C/002392/X/0084/G	21
4.1.2.	Skyrizi - risankizumab - EMEA/H/C/004759/X/0033	22
4.1.3.	Talzenna - talazoparib - EMEA/H/C/004674/X/0015/G.....	22
4.1.4.	Tecentriq - atezolizumab - EMEA/H/C/004143/X/0076	23
4.1.5.	Veltassa - patiromer - EMEA/H/C/004180/X/0031/G	23
4.2.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues	24
4.2.1.	Azacididine Accord - azacididine - EMEA/H/C/005147/X/0013.....	24
4.2.2.	Upravi - selexipag - EMEA/H/C/003774/X/0038.....	24
4.3.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question	24
4.3.1.	Abilify Maintena - aripiprazole - EMEA/H/C/002755/X/0045	24

4.3.2.	Reagila - cariprazine - EMEA/H/C/002770/X/0033	25
4.3.3.	Spevigo - spesolimab - EMEA/H/C/005874/X/0006/G.....	25
4.3.4.	Tepadina - thiotepa - EMEA/H/C/001046/X/0049.....	26
4.4.	Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008	26
4.5.	Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	26

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008 26

5.1.	Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information.....	26
5.1.1.	Abecma - idecabtagene vicleucel - Orphan - ATMP - EMEA/H/C/004662/II/0031.....	26
5.1.2.	Aspaveli - pegcetacoplan - Orphan - EMEA/H/C/005553/II/0011	27
5.1.3.	Ayvakyt - avapritinib - Orphan - EMEA/H/C/005208/II/0023	27
5.1.4.	Evkeeza - evinacumab - EMEA/H/C/005449/II/0011	28
5.1.5.	Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0043.....	28
5.1.6.	Jardiance - empagliflozin - EMEA/H/C/002677/II/0076	29
5.1.7.	Keytruda - pembrolizumab - EMEA/H/C/003820/II/0138	29
5.1.8.	Metalyse - tenecteplase - EMEA/H/C/000306/II/0070/G	30
5.1.9.	Mounjaro - tirzepatide - EMEA/H/C/005620/II/0007.....	30
5.1.10.	Moventig - naloxegol - EMEA/H/C/002810/II/0039	31
5.1.11.	NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0058.....	31
5.1.12.	Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0031	32
5.1.13.	Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0035.....	32
5.1.14.	Retsevmo - selpercatinib - EMEA/H/C/005375/II/0021	33
5.1.15.	Retsevmo - selpercatinib - EMEA/H/C/005375/II/0022	33
5.1.16.	Vabysmo - faricimab - EMEA/H/C/005642/II/0005.....	34
5.1.17.	Xromi - hydroxycarbamide - EMEA/H/C/004837/II/0019	34
5.1.18.	WS2552 Ongentys - opicapone - EMEA/H/C/002790/WS2552/0060 Ontilyv - opicapone - EMEA/H/C/005782/WS2552/0015	35
5.2.	Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	35
5.2.1.	Kisqali - ribociclib - EMEA/H/C/004213/II/0045	35
5.3.	Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	36

6. Medical devices 36

6.1.	Ancillary medicinal substances - initial consultation	36
-------------	--	-----------

6.2.	Ancillary medicinal substances – post-consultation update	36
6.3.	Companion diagnostics - initial consultation	36
6.3.1.	in vitro diagnostic medical device - EMEA/H/D/006372.....	36
6.3.2.	in vitro diagnostic medical device - EMEA/H/D/006373.....	36
6.3.3.	in vitro diagnostic medical device - EMEA/H/D/006310.....	36
6.4.	Companion diagnostics – follow-up consultation	37

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 37

7.1.	Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)	37
-------------	--	-----------

8. Pre-submission issues 37

8.1.	Pre-submission issue	37
8.1.1.	mozafancogene autotemcel – ATMP - Orphan - H0005537	37
8.1.2.	vorasidenib - Orphan - H0006284.....	37
8.2.	Priority Medicines (PRIME)	38

9. Post-authorisation issues 38

9.1.	Post-authorisation issues	38
9.1.1.	Arexvy - respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0002/G	38
9.1.2.	Bylvay - odeixibat - Orphan - EMEA/H/C/004691/II/0011	38
9.1.3.	Leqvio– Incdisiran – EMEA/H/C/005333.....	39
9.1.4.	Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0058/G	39
9.1.5.	Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0147/G.....	39
9.1.6.	Remsima - infliximab - EMEA/H/C/002576/II/0133/G.....	40
9.1.7.	Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0063, Orphan, ATMP	40
9.1.8.	Zynrelef - bupivacaine / meloxicam - EMEA/H/C/005205	41
9.1.9.	Translarna - ataluren - EMEA/H/C/002720/R/0071, Orphan	41
9.1.10.	Pazenir – paclitaxel – EMEA/H/C/004441	41
9.1.11.	Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan	42

10. Referral procedures 42

10.1.	Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004	42
10.1.1.	Ocaliva - obeticholic acid - EMEA/H/A-20/1531.....	42
10.1.2.	Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065	43
10.2.	Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 .	43
10.3.	Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004	43

10.4.	Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC	43
10.5.	Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC....	44
10.5.1.	Havrix - EMEA/H/A-30/1527	44
10.6.	Community Interests - Referral under Article 31 of Directive 2001/83/EC	44
10.6.1.	Azithromycin containing medicinal products for systemic use – EMEA/H/A-31/1532	44
10.7.	Re-examination Procedure under Article 32(4) of Directive 2001/83/EC.....	45
10.8.	Procedure under Article 107(2) of Directive 2001/83/EC	45
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	45
10.10.	Procedure under Article 29 of Regulation (EC) 1901/2006.....	45
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	45
11.	Pharmacovigilance issue	46
11.1.	Early Notification System	46
12.	Inspections	46
12.1.	GMP inspections	46
12.2.	GCP inspections.....	46
12.3.	Pharmacovigilance inspections.....	46
12.4.	GLP inspections	46
13.	Innovation Task Force	46
13.1.	Minutes of Innovation Task Force.....	46
13.2.	Innovation Task Force briefing meetings.....	46
13.3.	Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004	47
13.4.	Nanomedicines activities	47
14.	Organisational, regulatory and methodological matters	47
14.1.	Mandate and organisation of the CHMP	47
14.1.1.	Vote by proxy	47
14.1.2.	CHMP membership.....	47
14.1.3.	Guidance on SmPC section 5.1	47
14.2.	Coordination with EMA Scientific Committees.....	47
14.2.1.	Pharmacovigilance Risk Assessment Committee (PRAC)	47
14.2.2.	Paediatric Committee (PDCO).....	48
14.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	48
14.3.1.	Biologics Working Party (BWP)	48

14.3.2.	Scientific Advice Working Party (SAWP)	48
14.4.	Cooperation within the EU regulatory network	48
14.5.	Cooperation with International Regulators.....	48
14.6.	Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee	49
14.7.	CHMP work plan	49
14.8.	Planning and reporting	49
14.9.	Others	49
14.9.1.	CHMP Learnings	49
15.	Any other business	49
15.1.	AOB topic.....	49
List of participants		50
Explanatory notes		56

1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held in-person.

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

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

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

1.2. Adoption of agenda

CHMP agenda for 06-09 November 2023.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 09-12 October 2023.

The CHMP adopted the minutes for the 09-12 October 2023 plenary.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 12 October 2023 and 30 October 2023.

The CHMP adopted the minutes from the PROM meetings held on 12 October 2023 and 30 October 2023.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. tofersen - Orphan - EMEA/H/C/005493

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

Scope: Oral explanation

Action: Oral explanation to be held on 07 November 2023 at 14:00

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

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

See 3.2

2.2. Re-examination procedure oral explanations

2.2.1. Krazati - adagrasib - EMEA/H/C/006013

Mirati Therapeutics B.V.; treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation

Scope: Oral explanation

Action: Oral explanation to be held on 6 November 2023 at 16:00

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

Opinion adopted on 20.07.2023. List of Outstanding Issues adopted on 25.05.2023, 23.02.2023. List of Questions adopted on 15.09.2022.

An oral explanation was held on 6 November 2023. The presentation by the applicant focused on clinical data.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Veltassa - patiomer - EMEA/H/C/004180/X/0031/G

Vifor Fresenius Medical Care Renal Pharma France

Scope: "Extension application to introduce a new strength (1 g powder for oral suspension), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of population from 12 to 17 years old for Veltassa based on final results from paediatric study RLY5016-206P (EMERALD); this is a phase 2, open-label, multiple dose study to evaluate the pharmacodynamic effects, safety, and tolerability of patiomer for oral

suspension in children and adolescents 2 to less than 18 years of age with chronic kidney disease and hyperkalaemia. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 6.5 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes.”

Possible oral explanation

Action: Possible oral explanation to be held on 08 November 2023 at 16:00

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

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

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Azacitidine Kabi - azacitidine - EMEA/H/C/006154

Fresenius Kabi Deutschland GmbH; Treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and acute myeloid leukemia (AML)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 26.04.2023.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.2. Naveruclif - paclitaxel - EMEA/H/C/006173

Accord Healthcare S.L.U.; treatment of metastatic breast cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 25.05.2023.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.3. Omjjara - momelotinib - Orphan - EMEA/H/C/005768

Glaxosmithkline Trading Services Limited; treatment of disease-related splenomegaly or symptoms and anaemia

Scope: Opinion

Action: For adoption

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

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

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

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

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.4. Rimmyrah - ranibizumab - EMEA/H/C/006055

QILU PHARMA SPAIN S.L.; treatment of neovascular age-related macular degeneration (AMD)

Scope: Opinion

Action: For adoption

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

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

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

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

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

The CHMP noted the letter of recommendation dated 03 November 2023.

The summary of opinion was circulated for information.

3.1.5. [Rystiggo - rozanolixizumab - Orphan - EMEA/H/C/005824](#)

UCB Pharma; Treatment of generalised myasthenia gravis (gMG)

Scope: Opinion

Action: For adoption

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

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

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

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

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.6. [Spexotras - trametinib - Orphan - EMEA/H/C/005886](#)

Novartis Europharm Limited; Treatment of paediatric patients aged 1 year and older with glioma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023, 25.05.2023. List of Questions adopted on 26.01.2023.

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

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

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

The CHMP noted the letter of recommendation dated 06 November 2023.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.7. Uzpruvo - ustekinumab - EMEA/H/C/006101

STADA Arzneimittel AG; treatment of plaque psoriasis, arthritis psoriatic, Crohn's Disease and ulcerative colitis

Scope: Opinion

Action: For adoption

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

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

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

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

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

The summary of opinion was circulated for information.

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

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

SIFI SPA; treatment of acanthamoeba keratitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.09.2022.

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

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

3.2.2. [exagamglogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005763](#)

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

Scope: List of outstanding issues

Action: For information

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

The CHMP was updated on the discussions at the CAT. The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee endorsed the 2nd list of outstanding issues with a specific timetable as adopted by CAT.

3.2.3. [Zoonotic influenza vaccine \(H5N1\) \(surface antigen, inactivated, adjuvanted, prepared in cell cultures\) - EMEA/H/C/006052](#)

active immunisation for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

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

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

3.2.4. [cefepime / enmetazobactam - EMEA/H/C/005431](#)

treatment of: 1) complicated urinary tract infections (including pyelonephritis); 2) hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); 3) patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above and 4) infections due to aerobic Gram-negative organisms in adults with limited treatment options

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

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

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

3.2.5. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006051

prophylaxis of influenza

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

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

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

3.2.6. leniolisib - Orphan - EMEA/H/C/005927

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

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 24.01.2023.

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

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

3.2.7. catumaxomab - EMEA/H/C/005697

indicated for the treatment of malignant ascites

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

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

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

3.2.8. lecanemab - EMEA/H/C/005966

a disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer's disease and Mild Alzheimer's disease (Early Alzheimer's disease)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

The CHMP noted the third-party interventions.

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

The Committee adopted a list of outstanding issues.

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

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

3.2.9. bevacizumab - EMEA/H/C/005723

Treatment of neovascular (wet) age-related macular degeneration (nAMD).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.04.2023.

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

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

3.2.10. paliperidone - EMEA/H/C/006185

Treatment of schizophrenia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

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

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

3.2.11. pomalidomide - EMEA/H/C/006195

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

3.2.12. tofersen - Orphan - EMEA/H/C/005493

Biogen Netherlands B.V.; treatment of adults with amyotrophic lateral sclerosis (ALS),

associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

Scope: List of outstanding issues

Action: For adoption

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

See 2.1

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

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

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

3.2.13. danicopan - PRIME - Orphan - EMEA/H/C/005517

Alexion Europe; Treatment of extravascular haemolysis (EVH) in patients with paroxysmal nocturnal haemoglobinuria

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

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

3.3.1. dasiglucagon - EMEA/H/C/006214

treatment of severe hypoglycemia in patients with diabetes

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.2. levetiracetam - EMEA/H/C/006186

treatment of partial onset seizures

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.3. [ustekinumab - EMEA/H/C/006221](#)

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

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.4. [nilotinib - EMEA/H/C/006315](#)

treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.5. [crovalimab - EMEA/H/C/006061](#)

treatment of paroxysmal nocturnal haemoglobinuria

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.6. [Respiratory syncytial virus mRNA vaccine – OPEN – EMEA/H/C/006278](#)

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

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.7. teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.8. zolbetuximab - Orphan - EMEA/H/C/005868

Astellas Pharma Europe B.V.; treatment of locally advanced unresectable or metastatic HER2 negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.9. macitentan / tadalafil - EMEA/H/C/005001

treatment of pulmonary arterial hypertension (PAH) in adults patients

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

3.4.1. apadamtase alfa - Orphan - EMEA/H/C/006198

Takeda Manufacturing Austria AG; treatment of congenital thrombotic thrombocytopenic purpura (cTTP) due to ADAMTS13 deficiency

Scope: Letter by the applicant dated 24.10.2023 requesting an extension to the clock stop to respond to the list of questions adopted in September 2023.

Action: For adoption

List of Questions adopted on 14.09.2023.

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

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

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

Scope: Letter by the applicant dated 30.10.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2023.

Action: For adoption

List of Outstanding Issues adopted on 22 June 2023. List of Questions adopted on 10.11.2022.

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

3.4.3. ustekinumab - EMEA/H/C/006183

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

Scope: BMWP and MWP consultation

List of Questions adopted on 14.09.2023.

The CHMP agreed to consult the BMWP and MWP and adopted a list of questions to these working parties.

3.4.4. omalizumab - EMEA/H/C/005958

treatment of asthma

Scope: Letter by the applicant dated 08.11.2023 requesting an extension to the clock stop to respond to the list of questions adopted in September 2023.

List of Questions adopted on 14.09.2023.

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

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

3.5.1. Krazati - adagrasib - EMEA/H/C/006013

Mirati Therapeutics B.V.; treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation

Scope: Opinion

Action: For adoption

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

Opinion adopted on 20.07.2023. List of Outstanding Issues adopted on 25.05.2023, 23.02.2023. List of Questions adopted on 15.09.2022.

See 2.2

An oral explanation was held on 6 November 2023. The presentation by the applicant focused on clinical data.

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

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

The divergent position (Peter Mol, Jan Mueller-Berghaus, Robert Porszasz, Martina Weise) was appended to the opinion.

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

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Vijoice - alpelisib - Orphan - EMEA/H/C/005468

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

Scope: Withdrawal of initial marketing authorisation application

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

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 10.11.2022.

The CHMP noted the withdrawal of marketing authorisation application.

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

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

4.1.1. Eylea - aflibercept - EMEA/H/C/002392/X/0084/G

Bayer AG

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault

Scope: "Extension application to add a new strength of Aflibercept 114.3 mg/ml solution for injection (in a vial), to be indicated in adults for the (1) treatment of neovascular (wet) age-related macular degeneration (nAMD) and (2) visual impairment due to diabetic macular oedema (DME), grouped with a type II variation (B.II.g.2) to introduce a post-approval change management protocol to add a new presentation for Aflibercept solution 114.3

mg/ml in a single-use pre-filled syringe for intravitreal injection.”

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 22.06.2023.

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

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

4.1.2. [Skyrizi - risankizumab - EMEA/H/C/004759/X/0033](#)

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy

Scope: “Extension application to add a new strength of 90 mg solution for injection in pre-filled syringe, indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.”

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 20.07.2023.

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

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

4.1.3. [Talzenna - talazoparib - EMEA/H/C/004674/X/0015/G](#)

Pfizer Europe MA EEIG

Rapporteur: Filip Josephson, Co-Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: “Extension application for Talzenna to introduce a new strength of 0.1 mg hard capsules, grouped with a type II variation (C.I.6.a) in order to extend the indication for Talzenna in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), based on final results from study C3441021 (TALAPRO-2) as well as supplemental data from study C3441006 (TALAPRO-1). Study C3441021 (TALAPRO-2) is a randomized, double-blind, placebo-controlled, phase 3 study of talazoparib in combination with enzalutamide in mCRPC, while study C3441006 (TALAPRO-1) is a phase 2, open-label, response rate study of talazoparib in men with DNA repair defects and mCRPC who previously received taxane-based chemotherapy and progressed on at least one novel hormonal agent. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.5, 4.7, 4.8, 5.1, 5.2, 6.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 22.06.2023.

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

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

4.1.4. Tecentriq - atezolizumab - EMEA/H/C/004143/X/0076

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (1875 mg) and new route of administration (subcutaneous use). The RMP (version 24.0) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 30.03.2023.

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

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

4.1.5. Veltassa - patiomer - EMEA/H/C/004180/X/0031/G

Vifor Fresenius Medical Care Renal Pharma France

Rapporteur: Jayne Crowe, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension application to introduce a new strength (1 g powder for oral suspension), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of population from 12 to 17 years old for Veltassa based on final results from paediatric study RLY5016-206P (EMERALD); this is a phase 2, open-label, multiple dose study to evaluate the pharmacodynamic effects, safety, and tolerability of patiomer for oral suspension in children and adolescents 2 to less than 18 years of age with chronic kidney disease and hyperkalaemia. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 6.5 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes."

Action: For adoption

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

See 2.3

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

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

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

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

4.2.1. Azacitidine Accord - azacitidine - EMEA/H/C/005147/X/0013

Accord Healthcare S.L.U.

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (10 mg/ml powder for solution for infusion) and a new route of administration (intravenous use). The RMP version 2 is updated in accordance."

Action: For adoption

List of Questions adopted on 26.04.2023.

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

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

4.2.2. Uptravi - selexipag - EMEA/H/C/003774/X/0038

Janssen-Cilag International N.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Nathalie Gault

Scope: "Extension application to add a new strength of 100 µg film-coated tablets in HDPE bottle. The RMP (version 10.1) is updated in accordance."

Action: For adoption

List of Questions adopted on 22.06.2023.

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

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

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

4.3.1. Abilify Maintena - aripiprazole - EMEA/H/C/002755/X/0045

Otsuka Pharmaceutical Netherlands B.V.

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form associated with two new strengths (720 and 960 mg Prolonged-release suspension for injection). The RMP (version 12.1) is updated in accordance."

Action: For adoption

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

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

4.3.2. [Reagila - cariprazine - EMEA/H/C/002770/X/0033](#)

Gedeon Richter Plc.

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

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible tablets). The RMP (version 3.0) is updated in accordance."

Action: For adoption

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

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

4.3.3. [Spevigo - spesolimab - EMEA/H/C/005874/X/0006/G](#)

Boehringer Ingelheim International GmbH

Rapporteur: Kristina Dunder, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Nathalie Gault

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.

This line extension is grouped with a type II variation (C.I.6.a) to extend the indication for Spevigo 450 mg concentrate for solution for infusion to include treatment of generalised pustular psoriasis (GPP) flares in adolescents (from 12 years of age), based on final results from study 1368-0027 (Effisayil 2) and extrapolation; this is a multi-center, randomized, parallel group, double blind, placebo controlled, phase IIb dose-finding study to evaluate efficacy and safety of BI 655130 (spesolimab) compared to placebo in preventing GPP flares in patients with history of GPP. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet."

Action: For adoption

The Committee discussed the issues identified in this application relating to clinical aspects. The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

4.3.4. **Tepadina - thiotepa - EMEA/H/C/001046/X/0049**

ADIENNE S.r.l. S.U.

Rapporteur: Alexandre Moreau

Scope: "Extension application to add a new strength (200 mg powder and solvent for solution for infusion)."

Action: For adoption

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

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

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

No items

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

No items

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

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

5.1.1. Abecma - idecabtagene vicleucel - Orphan - ATMP - EMEA/H/C/004662/II/0031

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken, Co-Rapporteur: Heli Suila, CHMP Coordinators: Ingrid Wang and Johanna Lähteenvuo, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38 antibody and have demonstrated disease progression on the last therapy for Abecma (idecabtagene

vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells.”, 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 16.06.2023.

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

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

5.1.2. Aspaveli - pegcetacoplan - Orphan - EMEA/H/C/005553/II/0011

Swedish Orphan Biovitrum AB (publ)

Rapporteur: Alexandre Moreau, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Kimmo Jaakkola

Scope: “Extension of indication to include treatment of adult patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) not previously treated with a complement inhibitor for Aspaveli, based on final results from study APL2-308. This is a Phase III, randomized, open-label, comparator-controlled study that enrolled adult patients with PNH who had not been treated with a complement inhibitor. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023.

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

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

5.1.3. Ayvakyt - avapritinib - Orphan - EMEA/H/C/005208/II/0023

Blueprint Medicines (Netherlands) B.V.

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication to include treatment of adult patients with indolent systemic mastocytosis (ISM) for avapritinib based on results from the pivotal part of study BLU-285-2203 (PIONEER), this is a 3-part, randomized, double-blind, placebo-controlled, Phase 2 study to evaluate safety and efficacy of avapritinib (BLU-285) in indolent and smoldering systemic mastocytosis with symptoms inadequately controlled with standard therapy. As a

consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.4 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023, 26.04.2023.

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

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

The summary of opinion was circulated for information.

5.1.4. [Evkeeza - evinacumab - EMEA/H/C/005449/II/0011](#)

Ultragenyx Germany GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Mari Thorn

Scope: “Extension of indication to include the treatment of paediatric patients with homozygous familial hypercholesterolaemia (HoFH) aged 5 years and older for EVKEEZA, based on interim results from study R1500-CL-17100, as well as supportive information from an updated interim analysis of study R1500-CL-1719, and an extrapolation analysis (including population PK, population PK/PD, and simulation analyses). R1500-CL-17100 is an ongoing multicentre, three-part, single-arm, open-label study evaluating the efficacy, safety, and tolerability of evinacumab in paediatric patients aged ≥ 5 to 11 years with HoFH. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the marketing authorisation holder took the opportunity to introduce minor editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.3.”

Action: For adoption

Request for Supplementary Information adopted on 12.10.2023, 14.09.2023.

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

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

The summary of opinion was circulated for information.

5.1.5. [Fluad Tetra - influenza vaccine \(surface antigen, inactivated, adjuvanted\) - EMEA/H/C/004993/II/0043](#)

Seqirus Netherlands B.V.

Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné

Scope: “Extension of indication to include adults 50 years of age and older for Fluad Tetra, based on final results from study V118_23; this is a phase 3, randomized, observer-blind, controlled, multicenter, clinical study to evaluate immunogenicity and safety of an MF59-

adjuvanted quadrivalent subunit inactivated influenza vaccine in comparison with a licensed quadrivalent influenza vaccine, in adults 50 to 64 years of age. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 3.0 of the RMP has also been approved. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI. The variation leads to amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and to the Risk Management Plan (RMP).”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023.

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

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

The summary of opinion was circulated for information.

5.1.6. Jardiance - empagliflozin - EMEA/H/C/002677/II/0076

Boehringer Ingelheim International GmbH

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

Scope: “Extension of indication for Jardiance to include treatment of children aged 10 years and above with type 2 diabetes based on results from study DINAMO 1218-0091; this is a double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the product information. Version 21.1 of the RMP has also been submitted.

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

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 26.04.2023.

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

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

The CHMP noted the letter of recommendation dated 16 October 2023.

The summary of opinion was circulated for information.

5.1.7. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0138

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include Keytruda in combination with gemcitabine and cisplatin for the first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults, based on final results from study KEYNOTE-966; this is a Phase 3 randomized, double blind study of Pembrolizumab plus Gemcitabine/Cisplatin versus Placebo plus Gemcitabine/Cisplatin as first-line therapy in participants with advanced and/or unresectable biliary tract carcinoma. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.09.2023.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

5.1.8. [Metalyse - tenecteplase - EMEA/H/C/000306/II/0070/G](#)

Boehringer Ingelheim International GmbH

Rapporteur: Martina Weise

Scope: "Grouped application consisting of:

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

B.II.e.5.c (Type II): To add the new 25 mg presentation for the sterile parenteral biological medicinal product Metalyse (tenecteplase) powder and solvent for solution for injection.

B.II.b.3.a

B.II.e.1.b.2"

Action: For adoption

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

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

5.1.9. [Mounjaro - tirzepatide - EMEA/H/C/005620/II/0007](#)

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include chronic weight management, including weight loss and weight maintenance, for Mounjaro, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial body mass index (BMI) of ≥ 30 kg/m²

(obesity), or ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbid condition, based on a global, pivotal phase 3 study I8F-MC-GPHK (SURMOUNT-1) and five supportive phase 3 studies (SURPASS-1 to -5) in participants with T2DM and BMI ≥ 27 kg/m². SURMOUNT-1 is a phase 3, randomized, double-blind, placebo-controlled trial to investigate the efficacy and safety of tirzepatide once weekly in participants without type 2 diabetes who have obesity or are overweight with weight related comorbidities. As a consequence, sections 4.1, 4.8, 5.1 and 5.2 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 introduce minor editorial changes to the PI., 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 14.09.2023, 22.06.2023.

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

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

The summary of opinion was circulated for information.

5.1.10. [Moventig - naloxegol - EMEA/H/C/002810/II/0039](#)

Kyowa Kirin Holdings B.V.

Rapporteur: Christophe Focke, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update information regarding the use of naloxegol in OIC patients with cancer-related pain based on real-world data from non-interventional studies (NACASY, KYONAL, and MOVE studies), post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 26.04.2023.

The committee noted that the MAH decided not to pursue the extension to the therapeutic indication and the implementation of real-world data in 5.1 of the SmPC.

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

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

5.1.11. [NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0058](#)

MediWound Germany GmbH

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Extension of current indication for removal of eschar in adults with deep partial- and full-thickness thermal burns to the paediatric population for NexoBrid based on interim results from study MW2012-01-01 (CIDS study), listed as study MW2012-01-01 is a 3-stage, multi-centre, multi-national, randomised, controlled, open label, 2 arm study aiming to demonstrate the superiority of NexoBrid treatment over SOC treatment in paediatric patients (aged 0 to 18 years) with deep partial thickness (DPT) and full thickness (FT) thermal burns of 1% to 30% of total body surface area (TBSA).

As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 9 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2023, 15.12.2022.

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

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

The summary of opinion was circulated for information.

5.1.12. Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0031

Daiichi Sankyo Europe GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk, based on results from study 1002-043 (CLEAR). CLEAR Outcomes Study is a phase 3 multi-centre randomised, double-blind, placebo-controlled study to evaluate whether long-term treatment with bempedoic acid reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease who are statin intolerant. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

The Committee discussed the issues identified in this application relating to clinical aspects and the request for 1 year of market protection.

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

5.1.13. Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0035

Daiichi Sankyo Europe GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for Nustendi,

based on results from study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are statin intolerant; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

The Committee discussed the issues identified in this application relating to clinical aspects and the request for 1 year of market protection.

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

5.1.14. Retsevmo - selpercatinib - EMEA/H/C/005375/II/0021

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication to include the treatment of adults and adolescents 12 years and older with advanced RET fusion-positive thyroid cancer in the first-line setting for Retsevmo based on interim data from studies LIBRETTO-001 (LOXO-RET-17001) and LIBRETTO-121; LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in patients with RET-altered advanced solid tumours. LIBRETTO-121 is a Phase 1/2 study of selpercatinib in paediatric patients with advanced RET-altered solid or primary central nervous system tumours. 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 3.2 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

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

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

5.1.15. Retsevmo - selpercatinib - EMEA/H/C/005375/II/0022

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication for Retsevmo to include the treatment of adults with advanced or metastatic RET fusion-positive solid tumours with disease progression on or after prior systemic therapies or who have no satisfactory therapeutic options, based on interim data from study LIBRETTO-001 (LOXO-RET-17001); LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in adult and adolescent patients with advanced RET-altered tumours. As a consequence, sections 4.1, 4.2 and 5.1 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 MAH took the opportunity to implement editorial changes to the SmPC.”

Action: For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

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

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

5.1.16. Vabysmo - faricimab - EMEA/H/C/005642/II/0005

Roche Registration GmbH

Rapporteur: Jayne Crowe, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: “Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients with central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). These are global, multicenter, randomized, double-masked, active comparator-controlled, parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.”

Action: For adoption

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

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

5.1.17. Xromi - hydroxycarbamide - EMEA/H/C/004837/II/0019

Nova Laboratories Ireland Limited

Rapporteur: Anastasia Mountaki, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Jo Robays

Scope: “Extension of indication to include the prevention of vaso-occlusive complications of sickle cell disease in children from 6 months to 2 years of age for Xromi, based on final results from the paediatric study INV543, listed as a category 3 study in the RMP; this is a single-arm, open-label, multi-center study in children with sickle cell anaemia over 6 months of age. 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.”

Action: For adoption

Request for Supplementary Information adopted on 26.04.2023.

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

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

timetable.

5.1.18. **WS2552**
Ongentys - opicapone - EMEA/H/C/002790/WS2552/0060
Ontilyv - opicapone - EMEA/H/C/005782/WS2552/0015

Bial Portela & Companhia S.A.

Lead Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of signs and symptoms of Parkinson's Disease for Ongentys/Ontilyv, based on final results from study BIA-91067-303; this is a pivotal Phase III, multicentre, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of opicapone in patients with early idiopathic Parkinson's Disease receiving treatment with L-DOPA plus a DDCI, and who are without signs of any motor complication. 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 6.0 of the RMP has also been submitted (only applicable to Ongentys) to reflect the changes made upon approval of the informed consent application, to keep consistency between the eCTD lifecycles of the two marketing authorisations (Ongentys and Ontilyv). Furthermore, the PI is brought in line with the latest QRD template version 10.3. In addition, as part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

The Committee discussed the issues identified in this application relating to clinical aspects and the request for 1 year of market protection.

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

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

5.2.1. **Kisqali - ribociclib - EMEA/H/C/004213/II/0045**

Novartis Europharm Limited

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

Scope: "Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Stage II or Stage III early breast cancer, irrespective of nodal status, in combination with an AI for Kisqali based on study CLEE011012301C (NATALEE); This is a global, Phase III, multicenter, randomised, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Third-party intervention.

Action: For information

The CHMP noted the third-party intervention.

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

No items

6. **Medical devices**

6.1. **Ancillary medicinal substances - initial consultation**

No items

6.2. **Ancillary medicinal substances – post-consultation update**

No items

6.3. **Companion diagnostics - initial consultation**

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

next generation sequencing (NGS) assay for tumour mutation profiling

Scope: Request for supplementary information

Action: For adoption

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

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

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

detection of PD-L1 protein

Scope: Opinion

Action: For adoption

Request for supplementary information adopted on 12.10.2023.

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

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

6.3.3. in vitro diagnostic medical device - EMEA/H/D/006310

immunohistochemical assay utilising an anti-PD-L1 monoclonal primary antibody

Scope: Opinion

Action: For adoption

Request for supplementary information adopted on 12.10.2023, 14.09.2023.

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

The Committee adopted a positive opinion by consensus together with the CHMP assessment report.

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. mozafancogene autotemcel – ATMP - Orphan - H0005537

Rocket Pharmaceuticals B.V., Fanconi anemia Type A

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

Action: For adoption

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

8.1.2. vorasidenib - Orphan - H0006284

Les Laboratoires Servier, Treatment of patients with residual/recurrent Grade 2 glioma harbouring an isocitrate dehydrogenase 1 (IDH1) mutation or isocitrate dehydrogenase 2 (IDH2) mutation who have undergone surgery as their only treatment

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

Action: For adoption

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

8.2. Priority Medicines (PRIME)

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

The CHMP adopted the recommendations for PRIME eligibility.

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Arexvy - respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0002/G

GlaxoSmithkline Biologicals S.A.

Rapporteur: Patrick Vrijlandt

Scope: "Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV) based on final results from studies RSV OA=ADJ-008 and RSV OA=ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV), respectively."

Action: For adoption

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

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

9.1.2. Bylvay - odevixibat - Orphan - EMEA/H/C/004691/II/0011

Albireo

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jayne Crowe

Scope: "Extension of indication to include the treatment of cholestatic pruritus in Alagille syndrome (ALGS) in patients aged 6 months or older for Bylvay, based on final results from study A4250-012 and interim results from study A4250-015. Study A4250-012 is a 24-week, randomised, double-blind, placebo-controlled Phase III study conducted in 52 patients with a genetically confirmed diagnosis of ALGS and presence of pruritus and high serum bile acid levels at baseline. Study A4250-015 is an ongoing 72-week open-label

extension trial for patients who completed study A4250-012 and evaluates the long-term safety and efficacy of Bylvay in patients with ALGS. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and Annex II of the Marketing Authorisation are updated. The Package Leaflet is updated in accordance. Version 2.4 of the RMP has also been submitted. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet, Annex II and to the Risk Management Plan (RMP).”

Withdrawal of Type-II variation application

Action: For information

Opinion adopted on 20.07.2023. Request for Supplementary Information adopted on 22.06.2023, 30.03.2023.

The CHMP noted the withdrawal of the Type-II variation application.

9.1.3. [Leqvio– Inclisiran – EMEA/H/C/005333](#)

Novartis Europharm Limited; treatment for primary hypercholesterolaemia or mixed dyslipidaemia

Rapporteur: Martina Weise, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: DHPC and communication plan

Action: For adoption

The CHMP adopted the DHPC and communication plan.

9.1.4. [Nuvaxovid - Covid-19 Vaccine \(recombinant, adjuvanted\) - EMEA/H/C/005808/II/0058/G](#)

Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

Scope: quality

Positive opinion was adopted via written procedure on 31.10.2023.

Action: For information

The CHMP noted the positive opinion, which was adopted by consensus on 31.10.2023 via written procedure.

9.1.5. [Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0147/G](#)

Boehringer Ingelheim International GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: “A Grouped application consisting of:

C.I.7.a (type IB): to delete the pharmaceutical form “powder and solvent for oral solution, 6.25 mg/ml”, as agreed in procedure EMEA/H/C/000829/II/0144.

C.I.4 (type II): Update of section 4.1 of the SmPC in order to modify the indication following the deletion of the powder and solvent for oral solution; the Package Leaflet is updated

accordingly. The RMP version 41.2 has also been submitted.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.”

Action: For adoption

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

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

The summary of opinion was circulated for information.

9.1.6. Remsima - infliximab - EMEA/H/C/002576/II/0133/G

Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Kristina Dunder

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

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

- Update of sections 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.

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

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

Action: For adoption

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

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

9.1.7. Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0063, Orphan, ATMP

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Scope: "Primary Analysis from study KTE-C19-107 (ZUMA-7); this is a phase 3, randomized, open-label study evaluating the efficacy of axicabtagene ciloleucel versus standard of care therapy in subjects with relapsed/refractory diffuse large B cell lymphoma (DLBCL) in the 2nd line setting. In addition, the MAH took the opportunity to include the date of the latest renewal in section 9 and to submit a consolidated Environmental Risk Assessment (ERA) document."

Action: For adoption

Request for Supplementary Information adopted on 06.10.2023.

The CHMP was updated on discussions at the CAT.

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

Based on the opinion adopted by the CAT, the CHMP adopted a positive opinion by consensus together with the CHMP assessment report and translation timetable.

9.1.8. [Zynrelef - bupivacaine / meloxicam - EMEA/H/C/005205](#)

Heron Therapeutics, Zynrelef is indicated for treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Elita Poplavska

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

9.1.9. [Translarna - ataluren - EMEA/H/C/002720/R/0071, Orphan](#)

PTC Therapeutics International Limited

Scope: Appointment of re-examination rapporteurs

Action: For adoption

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

The CHMP appointed a re-examination rapporteur and a re-examination Co-Rapporteur.

The CHMP noted the re-examination timetable.

9.1.10. [Pazenir – paclitaxel – EMEA/H/C/004441](#)

Ratiopharm GmbH

Rapporteur: Daniela Philadelphly

Scope: DHPC and communication plan

Action: For adoption

Follow-up discussions from the October CHMP plenary. The CHMP did not consider a DHPC

appropriate to communicate on shortages of medicinal products, but to communicate by other means, e.g. list the product in the shortage catalogue on the EMA website.

The Committee did not adopt the DHPC and communication plan for Pazenir.

At a future PROM, further discussion is expected on the communication of shortages and specifically on criteria to identify situations when a DHPC is considered appropriate for a shortage.

9.1.11. [Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan](#)

GlaxoSmithKline (Ireland) Limited

Scope: Re-examination, list of questions to SAG

Action: For adoption

Opinion adoption on 14.09.2023. Request for Supplementary Information adopted on 26.04.2023.

The CHMP adopted the list of questions to the SAG.

10. Referral procedures

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

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

Advanz Pharma Limited

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

Scope: Revised timetable

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed. In addition, the EC requests the Agency/CHMP to give its opinion, as soon as possible, as to whether temporary measures are necessary to ensure the safe and effective use of this medicinal product taking into account, amongst other elements, findings from the type II variation procedure EMEA/H/C/004093/II/0038.

The CHMP adopted a revised timetable.

Notification: 12 October 2023

Start of the procedure (CHMP): October 2023 CHMP

List of questions: 12 October 2023

Submission of responses: 01 December 2023

Re-start of the procedure: 26 December 2023

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 05 January 2024

Comments: 11 January 2024

Updated Rapporteur/co-rapporteur ARs circulated to CHMP: 17 January 2024

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

10.1.2. [Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065](#)

Orexigen Therapeutics Ireland Limited

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

Scope: Letters from the MAH and response from EMA

Action: For information

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Mysimba (naltrexone/bupropion), taking into account any consequences from the failure to comply with the obligations laid down in the marketing authorisation.

This review of all available data on the potential long-term cardiovascular risk and its impact on the benefit-risk balance of Mysimba in its approved indication was considered needed in view of the remaining concern and lack of adequate study plan to address the uncertainty about this risk.

The CHMP noted the communication from the MAH and the response letter from EMA.

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

10.5.1. Havrix - EMEA/H/A-30/1527

GlaxoSmithKline Biologicals

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

Scope: List of question

Action: For adoption

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

The CHMP adopted a list of questions with a specific timetable.

CHMP list of questions: November 2023 CHMP

Submission of responses: 04 January 2024

Re-start of the procedure: 25 January 2024

Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 01 February 2024

Comments: 08 February 2024

Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 14 February 2024

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

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

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

MAH various (NAPs only)

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

Scope: Start of procedure, appointment of Rapporteurs, timetable, list of questions

Action: For adoption

Need to re-evaluate the benefit-risk ratio of the approved indications considering the current scientific knowledge, the increasing resistance rate, the consumption data suggesting overuse and the different indications in the EU Member States. Furthermore, the appropriate dose and duration of administration for both oral and intravenous formulations need to be discussed as well as the adequacy of safety relevant information, information on pregnancy and breastfeeding and pharmacological properties.

The German National Competent Authority triggered a referral under Article 31 of Directive 2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk

of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended or revoked.

The CHMP appointed Janet Koenig as Referral Rapporteur and Maria Concepcion Prieto Yerro as Referral Co-Rapporteur.

The CHMP adopted a list of questions with a specific timetable.

Start of the procedure (CHMP): November 2023 CHMP

List of questions: 9 November 2023

Submission of responses: 4 January 2024

Re-start of the procedure: 25 January 2024

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 26 February 2024

Comments: 7 March 2024

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 13 March 2024

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

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

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

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by proxy

Sol Ruiz gave a proxy to Maria Concepcion Prieto Yerro for the whole meeting.

14.1.2. CHMP membership

CHMP co-opted membership

The current expertise of Jan-Mueller-Berghaus is 'Quality, safety and efficacy of biological medicinal products, including advanced therapies, and with specific emphasis on vaccines.'

The CHMP agreed that a co-opted member should be appointed in the following area of expertise: Quality, safety and efficacy of biological medicinal products, including advanced therapies, and with specific emphasis on vaccines and biosimilars. A call for nomination of a co-opted member was launched following the October 2023 plenary.

Nomination(s) received

Action: For election

The CHMP elected Jan-Mueller-Berghaus as co-opted member for another 3-year term.

14.1.3. Guidance on SmPC section 5.1

Action: For discussion

The CHMP discussed the next steps for the guidance on SmPC section 5.1.

EMA will draft the timelines for the next steps and inform the network accordingly.

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for November 2023

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Agenda of the November 2023 PDCO plenary meeting

Action: For information

The CHMP noted the PDCO agenda.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-chair: Francesca Luciani

Reports from BWP November 2023 meeting to CHMP for adoption:

- 14 reports on products in scientific advice and protocol assistance
- 14 reports on products in pre-authorisation procedures
- 1 report on products in post-authorisation procedures
- 6 reports on products in plasma master file

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 23-26 October 2023. Table of conclusions

Action: For information

Scientific advice letters:

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

The CHMP noted the update.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

The CHMP noted the CHMP learnings.

15. Any other business

15.1. AOB topic

No items

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 06-09 November 2023 CHMP meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in person or remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphia	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate*	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No restrictions applicable to this meeting	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Finbarr Leacy	Alternate	Ireland	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Larisa Gorobets	Alternate*	Lithuania	No restrictions applicable to this meeting	
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate*	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No restrictions applicable to this meeting	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member*	Spain	No interests declared	
Danica Juricic Nahal	Expert	Croatia	No interests declared	
Lidija Prka	Expert	Croatia	No interests declared	
Ivona Jukić	Expert	Croatia	No interests declared	
Magdalena Kremer	Expert	Germany	No interests declared	
Peter Mayer	Expert	Germany	No interests declared	
Jana Klimasová	Expert	Slovakia	No restrictions applicable to this meeting	
Anna Kubandová	Expert	Slovakia	No interests declared	
Ivana Rusňáková	Expert	Slovakia	No interests declared	
Jana Schweigertová	Expert	Slovakia	No interests declared	
Peter Šišovský	Expert	Slovakia	No interests declared	
Eva Malikova	Expert	Slovakia	No interests declared	
Charlotte Anderberg	Expert	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jenny-Maria Jönsson	Expert	Sweden	No participation in final deliberations and voting on:	Tecentriq - atezolizumab - EMEA/H/C/004143 /X/0076
Matti Karvanen	Expert	Sweden	No interests declared	
Karin Fjordén	Expert	Sweden	No participation in final deliberations and voting on:	Keytruda - pembrolizumab - EMEA/H/C/003820 /II/0138
Daiana Vasilcanu	Expert	Sweden	No interests declared	
Helena Faust	Expert	Sweden	No interests declared	
Vincent Gazin	Expert	France	No interests declared	
Glenn Lastennet	Expert	France	No interests declared	
Roxane Fornacciarì	Expert	France	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Isabelle Puff	Expert	France	No interests declared	
Brenda Holingue	Expert	France	No interests declared	
Lama Caizergues Sargi	Expert	France	No interests declared	
Marika Doucet	Expert	France	No interests declared	
Ieva Rutkovska	Expert	Latvia	No interests declared	
Diāna Inga Paegle	Expert	Latvia	No interests declared	
Kairi Rooma	Expert	Estonia	No interests declared	
Rune Kjekken	Expert	Norway	No restrictions applicable to this meeting	
Kristine Moltu	Expert	Norway	No interests declared	
Fabrice Eroukhanoff	Expert	Norway	No interests declared	
Nina Pettersen Hessvik	Expert	Norway	No interests declared	
Lena Eroukhanoff	Expert	Norway	No participation in discussion, final deliberations and voting on:	Rystiggo - rozanolixumab - Orphan - EMEA/H/C/005824
Paolo Foggi	Expert	Italy	No interests declared	
Elisabeth Wischnitzki	Expert	Austria	No interests declared	
Anna Vikerfors	Expert	Sweden	No interests declared	
Flora Musuamba	Expert	Belgium	No restrictions applicable to this meeting	
Carin Bergquist	Expert	Sweden	No interests declared	
Karri Penttilä	Expert	Finland	No interests declared	
Maria Paile-Hyvärinen	Expert	Finland	No interests declared	
Kinga Nowicka-Matus	Expert	Denmark	No interests declared	
Ebru Karakoc Madsen	Expert	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Expert	Denmark	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Torsten Holm Nielsen	Expert	Denmark	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Line Præst Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Deirdre Mannion	Expert	Denmark	No restrictions applicable to this meeting	
Kristin Skougaard	Expert	Denmark	No interests declared	
Anne-Marie Dalseg	Expert	Denmark	No interests declared	
Camilla Göktürk	Expert	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Céline Jumeau	Expert	France	No interests declared	
Mona Kassem-Youssef	Expert	France	No interests declared	
Marta Lafuente Gonzalez	Expert	Spain	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Beatriz Gutiérrez Eugenio	Expert	Spain	No interests declared	
Agustín Portela	Expert	Spain	No interests declared	
Alicia Pérez González	Expert	Spain	No interests declared	
Ana Sagredo	Expert	Spain	No interests declared	
Daniel Fernández Soto	Expert	Spain	No interests declared	
Rosa Virto	Expert	Spain	No interests declared	
Carmen de la Morena Criado	Expert	Spain	No interests declared	
Ana Moreno Oliver	Expert	Spain	No interests declared	
Maria Luisa Valer Lopez-Fando	Expert	Spain	No interests declared	
Andrea García Caballero	Expert	Spain	No interests declared	
Eva Maria Nadal Elduayen	Expert	Spain	No interests declared	
Marte Fergestad	Expert	Norway	No interests declared	
Maja Sommerfelt Grønvold	Expert	Norway	No interests declared	
Viktor András Billes	Expert	Hungary	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Alexandru-Mihail Simion	Expert	Belgium	No interests declared	
Stefan Bonné	Expert	Belgium	No interests declared	
Nicolas Nyssen	Expert	Belgium	No interests declared	
Valérie Lescrainier	Expert	Belgium	No interests declared	
Harald Bernsteiner	Expert	Austria	No interests declared	
Walter Johannes Beiersdorf	Expert	Austria	No restrictions applicable to this meeting	
Matthias Braun	Expert	Austria	No interests declared	
Hannah Münch	Expert	Austria	No interests declared	
Tobias Glüxam	Expert	Austria	No interests declared	
Edo Richard	Expert	Netherlands	No restrictions against giving the SAG report on Qalsody	
Adriana Ammassari	Expert	Italy	No interests declared	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert	Italy	No participation in discussion, final deliberations and voting on:	Tepadina - thiotepa - EMEA/H/C/001046 /X/0049
Cristina Migali	Expert	Italy	No interests declared	
Serena Zamponi	Expert	Italy	No interests declared	
Gabriella Passacquale	Expert	Italy	No interests declared	
Milica Mitrevski	Expert	Italy	No interests declared	
Cinzia Ciceroni	Expert	Italy	No interests declared	
Valentina Conti	Expert	Italy	No interests declared	
Angela Garau	Expert	Italy	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Angelo Molinaro	Expert	Italy	No interests declared	
Michela Piezzo	Expert	Italy	No interests declared	
Larissa Higgins	Expert	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Brian Aylward	Expert	Ireland	No interests declared	
Sinead Harrington	Expert	Ireland	No interests declared	
Benita Cullen	Expert	Ireland	No interests declared	
Cathrine Wisbech	Expert	Norway	No restrictions applicable to this meeting	
Katja Findeisen	Expert	Germany	No restrictions applicable to this meeting	
Juliane Rau	Expert	Germany	No interests declared	
Attila Sebe	Expert	Germany	No interests declared	
Benjamin Hofner	Expert	Germany	No restrictions applicable to this meeting	
Michal Zwiewka	Expert	Germany	No interests declared	
Irene Nowotny	Expert	Germany	No restrictions applicable to this meeting	
Annette Lommel	Expert	Germany	No interests declared	
Poleta Luga	Expert	Germany	No interests declared	
Niklas Walther	Expert	Germany	No restrictions applicable to this meeting	
Hilke Zander	Expert	Germany	No interests declared	
Julia Katharina Maier	Expert	Germany	No interests declared	
Susanne Müller-Egert	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Matea Cartolano	Expert	Germany	No interests declared	
Yasmin Molter	Expert	Germany	No interests declared	
Robert Pollmann	Expert	Germany	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
Hinke Johanna van der Woude	Expert	Netherlands	No interests declared	
Angela de Kleynen	Expert	Netherlands	No interests declared	
Friederike Marei Feldmann	Expert	Germany	No interests declared	
Febrin Hennemann	Expert	Germany	No interests declared	
Georgios Aislaitner	Expert	Germany	No interests declared	
Andreas Brandt	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Sylvia Kühn	Expert	Germany	No restrictions applicable to this meeting	
Miriam Fürst-Wilmes	Expert	Germany	No interests declared	
Danila Renzo	Expert	Italy	No interests declared	
Valeria Zoccano	Expert	Italy	No interests declared	
Loes den Otter	Expert	Netherlands	No interests declared	
Thurid Buch	Expert	Germany	No interests declared	
Emline Leon	Expert	France	No restrictions applicable to this meeting	
Sigurros Sigmarsdottir	Expert	Iceland	No restrictions applicable to this meeting	
Kristian Wennmalm	Expert	Sweden	No interests declared	
Norbert Benda	Expert	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Tarec Christoffer El-Galaly	Expert	Denmark	No restrictions against giving the SAG report for Krazati	
Sine Buhl Næss-Schmidt	Expert	Denmark	No restrictions applicable to this meeting	
Emilie Birch Kristensen	Expert	Denmark	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Thadeus Bao Quan Nguyen	Expert	Denmark	No interests declared	
Mette Steen Tranholm	Expert	Denmark	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Gunnar Thor Gunnarsson	Expert	Iceland	No interests declared	
Kira Blankenbach	Expert	Swissmedic	No interests declared	
Regula Johner	Expert	Swissmedic	No interests declared	
Thomas Schochat	Expert	Swissmedic	No interests declared	

A representative from the European Commission attended the meeting.

Meeting run with the help of EMA staff.

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

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

Explanatory notes

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

Oral explanations (section 2)

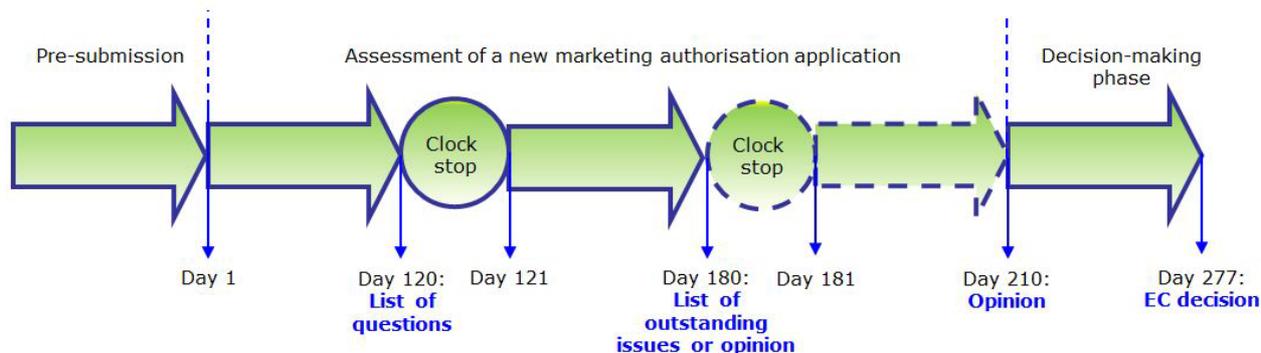
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

Ancillary medicinal substances in medical devices (section 6)

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

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

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

Re-examination procedures (section 5.3)

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

Withdrawal of application (section 3.7)

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

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

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

Pre-submission issues (section 8)

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

Post-authorisation issues (section 9)

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

Referral procedures (section 10)

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

Pharmacovigilance issues (section 11)

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

Inspections Issues (section 12)

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

Innovation task force (section 13)

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

Scientific advice working party (SAWP) (section 14.3.1)

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

Satellite groups / other committees (section 14.2)

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

Invented name issues (section 14.3)

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

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



10 January 2024
EMA/CHMP/500954/2023

Annex to 06-09 November 2023 CHMP Minutes

Pre-submission and post-authorisations issues

A. PRE-SUBMISSION ISSUES	3
A.1. ELIGIBILITY REQUESTS.....	3
A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications	3
A.3. PRE-SUBMISSION ISSUES FOR INFORMATION	3
B. POST-AUTHORISATION PROCEDURES OUTCOMES	3
B.1. Annual re-assessment outcomes	3
B.1.1. Annual reassessment for products authorised under exceptional circumstances	3
B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES.....	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.....	5
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES.....	5
B.4. EPARs / WPARs	7
B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES	9
B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects	9
B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects.....	14
B.5.3. CHMP-PRAC assessed procedures	24
B.5.4. PRAC assessed procedures.....	29
B.5.5. CHMP-CAT assessed procedures	34
B.5.6. CHMP-PRAC-CAT assessed procedures	36
B.5.7. PRAC assessed ATMP procedures	36
B.5.8. Unclassified procedures and worksharing procedures of type I variations.....	36
B.5.9. Information on withdrawn type II variation / WS procedure	38
B.5.10. Information on type II variation / WS procedure with revised timetable.....	39
B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION	39
B.6.1. Start of procedure for New Applications: timetables for information	39
B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information	40



B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information.....	42
B.6.4. Annual Re-assessments: timetables for adoption	43
B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed	44
B.6.6. VARIATIONS – START OF THE PROCEDURE.....	45
B.6.7. Type II Variations scope of the Variations: Extension of indication	45
B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects	50
B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects.....	52
B.6.10. CHMP-PRAC assessed procedures.....	56
B.6.11. PRAC assessed procedures	57
B.6.12. CHMP-CAT assessed procedures	57
B.6.13. CHMP-PRAC-CAT assessed procedures.....	58
B.6.14. PRAC assessed ATMP procedures	58
B.6.15. Unclassified procedures and worksharing procedures of type I variations	58
B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY.....	59
B.7.1. Yearly Line listing for Type I and II variations.....	59
B.7.2. Monthly Line listing for Type I variations.....	59
B.7.3. Opinion on Marketing Authorisation transfer (MMD only)	59
B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)	59
B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)	59
B.7.6. Notifications of Type I Variations (MMD only)	59
C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)	59
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)	59
E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES	59
E.1. PMF Certification Dossiers.....	60
E.1.1. Annual Update.....	60
E.1.2. Variations	60
E.1.3. Initial PMF Certification	60
E.2. Time Tables – starting & ongoing procedures: For information	60
F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver	60
G. ANNEX G.....	60
G.1. Final Scientific Advice (Reports and Scientific Advice letters):	60
G.2. PRIME.....	60
H. ANNEX H - Product Shared Mailboxes – e-mail address.....	60

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for November 2023: For adoption	Adopted
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A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for November 2023: For adoption	Adopted
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A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Atriance - nelarabine - EMEA/H/C/000752/S/0062 Sandoz Pharmaceuticals d.d., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Mepsevii - vestronidase alfa - EMEA/H/C/004438/S/0036, Orphan Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Dectova - zanamivir - EMEA/H/C/004102/R/0017 GlaxoSmithKline Trading Services Limited, Rapporteur: Ingrid Wang, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can
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	be granted with unlimited validity.
<p>Mulpleo - lusutrombopag - EMEA/H/C/004720/R/0018 Shionogi B.V., Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Mari Thorn Request for Supplementary Information adopted on 14.09.2023.</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.</p>
<p>Pazenir - paclitaxel - EMEA/H/C/004441/R/0015 ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.</p>
<p>Palynziq - Pegvaliase - EMEA/H/C/004744/R/0038, Orphan BioMarin International Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 09.11.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Skyrizi - risankizumab - EMEA/H/C/004759/R/0039 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Gross-Martirosyan Request for Supplementary Information adopted on 14.09.2023.</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.</p>
<p>Trecondi - treosulfan - EMEA/H/C/004751/R/0019, Orphan medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Fátima Ventura, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Julia Pallos</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.</p>

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 23-26 October 2023
PRAC:

Signal of acquired phimosis and phimosis	Adopted
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Edistride, Forxiga, Ebymect, Xigduo, Qtern
(CAP & NAP) – Dapagliflozin

Rapporteur: multiple, Co-Rapporteur: multiple,
PRAC Rapporteur: Mari Thorn
PRAC recommendation on a variation

Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its November 2023 meeting:

EMA/H/C/PSUSA/0002491/202304	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of sections 4.2, 4.4 and 4.8 of the SmPC to highlight that the lowest effective dose should be used, amend the warning/precaution regarding restless legs augmentation syndrome and to add the adverse reaction restless legs augmentation syndrome with a frequency 'very common'. The package leaflet is updated accordingly.
(pramipexole)	

CAPS:

Mirapexin (EMA/H/C/000134)

(pramipexole), Boehringer Ingelheim International GmbH, Rapporteur: Thalia Marie Estrup Blicher

Sifrol (EMA/H/C/000133) (pramipexole), Boehringer Ingelheim International GmbH, Rapporteur: Thalia Marie Estrup Blicher

NAPS:

NAPs – EU

PRAC Rapporteur: Karin Erneholm,
"06/04/2022 To: 06/04/2023"

EMA/H/C/PSUSA/00010499/202303	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends, by consensus, the variation to the terms of the marketing authorisation for the above-mentioned medicinal product, concerning the following change(s): Update of section 4.8 of the SmPC to include "Anaphylactic Shock" as an Adverse Drug Reaction with frequency unknown. The package
(eftrenonacog alfa)	

CAPS:

Alprolix (EMA/H/C/004142) (eftrenonacog

alfa), Swedish Orphan Biovitrum AB (publ),

Rapporteur: Daniela Philadelpho, PRAC

Rapporteur: Gabriele Maurer, "20/03/2020 To: 19/03/2023"

<p>EMA/H/C/PSUSA/00010635/202303 (avelumab) CAPS: Bavencio (EMA/H/C/004338) (avelumab), Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Erneholm, "23/03/2022 To: 22/03/2023"</p>	<p>leaflet has been updated accordingly.</p> <p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to amend a warning/precaution regarding the risk of autoimmune reactions. The package leaflet is updated accordingly. Update of sections 4.4 and 4.8 of the SmPC to amend a warning/precaution regarding other immune-related adverse reactions and add the adverse reaction sarcoidosis with a frequency uncommon. The package leaflet is updated accordingly.</p>
<p>EMA/H/C/PSUSA/00010760/202303 (lorlatinib) CAPS: Lorviqua (EMA/H/C/004646) (lorlatinib), Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Nikica Mirošević Skvrce, "21/09/2022 To: 20/03/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction proteinuria with a frequency common. The package leaflet is updated accordingly.</p>
<p>EMA/H/C/PSUSA/00010818/202303 (siponimod) CAPS: Mayzent (EMA/H/C/004712) (Siponimod), Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Maria del Pilar Rayon, "26/03/2022 To: 25/03/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to amend the PML frequency from "unknown" to "rare". The package leaflet is updated accordingly. Update of section 4.4 of the SmPC to amend a warning regarding reduction in heart rate and atrioventricular conduction.</p>
<p>EMA/H/C/PSUSA/00010879/202303 (filgotinib)</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004</p>

CAPS:
Jyseleca (EMA/H/C/005113) (Filgotinib), Galapagos N.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, "24/09/2022 To 23/03/2023"

the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of sections 4.7 and 4.8 of the SmPC to add the adverse reaction vertigo with a frequency of uncommon. The package leaflet should be updated accordingly.

EMA/H/C/PSUSA/00010921/202303
(cenobamate)
CAPS:
Ontozry (EMA/H/C/005377) (Cenobamate), Angelini S.p.A., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Jo Robays, "19/05/2022 To: 26/03/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of sections 4.4 and 4.8 of the SmPC to amend /add information relating to suicidality following the use of cenobamate. The package leaflet is updated accordingly.

EMA/H/C/PSUSA/00011003/202303
(olipudase alfa)
CAPS:
Xenpozyme (EMA/H/C/004850) (Olipudase alfa), Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "28/09/2022 To: 28/03/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of sections 4.2, 4.4 and 4.9 of the SmPC to amend the wording about the dose escalation scheme and to reflect the cases of overdose. The package leaflet is updated accordingly.

B.4. EPARs / WPARs

Agamree - vamorolone - EMA/H/C/005679, Orphan
Santhera Pharmaceuticals (Deutschland) GmbH, treatment of Duchenne muscular dystrophy (DMD), New active substance (Article 8(3) of Directive No 2001/83/EC)

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

Elrexfio - elranatamab - EMA/H/C/005908

For information only. Comments can be sent to

Pfizer Europe MA EEIG, treatment of adult patients with relapsed or refractory multiple myeloma, New active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
Elucirem - gadopiclesol - EMEA/H/C/005626 Guerbet, for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate)., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Loargys - pegzilarginase - EMEA/H/C/005484, Orphan Immedica Pharma AB, treatment of hyperargininemia, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Rezzayo - rezafungin - EMEA/H/C/005900, Orphan Mundipharma GmbH, treatment of invasive candidiasis, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Sugammadex Lorien (WD) - sugammadex - EMEA/H/C/006115 LABORATORIOS LORIEN, S.L, reversal of neuromuscular blockade induced by rocuronium or vecuronium, Generic, Generic of Bridion, Generic application (Article 10(1) of Directive No 2001/83/EC) WPAR	For information only. Comments can be sent to the PL in case necessary.
Veozza - fezolinetant - EMEA/H/C/005851 Astellas Pharma Europe B.V., treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Vueway - gadopiclesol - EMEA/H/C/006172 Bracco Imaging S.p.A., for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate)., Duplicate, Duplicate of Elucirem, New active substance (Article 8(3))	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Adjupanrix - pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) - EMEA/H/C/001206/II/0086/G GlaxoSmithkline Biologicals SA, Informed Consent of Pandemrix (EXP), Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 26.10.2023.	Request for supplementary information adopted with a specific timetable.
Adtralza - tralokinumab - EMEA/H/C/005255/II/0010 LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 09.11.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 09.11.2023.
Briumvi - Ublituximab - EMEA/H/C/005914/II/0001 Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra Opinion adopted on 09.11.2023.	Positive Opinion adopted by consensus on 09.11.2023.
Budesonide/Formoterol Teva Pharma B.V. - budesonide / formoterol fumarate dihydrate - EMEA/H/C/004882/II/0012/G Teva Pharma B.V., Duplicate, Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, PRAC Rapporteur: Marie Louise Schougaard Christiansen Request for Supplementary Information adopted on 09.11.2023, 30.03.2023.	Request for supplementary information adopted with a specific timetable.
Cosentyx - secukinumab - EMEA/H/C/003729/II/0107 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 09.11.2023.	Request for supplementary information adopted with a specific timetable.
Dukoral - cholera vaccine (inactivated, oral) - EMEA/H/C/000476/II/0071 Valneva Sweden AB, Rapporteur: Kristina Dunder	Positive Opinion adopted by consensus on 26.10.2023.

Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

**Eptifibatide Accord - eptifibatide -
EMA/H/C/004104/II/0015/G**

Accord Healthcare S.L.U., Generic, Generic of
Integrilin, Rapporteur: Jayne Crowe
Request for Supplementary Information adopted
on 26.10.2023, 12.05.2023.

Request for supplementary information adopted
with a specific timetable.

**Flucelvax Tetra - Influenza vaccine
(surface antigen, inactivated, prepared in
cell cultures) -
EMA/H/C/004814/II/0039**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Opinion adopted on 09.11.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
09.11.2023.

**Flucelvax Tetra - Influenza vaccine
(surface antigen, inactivated, prepared in
cell cultures) -
EMA/H/C/004814/II/0041**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Request for Supplementary Information adopted
on 09.11.2023.

Request for supplementary information adopted
with a specific timetable.

**Gonal-f - follitropin alfa -
EMA/H/C/000071/II/0163/G**

Merck Europe B.V., Rapporteur: Patrick Vrijlandt
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
19.10.2023.

**Hemlibra - Emicizumab -
EMA/H/C/004406/II/0037**

Roche Registration GmbH, Rapporteur:
Alexandre Moreau
Opinion adopted on 09.11.2023.

Positive Opinion adopted by consensus on
09.11.2023.

**Hizentra - human normal immunoglobulin -
EMA/H/C/002127/II/0146/G**

CSL Behring GmbH, Rapporteur: Jan Mueller-
Berghaus
Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on
26.10.2023.

**Imraldi - adalimumab -
EMA/H/C/004279/II/0066/G**

Samsung Bioepis NL B.V., Rapporteur: Outi
Mäki-Ikola
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
19.10.2023.

<p>Nepexto - etanercept - EMA/H/C/004711/II/0023</p> <p>Biosimilar Collaborations Ireland Limited, Rapporteur: Martina Weise Opinion adopted on 26.10.2023. Request for Supplementary Information adopted on 31.08.2023.</p>	<p>Positive Opinion adopted by consensus on 26.10.2023.</p>
<p>Nepexto - etanercept - EMA/H/C/004711/II/0024</p> <p>Biosimilar Collaborations Ireland Limited, Rapporteur: Martina Weise Request for Supplementary Information adopted on 09.11.2023, 07.09.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMA/H/C/002226/II/0129/G</p> <p>Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang Opinion adopted on 09.11.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>Nplate - Romiplostim - EMA/H/C/000942/II/0089</p> <p>Amgen Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 09.11.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>Omnitrope - somatropin - EMA/H/C/000607/II/0076</p> <p>Sandoz GmbH, Rapporteur: Patrick Vrijlandt Opinion adopted on 09.11.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>Ontruzant - Trastuzumab - EMA/H/C/004323/II/0048/G</p> <p>Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn Opinion adopted on 09.11.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>Orencia - abatacept - EMA/H/C/000701/II/0158/G</p> <p>Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 26.10.2023. Request for Supplementary Information adopted on 21.09.2023.</p>	<p>Positive Opinion adopted by consensus on 26.10.2023.</p>
<p>Palynziq - Pegvaliase - EMA/H/C/004744/II/0039/G, Orphan</p> <p>BioMarin International Limited, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 09.11.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>

<p>Pegasys - peginterferon alfa-2a - EMEA/H/C/000395/II/0115</p> <p>Pharmaand GmbH, Rapporteur: Filip Josephson</p> <p>Opinion adopted on 19.10.2023.</p> <p>Request for Supplementary Information adopted on 14.09.2023.</p>	<p>Positive Opinion adopted by consensus on 19.10.2023.</p>
<p>Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0087/G</p> <p>Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher</p> <p>Opinion adopted on 19.10.2023.</p> <p>Request for Supplementary Information adopted on 31.08.2023.</p>	<p>Positive Opinion adopted by consensus on 19.10.2023.</p>
<p>Perjeta - Pertuzumab - EMEA/H/C/002547/II/0068/G</p> <p>Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia</p> <p>Opinion adopted on 09.11.2023.</p> <p>Request for Supplementary Information adopted on 28.09.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>Phesgo - pertuzumab / trastuzumab - EMEA/H/C/005386/II/0020/G</p> <p>Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia</p> <p>Opinion adopted on 26.10.2023.</p>	<p>Positive Opinion adopted by consensus on 26.10.2023.</p>
<p>Pyrukynd - mitapivat - EMEA/H/C/005540/II/0003/G, Orphan</p> <p>Agios Netherlands B.V., Rapporteur: Alexandre Moreau</p> <p>Request for Supplementary Information adopted on 26.10.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0068</p> <p>GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke</p> <p>Opinion adopted on 09.11.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>Soliris - eculizumab - EMEA/H/C/000791/II/0128/G, Orphan</p> <p>Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez</p> <p>Request for Supplementary Information adopted on 19.10.2023, 31.08.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Strensiq - asfotase alfa - EMEA/H/C/003794/II/0065/G, Orphan</p> <p>Alexion Europe SAS, Rapporteur: Paolo Gasparini</p>	<p>Positive Opinion adopted by consensus on 19.10.2023.</p>

Opinion adopted on 19.10.2023.

**Toujeo - Insulin glargine -
EMA/H/C/000309/II/0127/G**

Sanofi-Aventis Deutschland GmbH, Duplicate,
Duplicate of Lantus, Rapporteur: Patrick
Vrijlandt
Request for Supplementary Information adopted
on 09.11.2023.

Request for supplementary information adopted
with a specific timetable.

**Vaxelis - Diphtheria, tetanus, pertussis
(acellular, component), hepatitis B (rDNA),
poliomyelitis (inact.) and haemophilus type
B conjugate vaccine (adsorbed) -
EMA/H/C/003982/II/0132**

MCM Vaccine B.V., Rapporteur: Christophe
Focke
Opinion adopted on 09.11.2023.

Positive Opinion adopted by consensus on
09.11.2023.

**Xgeva - denosumab -
EMA/H/C/002173/II/0082/G**

Amgen Europe B.V., Rapporteur: Kristina
Dunder
Request for Supplementary Information adopted
on 19.10.2023.

Request for supplementary information adopted
with a specific timetable.

**Zaltrap - aflibercept -
EMA/H/C/002532/II/0069/G**

Sanofi Winthrop Industrie, Rapporteur: Filip
Josephson
Request for Supplementary Information adopted
on 19.10.2023.

Request for supplementary information adopted
with a specific timetable.

**WS2522/G
Dengue Tetravalent Vaccine (Live,
Attenuated) Takeda-
EMA/H/W/005362/WS2522/0007/G
Qdenga-**

EMA/H/C/005155/WS2522/0008/G
Takeda GmbH, Lead Rapporteur: Sol Ruiz
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted
on 07.09.2023.

Positive Opinion adopted by consensus on
19.10.2023.

**WS2547
Blitzima-
EMA/H/C/004723/WS2547/0068
Truxima-
EMA/H/C/004112/WS2547/0071**

Celltrion Healthcare Hungary Kft., Lead
Rapporteur: Sol Ruiz
Opinion adopted on 19.10.2023.

Positive Opinion adopted by consensus on
19.10.2023.

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

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

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

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

Request for supplementary information adopted with a specific timetable.

See 9.1

BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer -

EMA/H/C/006058/II/0002

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final study report HIPRA-HH-1 listed as a category 3 study in the RMP. This is a phase I/IIa study to evaluate safety and immunogenicity of PHH-1V against SARS-COV-2 in adult healthy volunteers."

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 09.11.2023.

BLINCYTO - blinatumomab - EMA/H/C/003731/II/0051, Orphan

Amgen Europe B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to update immunogenicity information to remove reference to antibody testing based on an analysis of all completed clinical studies and post-marketing data."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 29.06.2023.

Positive Opinion adopted by consensus on 26.10.2023.

<p>Caprelsa - Vandetanib - EMA/H/C/002315/II/0059</p> <p>Sanofi B.V., Rapporteur: Alexandre Moreau, "Submission of a safety evaluation report (SER) focused on long term use in association with vandetanib." Opinion adopted on 09.11.2023.</p>	<p>Positive Opinion adopted by consensus on 09.11.2023.</p>
<p>COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMA/H/C/005735/II/0187</p> <p>BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Submission of the final report from study BNT162-01, a multi-site, open-label, first-in-human (FIH), Phase 1/2, two-part, dose- escalation trial investigating the safety and immunogenicity of four prophylactic SARS-CoV- 2 RNA vaccines against COVID-19 using different dosing regimens in healthy and immunocompromised adults, listed as category 3 study in the RMP." Opinion adopted on 26.10.2023.</p>	<p>Positive Opinion adopted by consensus on 26.10.2023.</p>
<p>Dynastat - Parecoxib - EMA/H/C/000381/II/0088</p> <p>Pfizer Europe MA EEIG, Duplicate, Duplicate of Xapit (SRD), Rapporteur: Finbarr Leacy, "Update of section 4.4 of the SmPC in order to update skin reactions information based on literature and post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to align the Package Leaflet with the SmPC." Request for Supplementary Information adopted on 09.11.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Fabrazyme - agalsidase beta - EMA/H/C/000370/II/0129</p> <p>Sanofi B.V., Rapporteur: Patrick Vrijlandt, "Update of section 4.6 of the SmPC in order to update the safety information on pregnancy and breast-feeding based on results from AGAL02603/MS12868: "A Multicenter, Multinational Study of the Effects of Fabrazyme (agalsidase beta) Treatment on Lactation and Infants", listed as a category 3 study in the RMP, MAH safety database and literature search; the Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted</p>	<p>Request for supplementary information adopted with a specific timetable.</p>

on 26.10.2023.

**IMCIVREE - setmelanotide -
EMA/H/C/005089/II/0015, Orphan**

Rhythm Pharmaceuticals Netherlands B.V.,
Rapporteur: Karin Janssen van Doorn,
"Submission of the final report from study RM-
493-014. This is a phase 2 treatment trial of
setmelanotide in patients with rare genetic
disorders of obesity."
Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on
26.10.2023.

**Keytruda - Pembrolizumab -
EMA/H/C/003820/II/0139**

Merck Sharp & Dohme B.V., Rapporteur: Paolo
Gasparini, "Update of section 5.1 of the SmPC in
order to update clinical information, based on
results from study KEYNOTE-716 listed as a
PAES in the Annex II. This is a randomized,
double-blind phase 3 study of adjuvant therapy
with pembrolizumab versus placebo in resected
high-risk stage II melanoma. The Annex II is
updated accordingly."
Opinion adopted on 09.11.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
09.11.2023.

**Lonquex - lipegfilgrastim -
EMA/H/C/002556/II/0080**

Teva B.V., Rapporteur: Outi Mäki-Ikola, "Update
of section 4.4 of the SmPC in order to add a
class-effect warning risk of Acute Myeloid
Leukaemia and Myelodysplastic Syndrome in
breast and lung cancer patients in conjunction
with chemotherapy and/or radiotherapy based
on the cumulative review of literature and MAH
safety database. The Package Leaflet is updated
accordingly."
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
26.10.2023.

**Mounjaro - Tirzepatide -
EMA/H/C/005620/II/0010**

Eli Lilly Nederland B.V., Rapporteur: Martina
Weise, "Update of section 4.8 of the SmPC in
order to add 'anaphylactic reaction' and
'angioedema' to the list of adverse drug
reactions (ADRs) with frequency rare, based on
reviews of post-marketing safety data. The
Package Leaflet is updated accordingly. In
addition, the MAH took the opportunity to

Positive Opinion adopted by consensus on
09.11.2023.

introduce minor changes to the PI.”
Opinion adopted on 09.11.2023.
Request for Supplementary Information adopted
on 07.09.2023.

**NUVAXOVID - Covid-19 vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0058/G**

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt
Opinion adopted on 31.10.2023.
Request for Supplementary Information adopted
on 12.10.2023.

Positive Opinion adopted by consensus on
31.10.2023.

See 9.1

**Opzelura - ruxolitinib -
EMA/H/C/005843/II/0003**

Incyte Biosciences Distribution B.V.,
Rapporteur: Peter Mol, “Update of sections 4.2,
4.4 and 5.1 of the SmPC in order to update
posology, safety and efficacy information based
on final results from study INCB 18424-308;
this is a Phase III, double-blind, vehicle-
controlled, randomized withdrawal and
treatment-extension study to assess the long-
term efficacy and safety of ruxolitinib cream in
participants with vitiligo (TRuE-V LTE). The
Package Leaflet is updated accordingly. In
addition, the MAH took the opportunity to
implement editorial changes in the SmPC.”
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted
on 31.08.2023.

Positive Opinion adopted by consensus on
19.10.2023.

**Paxlovid - Nirmatrelvir / Ritonavir -
EMA/H/C/005973/II/0049/G**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel
Race, “Grouped application comprising two type
II variations (C.I.4) as follows:
- Update of sections 4.4 and 4.8 of the SmPC in
order to clarify that toxic epidermal necrolysis
has been reported with Paxlovid and to add
toxic epidermal necrolysis to the list of adverse
drug reactions (ADRs) with frequency Rare
based on the cumulative review of MAH safety
database and literature.
- Update of sections 4.4 and 4.8 of the SmPC in
order to clarify that Stevens-Johnson syndrome
has been reported with Paxlovid and to add
Stevens-Johnson syndrome to the list of
adverse drug reactions (ADRs) with frequency
Rare, based on the cumulative review of MAH
safety database and literature.
The Package Leaflet is updated accordingly.”

Request for supplementary information adopted
with a specific timetable.

Request for Supplementary Information adopted on 09.11.2023.

Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0021

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Submission of the final report from study MO40628 (PHranceSCa), a Phase II, randomized, multicenter, open-label, cross-over study to evaluate patient reported preference for Phesgo compared with intravenous pertuzumab and trastuzumab in patients with HER2-positive EBC."

Opinion adopted on 09.11.2023.

Positive Opinion adopted by consensus on 09.11.2023.

RAYVOW - Lasmiditan - EMEA/H/C/005332/II/0004

Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with dabigatran and rosuvastatin based on the results from study LAIO, An Open-Label, 2-Part Study to Investigate the Effect of Lasmiditan on the Pharmacokinetics of Dabigatran and Rosuvastatin in Healthy Volunteers. The aim of study LAIO was to investigate the effect of lasmiditan on the pharmacokinetic profiles of dabigatran (a P-glycoprotein substrate) and rosuvastatin (breast cancer resistance protein substrate) in healthy volunteers. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Request for Supplementary Information adopted on 09.11.2023.

Request for supplementary information adopted with a specific timetable.

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

Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising three type II variations (C.I.4) as follows:
- Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information based on week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (crohn's disease), listed as a category 3 study in

Request for supplementary information adopted with a specific timetable.

See 9.1

the RMP; study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease.

- Update of sections 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.

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

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

Request for Supplementary Information adopted on 09.11.2023.

**RINVOQ - upadacitinib -
EMA/H/C/004760/II/0042**

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, "Submission of the final report from study M13-545 listed as a category 3 study in the RMP (MEA/10).

This is a Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects with Moderately to Severely Active Rheumatoid Arthritis."

Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

**Shingrix - herpes zoster vaccine
(recombinant, adjuvanted) -
EMA/H/C/004336/II/0065**

GlaxoSmithkline Biologicals SA, Rapporteur:

Positive Opinion adopted by consensus on 26.10.2023.

Christophe Focke, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information with COVID-19 mRNA-1273 booster vaccine, based on final results from study ZOSTER-091; this is a phase 3, randomized, open-label, controlled, multi-center clinical study to evaluate the immune response and safety of both herpes zoster subunit vaccine (HZ/su or Shingrix) in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine (Flu D-QIV or Fluarix Quadrivalent) in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination. The Package Leaflet is updated accordingly."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 13.07.2023.

**Spravato - esketamine -
EMA/H/C/004535/II/0018**

Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study 54135419TRD3013 (ESCAPE). This is A Randomized, Open-label, Rater-Blinded, Active-Controlled, International, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Flexibly Dosed Esketamine Nasal Spray Compared With Quetiapine Extended-Release in Adult and Elderly Participants With Treatment-Resistant Major Depressive Disorder Who are Continuing a Selective Serotonin Reuptake Inhibitor/ Serotonin-Norepinephrine Reuptake Inhibitor.

In addition, the MAH took the opportunity to introduce minor editorial changes, to update Annex IV and to update the list of local representatives in the Package Leaflet."

Opinion adopted on 19.10.2023.

Request for Supplementary Information adopted on 20.07.2023.

Positive Opinion adopted by consensus on 19.10.2023.

**Toviaz - fesoterodine -
EMA/H/C/000723/II/0068**

Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of sections 4.4 of the SmPC to amend an existing warning on angioedema and 4.8 of the SmPC in order to

Positive Opinion adopted by consensus on 19.10.2023.

add hypoaesthesia oral to the list of adverse drug reactions (ADRs) with a frequency rare based on a cumulative review of safety database cases and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the QRD template v10.3.”
Opinion adopted on 19.10.2023.
Request for Supplementary Information adopted on 13.07.2023.

**Veklury - Remdesivir -
EMA/H/C/005622/II/0052**

Positive Opinion adopted by consensus on 09.11.2023.

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, “Update of section 5.1 of the SmPC with non-clinical information related to the antiviral activity of Remdesivir against Omicron subvariants BF.7, BQ.1, XBB.1.5, CH.1.1. In addition, the MAH took the opportunity to implement editorial changes in the SmPC.”
Opinion adopted on 09.11.2023.
Request for Supplementary Information adopted on 05.10.2023.

**Verzenios - Abemaciclib -
EMA/H/C/004302/II/0028**

Positive Opinion adopted by consensus on 09.11.2023.

Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, “Update of section 4.4 of the SmPC in order to add a new warning on “arterial thromboembolic events”, based on a safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 9 of the SmPC.”
Opinion adopted on 09.11.2023.
Request for Supplementary Information adopted on 28.09.2023.

**Vipdomet - alogliptin / metformin -
EMA/H/C/002654/II/0044**

Positive Opinion adopted by consensus on 26.10.2023.

Takeda Pharma A/S, Rapporteur: Patrick Vrijlandt, “Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Vitamin B12 decrease or deficiency and to update the list of adverse drug reactions (ADRs) in accordance with the recent update of the PI for Glucophage, which is the reference label for the compound metformin, and following the request by MHRA on 20 June 2022 for all products containing metformin.”
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted

on 06.07.2023.

**Xevudy - sotrovimab -
EMA/H/C/005676/II/0019/G**

Glaxosmithkline Trading Services Limited,
Rapporteur: Thalia Marie Estrup Blicher,
"Update of sections 4.2, 4.8, 4.9, 5.1 and 5.2 of
the SmPC in order to update posology
recommendations and administration
instructions as well as efficacy, pharmacokinetic
and safety information, based on results from
studies COMET-TAIL (phase 3 study and safety
sub study; 217114), COMET-PEAK (216912),
Japan-PK (217653) and BLAZE-4, and from a
Population PK (PopPK) report. The MAH took the
opportunity to add some editorial changes. The
Package Leaflet is updated accordingly."
Opinion adopted on 09.11.2023.
Request for Supplementary Information adopted
on 14.09.2023.

Positive Opinion adopted by consensus on
09.11.2023.

**Zavicefta - Ceftazidime / Avibactam -
EMA/H/C/004027/II/0033**

Pfizer Ireland Pharmaceuticals, Rapporteur:
Ingrid Wang, "Update of section 4.8 of the
SmPC in order to add 'Kounis syndrome' to the
list of adverse drug reactions (ADRs). The
Package Leaflet is updated accordingly. In
addition, the MAH is taking the opportunity to
introduce minor changes to the PI and to update
the list of local representatives in the Package
Leaflet."
Request for Supplementary Information adopted
on 09.11.2023.

Request for supplementary information adopted
with a specific timetable.

**WS2509/G
Anoro Ellipta-
EMA/H/C/002751/WS2509/0042/G
Laventair Ellipta-
EMA/H/C/003754/WS2509/0045/G**

GlaxoSmithKline (Ireland) Limited, Lead
Rapporteur: Finbarr Leacy, "Grouped application
comprising two type II variations (C.I.4) as
follows:
- Update of section 4.8 of the SmPC in order to
remove the duplication of 'rash' from the list of
adverse drug reactions (ADRs) with frequency
uncommon to align with a similar change
previously accepted as part of the renewal
procedure of Rolufta Ellipta.
- To include significant changes to sections 2,
4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.5 of the SmPC,

Positive Opinion adopted by consensus on
09.11.2023.

sections 3, 4, 5, 7 and 11 of the Labelling and sections 2, 3, 4, 5 and 6 of the Package Leaflet for the medicinal products Anoro and Laventair containing the active substances Umeclidinium Bromide and Vilanterol following the assessment of the medicinal products Trelegy and Roluфта Ellipta, which also contains the active substances fluticasone furoate, umeclidinium bromide and vilanterol, via procedure EMEA/H/C/004363/R/0023 and EMEA/H/C/004654/R/0019. The same wording is used for the combination product.

The Package Leaflet and Labelling are updated accordingly. The Annex II is updated. In addition, the MAH took the opportunity to introduce minor editorial changes and to bring the PI in line with the latest QRD template (version 10.3)."

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 14.09.2023.

WS2534

Abseamed-

EMEA/H/C/000727/WS2534/0104

Binocrit-

EMEA/H/C/000725/WS2534/0103

Epoetin alfa Hexal-

EMEA/H/C/000726/WS2534/0103

Sandoz GmbH, Lead Rapporteur: Alexandre Moreau, "Update of section 4.4 of the SmPC in order to allow for iron supplementation in accordance with patient needs and up-to-date treatment guidelines by removing the restrictions to exclusively use the oral route of administration for iron supplementation. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, bring it in line with the latest QRD template version 10.3, align it with the reference product and update instructions for use."

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 09.11.2023.

WS2543

Imfinzi-EMEA/H/C/004771/WS2543/0062

IMJUDO-

EMEA/H/C/006016/WS2543/0003

AstraZeneca AB, Lead Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2, 4.8, 5.1 and 5.2

Request for supplementary information adopted with a specific timetable.

of the SmPC in order to include paediatric information based on final results from study D419EC00001 "Phase I/II, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy or Durvalumab in Combination with Tremelimumab in Pediatric Patients with Advanced Solid Tumors and Hematological Malignancies". In addition, the MAH took this opportunity to introduce editorial changes."

Request for Supplementary Information adopted on 09.11.2023.

B.5.3. CHMP-PRAC assessed procedures

Brineura - Cerliponase alfa - EMEA/H/C/004065/II/0039, Orphan

BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 9 of the SmPC in order to state that clinical data are available for patients aged 1 year and older and to include updates to the frequency of adverse reactions, immunogenicity, pharmacokinetic, and paediatric population sections based on the final results from studies 190-203, listed as a specific obligation and 190-202 (submitted in P46/013).

Study 190-203 was a Phase 2, open-label, multicentre study in paediatric patients < 18 years of age with CLN2 disease, confirmed by deficiency of TPP1 enzyme activity and mutation of the CLN2 gene.

The Annex II.E and Package Leaflet are updated accordingly.

The RMP version 4.0 has also been submitted."

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 12.10.2023, 25.05.2023.

Positive Opinion adopted by consensus on 09.11.2023.

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

EMEA/H/C/005735/II/0188/G

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, "Grouped application comprising two type II variations as follows:

C.I.4 – Update of section 4.8 of the SmPC in order to update the safety information based on interim (6 months post-dose 3 in 12-15 years

Positive Opinion adopted by consensus on 26.10.2023.

old) and final results from study C4591001, listed as a category 3 study in the RMP. This is a phase 1/2/3, placebo-controlled, randomised, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of COMIRNATY against COVID-19 in healthy individuals.

C.I.11.b – Update of the RMP to version 11.0 in order to revise RMP milestones of final study reports of other on-going procedures, including other administrative and editorial changes.”

Opinion adopted on 26.10.2023.

**Gavreto - pralsetinib -
EMA/H/C/005413/II/0012**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.2, 4.4 and 4.5 of the SmPC in order to amend posology recommendations, warnings and drug-drug interaction information regarding the co-administration with CYP3A4 inhibitors, P-gp inhibitors and CYP3A4 inducers based on final results from the DDI study GP43162, listed as a category 3 study in the RMP, as well as results from the physiologically based pharmacokinetic (PBPK) analyses summarised in the PBPK Report 1120689. Study GP43162 is a phase 1, open-label, fixed-sequence study to evaluate the effect of a single dose of cyclosporine on the single dose pharmacokinetics of pralsetinib in healthy subjects. The RMP version 1.6 has also been submitted.”

Request for Supplementary Information adopted on 09.11.2023, 22.06.2023, 30.03.2023.

Request for supplementary information adopted with a specific timetable.

**Increlex - mecasermin -
EMA/H/C/000704/II/0080**

Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, “Update of sections 4.2, 4.6 and 4.8 of the SmPC in order to modify administration instructions recommendation regarding the monitoring of pre-prandial blood glucose in pre- prandial condition and in case of symptoms and to prevent the risk of lipohypertrophy, delete wording in the pregnancy section and update on number of patients with severe primary IGFD based on the cumulative review of safety database, scientific literature and clinical trials data. The Package Leaflet is updated

Positive Opinion adopted by consensus on 26.10.2023.

accordingly. The RMP version 14.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 31.08.2023.

**Lenvima - lenvatinib -
EMA/H/C/003727/II/0050**

Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information based on final results from studies E7080-G000-207 and E7080-G000-230. Study E7080-G000-207 is a multicenter, open-label, Phase 1/2 study of lenvatinib in children and adolescents with refractory or relapsed solid malignancies and young adults with osteosarcoma; Study E7080-G000-230 is a multicenter, open-label, randomized Phase 2 study to compare the efficacy and safety of lenvatinib in combination with ifosfamide and etoposide versus ifosfamide and etoposide in children, adolescents and young adults with Relapsed or Refractory Osteosarcoma (OLIE). The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted.”

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 14.09.2023.

Positive Opinion adopted by consensus on 09.11.2023.

**Lumykras - sotorasib -
EMA/H/C/005522/II/0007**

Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Update of sections 4.2 and 5.2 of the SmPC in order to update recommendations for patients with moderate to severe hepatic impairment following final results from study 20200362 listed as a category 3 PASS study in the EU RMP; this is a Phase I clinical study to evaluate the pharmacokinetics (PK) of a single oral dose of sotorasib administered in subjects with moderate or severe hepatic impairment compared with subjects who have normal hepatic function. The EU RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3.”

Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 26.10.2023, 06.07.2023, 16.03.2023.

Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0095

Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, "Update of sections 4.4 and 5.2 of the SmPC in order to update a warning on immunogenicity. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 14.04.2023.

Positive Opinion adopted by consensus on 26.10.2023.

Onglyza - saxagliptin - EMEA/H/C/001039/II/0057

AstraZeneca AB, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update safety, efficacy and pharmacokinetic information in paediatric patients with Type 2 diabetes mellitus (T2DM) aged 10 to <18 years of age based on interim results from study D1680C00019 (T2NOW). This is a 26-week, multicentre, randomised, placebo-controlled, double-blind, parallel group, Phase III trial with a 26-week safety extension period evaluating the safety and efficacy of dapagliflozin (5 and 10 mg), and, separately, saxagliptin (2.5 and 5 mg) in paediatric patients with T2DM who were between 10 and below 18 years of age. The Package Leaflet is updated accordingly. The RMP version 17.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template and to introduce editorial changes."

Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

Pradaxa - Dabigatran etexilate - EMEA/H/C/000829/II/0147/G

Boehringer Ingelheim International GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "A Grouped application consisting of:

C.I.7.a (type IB): to delete the pharmaceutical form "powder and solvent for oral solution, 6.25 mg/ml", as agreed in procedure

Positive Opinion adopted by consensus on 09.11.2023.

See 9.1

EMA/H/C/000829/II/0144.

C.I.4 (type II): Update of section 4.1 of the SmPC in order to modify the indication following the deletion of the powder and solvent for oral solution; the Package Leaflet is updated accordingly. The RMP version 41.2 has also been submitted.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.”

Opinion adopted on 09.11.2023.

**Prolia - denosumab -
EMA/H/C/001120/II/0099**

Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, “Update of sections 4.4 and 4.8 of the SmPC in order to update a warning regarding hypocalcaemia and to include reports of life-threatening events and fatal cases occurred in the post-marketing setting, particularly in patients with severe renal impairment, receiving dialysis or treatment with other calcium lowering drugs based on the cumulative review of the MAH safety database and literature. The Package Leaflet is updated accordingly. The RMP version 32.0 has also been submitted.”

Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

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

Gedeon Richter Plc., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ana Sofia Diniz Martins, “Update of sections 4.3 and 4.5 of the SmPC in order to update an existing contraindication and update drug-drug interaction information with CYP3A4 inhibitors, based on final results from study RGH-188-301 (CYPRESS) listed as a category 3 study in the RMP; this is an open-label, single-arm, fixed-sequence study to investigate the effect of erythromycin, a moderate CYP3A4 inhibitor on the pharmacokinetics of cariprazine in male patients with schizophrenia. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Request for Supplementary Information adopted

Request for supplementary information adopted with a specific timetable.

on 26.10.2023.

**Tysabri - natalizumab -
EMA/H/C/000603/II/0136**

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 4.4 of the SmPC to modify administration instructions and update educational guidance to enable the subcutaneous formulation to be administered outside a clinical setting by healthcare professionals based on the cumulative review of post-marketing and clinical study data. The Package Leaflet and Annex IID are updated accordingly. The RMP version 29.1 has also been submitted. In addition, the MAH took this opportunity to introduce minor editorial changes."

Request for Supplementary Information adopted on 09.11.2023, 20.07.2023.

Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led

**Aldurazyme - laronidase -
EMA/H/C/000477/II/0085**

Sanofi B.V., PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "To update section 4.2 of the SmPC in order to modify the administration instructions following the assessment of procedure PSUSA/00001830/202104 based on literature review.

The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted."

Request for Supplementary Information adopted on 26.10.2023, 08.06.2023, 09.02.2023.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Benlysta - belimumab -
EMA/H/C/002015/II/0116**

GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report for the Belimumab Pregnancy registry (BEL114256) listed as a category 3 study in the RMP. This is a non-interventional study to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months

Request for supplementary information adopted with a specific timetable.

preconception and/or during pregnancy. In addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with SLE and SABLE (Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus) protocol who were not exposed to belimumab and enrolled in BPR. The RMP version 45.0 has also been submitted.”
Request for Supplementary Information adopted on 26.10.2023.

PRAC Led
Evusheld - tixagevimab / cilgavimab - EMEA/H/C/005788/II/0013
AstraZeneca AB, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, “The RMP is updated to version 5.0 with the removal of the commitment to conduct the post-authorisation safety study (PASS) D8850R00006: A post-authorization Observational Study of Women exposed to EVUSHELD During Pregnancy (O-STEREO).”
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 26.10.2023.

PRAC Led
Lenvima - lenvatinib - EMEA/H/C/003727/II/0053
Eisai GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, “Update of section 5.1 of the SmPC in order to update safety and efficacy information for the hepatocellular carcinoma (HCC) indication, based on interim results from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP. This is a non-interventional multicentre, observational, phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. RMP version 15.2 has also been submitted.”
Request for Supplementary Information adopted on 26.10.2023.

Request for supplementary information adopted with a specific timetable.

PRAC Led
Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0093
Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, “Submission of the final non-interventional Pompe Registry Report 2022 (MEA024 and MEA025).”

Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 26.10.2023, 16.03.2023.

PRAC Led Positive Opinion adopted by consensus on 26.10.2023.

**Ozurdex - dexamethasone -
EMA/H/C/001140/II/0044**

AbbVie Deutschland GmbH & Co. KG, PRAC
Rapporteur: Maria del Pilar Rayon, PRAC-CHMP
liaison: Maria Concepcion Prieto Yerro,
"Submission of an updated RMP version 12.1."
Opinion adopted on 26.10.2023.
Request for Supplementary Information adopted on 08.06.2023, 16.03.2023.

PRAC Led Positive Opinion adopted by consensus on 26.10.2023.

**Remicade - infliximab -
EMA/H/C/000240/II/0243**

Janssen Biologics B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To update section 4.8 of the SmPC to add weight increased to the list of adverse drug reactions (ADRs) with frequency Uncommon following PRAC PSUR assessment report (EMA/PRAC/158162/2023-Corr.1) based on the cumulative literature review. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial changes."
Opinion adopted on 26.10.2023.

PRAC Led Positive Opinion adopted by consensus on 26.10.2023.

**Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) -
EMA/H/C/005791/II/0110**

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report of study P903 - US PASS (Post-authorisation safety in the US Study, NCT04958954), listed as a category 3 study in the RMP: Post-marketing safety of Spikevax vaccine in the US: Active surveillance, signal refinement and self-controlled risk interval (SCRI) signal evaluation in HealthVerity."
Opinion adopted on 26.10.2023.

PRAC Led Positive Opinion adopted by consensus on 26.10.2023.

**Tecfidera - dimethyl fumarate -
EMA/H/C/002601/II/0082**

Biogen Netherlands B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina

Weise, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on results from study 109MS402 - Tecfidera (dimethyl fumarate) Pregnancy Exposure Registry, listed as a category 3 study in the RMP; This is an observational study and aims to address the safety concern of effects on pregnancy outcome and prospectively evaluates pregnancy outcomes in women with MS who were exposed to a Registry-specified Biogen MS product during the eligibility window for that product.

The Package Leaflet is updated accordingly. The RMP version 16.0 has also been approved. In addition, the MAH has taken the opportunity to introduce editorial changes to the Product Information."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 31.08.2023, 12.05.2023.

PRAC Led

**Xeljanz - tofacitinib -
EMA/H/C/004214/II/0054**

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Peter Mol, "Submission of an updated RMP version 31.1 in order to modify study A3921427 from an interventional to a non-interventional study. In addition, the MAH has taken the opportunity to update other sections of the RMP."

Opinion adopted on 26.10.2023.

Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 26.10.2023.

PRAC Led

**Zavesca - miglustat -
EMA/H/C/000435/II/0076**

Janssen-Cilag International N.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.4 of the SmPC with information regarding the fact that cases of Crohn's disease have been reported post-marketing. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and Package Leaflet, and to update the contact details of the local representatives in the Package Leaflet.

Submission of an updated RMP version 15.1 in order to remove risks in line with GVP module V

Positive Opinion adopted by consensus on 09.11.2023.

revision 2. The MAH has also taken the opportunity to introduce minor changes, such as update of the post-marketing exposure data and alignment with the latest Company EU-RMP Template.”

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 06.07.2023, 16.03.2023.

PRAC Led

WS2486

**Emtricitabine/Tenofovir disoproxil Zentiva-
EMEA/H/C/004137/WS2486/0025**

Zentiva k.s., Generic, Generic of Truvada, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, “C.I.11.z - To update the RMP for Emtricitabine/Tenofovir disoproxil according to reference product update, Truvada (EMEA/H/C/WS2320).”

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 09.11.2023.

PRAC Led

WS2515

Lacosamide UCB-

EMEA/H/C/005243/WS2515/0018

Vimpat-EMEA/H/C/000863/WS2515/0100

UCB Pharma S.A., Lead PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, “Submission of an updated RMP version 17.0 in order to introduce new updates including the removal of category 3 study EP0158 due to study closure by lack of enrolment, and the removal of category 3 studies (SP848 and EP0034).”

Opinion adopted on 26.10.2023.

Positive Opinion adopted by consensus on 26.10.2023.

PRAC Led

WS2519/G

Advagraf-

EMEA/H/C/000712/WS2519/0071/G

Modigraf-

EMEA/H/C/000954/WS2519/0046/G

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

Type II (C.I.13): Submission of the final report from study F506-PV-0001 listed as a category 3 study in the RMP for Advagraf and Modigraf.

This is a non-interventional post-authorisation

Request for supplementary information adopted with a specific timetable.

safety study (NI-PASS) of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from Transplant Pregnancy Registry International (TPRI). The RMP version 5.0 has also been submitted.

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

Request for Supplementary Information adopted on 26.10.2023.

B.5.5. CHMP-CAT assessed procedures

Carvykti - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0018, Orphan, ATMP

Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Opinion adopted on 09.11.2023, 31.10.2023.
Request for Supplementary Information adopted on 14.07.2023.

Positive Opinion adopted by consensus on 09.11.2023.

Hemgenix - etranacogene dezaparvovec - EMEA/H/C/004827/II/0009/G, Orphan, ATMP

CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy
Request for Supplementary Information adopted on 31.10.2023.

Request for supplementary information adopted with a specific timetable.

Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0071, Orphan, ATMP

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang,
“Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study CCTL019B2202 (a phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in pediatric patients with relapsed and refractory B-cell acute

Request for supplementary information adopted with a specific timetable.

lymphoblastic leukemia). Submission of cellular kinetic report for the B-cell acute lymphoblastic leukaemia (ALL) indication based on data from pivotal study CCTL019B2202 and the supportive study CCTL019B2205J involving paediatric ALL patients (partially fulfil REC).

In addition, the MAH took this opportunity to introduce editorial changes.”

Request for Supplementary Information adopted on 31.10.2023.

Roctavian - valoctocogene roxaparvovec - EMEA/H/C/005830/II/0008/G, Orphan, ATMP

Positive Opinion adopted by consensus on 09.11.2023.

BioMarin International Limited, Rapporteur:

Violaine Closson Carella, CHMP Coordinator:

Jean-Michel Race, “Grouped application comprising two variations as follows:

C.I.4 - Update of section 4.5 of the SmPC in order to add drug-drug interaction information with Isotretinoin and Efavirenz based on results from study “In vitro Drug-Drug Interaction Study: Effects of Concomitant Administration of Isotretinoin, Amphetamine, Omeprazole, Celecoxib and Selected HAART Medications with AAV5-FVIII-SQ on Cytotoxicity and AAV5-FVIII-SQ DNA and RNA Expression in Primary Human Hepatocytes”.

A.6 - To change the ATC Code from B02BD1 to “not yet assigned”.”

Opinion adopted on 09.11.2023, 31.10.2023.

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0063, Orphan, ATMP

Positive Opinion adopted by consensus on 09.11.2023.

See 9.1

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

Berghaus, CHMP Coordinator: Jan Mueller-

Berghaus, “Primary Analysis from study KTE-C19-107 (ZUMA-7); this is a phase 3,

randomized, open-label study evaluating the efficacy of axicabtagene ciloleucel versus

standard of care therapy in subjects with relapsed/refractory diffuse large B cell

lymphoma (DLBCL) in the 2nd line setting. In

addition, the MAH took the opportunity to

include the date of the latest renewal in section

9 and to submit a consolidated Environmental

Risk Assessment (ERA) document.”

Opinion adopted on 09.11.2023, 31.10.2023.

Request for Supplementary Information adopted on 06.10.2023.

B.5.6. CHMP-PRAC-CAT assessed procedures

**Kymriah - tisagenlecleucel -
EMA/H/C/004090/II/0075, Orphan,
ATMP**

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study CCTL019C2201 PAES in the Annex II (ANX008); this is a Phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The RMP version 6 has also been submitted. In addition, the MAH took the opportunity to update Annex II.D of the PI."

Request for Supplementary Information adopted on 31.10.2023.

Request for supplementary information adopted with a specific timetable.

B.5.7. PRAC assessed ATMP procedures

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

WS2503/G**Afstyla-****EMA/H/C/004075/WS2503/0051/G****IDELVION-****EMA/H/C/003955/WS2503/0067/G****Respreeza-****EMA/H/C/002739/WS2503/0073/G****Voncento-****EMA/H/C/002493/WS2503/0060/G**

CSL Behring GmbH, Lead Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 05.10.2023.

Positive Opinion adopted by consensus on 09.11.2023.

WS2521**Riltrava Aerosphere-****EMA/H/C/005311/WS2521/0007****Trixeo Aerosphere-****EMA/H/C/004983/WS2521/0014**

AstraZeneca AB, Lead Rapporteur: Finbarr Leacy, "C.I.z - To submit the new results for the conducted fish full life-cycle study for budesonide and an updated Environmental Risk Assessment (ERA) report."

Opinion adopted on 19.10.2023.

Positive Opinion adopted by consensus on 19.10.2023.

Request for Supplementary Information adopted on 31.08.2023.

WS2536
Rixathon-
EMA/H/C/003903/WS2536/0067

Positive Opinion adopted by consensus on 09.11.2023.

Riximyo-
EMA/H/C/004729/WS2536/0068

Sandoz GmbH, Lead Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 09.11.2023.

Request for Supplementary Information adopted on 14.09.2023.

WS2576
Elebrato Ellipta-
EMA/H/C/004781/WS2576/0037

Request for supplementary information adopted with a specific timetable.

Relvar Ellipta-
EMA/H/C/002673/WS2576/0064

Revinty Ellipta-
EMA/H/C/002745/WS2576/0061

Trelegy Ellipta-
EMA/H/C/004363/WS2576/0034

GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro

Request for Supplementary Information adopted on 09.11.2023.

WS2578
Fluenz Tetra-
EMA/H/C/002617/WS2578/0133

Positive Opinion adopted by consensus on 09.11.2023.

Pandemic influenza vaccine H5N1
AstraZeneca-

EMA/H/C/003963/WS2578/0067

AstraZeneca AB, Lead Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 09.11.2023.

WS2579/G
Fluenz Tetra-
EMA/H/C/002617/WS2579/0134/G

Positive Opinion adopted by consensus on 09.11.2023.

Pandemic influenza vaccine H5N1
AstraZeneca-

EMA/H/C/003963/WS2579/0068/G

AstraZeneca AB, Lead Rapporteur: Christophe Focke

Opinion adopted on 09.11.2023.

WS2582
HyQvia-EMA/H/C/002491/WS2582/0092
Kiovig-EMA/H/C/000628/WS2582/0124

Request for supplementary information adopted with a specific timetable.

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

Request for Supplementary Information adopted on 09.11.2023.

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

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0193/G

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson
Withdrawal request submitted on 02.11.2023.

The MAH withdrew the procedure on 02.11.2023.

Mozobil - plerixafor - EMEA/H/C/001030/II/0051

Sanofi B.V., Rapporteur: Peter Mol, "Update of section 4.6 of the SmPC in order to update information regarding duration of contraception after cessation of treatment; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor update to the Labelling section."
Request for Supplementary Information adopted on 28.09.2023.
Withdrawal request submitted on 18.10.2023.

The MAH withdrew the procedure on 18.10.2023.

Nuvaxovid - COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0030

Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege, "Submission of 6-month efficacy and safety interim data from the ongoing randomised, observer-blinded, placebo-controlled clinical studies 2019nCoV-501, 2019nCoV-301 and 2019nCoV-302."
Request for Supplementary Information adopted on 22.06.2023, 15.12.2022.
Withdrawal request submitted on 23.10.2023.

The MAH withdrew the procedure on 23.10.2023.

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

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

The MAH withdrew the procedure.

hematological malignancies.”

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

guanfacine - EMEA/H/C/006312

treatment of ADHD

apremilast - EMEA/H/C/006193

treatment of psoriatic arthritis, psoriasis,
Behçet’s disease

troriluzole - EMEA/H/C/006068, Orphan

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

mirvetuximab soravtansine - EMEA/H/C/005036, Orphan

Immunogen Biopharma (Ireland) Limited,
treatment of ovarian, fallopian tube, or primary
peritoneal cancer

tiratricol - EMEA/H/C/005220, Orphan

Rare Thyroid Therapeutics International AB,
treatment of monocarboxylate transporter 8
(MCT8) deficiency

eplontersen - EMEA/H/C/006295, Orphan

AstraZeneca AB, indicated for the treatment of
adult patients with polyneuropathy associated
with hereditary transthyretin-mediated
amyloidosis (ATTRv).

marstacimab - EMEA/H/C/006240, Orphan

Pfizer Europe Ma EEIG, Tradename is indicated
for routine prophylaxis of bleeding episodes in
patients with haemophilia A or haemophilia B

elafibranor - EMEA/H/C/006231, Orphan

Ipsen Pharma, treatment of primary biliary
cholangitis (PBC)

сотatercept - EMEA/H/C/005647, Orphan Accelerated review

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

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

detection of the anaplastic lymphoma kinase

(ALK) protein

clascoterone - EMEA/H/C/006138

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

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

Mounjaro - tirzepatide -

EMEA/H/C/005620/X/0015

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, "Extension application to add 6 new strengths of 2.5 mg (4.17 mg/ml), 5 mg (8.33 mg/ml), 7.5 mg (12.5 mg/ml), 10 mg (16.67 mg/ml), 12.5 mg (20.83 mg/ml) and 15 mg (25 mg/ml) for Mounjaro solution for injection in pre-filled pen (KwikPen), multidose. The Package Leaflet and Labelling are updated in accordance."

Ofev - nintedanib -

EMEA/H/C/003821/X/0057/G

Boehringer Ingelheim International GmbH, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Nikica Mirošević Skvrce, "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children

and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted.”

Opsumit - macitentan -

EMA/H/C/002697/X/0051/G, Orphan

Janssen-Cilag International N.V., Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, “Extension application to introduce a new pharmaceutical form associated with new strengths (1 and 2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 1 month to less than 18 years of age of WHO Functional Class (FC) I to III for OPSUMIT, based on interim results from AC-055-312 study (TOMORROW). This is a multicenter, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP has also been submitted.”

Ozempic - semaglutide -

EMA/H/C/004174/X/0043

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

Rybelsus - semaglutide -

EMA/H/C/004953/X/0038

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, “Extension application to introduce three new strengths of tablets (1.5 mg, 4 mg and 9 mg) for semaglutide.”

Rybelsus - semaglutide -

EMA/H/C/004953/X/0039

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

Wegovy - semaglutide -

EMA/H/C/005422/X/0016

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

apremilast - EMEA/H/C/006208

treatment of psoriatic arthritis, psoriasis,
Behçet's disease
List of Questions adopted on 20.07.2023.

aumolertinib - EMEA/H/C/006069

treatment of non-small cell lung cancer
List of Questions adopted on 30.03.2023.

buprenorphine - EMEA/H/C/006188

treatment of opioid drug dependence
List of Questions adopted on 22.06.2023.

sugemalimab - EMEA/H/C/006088

treatment of adults with metastatic non-small-
cell lung cancer (NSCLC)
List of Questions adopted on 22.06.2023.

serplulimab - EMEA/H/C/006170, Orphan

Henlius Europe GmbH, first-line treatment of
adult patients with extensive-stage small cell
lung cancer (ES-SCLC)
List of Questions adopted on 20.07.2023.

aprocitentan - EMEA/H/C/006080

treatment of resistant hypertension
List of Questions adopted on 22.06.2023.

omecamtiv mecarbil - EMEA/H/C/006112

treatment of adult patients with symptomatic
chronic heart failure and reduced ejection
fraction less than 30%
List of Questions adopted on 26.04.2023.

sotorasib - EMEA/H/C/005522/X/0009

Amgen Europe B.V., Rapporteur: Alexandre
Moreau, "Extension application to add a new
strength of 240 mg film-coated tablet."
List of Questions adopted on 22.06.2023.

nintedanib - EMEA/H/C/006179

treatment of idiopathic pulmonary fibrosis (IPF),
chronic fibrosing interstitial lung diseases (ILDs)
and lung diseases (ILDs) systemic sclerosis
associated interstitial lung disease (SSc-ILD)
List of Questions adopted on 26.04.2023.

nivolumab - EMEA/H/C/003985/X/0132

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Carolina Prieto Fernandez, PRAC Rapporteur:

Martin Huber

List of Questions adopted on 14.09.2023.

in vitro diagnostic medical device -

EMA/H/D/006373

detection of PD-L1 protein

Request for Supplementary Information adopted on 12.10.2023.

ustekinumab - EMA/H/C/006183

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

List of Questions adopted on 14.09.2023.

flortaucipir (18F) - EMA/H/C/006064

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

List of Questions adopted on 20.07.2023.

teriflunomide -

EMA/H/C/005960/X/0002

Accord Healthcare S.L.U., Generic, Generic of AUBAGIO, Rapporteur: Kristina Nadrah, PRAC Rapporteur: Martin Huber, "Extension application to add a new strength of 7 mg film-coated tablets. The bioequivalence study data were submitted."

List of Questions adopted on 20.07.2023.

in vitro diagnostic medical device -

EMA/H/D/006310

immunohistochemical assay utilising an anti-PD-L1 monoclonal primary antibody

Request for Supplementary Information adopted on 12.10.2023, 14.09.2023.

retifanlimab - EMA/H/C/006194, Orphan

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

List of Questions adopted on 20.07.2023.

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

Bylvay - odevixibat -

EMA/H/C/004691/S/0016, Orphan

Albireo, Rapporteur: Patrick Vrijlandt, PRAC

Rapporteur: Adam Przybylkowski

Myalepta - metreleptin -

EMA/H/C/004218/S/0035, Orphan

Amryt Pharmaceuticals DAC, Rapporteur: Karin

Janssen van Doorn, PRAC Rapporteur: Adam

Przybylkowski

Zokinvy - lonafarnib -

EMA/H/C/005271/S/0008, Orphan

EigerBio Europe Limited, Rapporteur: Patrick

Vrijlandt, PRAC Rapporteur: Adam

Przybylkowski

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

Cufence - trientine -

EMA/H/C/004111/R/0016

Univar Solutions BV, Rapporteur: Daniela

Philadelphia, Co-Rapporteur: Konstantina

Alexopoulou, PRAC Rapporteur: Ana Sofia Diniz

Martins

Deltyba - delamanid -

EMA/H/C/002552/R/0070, Orphan

Otsuka Novel Products GmbH, Rapporteur:

Christophe Focke, PRAC Rapporteur: Jo Robays

Dovato - dolutegravir / lamivudine -

EMA/H/C/004909/R/0045

ViiV Healthcare B.V., Rapporteur: Filip

Josephson, Co-Rapporteur: Bruno Sepodes,

PRAC Rapporteur: David Olsen

Giapreza - angiotensin II -

EMA/H/C/004930/R/0027

Paion Deutschland GmbH, Rapporteur: Maria

Concepcion Prieto Yerro, Co-Rapporteur: Jean-

Michel Race, PRAC Rapporteur: Menno van der

Elst

Jemperli - dostarlimab -

EMA/H/C/005204/R/0026

GlaxoSmithKline (Ireland) Limited, Rapporteur:

Carolina Prieto Fernandez, PRAC Rapporteur:

Ana Sofia Diniz Martins

LysaKare - L-lysine hydrochloride / L-arginine hydrochloride -

EMA/H/C/004541/R/0016

Advanced Accelerator Applications, Rapporteur:

Janet Koenig, Co-Rapporteur: Aaron Sosa Mejia,

PRAC Rapporteur: Adam Przybylkowski

Natpar - parathyroid hormone -

EMA/H/C/003861/R/0054, Orphan

Takeda Pharmaceuticals International AG

Ireland Branch, Rapporteur: Karin Janssen van

Doorn, Co-Rapporteur: Beata Maria Jakline

Ullrich, PRAC Rapporteur: Rhea Fitzgerald

**Pemazyre - pemigatinib -
EMA/H/C/005266/R/0013, Orphan**

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

**Sixmo - buprenorphine -
EMA/H/C/004743/R/0017**

L. Molteni & C. dei Fratelli Alitti Societa di
Esercizio S.p.A., Rapporteur: Finbarr Leacy, Co-
Rapporteur: Petr Vrbata, PRAC Rapporteur:
Adam Przybylkowski

**Striascan - ioflupane (123i) -
EMA/H/C/004745/R/0012**

CIS BIO International, Generic, Generic of
DaTSCAN, Rapporteur: Ewa Balkowiec Iskra,
Co-Rapporteur: Simona Badoi, PRAC
Rapporteur: Tiphaine Vaillant

**Talzenna - talazoparib -
EMA/H/C/004674/R/0017**

Pfizer Europe MA EEIG, Rapporteur: Filip
Josephson, Co-Rapporteur: Hrefna
Gudmundsdottir, PRAC Rapporteur: Ana Sofia
Diniz Martins

**Ultomiris - ravulizumab -
EMA/H/C/004954/R/0040**

Alexion Europe SAS, Rapporteur: Carolina Prieto
Fernandez, Co-Rapporteur: Robert Porszasz,
PRAC Rapporteur: Kimmo Jaakkola

**Waylivra - volanesorsen -
EMA/H/C/004538/R/0026, Orphan**

Akcea Therapeutics Ireland Limited, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Karin Janssen
van Doorn, PRAC Rapporteur: Martin Huber

**Xromi - hydroxycarbamide -
EMA/H/C/004837/R/0023**

Nova Laboratories Ireland Limited, Rapporteur:
Anastasia Mountaki, PRAC Rapporteur: Jo
Robays

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

Amyvid - Florbetapir (18F) -

EMA/H/C/002422/II/0046

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

**Dupixent - dupilumab -
EMA/H/C/004390/II/0079**

Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Kimmo Jaakkola, "Extension of indication for DUPIXENT to include treatment of adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) with type 2 inflammation on triple therapy or double therapy if inhaled corticosteroids (ICS) are contraindicated, based on final results from study EFC15804 (BOREAS); this is a phase 3, randomized, double blind, placebo-controlled, multi-center, parallel group, 52-week study to assess the efficacy, safety and tolerability of dupilumab in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) with type 2 inflammation. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted."

**Keytruda - pembrolizumab -
EMA/H/C/003820/II/0145**

Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) the treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [Stage IB2-IIB (with node-positive disease) or Stage III-IVA based on FIGO 2014] for Keytruda,

based on KEYNOTE-A18: A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.1 of the RMP has also been submitted.”

Kinpeygo - budesonide -

EMA/H/C/005653/II/0008, Orphan

STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II; this is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, and tolerability of oral Nefecon compared to matching placebo in patients with primary IgAN on a background of optimized RAS inhibitor therapy. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.”

Opdivo - nivolumab -

EMA/H/C/003985/II/0137

Bristol-Myers Squibb Pharma EEIG, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, “Extension of indication to include in combination with cisplatin-based chemotherapy the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma for OPDIVO, based on interim results from study CA209901 (CheckMate901); this is a Phase 3, open-label, randomized study of nivolumab combined with ipilimumab, or with standard of care chemotherapy, versus standard of care chemotherapy in participants with previously untreated unresectable or metastatic urothelial cancer. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 35.0 of the RMP has also been submitted.”

RYBREVANT - amivantamab -

EMA/H/C/005454/II/0010

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

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

Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0116

ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Extension of indication to include treatment of paediatric patients from 6 kg to less than 25 kg for Triumeq Dispersible Tablets, based on PK, safety and efficacy data observed in the final results of study 205860 (IMPAACT 2019), further supported by extrapolation to data generated in adults and additional data in paediatric patients with the single entities. IMPAACT 2019 is a Phase 1/2 open-label, multicenter, multiple dose study of dolutegravir/lamivudine/abacavir fixed dose

combination tablets in treatment-experienced and treatment-naïve HIV-1-infected children less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.”

Wegovy - semaglutide -

EMA/H/C/005422/II/0017

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher,

“Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with established cardiovascular disease and BMI ≥ 27 kg/m² for WEGOVY, based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. As part of the application the MAH is requesting a 1-year extension of the market protection.”

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

WS2463

Imfinzi-EMA/H/C/004771/WS2463/0063

Lynparza-

EMA/H/C/003726/WS2463/0066

AstraZeneca AB, Lead Rapporteur: Carolina Prieto Fernandez, Lead PRAC Rapporteur: Amelia Cupelli, “Extension of indication for Lynparza in combination with Imfinzi for the maintenance treatment of adult patients with newly diagnosed advanced or recurrent endometrial cancer following treatment with Imfinzi and platinum-based chemotherapy, based on results from pivotal phase III study, D9311C00001 (DUO-E). This was a phase III, randomised, double-blind, placebo-controlled,

multicentre study evaluating the efficacy and safety of durvalumab in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance durvalumab with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 30 of the RMP has also been submitted.”

WS2538

Braftovi-

EMA/H/C/004580/WS2538/0034

Mektovi-

EMA/H/C/004579/WS2538/0030

Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, Lead PRAC Rapporteur: Rugile Pilviniene, “Extension of indication to include binimetinib in combination with encorafenib for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600 mutation for MEKTOVI and BRAFTOVI based on results from study PHAROS (study ARRAY-818-202) at the primary completion date; this is a Phase II, open-label, multicentre, non-comparative study (interventional). As a consequence, sections 4.1, 4.4, 4.8, 5.1, 5.2, 9 and 10 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection for Mektovi.” Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Abiraterone Krka - abiraterone acetate -

EMA/H/C/005649/II/0004

KRKA, d.d., Novo mesto, Generic, Generic of Zytiga, Rapporteur: Andreja Kranjc

Abrysvo - respiratory syncytial virus vaccine (bivalent, recombinant) -

EMA/H/C/006027/II/0001

Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe

**Bimzelx - bimekizumab -
EMA/H/C/005316/II/0023/G**

UCB Pharma S.A., Rapporteur: Finbarr Leacy

**Cerezyme - imiglucerase -
EMA/H/C/000157/II/0131**

Sanofi B.V., Rapporteur: Patrick Vrijlandt

**Comirnaty - COVID-19 mRNA vaccine
(nucleoside-modified) -
EMA/H/C/005735/II/0192**

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson

**Kalydeco - ivacaftor -
EMA/H/C/002494/II/0120/G**

Vertex Pharmaceuticals (Ireland) Limited,
Rapporteur: Maria Concepcion Prieto Yerro

**Keytruda - pembrolizumab -
EMA/H/C/003820/II/0144**

Merck Sharp & Dohme B.V., Rapporteur: Paolo
Gasparini

**Ryzodeg - insulin aspart / insulin degludec
- EMA/H/C/002499/II/0054**

Novo Nordisk A/S, Rapporteur: Kristina Dunder

**Spikevax - COVID-19 mRNA vaccine
(nucleoside-modified) -
EMA/H/C/005791/II/0116/G**

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

**Suliqua - insulin glargine / lixisenatide -
EMA/H/C/004243/II/0037/G**

Sanofi Winthrop Industrie, Rapporteur: Kristina
Dunder

**Surgiflo Haemostatic Matrix Kit - human
thrombin - EMA/H/D/002301/II/0036/G**

Ferrosan Medical Devices A/S, Rapporteur: Jan
Mueller-Berghaus

**TachoSil - human thrombin / human
fibrinogen -
EMA/H/C/000505/II/0125/G**

Corza Medical GmbH, Rapporteur: Jan Mueller-
Berghaus

**Tresiba - insulin degludec -
EMA/H/C/002498/II/0060**

Novo Nordisk A/S, Rapporteur: Kristina Dunder

**Trumenba - meningococcal group B vaccine
(recombinant, adsorbed) -**

EMA/H/C/004051/II/0050/G

Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt

Zejula - niraparib -**EMA/H/C/004249/II/0046/G, Orphan**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang

WS2575**Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-****EMA/H/W/005362/WS2575/0009****Qdenga-****EMA/H/C/005155/WS2575/0010**

Takeda GmbH, Lead Rapporteur: Sol Ruiz

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

Alkindi - hydrocortisone -**EMA/H/C/004416/II/0019**

Diurnal Europe BV, Rapporteur: Karin Janssen van Doorn, "Update of section 4.2 of the SmPC in order to update posology recommendations in case of incomplete dosing, following the request by PRAC in the AR for procedure PSUSA/00010674/202208; the Package Leaflet is updated accordingly."

Drovelis - drospirenone / estetrol -**EMA/H/C/005336/II/0021**

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label, parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in subjects with varying degrees of hepatic function."

Dupixent - dupilumab -**EMA/H/C/004390/II/0078**

Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.2 of the SmPC in order to allow the use of the Dupixent Prefilled Pen presentations for patients aged 2 to < 12 years of age based on final results of the R668-AD-1434 sub-study; this is an interventional open-label sub-study which purpose is to evaluate the PK, safety,

immunogenicity, and efficacy of repeat doses of dupilumab (200 mg Q4W, 300 mg Q4W, and 200 mg Q2W) administered SC using a PFP with a skin pinch in children ≥ 2 to < 12 years of age. The Package Leaflet is updated accordingly. In addition, the MA took the opportunity to update the list of local representatives in the Package Leaflet.”

**Fetcroja - cefiderocol -
EMA/H/C/004829/II/0017**

Shionogi B.V., Rapporteur: Filip Josephson, “Update of sections 4.5 and 5.2 of the SmPC in order to update drug-drug interaction information with CYP3A4 based on final results from study 2136R2118; this is a Phase 1, open-label, 1-sequence crossover, drug-drug interaction study to assess the effect of repeated doses of cefiderocol on the pharmacokinetics of midazolam in healthy adult participants.”

**Kesimpta - ofatumumab -
EMA/H/C/005410/II/0013/G**

Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, “A grouped application consisting of:
Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on injection-related reactions and to add ‘Hypersensitivity reactions’ to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly.
Type IB (C.I.z): Addition of a statement in the pre-filled syringes (PFS) instructions for use when PFS has been dropped on a hard surface.
Type IA (A.6): To change the ATC Code of ofatumumab from L04AA52 to L04AG12.
In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

**Lydisilka - drospirenone / estetrol -
EMA/H/C/005382/II/0021**

Estetra SRL, Duplicate, Duplicate of Drovelis, Rapporteur: Kristina Dunder, “Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label, parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in

subjects with varying degrees of hepatic function.”

**Skilarence - dimethyl fumarate -
EMA/H/C/002157/II/0034**

Almirall S.A, Rapporteur: Janet Koenig, “Update of section 5.1 of the SmPC in order to update long-term efficacy and safety information based on final results from study M-41008-41 (Dimeskin 1); this is a phase IV non-randomised, non-interventional, open label study in adult patients with moderate to severe chronic plaque psoriasis to further assess long-term (12 months) efficacy and safety of Skilarence in routine daily practice in Spain.”

**Spikevax - COVID-19 mRNA vaccine
(nucleoside-modified) -
EMA/H/C/005791/II/0114/G**

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, “Grouped application consisting of:
C.I.4 (Type II): Update of sections 4.4, 4.8 and 5.1 of the SmPC to update the safety information regarding the administration of Spikevax to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, based on updated clinical literature and internal data; the Package Leaflet is updated accordingly.
C.I.Z (Type IB): To update section 6.6 of the SmPC in order to clarify the handling instructions for the pre-filled syringes; the Package Leaflet is updated accordingly.”

**Translarna - ataluren -
EMA/H/C/002720/II/0074, Orphan**

PTC Therapeutics International Limited, Rapporteur: Peter Mol, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations in the paediatric population, to update the summary of safety profile and to update efficacy, safety and pharmacokinetic information on the paediatric population based on the final results from study PTC124-GD-048-DMD “A Phase 2, multiple-dose, open-label study evaluating the safety and PK of ataluren in patients with nmDMD aged ≥6 months to <2 years old” (MEA-018). The Package Leaflet is updated accordingly. In

addition, the MAH took this opportunity to introduce editorial changes to the PI.”

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0134

MCM Vaccine B.V., Rapporteur: Christophe Focke, “Update of section 4.8 of the SmPC in order to add Extensive swelling of vaccinated limb to the list of adverse drug reactions (ADRs) with frequency rare and to update its description based on the cumulative review of clinical studies, literature and safety database. The Package Leaflet is updated accordingly.”

Vaxzevria - covid 19 vaccine (chadox1 s [recombinant]) - EMEA/H/C/005675/II/0095

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

VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMEA/H/C/005754/II/0007/G

Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, “A grouped application consisting of: Type II (C.I.4): Update of section 4.8 of the SmPC in order to include additional safety data based on safety update reports from studies VAT00008 booster extension and VAT00002 Cohort 2, in order to fulfil REC 20. Type IA (A.6): To change the ATC Code of the COVID-19 protein subunit vaccine from J07BX03 to J07BN04.”

Yselty - linzagolix choline - EMEA/H/C/005442/II/0010

Theramex Ireland Limited, Rapporteur: Finbarr Leacy, “Submission of the final report from study PRIMROSE 3 (20-OBE2109-007), listed as a category 3 study in the RMP. This is a long-term follow-up study to assess bone mineral density in subjects with uterine fibroids completing the Phase 3 studies of linzagolix,

PRIMROSE 1 or PRIMROSE 2.”

Ztalmy - ganaxolone -

EMA/H/C/005825/II/0002, Orphan

Marinus Pharmaceuticals Emerald Limited,
Rapporteur: Peter Mol, “Submission of the final report from study 1042-HME-1001 listed as post-authorisation measure (PAM) recommendation. This is an interventional Phase 1 Single Dose, Open-Label Crossover Comparative Bioavailability Study of Two Oral Formulations of Ganaxolone. The primary objective of this study was to evaluate and compare the pharmacokinetics of a new ganaxolone formulation with ganaxolone oral suspension after a single oral dose administration under fed conditions.”

B.6.10. CHMP-PRAC assessed procedures

Gavreto - pralsetinib -

EMA/H/C/005413/II/0017

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.2 and 5.2 of the SmPC in order to include information regarding moderate and severe hepatic impairment based on final results from study GP43163 listed as a category 3 study in the RMP; this is a Phase I, open-label, single-dose study to evaluate the pharmacokinetics and safety of pralsetinib in subjects with moderate or severe hepatic impairment compared to healthy subjects. The RMP version 1.8 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the marketing authorisation renewal date in Annex I.”

Vpriv - velaglucerase alfa -

EMA/H/C/001249/II/0063

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, “Update of section 4.2 of the SmPC in order to add information to support at-home self-administration of VPRIV by a trained patient and/or a caregiver based on post-marketing data and literature. The Package Leaflet and Annex IID are updated accordingly. The updated RMP version 13.0 has also been submitted.”

B.6.11. PRAC assessed procedures

PRAC Led

WS2569

Corlantor-

EMA/H/C/000598/WS2569/0059

Ivabradine Anpharm-

EMA/H/C/004187/WS2569/0019

Procoralan-

EMA/H/C/000597/WS2569/0058

Les Laboratoires Servier, Lead PRAC

Rapporteur: Menno van der Elst, PRAC-CHMP

liaison: Patrick Vrijlandt, "C.I.11.z - To update the RMP to delete the obsolete products (Ivabradine Egis and Ivabradine Proterapia) that are still mentioned in the RMP."

B.6.12. CHMP-CAT assessed procedures

**Breyanzi - lisocabtagene maraleucel /
lisocabtagene maraleucel -**

EMA/H/C/004731/II/0032, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini

Libmeldy - atidarsagene autotemcel -

**EMA/H/C/005321/II/0021, Orphan,
ATMP**

Orchard Therapeutics (Netherlands) B.V.,

Rapporteur: Emmely de Vries, CHMP

Coordinator: Peter Mol

**Strimvelis - autologous CD34+ enriched
cell fraction that contains CD34+ cells
transduced with retroviral vector that
encodes for the human ADA cDNA
sequence - EMA/H/C/003854/II/0039,
Orphan, ATMP**

Fondazione Telethon ETS, Rapporteur: Sol Ruiz,

CHMP Coordinator: Maria Concepcion Prieto

Yerro

Yescarta - axicabtagene ciloleucel -

**EMA/H/C/004480/II/0065, Orphan,
ATMP**

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

Berghaus, CHMP Coordinator: Jan Mueller-

Berghaus, "Update of section 4.8 of the SmPC in

order to add Infusion Related Reactions to the

list of adverse drug reactions (ADRs) with

frequency Common, based on a cumulative

review of the MAH safety database, clinical trials and post-marketing data. The Package Leaflet is updated accordingly.”

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2572/G

Herceptin-

EMA/H/C/000278/WS2572/0191/G

MabThera-

EMA/H/C/000165/WS2572/0200/G

Roche Registration GmbH, Lead Rapporteur: Jan
Mueller-Berghaus

WS2581/G

Fluenz Tetra-

EMA/H/C/002617/WS2581/0136/G

Pandemic influenza vaccine H5N1

AstraZeneca-

EMA/H/C/003963/WS2581/0070/G

AstraZeneca AB, Lead Rapporteur: Christophe
Focke

WS2589

Ongentys-

EMA/H/C/002790/WS2589/0062

Ontilyv-EMA/H/C/005782/WS2589/0017

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

WS2592/G

Nuwiq-

EMA/H/C/002813/WS2592/0056/G

Vihuma-

EMA/H/C/004459/WS2592/0038/G

Octapharma AB, Lead Rapporteur: Jan Mueller-
Berghaus

WS2602/G

Eucreas-

EMA/H/C/000807/WS2602/0104/G

Icandra-

EMA/H/C/001050/WS2602/0109/G

Zomarist-

EMA/H/C/001049/WS2602/0106/G

Novartis Europharm Limited, Lead Rapporteur:

WS2614

Cegfila-EMA/H/C/005312/WS2614/0019

Pelmeg-EMA/H/C/004700/WS2614/0027

Mundipharma Corporation (Ireland) Limited,

Lead Rapporteur: Karin Janssen van Doorn

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers

E.1.1. Annual Update

E.1.2. Variations

E.1.3. Initial PMF Certification

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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