



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2022
EMA/CHMP/608233/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 18-21 July 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 July 2022, 13:00 – 19:30, virtual meeting/room 1C

19 July 2022, 08:30 – 19:30, virtual meeting/room 1C

20 July 2022, 08:30 – 19:30, virtual meeting/room 1C

21 July 2022, 08:30 – 15:00, virtual meeting/room 1C

Health and safety information

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

Disclaimers

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

Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to 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	8
2.1.	Pre-authorisation procedure oral explanations.....	8
2.1.1.	mobocertinib - EMEA/H/C/005621	8
2.1.2.	voclosporin - EMEA/H/C/005256.....	8
2.1.3.	fosdenopterin - Orphan - EMEA/H/C/005378.....	9
2.1.4.	mitapivat - Orphan - EMEA/H/C/005540	9
2.1.5.	tezepelumab - EMEA/H/C/005588.....	9
2.1.6.	faricimab - EMEA/H/C/005642.....	9
2.2.	Re-examination procedure oral explanations	9
2.3.	Post-authorisation procedure oral explanations	9
2.4.	Referral procedure oral explanations	10
3.	Initial applications	10
3.1.	Initial applications; Opinions.....	10
3.1.1.	vutrisiran - Orphan - EMEA/H/C/005852.....	10
3.1.2.	doxorubicin hydrochloride - EMEA/H/C/005330	10
3.1.3.	lutetium (177Lu) chloride - EMEA/H/C/005859.....	10
3.1.4.	teriparatide - EMEA/H/C/004932	10
3.1.5.	tirzepatide - EMEA/H/C/005620.....	11
3.1.6.	relatlimab / nivolumab - EMEA/H/C/005481	11
3.1.7.	teclistamab - PRIME - Orphan - EMEA/H/C/005865.....	11
3.1.8.	thalidomide - EMEA/H/C/005715	11
3.2.	Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)	11
3.2.1.	nirsevimab - PRIME - EMEA/H/C/005304	11
3.2.2.	mavacamten - EMEA/H/C/005457.....	12
3.2.3.	dimethyl fumarate - EMEA/H/C/005963.....	12
3.2.4.	gozetotide - EMEA/H/C/005488	12
3.2.5.	plerixafor - EMEA/H/C/005943	12
3.2.6.	lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483	12
3.2.7.	efbemalenograstim alfa - EMEA/H/C/005828.....	13
3.2.8.	spesolimab - EMEA/H/C/005874	13
3.2.9.	teriflunomide - EMEA/H/C/005960	13

3.2.10.	deucravacitinib - EMEA/H/C/005755	13
3.2.11.	loncastuximab tesirine - Orphan - EMEA/H/C/005685.....	13
3.3.	Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)	14
3.3.1.	enalapril maleate ph. eur. - PUMA - EMEA/H/C/005731	14
3.3.2.	eculizumab - EMEA/H/C/005652.....	14
3.3.3.	dabigatran etexilate - EMEA/H/C/006023.....	14
3.3.4.	etranacogene dezaparvovec - PRIME - Orphan - ATMP - EMEA/H/C/004827	14
3.3.5.	tislelizumab - Orphan - EMEA/H/C/005919	14
3.3.6.	raltegravir potassium - EMEA/H/C/005813.....	14
3.3.7.	tislelizumab - EMEA/H/C/005542	15
3.3.8.	ivosidenib - Orphan - EMEA/H/C/005936	15
3.3.9.	tremelimumab - Orphan - EMEA/H/C/006016.....	15
3.4.	Update on on-going initial applications for Centralised procedure.....	15
3.4.1.	dengue tetravalent vaccine (live, attenuated) - Article 58 - EMEA/H/W/005362	15
3.4.2.	artesanate - Orphan - EMEA/H/C/005718	15
3.4.3.	gefapixant - EMEA/H/C/005884	16
3.4.4.	gefapixant - EMEA/H/C/005476	16
3.4.5.	bardoxolone methyl - Orphan - EMEA/H/C/005869	16
3.4.6.	iodine (131I) omburtamab - Orphan - EMEA/H/C/005499.....	16
3.4.7.	bevacizumab - EMEA/H/C/005574	16
3.4.8.	dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/005155	17
3.4.9.	infigratinib - Orphan - EMEA/H/C/005361	17
3.5.	Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004	17
3.5.1.	Tuznue - trastuzumab - EMEA/H/C/005066 / Hervalous - trastuzumab - EMEA/H/C/00588017	
3.6.	Initial applications in the decision-making phase.....	17
3.7.	Withdrawals of initial marketing authorisation application	18
3.7.1.	paraclisib - Orphan - EMEA/H/C/005893	18

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

4.1.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion	18
4.1.1.	Biktarvy - bictegravir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/X/0040/G18	
4.1.2.	Calquence - acalabrutinib - EMEA/H/C/005299/X/0009/G	18
4.1.3.	Dupixent - dupilumab - EMEA/H/C/004390/X/0057.....	19
4.1.4.	Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/X/0079/G	19
4.1.5.	Skyrizi - risankizumab - EMEA/H/C/004759/X/0020/G.....	19
4.1.6.	Spikevax - elasomeran - EMEA/H/C/005791/X/0064	19

4.1.7.	Spikevax - elasomeran - EMEA/H/C/005791/X/0065	20
4.2.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues	20
4.3.	Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question	20
4.3.1.	Refixia - nonacog beta pegol - EMEA/H/C/004178/X/0027/G.....	20
4.3.2.	Tenkasi - oritavancin - EMEA/H/C/003785/X/0036.....	20
4.3.3.	Ultomiris - ravulizumab - EMEA/H/C/004954/X/0027/G	20
4.4.	Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008	21
4.5.	Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008	21

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

5.1.	Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information.....	21
5.1.1.	Ceprothin - human protein c - EMEA/H/C/000334/II/0127	21
5.1.2.	Dupixent - dupilumab - EMEA/H/C/004390/II/0062	22
5.1.3.	Dupixent - dupilumab - EMEA/H/C/004390/II/0063	22
5.1.4.	Evrysdi - risdiplam - Orphan - EMEA/H/C/005145/II/0005/G.....	22
5.1.5.	Imcivree - setmelanotide - Orphan - EMEA/H/C/005089/II/0002/G.....	23
5.1.6.	Imfinzi - durvalumab - EMEA/H/C/004771/II/0045	23
5.1.7.	Imfinzi - durvalumab - EMEA/H/C/004771/II/0046	24
5.1.8.	Imvanex - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0076	24
5.1.9.	Keytruda - pembrolizumab - EMEA/H/C/003820/II/0121	24
5.1.10.	Libtayo - cemiplimab - EMEA/H/C/004844/II/0028	24
5.1.11.	Lynparza - olaparib - EMEA/H/C/003726/II/0053.....	25
5.1.12.	Lyumjev - insulin lispro - EMEA/H/C/005037/II/0014	25
5.1.13.	Olumiant - baricitinib - EMEA/H/C/004085/II/0028	26
5.1.14.	Retsevmo - selpercatinib - EMEA/H/C/005375/II/0014/G.....	26
5.1.15.	Tecartus - brexucabtagene autoleucel - Orphan - ATMP - EMEA/H/C/005102/II/0008/G ...	26
5.1.16.	Trecondi - treosulfan - Orphan - EMEA/H/C/004751/II/0014	27
5.1.17.	Ultomiris - ravulizumab - EMEA/H/C/004954/II/0026	27
5.1.18.	Vaxneuvance - pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/005477/II/0001	27
5.1.19.	Yescarta - axicabtagene ciloleucel - Orphan - ATMP - EMEA/H/C/004480/II/0046	28
5.1.20.	WS2150 DuoPlavin - clopidogrel / acetylsalicylic acid - EMEA/H/C/001143/WS2150/0060 Iscover - clopidogrel - EMEA/H/C/000175/WS2150/0146 Plavix - clopidogrel - EMEA/H/C/000174/WS2150/0145	28

5.2.	Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	29
5.3.	Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	29
6.	Medical devices	29
6.1.	Ancillary medicinal substances - initial consultation	29
6.2.	Ancillary medicinal substances – post-consultation update	29
6.3.	Companion diagnostics - initial consultation	29
6.4.	Companion diagnostics – follow-up consultation	29
7.	Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)	29
7.1.	Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)	29
8.	Pre-submission issues	30
8.1.	Pre-submission issue	30
8.1.1.	Ileniolisib - Orphan - H0005927	30
8.2.	Priority Medicines (PRIME)	30
8.2.1.	List of applications received	30
8.2.2.	Recommendation for PRIME eligibility	30
9.	Post-authorisation issues	30
9.1.	Post-authorisation issues	30
9.1.1.	Nuvaxovid - SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from Spodoptera frugiperda - EMEA/H/C/005808/II/0011/G	30
9.1.2.	Nuvaxovid - SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from Spodoptera frugiperda - EMEA/H/C/005808/II/0014	31
9.1.3.	Spikevax - elasomeran - EMEA/H/C/005791/II/0057	31
9.1.4.	Spikevax - elasomeran - EMEA/H/C/005791/II/0066	32
9.1.5.	Veklury - remdesivir - EMEA/H/C/005622/II/0034/G	32
9.1.6.	Darunavir Krka d.d. – darunavir – EMEA/H/C/004891	32
9.1.7.	Visudyne - verteporfin – EMEA/H/C/000305	32
9.1.8.	Crysvita - burosumab – Orphan - EMEA/H/C/004275/II/0028	33
9.1.9.	JCOVDEN - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0053/G	33
9.1.10.	Rubraca - rucaparib - EMEA/H/C/004272/II/0029	33
9.1.11.	NeuroBloc – botulinum toxin type B – EMEA/H/C/000301	34
9.1.12.	Zejula - niraparib – Orphan - EMEA/H/C/004249/II/0033	34
10.	Referral procedures	34
10.1.	Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004	34

10.1.1.	Rubraca - rucaparib - EMEA/H/A-20/1518/C/4272/0033.....	34
10.2.	Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 .	35
10.3.	Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004	35
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	35
10.5.	Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC....	35
10.6.	Community Interests - Referral under Article 31 of Directive 2001/83/EC	35
10.7.	Re-examination Procedure under Article 32(4) of Directive 2001/83/EC.....	35
10.8.	Procedure under Article 107(2) of Directive 2001/83/EC	35
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	35
10.10.	Procedure under Article 29 of Regulation (EC) 1901/2006.....	36
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	36
11.	Pharmacovigilance issue	36
11.1.	Early Notification System	36
12.	Inspections	36
12.1.	GMP inspections	36
12.2.	GCP inspections	36
12.3.	Pharmacovigilance inspections.....	36
12.4.	GLP inspections	36
13.	Innovation Task Force	37
13.1.	Minutes of Innovation Task Force.....	37
13.2.	Innovation Task Force briefing meetings.....	37
13.3.	Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004	37
13.4.	Nanomedicines activities	37
14.	Organisational, regulatory and methodological matters	37
14.1.	Mandate and organisation of the CHMP	37
14.1.1.	CHMP membership.....	37
14.1.2.	Vote by proxy	37
14.1.3.	Election of Co-opted Member	37
14.1.4.	Timetable for August 2022 Written Procedure	38
14.1.5.	CHMP Co-rapporteur critique.....	38
14.2.	Coordination with EMA Scientific Committees.....	38
14.2.1.	Pharmacovigilance Risk Assessment Committee (PRAC)	38

14.2.2.	Paediatric Committee (PDCO).....	38
14.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	38
14.3.1.	Biologics Working Party (BWP)	38
14.3.2.	Name Review Group (NRG).....	38
14.3.3.	Scientific Advice Working Party (SAWP)	39
14.3.4.	Vice-Chair election of the Oncology Working Party (ONCWP)	39
14.3.5.	Vice-Chair election of the Rheumatology and Immunology Working Party (RIWP)	39
14.3.6.	EC Request for a scientific opinion on the classification as medicinal products of certain substances used in blood bags CDP (citrate, dextrose and phosphate) and CPDA (citrate, dextrose, phosphate and adenine)	39
14.4.	Cooperation within the EU regulatory network.....	39
14.5.	Cooperation with International Regulators.....	39
14.6.	Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee	40
14.6.1.	Outcome of CHMP Pilot on early dialogue with patient organisations	40
14.7.	CHMP work plan	40
14.8.	Planning and reporting	40
14.9.	Others	40
15.	Any other business	40
15.1.	AOB topic.....	40
15.1.1.	Update on COVID-19	40
15.1.2.	COVID-19 vaccine – EMEA/H/C/006058.....	40
	Explanatory notes	41

1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 18-21 July 2022. See July 2022 CHMP minutes (to be published post September 2022 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 18-21 July 2022.

1.3. Adoption of the minutes

CHMP minutes for 20-23 June 2022.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 11 July 2022.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. mobocertinib - EMEA/H/C/005621

Treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).

Scope: Oral explanation

Action: Oral explanation to be held on 20 July 2022 at 09:00

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 11.11.2021.

2.1.2. voclosporin - EMEA/H/C/005256

indicated in combination with background immunosuppressive therapies for the treatment of adult patients with class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN).

Scope: Possible oral explanation

Action: Oral explanation to be held on 20 July 2022 at 15:30

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 11.11.2021.

2.1.3. fosdenopterin - Orphan - EMEA/H/C/005378

Comharsa Life Sciences Ltd; treatment of molybdenum cofactor deficiency type A

Scope: Possible oral explanation

Action: Oral explanation to be held on 20 July 2022 at 11:00

List of Outstanding Issues adopted on 23.06.2022, 20.04.2022. List of Questions adopted on 22.02.2022.

2.1.4. mitapivat - Orphan - EMEA/H/C/005540

Agios Netherlands B.V.; treatment of pyruvate kinase deficiency

Scope: Possible oral explanation

Action: Oral explanation to be held on 20 July 2022 at 17:00

List of Outstanding Issues adopted on 19.05.2022, 24.03.2022. List of Questions adopted on 11.11.2021.

2.1.5. tezepelumab - EMEA/H/C/005588

add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma

Scope: Possible oral explanation

Action: Oral explanation to be held on 19 July 2022 at 16:00

List of Outstanding Issues adopted on 19.05.2022, 24.03.2022. List of Questions adopted on 14.10.2021.

2.1.6. faricimab - EMEA/H/C/005642

treatment of neovascular (wet) age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DME)

Scope: Possible oral explanation

Action: Oral explanation to be held on 19 July 2022 at 14:00

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 14.10.2021.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. vutrisiran - Orphan - EMEA/H/C/005852

Alnylam Netherlands B.V.; treatment of hereditary transthyretin-mediated amyloidosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 27.01.2022.

3.1.2. doxorubicin hydrochloride - EMEA/H/C/005330

treatment of breast cancer, treatment of ovarian cancer, treatment of multiple myeloma, treatment of AIDS related Kaposi's sarcoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.03.2022. List of Questions adopted on 28.05.2020.

3.1.3. lutetium (177Lu) chloride - EMEA/H/C/005859

a radiopharmaceutical precursor, and it is not intended for direct use in patients. It is to be used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 16.12.2021.

3.1.4. teriparatide - EMEA/H/C/004932

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 16.12.2021. List of Questions adopted on 28.01.2021.

3.1.5. [tirzepatide - EMEA/H/C/005620](#)

treatment of adults with type 2 diabetes mellitus

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.06.2022. List of Questions adopted on 24.02.2022.

3.1.6. [relatlimab / nivolumab - EMEA/H/C/005481](#)

indicated for the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents (12 years and older and weighing at least 40 kg).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 27.01.2022.

3.1.7. [teclistamab - PRIME - Orphan - EMEA/H/C/005865](#)

Accelerated assessment

Janssen-Cilag International N.V.; treatment of relapsed or refractory multiple myeloma

Scope: Opinion

Action: For adoption

List of Questions adopted on 17.05.2022.

3.1.8. [thalidomide - EMEA/H/C/005715](#)

treatment of multiple myeloma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 16.09.2021.

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

3.2.1. [nirsevimab - PRIME - EMEA/H/C/005304](#)

Accelerated assessment

Prevention of RSV lower respiratory tract infection. Immunise infants from birth entering their first Respiratory Syncytial Virus (RSV) season for the prevention of RSV lower respiratory tract disease.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.05.2022.

3.2.2. [mavacamten - EMEA/H/C/005457](#)

treatment of symptomatic obstructive hypertrophic cardiomyopathy

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.01.2022.

3.2.3. [dimethyl fumarate - EMEA/H/C/005963](#)

treatment of multiple sclerosis

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 22.04.2022. List of Questions adopted on 27.01.2022.

3.2.4. [gozetotide - EMEA/H/C/005488](#)

indicated for the identification of prostate-specific membrane antigen (PSMA)-positive lesions after radiolabelling with gallium-68

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

3.2.5. [plerixafor - EMEA/H/C/005943](#)

treatment of lymphoma and multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

3.2.6. [lutetium \(177Lu\) vipivotide tetraxetan - EMEA/H/C/005483](#)

treatment of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

3.2.7. [efbemalenograstim alfa - EMEA/H/C/005828](#)

Reduction in the duration of neutropenia and the incidence of febrile neutropenia.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.01.2022.

3.2.8. [spesolimab - EMEA/H/C/005874](#)

treatment of flares in adult patients with generalised pustular psoriasis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

3.2.9. [teriflunomide - EMEA/H/C/005960](#)

treatment of multiple sclerosis (MS)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

3.2.10. [deucravacitinib - EMEA/H/C/005755](#)

treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

3.2.11. [loncastuximab tesirine - Orphan - EMEA/H/C/005685](#)

FGK Representative Service GmbH; treatment of adult patients with relapsed or refractory large B-cell lymphoma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.02.2022.

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

3.3.1. enalapril maleate ph. eur. - PUMA - EMEA/H/C/005731

treatment of heart failure in children from birth to less than 18 years.

Scope: List of questions

Action: For adoption

3.3.2. eculizumab - EMEA/H/C/005652

treatment of paroxysmal nocturnal haemoglobinuria

Scope: List of questions

Action: For adoption

3.3.3. dabigatran etexilate - EMEA/H/C/006023

Prevention of venous thromboembolic events

Scope: List of questions

Action: For adoption

3.3.4. etranacogene dezaparvovec - PRIME - Orphan - ATMP - EMEA/H/C/004827

Accelerated assessment

CSL Behring GmbH; treatment of adults with Haemophilia B

Scope: List of questions

Action: For information

3.3.5. tislelizumab - Orphan - EMEA/H/C/005919

Novartis Europharm Limited; treatment of adult patients with unresectable, recurrent, locally advanced or metastatic oesophageal squamous cell carcinoma after prior chemotherapy

Scope: List of questions

Action: For adoption

3.3.6. raltegravir potassium - EMEA/H/C/005813

treatment of human immunodeficiency virus (HIV-1)

Scope: List of questions

Action: For adoption

3.3.7. tislelizumab - EMEA/H/C/005542

treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in adults, treatment of locally advanced or metastatic squamous non-small cell lung cancer in adults, locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults

Scope: List of questions

Action: For adoption

3.3.8. ivosidenib - Orphan - EMEA/H/C/005936

Les Laboratoires Servier; treatment of acute myeloid leukaemia and treatment of metastatic cholangiocarcinoma

Scope: List of questions

Action: For adoption

3.3.9. tremelimumab - Orphan - EMEA/H/C/006016

AstraZeneca AB; For use in combination with durvalumab for the treatment of adults with unresectable hepatocellular carcinoma.

Scope: List of questions

Action: For adoption

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

3.4.1. dengue tetravalent vaccine (live, attenuated) - Article 58 - EMEA/H/W/005362

prevention of dengue disease

Scope: Update on the status of the procedure

Action: For information

List of Outstanding Issues adopted on 23.06.2022, 11.11.2021. List of Questions adopted on 24.06.2021.

3.4.2. artesunate - Orphan - EMEA/H/C/005718

B And O Pharm; Treatment of severe malaria

Scope: Letter by the applicant dated 28.06.2022 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in January 2022.

Action: For adoption

List of Outstanding Issues adopted on 27.01.2022, 16.09.2021, 22.07.2021. List of Questions adopted on 22.04.2021.

3.4.3. [gefapixant - EMEA/H/C/005884](#)

treatment of refractory or unexplained chronic cough

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in January 2022.

Action: For adoption

List of Outstanding Issues adopted on 27.01.2022, 16.12.2021, 14.10.2021. List of Questions adopted on 24.06.2021.

3.4.4. [gefapixant - EMEA/H/C/005476](#)

treatment of refractory or unexplained chronic cough

Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in January 2022.

Action: For adoption

List of Outstanding Issues adopted on 27.01.2022, 16.12.2021, 14.10.2021. List of Questions adopted on 24.06.2021.

3.4.5. [bardoxolone methyl - Orphan - EMEA/H/C/005869](#)

Reata Ireland Limited; treatment of chronic kidney disease

Scope: Letter by the applicant dated 01.07.2022 requesting an extension to the clock stop to respond to the list of questions adopted in February 2022.

Action: For adoption

List of Questions adopted on 24.02.2022.

3.4.6. [iodine \(131I\) omburtamab - Orphan - EMEA/H/C/005499](#)

Y-Mabs Therapeutics A/S; treatment of neuroblastoma

Scope: Letter by the applicant dated 28.06.2022 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2022.

Action: For adoption

List of Outstanding Issues adopted on 23.06.2022. List of Questions adopted on 16.09.2021.

3.4.7. [bevacizumab - EMEA/H/C/005574](#)

treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer; first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer; first-line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: Letter by the applicant dated 27.06.2022 requesting an extension to the clock stop

to respond to the list of outstanding issues adopted in February 2022.

Action: For adoption

List of Outstanding Issues adopted on 24.02.2022. List of Questions adopted on 22.04.2021.

3.4.8. dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/005155

prevention of dengue disease

Scope: Update on the status of the procedure

Action: For information

List of Outstanding Issues adopted on 23.06.2022, 11.11.2021. List of Questions adopted on 24.06.2021.

3.4.9. infigratinib - Orphan - EMEA/H/C/005361

Helsinn Birex Pharmaceuticals Limited; treatment of cholangiocarcinoma

Scope: Letter by the applicant dated 01.07.2022 requesting an extension to the clock stop to respond to the list of questions adopted in March 2022.

Action: For adoption

List of Questions adopted on 28.03.2022.

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

3.5.1. Tuznue - trastuzumab - EMEA/H/C/005066 / Hovelous - trastuzumab - EMEA/H/C/005880

Prestige Biopharma Belgium, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)

Scope: re-examination timetable; re-examination rapporteurs were appointed at the CHMP PROM on 11 July 2022

Action: For adoption

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

Opinion: 19.05.2022. List of Outstanding Issues adopted on 27.01.2022, 25.03.2021, 10.12.2020. List of Questions adopted on 19.09.2019.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. paraclisib – Orphan - EMEA/H/C/005893

Incyte Biosciences Distribution B.V.; treatment of relapsed or refractory marginal zone lymphoma (MZL)

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Questions adopted on 22.04.2022.

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. Biktarvy - bictegrovir / emtricitabine / tenofovir alafenamide - EMEA/H/C/004449/X/0040/G

Gilead Sciences Ireland UC

Rapporteur: Jean-Michel Race, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension application to introduce a new strength 30/120/15 mg. The extension application is grouped with a type II variation (C.I.6.a) to include paediatric indication: use in patients 2 years of age and older and weighing at least 14 kg. Sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated to support the extended indication. The RMP (version 3.1) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 24.03.2022. List of Questions adopted on 14.10.2021.

4.1.2. Calquence - acalabrutinib - EMEA/H/C/005299/X/0009/G

AstraZeneca AB

Rapporteur: Filip Josephson, PRAC Rapporteur: Željana Margan Koletić

Scope: "Extension application to introduce a new pharmaceutical form, film-coated tablet. A.6 - To change the ATC Code of acalabrutinib from L01XE51 to L01EL02."

Action: For adoption

List of Outstanding Issues adopted on 19.05.2022. List of Questions adopted on 24.02.2022.

4.1.3. Dupixent - dupilumab - EMEA/H/C/004390/X/0057

sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: For adoption

List of Questions adopted on 22.04.2022.

4.1.4. Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/X/0079/G

Gilead Sciences Ireland UC

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension application to introduce a new strength (90 mg/90 mg/120 mg/6 mg film-coated tablets). The extension application is grouped with a type II variation (C.I.6.a) to include treatment of human immunodeficiency virus 1 (HIV 1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in paediatric patients aged from 2 years and with body weight of at least 14 kg. Sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated to support the extended indication. The RMP (version 5.1) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 24.03.2022. List of Questions adopted on 11.11.2021.

4.1.5. Skyrizi - risankizumab - EMEA/H/C/004759/X/0020/G

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Jayne Crowe, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension application to:

- introduce a new pharmaceutical form (concentrate for solution for infusion), a new strength (600 mg) and a new route of administration (intravenous use).
- add a new strength of 360 mg (150 mg/ml) for risankizumab solution for injection (in cartridge) for subcutaneous use.

The above new presentations are indicated for the treatment of patients 16 years and older 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, or if such therapies are not advisable. The RMP (version 4.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 22.04.2022.

4.1.6. Spikevax - elasomeran - EMEA/H/C/005791/X/0064

Moderna Biotech Spain, S.L.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop

Scope: "Extension application to add a new strength of 0.10 mg/ml in a 5-dose vial."

Action: For adoption

4.1.7. [Spikevax - elasomeron - EMEA/H/C/005791/X/0065](#)

Moderna Biotech Spain, S.L.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop

Scope: "Extension application to add a new strength of 0.10 mg/ml in pre-filled syringe."

Action: For adoption

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

No items

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

4.3.1. [Refixia - nonacog beta pegol - EMEA/H/C/004178/X/0027/G](#)

Novo Nordisk A/S

Rapporteur: Andrea Laslop

Scope: "Extension application to introduce a new strength (3000 IU Powder and solvent for solution for injection). The extension application is grouped with a type II variation (B.II.d.1.e). Sections 1, 2, 5.3, 6.3, 6.6 and 8 of the SmPC, the Labelling and Package Leaflet are updated."

Action: For adoption

4.3.2. [Tenkasi - oritavancin - EMEA/H/C/003785/X/0036](#)

Menarini International Operations Luxembourg S.A.

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 1200 mg for powder for concentrate for solution for infusion. The RMP (version 4) is updated in accordance."

Action: For adoption

4.3.3. [Ultomiris - ravulizumab - EMEA/H/C/004954/X/0027/G](#)

Alexion Europe SAS

Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with new strength (245 mg) and route of administration (subcutaneous use), grouped with a type II variation (C.I.4) to align the summary of product characteristics and labelling of Ultomiris intravenous formulation (IV) with the proposed Ultomiris subcutaneous formulation (SC).

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

Action: For adoption

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

No items

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

No items

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

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

5.1.1. Ceprotin - human protein c - EMEA/H/C/000334/II/0127

Takeda Manufacturing Austria AG

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include long-term prophylaxis (deletion of wording 'short-term' and currently listed conditions) of purpura fulminans and coumarin induced skin necrosis in patients with severe congenital protein C deficiency, based on a re-analysis of long-term prophylaxis data from the pivotal study 400101; a phase 2/3 clinical study undertaken to evaluate PK, safety and efficacy of Ceprotin in patients with severe congenital PC deficiency for the treatment of acute thrombotic episodes, for short-term thromboembolic prophylaxis and for long-term prophylactic treatment. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated and the Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. Version 2.0 of the RMP has also been submitted. In addition, MAH took the opportunity to correct the address of the manufacturer of the biological active substance in Annex II following variation EMEA/H/C/000334/IAIN/0126/G."

Action: For adoption

5.1.2. Dupixent - dupilumab - EMEA/H/C/004390/II/0062

sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of eosinophilic esophagitis (EoE) in adults and adolescents 12 years and older who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy, based on the pivotal study R668-EE-1774. This is an ongoing phase 3, randomized, double-blind, placebo-controlled, 3-part (A, B, C) safety and efficacy study with an initial 24-week treatment period in adults (≥ 18 years of age) and adolescents (≥ 12 to < 18 years of age) with EoE, and which includes an extended treatment period to a total of 52 weeks. 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 8.0 of the RMP has also been submitted."

Action: For adoption

5.1.3. Dupixent - dupilumab - EMEA/H/C/004390/II/0063

sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with moderate to severe prurigo nodularis (PN) who are candidates for systemic therapy, based on results from studies EFC16459 and EFC16460 (PRIME and PRIME2); these are two phase 3, 24-week, randomized, double-blind, placebo-controlled, multi-centre, parallel group studies undertaken to evaluate the efficacy and safety of dupilumab in patients 18 years of age and older with moderate to severe PN, who are inadequately controlled on topical prescription therapies or when those therapies are not advisable. 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 8.0 of the RMP has also been submitted. As part of this application, the MAH is also 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

5.1.4. Evrysdi - risdiplam - Orphan - EMEA/H/C/005145/II/0005/G

Roche Registration GmbH

Rapporteur: Bruno Sepodes, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Jan Neuhauser

Scope: "Grouping of three variations as follows:

Extension of indication to include treatment of patients below 2 months of age based on interim results from study BN40703 (RAINBOWFISH). The pivotal study RAINBOWFISH is an ongoing phase II multicentre, open-label, and single-arm study designed to evaluate the

efficacy, safety, tolerability and PK/PD of risdiplam in pre-symptomatic infants below 2 months of age who were genetically diagnosed with SMA. As a consequence, SmPC sections 4.1, 4.2, 4.8, 5.1 and 5.2 have been updated and the Package Leaflet has been updated in accordance. In addition, the MAH took the opportunity to make some editorial improvements in the product information. A revised RMP version 1.1 was also submitted as part of the application.

Type IAIN, B.IV.1.a.1 variation to update Evrysdi pack configuration with the addition of a new 1 mL oral syringe into the product carton allowing precise dosing of infants below 2 months of age. As a consequence, section 6.5 of the SmPC has been updated and the labelling and Package Leaflet have been updated in accordance.

Type IAIN, B.IV.1.b variation to remove the spare unit of 12 mL oral syringe out of the two units currently provided in the product carton. As a consequence, section 6.5 of the SmPC has been updated and the labelling and Package Leaflet have been updated in accordance.”

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022.

5.1.5. [Imcivree - setmelanotide - Orphan - EMEA/H/C/005089/II/0002/G](#)

Rhythm Pharmaceuticals Netherlands B.V.

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Anna Mareková

Scope: “Group of variations consisting of:

C.I.6.a - To add the new therapeutic indication for the treatment of obesity and the control of hunger associated with genetically confirmed Bardet-Biedl syndrome (BBS). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC and sections 1, 3 and 4 of the PL are updated accordingly. The updated RMP version 1.0 has also been submitted.

C.I.6.a - To add the new therapeutic indication for the treatment of obesity and the control of hunger associated with genetically confirmed Alström syndrome (AS). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC and sections 1, 3 and 4 of the PL are updated accordingly. The updated RMP version 1.0 has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022, 27.01.2022.

5.1.6. [Imfinzi - durvalumab - EMEA/H/C/004771/II/0045](#)

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: “Extension of indication to include Imfinzi in combination with tremelimumab for the treatment of adults with unresectable hepatocellular carcinoma (uHCC), based on final results from study D419CC00002 (HIMALAYA); This was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma. 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. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. Version 6.1 of the RMP has also been submitted.”

Action: For adoption

5.1.7. [Imfinzi - durvalumab - EMEA/H/C/004771/II/0046](#)

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi in combination with chemotherapy for the treatment of adults with locally advanced or metastatic biliary tract cancer (BTC), based on the second interim analysis from the ongoing pivotal study D933AC00001 (TOPAZ-1); a phase III randomized, double-blind, placebo-controlled, multi-regional, international study conducted to assess the efficacy and safety of durvalumab in combination with the current standard of care Gemcitabine/Cisplatin for the first-line treatment of patients with locally advanced or metastatic BTC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the package leaflet has been updated accordingly. Version 7.1 of the RMP has also been submitted."

Action: For adoption

5.1.8. [Imvanex - smallpox vaccine \(live modified vaccinia virus Ankara\) - EMEA/H/C/002596/II/0076](#)

Bavarian Nordic A/S

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include active immunisation against monkeypox and related orthopoxvirus infection and disease in adults 18 years of age and older for Imvanex; as a consequence, sections 1, 4.1, 4.2, 4.4, 4.6 and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 9.0 of the RMP has also been submitted."

Action: For adoption

5.1.9. [Keytruda - pembrolizumab - EMEA/H/C/003820/II/0121](#)

Merck Sharp & Dohme B.V.

Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include Keytruda as monotherapy for the adjuvant treatment of adults with stage IB (T2a $\geq$ 4 cm), II or IIIA non-small cell lung carcinoma (NSCLC) who have undergone complete resection, based on study KEYNOTE-091; an ongoing Phase 3, randomized, triple-blinded, placebo-controlled, multicenter study of pembrolizumab versus placebo in patients with early-stage NSCLC after resection and completion of standard adjuvant therapy. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are being updated and the Package Leaflet is updated in accordance. An updated RMP version 39.1 was also submitted."

Action: For adoption

5.1.10. [Libtayo - cemiplimab - EMEA/H/C/004844/II/0028](#)

Regeneron Ireland Designated Activity Company (DAC)

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include LIBTAYO in combination with platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced NSCLC who are not candidates for definitive chemoradiation or metastatic NSCLC with no EGFR, ALK or ROS1 aberrations; 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 4.0 of the RMP has also been submitted."

Action: For adoption

5.1.11. Lynparza - olaparib - EMEA/H/C/003726/II/0053

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Karin Janssen van Doorn, PRAC
Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adults with metastatic castration resistant prostate cancer (mCRPC), with Lynparza in combination with abiraterone and prednisone or prednisolone, based on the results of the pivotal Phase III study PROpel (D081SC00001) and supportive evidence from study 8 (D081DC00008). PROpel is a Phase III, randomised, double-blind, placebo-controlled, multicentre study evaluating olaparib vs placebo in combination with abiraterone as first-line treatment for men with mCRPC. Consequently, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC for Lynparza tablets are being updated. In addition, sections 4.4 and 4.8 of the SmPC for Lynparza hard capsules are revised based on the updated safety data analysis. The Package Leaflet is updated accordingly. The RMP version 24 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022.

5.1.12. Lyumjev - insulin lispro - EMEA/H/C/005037/II/0014

Eli Lilly Nederland B.V.

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Annika Folin

Scope: "Extension of indication to include the treatment of diabetes mellitus in adolescents and children aged 1 year and above, based on final results from study I8B-MC-ITSB; this is a pivotal Phase 3 study designed to evaluate the safety and efficacy of Lyumjev compared to Humalog in combination with basal insulin in children and adolescent patients with T1D. The study was designed to compare change in HbA1c as the primary endpoint. 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. In addition, the MAH took the opportunity to implement minor editorial and linguistic changes in the SmPC and Package Leaflet. As part of the application, the MAH is also requesting one additional year of market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022.

5.1.13. Olumiant - baricitinib - EMEA/H/C/004085/II/0028

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Adam Przybylkowski

Scope: "C.I.6 - Extension of indication to include treatment of coronavirus disease 2019 (COVID 19) in hospitalised adult and paediatric patients aged 10 years and older who require low-flow oxygen or non-invasive ventilation/high flow oxygen for Olumiant; as a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 11.1 of the RMP has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 14.10.2021, 22.07.2021.

5.1.14. Retsevmo - selpercatinib - EMEA/H/C/005375/II/0014/G

Eli Lilly Nederland B.V.

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

Scope: "Extension of indication to include first-line treatment of advanced RET-mutant medullary thyroid cancer (MTC) in adults and adolescents 12 years and older based on interim results from study LIBRETTO-001 (LOXO-RET-17001) on the clinical safety and efficacy of selpercatinib in patients with RET-mutant MTC who are cabozantinib and vandetanib treatment-naïve (MTC:-Cab/-Van). LIBRETTO-001 is a global, multicohort, open-label, Phase 1/2 study in adult and adolescent patients with advanced RET-altered tumours. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection. The application also includes an updated Phase II Environmental Risk Assessment in order to reflect the patient population as per the approved indication." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.15. Tecartus - brexucabtagene autoleucel - Orphan - ATMP - EMEA/H/C/005102/II/0008/G

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst

Scope: "Group of variations including an extension of indication to include treatment of adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) for Tecartus and a type IB variation. As a consequence, sections 2.2, 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template." 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 18.03.2022, 10.09.2021.

5.1.16. Trecondi - treosulfan - Orphan - EMEA/H/C/004751/II/0014

medac Gesellschaft für klinische Spezialpräparate mbH

Rapporteur: Fátima Ventura, PRAC Rapporteur: Julia Pallos

Scope: "Extension of indication to include additional non-malignant transplant indications (non-malignant diseases in the paediatric population) for Trecondi 1 g/5 g powder for solution for infusion based on final 12-months follow-up results of study MC-FludT.16/NM; a randomised phase II interventional study aimed to compare Treosulfan-based conditioning therapy with Busulfan-based conditioning prior to allogeneic haematopoietic stem cell transplantation in paediatric patients with non-malignant diseases.

Further, the MAH proposes to amend an existing warning on skin toxicity based on new literature data. Moreover, the MAH proposes to introduce a slightly modified dosing regimen according to the patient's body surface based on long-term follow-up data of paediatric study MC-FludT.17/M, a Phase II trial to describe the safety and efficacy of Treosulfan based conditioning therapy prior to allogeneic haematopoietic stem cell transplantation in paediatric patients with haematological malignancies, as well as a final analysis of the population pharmacokinetics of treosulfan in paediatric patients. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.0 of the RMP has also been submitted."

Action: For adoption

5.1.17. Ultomiris - ravulizumab - EMEA/H/C/004954/II/0026

Alexion Europe SAS

Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adult patients with generalised myasthenia gravis (gMG). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC and corresponding sections in the Package Leaflet are updated accordingly. The RMP has been updated to version 4.0 to align with the indication extension. Lastly, the minor editorial corrections are made throughout the SmPC and package leaflet. The Applicant also requested 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)." 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 23.06.2022, 24.03.2022.

5.1.18. Vaxneuvance - pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/005477/II/0001

Merck Sharp & Dohme B.V.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Daniela Philadelphy, PRAC
Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of infants, children and adolescents from 6 weeks to less than 18 years of age for active immunisation for the prevention of invasive disease, pneumonia and acute otitis media for Vaxneuvance, based on final results from 1 Phase II study (V114-008) and 7 Phase III studies (V114-023, V114-024, V114-025, V114-027, V114-029, V114-030, V114-031); these are interventional studies to evaluate the safety, tolerability and immunogenicity of V114 in healthy and immunocompromised infants, children and adolescents. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to include editorial changes in the product information. Version 1.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022.

5.1.19. [Yescarta - axicabtagene ciloleucel - Orphan - ATMP - EMEA/H/C/004480/II/0046](#)

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, CHMP Coordinators: Jan Mueller-Berghaus and Karin Janssen van Doorn, PRAC Rapporteur: Anette Kirstine Stark

Scope: "Extension of indication to include treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) for Yescarta; 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 5.3 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the product information with minor editorial changes." 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 13.05.2022, 18.02.2022.

5.1.20. [WS2150](#) [DuoPlavin - clopidogrel / acetylsalicylic acid - EMEA/H/C/001143/WS2150/0060](#) [Iscover - clopidogrel - EMEA/H/C/000175/WS2150/0146](#) [Plavix - clopidogrel - EMEA/H/C/000174/WS2150/0145](#)

sanofi-aventis groupe

Lead Rapporteur: Bruno Sepodes, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: "Extension of indication to include clopidogrel in combination with acetylsalicylic acid in ST segment elevation acute myocardial infarction (STEMI) patients undergoing percutaneous coronary intervention (PCI); as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. Version 1.5 of the RMP has also been submitted. In addition, an editorial update has been made to the labelling."

Action: For adoption

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

6.4. Companion diagnostics – follow-up consultation

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. leniolisib - Orphan - H0005927

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

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

Action: For adoption

8.2. Priority Medicines (PRIME)

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

8.2.1. List of applications received

Action: For information

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Nuvaxovid - SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from *Spodoptera frugiperda* - EMEA/H/C/005808/II/0011/G

Novavax CZ, a.s.

Rapporteur: Johann Lodewijk Hillege

Scope: "Grouped variation:

- C.I.4 (Type II): Update of section 5.1 of the SmPC in order to introduce data on clinical efficacy against the Omicron variant of concern, based on data from study 2019nCoV-101 (Parts 1 and 2), a Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M Adjuvant in Healthy Subjects (NCT04368988), study 2019nCoV-501, a Phase 2a/b, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Immunogenicity, and Safety of a SARS-CoV-2 Recombinant

Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Matrix-M Adjuvant in South African Adult Subjects Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV (NCT04533399) and published literature. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial corrections throughout the product information.

- C.I.13 (Type II): Submission of the final clinical report from study 2019nCoV-101 (Part 1), a Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M Adjuvant in Healthy Subjects (NCT04368988). This submission addresses the post-authorisation measures MEA 009, REC 041 and REC 042."

Action: For adoption

9.1.2. [Nuvaxovid - SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from *Spodoptera frugiperda* - EMEA/H/C/005808/II/0014](#)

Novavax CZ, a.s.

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Brigitte Keller-Stanislowski

Scope: "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to include a 0.5 mL third dose for Nuvaxovid, to boost subjects that have previously completed a primary vaccination series with Nuvaxovid (homologous booster dose) or with an authorised mRNA or adenoviral vector vaccine (heterologous booster dose), based on interim data from study 2019nCoV-101 (Part 2), a Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M Adjuvant in Healthy Subjects (NCT04368988), final data from study 2019nCoV-501, a Phase 2a/b, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Immunogenicity, and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Matrix-M Adjuvant in South African Adult Subjects Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV (NCT04533399) and data from the COV-BOOST study (Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial); the Package Leaflet is updated accordingly. The RMP version 1.2 has also been submitted. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial corrections throughout the product information."

Action: For adoption

9.1.3. [Spikevax - elasomeran - EMEA/H/C/005791/II/0057](#)

Moderna Biotech Spain, S.L.

Rapporteur: Jan Mueller-Berghaus

Scope: "Update of section 4.2 of the Spikevax SmPC to include a 50 µg booster dose for adolescents 12 to 18 years of age, based on the extrapolation of safety and efficacy data from young adults (18 to 24 years of age). The package leaflet is updated accordingly."

Action: For adoption

9.1.4. Spikevax - elasomeran - EMEA/H/C/005791/II/0066

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

Scope: "Update of sections 4.5 and 5.1 of the SmPC in order to introduce new clinical data regarding the co-administration of Spikevax with a high-dose quadrivalent influenza vaccine (QIV-HD), based on final results from study QHD00028 (NCT04969276), a Phase II, Open-label Study to 'Assess the Safety and Immunogenicity of Fluzone High-Dose Quadrivalent (Influenza Vaccine), 2021-2022 Formulation and a Third Dose of Moderna COVID-19 Vaccine (mRNA-1273 Vaccine) Administered Either Concomitantly or Singly in Adults 65 Years of Age and Older Previously Vaccinated With a 2-dose Schedule of Moderna COVID-19 Vaccine'."

Action: For adoption

9.1.5. Veklury - remdesivir - EMEA/H/C/005622/II/0034/G

Gilead Sciences Ireland UC

Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová

Scope: "Grouping variation to update sections 5.1 and 5.2 of the SmPC as a consequence of the submission of the final component of the Specific Obligation 012 agreed in the renewal of the CMA (EMEA/H/C/005622/R/0015) and listed in the Annex II of the Product Information. This submission includes the ACTT-1 final sequencing and phenotyping analysis and the full virology report including activity against variants. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022.

9.1.6. Darunavir Krka d.d. – darunavir – EMEA/H/C/004891

KRKA d.d. Novo mesto; treatment of HIV-1 infection

Rapporteur: John Joseph Borg

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.7. Visudyne - verteporfin – EMEA/H/C/000305

CHEPLAPHARM Arzneimittel GmbH

Rapporteur: Alexandre Moreau, Co-Rapporteur: Kirstine Moll Harboe

Scope: Adoption of a DHPC

Action: For adoption

9.1.8. Crysvida - burosumab – Orphan - EMEA/H/C/004275/II/0028

Kyowa Kirin Holdings B.V.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: , "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of the adverse drug reactions, to split immunogenicity data into paediatric and adult populations and to update clinical efficacy in paediatric patients, upon request by the CHMP following the assessment of PAM procedures P46/006 and P46/007 and type II variations II/04 and II/10/G, based on the final results from studies UX023-CL201, UX023-CL205 and UX023-CL301. As a consequence, the last remaining specific obligation, the provision of the final CSR for study UX023-CL205, was deleted from the Annex II. This was an open-label, phase 2 study undertaken to assess the safety, pharmacodynamics, and efficacy of KRN23 in paediatric patients between 1 and 4 years old with X-linked Hypophosphataemia (XLH). With the fulfilment of this specific obligation the MAH is requesting for the Crysvida MA to no longer be subject to specific obligations. The Package Leaflet was updated accordingly. The RMP version 5.0 was agreed during the procedure."

Action: For adoption

Request for Supplementary Information adopted on 22.04.2022.

9.1.9. JCOVDEN - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0053/G

Janssen-Cilag International N.V.

Rapporteur: Christophe Focke

Scope: "Update of section 4.2 of the SmPC to introduce a heterologous booster dose of JCOVDEN following priming with another adenoviral vector-based vaccine and an inactivated whole virion COVID-19 vaccine based on literature evidence from studies COV-BOOST and RHH-01 respectively. Update of sections 4.8 and 5.1 of the SmPC to include safety and immunogenicity data of JCOVDEN as homologous and heterologous booster dose based on data from studies COV2008, a randomised, double-blind Phase 2 Study and literature evidence from studies COV-BOOST, RHH-001 and DMID 21-0012. The Package Leaflet is updated accordingly."

Action: For adoption

9.1.10. Rubraca - rucaparib - EMEA/H/C/004272/II/0029

Clovis Oncology Ireland Limited

Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin

Scope: "Update of sections 4.4, 4.8 and 5.1 of the SmPC based on final results from study CO-338-043 (ARIEL4); this is a phase 3, multicentre, open-label, randomised study evaluating the efficacy and safety of rucaparib versus chemotherapy for treatment of relapsed ovarian cancer listed as a specific obligation in the Annex II; the Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. With this variation application, the MAH requests for the Rubraca marketing authorisation to no longer be subject to specific obligations. The SmPC, Annex II and PL are updated accordingly. In

addition, the MAH took the opportunity to make minor editorial changes and bring the PI in line with the latest QRD template version 10.2 Rev.1.”

Action: For adoption

Request for Supplementary Information adopted on 24.03.2022, 11.11.2021.

9.1.11. NeuroBloc – botulinum toxin type B – EMEA/H/C/000301

Sloan Pharma S.a.r.l; treatment of cervical dystonia

Rapporteur: Bruno Sepodes, Co-Rapporteur: Jayne Crowe

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.12. Zejula - niraparib – Orphan - EMEA/H/C/004249/II/0033

GlaxoSmithKline (Ireland) Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the request for supplementary information adopted in May 2022.

Action: For adoption

Request for Supplementary Information adopted on 19.05.2022, 10.02.2022.

10. Referral procedures

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

10.1.1. Rubraca - rucaparib - EMEA/H/A-20/1518/C/4272/0033

Clovis Oncology Ireland Limited

Referral Rapporteur: Blanca Garcia-Ochoa, Referral Co-Rapporteur: Paula Boudewina van Hennik

Scope: List of outstanding issues/ Opinion

Action: For adoption

In April 2022, 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 the centrally authorised medicinal product Rubraca (rucaparib) in the approved ‘3rd line or more treatment’.

The EMA has conducted a review of the cancer medicine Rubraca (rucaparib camsylate) when it is used to treat cancer of the ovary, fallopian tubes or peritoneum with a BRCA mutation in patients whose cancer has come back after platinum-based chemotherapy and

who can no longer have these medicines. The review is based on results from study ARIEL4 comparing Rubraca with chemotherapy in patients with high-grade cancer of the ovary, fallopian tubes or peritoneum with a BRCA mutation whose cancer has come back after chemotherapy indicating that overall survival was shorter in these patients than in those receiving chemotherapy.

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

No items

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

No items

10.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

July 2022 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

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. CHMP membership

End of membership

Action: For information

14.1.2. Vote by proxy

Bulgaria gave a PROXY to Bruno Sepodes for the entire meeting.

14.1.3. Election of Co-opted Member

Election of CHMP co-opted member in light of the expiry of mandate of co-opted member Sol Ruiz in July 2022.

Agreed areas of expertise: quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies)

Nomination(s) received

Action: For election

14.1.4. Timetable for August 2022 Written Procedure

Action: For adoption

14.1.5. CHMP Co-rapporteur critique

Experience of the implementation of Co-Rapp Critique in initial marketing authorisation applications.

Action: For discussion

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 July 2022

Action: For adoption

Summary of recommendations and advice of PRAC meeting held on 04 July - 07 July 2022

Action: For information

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2022 PDCO

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sol Ruiz/ Sean Barry

Reports from BWP July 2022 meeting to CHMP for adoption:

- 16 reports on products in scientific advice and protocol assistance
- 18 reports on products in pre-authorisation procedures
- 1 report on products in post-authorisation procedures
- 3 reports on products in plasma master file

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 28-29 June 2022.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 04-07 July 2022. Table of conclusions

Action: For information

Scientific advice letters:

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

14.3.4. Vice-Chair election of the Oncology Working Party (ONCWP)

Election of vice-chair of the Oncology Working Party.

Nomination(s) received

Action: For election

14.3.5. Vice-Chair election of the Rheumatology and Immunology Working Party (RIWP)

Election of vice-chair of the Rheumatology and Immunology Working Party.

Nomination(s) received

Action: For election

14.3.6. EC Request for a scientific opinion on the classification as medicinal products of certain substances used in blood bags CDP (citrate, dextrose and phosphate) and CPDA (citrate, dextrose, phosphate and adenine)

- EC request dated June 2022
- European Blood Alliance communication on risk of up-classification of whole blood collection and storage devices from Class IIb to Class III
- CHMP scientific opinion to DG SANCO, Unit B2 Medical devices and cosmetics on citrate solutions used in bags for anticoagulation in apheresis or continuous renal replacement therapy dated April 2012

Action: For information

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

14.6.1. Outcome of CHMP Pilot on early dialogue with patient organisations

Presentation of the results of the pilot (Jan 2021 – May 2022) which reached out to patient organisations for their insights at the beginning of new orphan MAAs. Results from questionnaires completed by Co-/Rapporteurs to be discussed and way forward decided.

Action: For discussion

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

15.1.2. COVID-19 vaccine – EMEA/H/C/006058

immunisation to prevent COVID-19 caused by SARS-CoV-2

Scope: Rolling review

Action: For adoption

Explanatory notes

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

Oral explanations (section 2)

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

Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section 5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures (section 10)

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

Pharmacovigilance issues (section 11)

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

Inspections Issues (section 12)

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

Innovation task force (section 13)

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

Scientific advice working party (SAWP) (section 14.3.1)

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

Satellite groups / other committees (section 14.2)

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

Invented name issues (section 14.3)

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

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2022
EMA/CHMP/608233/2022

Annex to 18-21 July 2022 CHMP Agenda

Pre-submission and post-authorisations issues

A. PRE-SUBMISSION ISSUES	4
A.1. ELIGIBILITY REQUESTS.....	4
A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications	4
A.3. PRE-SUBMISSION ISSUES FOR INFORMATION	4
B. POST-AUTHORISATION PROCEDURES OUTCOMES	4
B.1. Annual re-assessment outcomes	4
B.1.1. Annual reassessment for products authorised under exceptional circumstances	4
B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES.....	5
B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal	5
B.2.2. Renewals of Marketing Authorisations for unlimited validity.....	5
B.2.3. Renewals of Conditional Marketing Authorisations	6
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES.....	7
B.4. EPARs / WPARs	8
B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES	10
B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects	10
B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects	17
B.5.3. CHMP-PRAC assessed procedures	31
B.5.4. PRAC assessed procedures.....	43
B.5.5. CHMP-CAT assessed procedures	50
B.5.6. CHMP-PRAC-CAT assessed procedures	51
B.5.7. PRAC assessed ATMP procedures	52
B.5.8. Unclassified procedures and worksharing procedures of type I variations	53
B.5.9. Information on withdrawn type II variation / WS procedure	56
B.5.10. Information on type II variation / WS procedure with revised timetable	56
B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION	56
B.6.1. Start of procedure for New Applications: timetables for information	56
B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information	57



B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information.....	59
B.6.4. Annual Re-assessments: timetables for adoption	60
B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed	60
B.6.6. VARIATIONS – START OF THE PROCEDURE.....	62
B.6.7. Type II Variations scope of the Variations: Extension of indication	62
B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects	63
B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects.....	67
B.6.10. CHMP-PRAC assessed procedures.....	76
B.6.11. PRAC assessed procedures	80
B.6.12. CHMP-CAT assessed procedures	82
B.6.13. CHMP-PRAC-CAT assessed procedures.....	82
B.6.14. PRAC assessed ATMP procedures	82
B.6.15. Unclassified procedures and worksharing procedures of type I variations	83
B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY.....	85
B.7.1. Yearly Line listing for Type I and II variations.....	85
B.7.2. Monthly Line listing for Type I variations.....	85
B.7.3. Opinion on Marketing Authorisation transfer (MMD only)	85
B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)	85
B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)	85
B.7.6. Notifications of Type I Variations (MMD only)	85
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)	85
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)	85
E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES	85
E.1. PMF Certification Dossiers:.....	85
E.1.1. Annual Update.....	85
E.1.2. Variations:	85
E.1.3. Initial PMF Certification:.....	85
E.2. Time Tables – starting & ongoing procedures: For information	85
F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver	85
G. ANNEX G.....	86
G.1. Final Scientific Advice (Reports and Scientific Advice letters):	86
G.2. PRIME.....	86
G.2.1. List of procedures concluding at 18-21 July 2022 CHMP plenary	86
G.2.2. List of procedures starting in July 2022 for August 2022 CHMP adoption of outcomes	86

H. ANNEX H - Product Shared Mailboxes – e-mail address..... 86

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for
July 2022: **For adoption**

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

Final Outcome of Rapporteurship allocation for
July 2022: **For adoption**

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

Chenodeoxycholic acid Lediart -
chenodeoxycholic acid -
EMA/H/C/004061/S/0020, Orphan
Lediart GmbH, Rapporteur: Anastasia
Mountaki, PRAC Rapporteur: Adam
Przybylkowski

DECTOVA - zanamivir -
EMA/H/C/004102/S/0013
GlaxoSmithKline Trading Services Limited,
Rapporteur: Ingrid Wang, PRAC Rapporteur:
Ulla Wändel Liminga

Elaprase - idursulfase -
EMA/H/C/000700/S/0099
Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Johann Lodewijk
Hillege, PRAC Rapporteur: Liana Gross-
Martirosyan

Evoltra - clofarabine -
EMA/H/C/000613/S/0076
Genzyme Europe BV, Rapporteur: Alexandre
Moreau, PRAC Rapporteur: Tiphaine Vaillant

Firdapse - amifampridine -
EMA/H/C/001032/S/0073

SERB SA, Rapporteur: Kristina Dunder, PRAC
Rapporteur: Ulla Wändel Liminga

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Jorveza - budesonide -

EMA/H/C/004655/R/0016, Orphan

Dr. Falk Pharma GmbH, Rapporteur: Martina
Weise, Co-Rapporteur: Tomas Radimersky,
PRAC Rapporteur: Zane Neikena

Ozempic - semaglutide -

EMA/H/C/004174/R/0030

Novo Nordisk A/S, Rapporteur: Johann Lodewijk
Hillege, Co-Rapporteur: Thalia Marie Estrup
Blicher, PRAC Rapporteur: Annika Folin

TOOKAD - padeliporfin -

EMA/H/C/004182/R/0019

STEB A Biotech S.A, Rapporteur: Bruno Sepodes,
Co-Rapporteur: Armando Genazzani, PRAC
Rapporteur: Maia Uusküla
Request for Supplementary Information adopted
on 23.06.2022.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

ADYNOVI - ruriotocog alfa pegol -

EMA/H/C/004195/R/0033

Baxalta Innovations GmbH, Rapporteur: Andrea
Laslop, Co-Rapporteur: Kristina Dunder, PRAC
Rapporteur: Menno van der Elst

Alkindi - hydrocortisone -

EMA/H/C/004416/R/0014

Diurnal Europe BV, Rapporteur: Karin Janssen
van Doorn, PRAC Rapporteur: Annika Folin

Fasenra - benralizumab -

EMA/H/C/004433/R/0044

AstraZeneca AB, Rapporteur: Fátima Ventura,
Co-Rapporteur: Thalia Marie Estrup Blicher,
PRAC Rapporteur: David Olsen

Hemlibra - emicizumab -

EMA/H/C/004406/R/0032

Roche Registration GmbH, Rapporteur:
Alexandre Moreau, Co-Rapporteur: Jan Mueller-
Berghaus, PRAC Rapporteur: Amelia Cupelli

Intrarosa - prasterone -
EMA/H/C/004138/R/0022

Endoceutics S.A., Rapporteur: Jean-Michel Race,
Co-Rapporteur: Jayne Crowe, PRAC Rapporteur:
Menno van der Elst

Miglustat Gen.Orph - miglustat -
EMA/H/C/004366/R/0022

Gen.Orph, Generic, Generic of Zavesca,
Rapporteur: Daniela Philadelphia, PRAC
Rapporteur: Ulla Wändel Liminga
Request for Supplementary Information adopted
on 23.06.2022.

MVASI - bevacizumab -
EMA/H/C/004728/R/0025

Amgen Technology (Ireland) Unlimited
Company, Duplicate, Duplicate of KYOMARC,
Rapporteur: Eva Skovlund, Co-Rapporteur: Jan
Mueller-Berghaus, PRAC Rapporteur: Anette
Kirstine Stark

Nyxoid - naloxone -
EMA/H/C/004325/R/0014

Mundipharma Corporation (Ireland) Limited,
Rapporteur: Bruno Sepodes, Co-Rapporteur:
Elita Poplavska, PRAC Rapporteur: Liana Gross-
Martirosyan
Request for Supplementary Information adopted
on 19.05.2022.

Ocrevus - ocrelizumab -
EMA/H/C/004043/R/0033

Roche Registration GmbH, Rapporteur: Thalia
Marie Estrup Blicher, Co-Rapporteur: Armando
Genazzani, PRAC Rapporteur: Brigitte Keller-
Stanislowski

**VeraSeal - human fibrinogen / human
thrombin - EMA/H/C/004446/R/0018**

Instituto Grifols, S.A., Rapporteur: Andrea
Laslop, Co-Rapporteur: Ewa Balkowiec Iskra,
PRAC Rapporteur: Amelia Cupelli
Request for Supplementary Information adopted
on 19.05.2022.

B.2.3. Renewals of Conditional Marketing Authorisations

GAVRETO - pralsetinib -
EMA/H/C/005413/R/0006

Roche Registration GmbH, Rapporteur: Aaron

Sosa Mejia, PRAC Rapporteur: Annika Folin

NINLARO - ixazomib -

EMA/H/C/003844/R/0040, Orphan

Takeda Pharma A/S, Rapporteur: Armando
Genazzani, Co-Rapporteur: Filip Josephson,
PRAC Rapporteur: Annika Folin

RYBREVANT - amivantamab -

EMA/H/C/005454/R/0002

Janssen-Cilag International N.V., Rapporteur:
Filip Josephson, PRAC Rapporteur: Brigitte
Keller-Stanislowski

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

PSUR procedures for which PRAC adopted a
recommendation for variation of the terms of
the MA at its July 2022 meeting:

EMA/H/C/PSUSA/00002798/202111

(sufentanil)

CAPS:

Dzueo (EMA/H/C/004335) (sufentanil),
Laboratoire Aguettant, Rapporteur: Hrefna
Gudmundsdottir

Zalviso (EMA/H/C/002784) (sufentanil), FGK
Representative Service GmbH, Rapporteur:
Daniela Philadelphy

NAPS:

NAP - EU

PRAC Rapporteur: Adam Przybylkowski,
"30/11/2018 To: 30/11/2021"

EMA/H/C/PSUSA/00010180/202111

(cabozantinib)

CAPS:

CABOMETYX (EMA/H/C/004163)

(cabozantinib), Ipsen Pharma, Rapporteur:
Ingrid Wang

Cometriq (EMA/H/C/002640) (cabozantinib),
Ipsen Pharma, Rapporteur: Paula Boudewina
van Hennik, PRAC Rapporteur: Menno van der
Elst, "28/11/2018 To: 28/11/2021"

EMA/H/C/PSUSA/00010472/202111

(osimertinib)

CAPS:

TAGRISO (EMA/H/C/004124) (osimertinib),
AstraZeneca AB, Rapporteur: Blanca Garcia-
Ochoa, PRAC Rapporteur: Menno van der Elst,
"13/11/2019 To: 12/11/2021"

EMA/H/C/PSUSA/00010552/202112

(edotreotide)

CAPS:

SomaKit TOC (EMA/H/C/004140)

(edotreotide), Advanced Accelerator

Applications, Rapporteur: Maria Concepcion

Prieto Yerro

NAPS:

NAPs - EU

PRAC Rapporteur: Ronan Grimes, "08/12/2020

To: 07/12/2021"

EMA/H/C/PSUSA/00010643/202112

(lutetium (177Lu) oxodotreotide)

CAPS:

LUTATHERA (EMA/H/C/004123) (lutetium

(177Lu) oxodotreotide), Advanced Accelerator

Applications, Rapporteur: Janet Koenig, PRAC

Rapporteur: Adam Przybylowski, "20/12/2020

To: 19/12/2021"

EMA/H/C/PSUSA/00010897/202112

(elasomeran)

CAPS:

Spikevax (EMA/H/C/005791) (elasomeran),

Moderna Biotech Spain, S.L., Rapporteur: Jan

Mueller-Berghaus, PRAC Rapporteur: Marie

Louise Schougaard Christiansen, "30/06/2021

To: 30/12/2021"

EMA/H/C/PSUSA/00010912/202112

(COVID-19 Vaccine (ChAdOx1-S [recombinant]))

(Vaxzevria))

CAPS:

Vaxzevria (EMA/H/C/005675) (COVID 19

Vaccine (ChAdOx1 S [recombinant])),

AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC

Rapporteur: Jean-Michel Dogné, "29/06/2021

To: 28/12/2021"

EMA/H/C/PSUSA/00010955/202112

(roxadustat)

CAPS:

Evrenzo (EMA/H/C/004871) (roxadustat),

Astellas Pharma Europe B.V., Rapporteur:

Johann Lodewijk Hillege, PRAC Rapporteur: Anna

Mareková, "17/06/2021 To: 16/12/2021"

B.4. EPARs / WPARs

COVID-19 Vaccine (inactivated, adjuvanted) Valneva - SARS-CoV-2 virus,

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

**strain wuhan hCoV-19/Italy/INMI1-
isl/2020, inactivated - EMEA/H/C/006019**

Valneva Austria GmbH, indicated for active immunisation against coronavirus disease 2019 (COVID-19), New active substance (Article 8(3) of Directive No 2001/83/EC)

**Parsaclisib Incyte Biosciences Distribution
B.V. (WD) - parsaclisib -
EMA/H/C/005893, Orphan**

Incyte Biosciences Distribution B.V., treatment of relapsed or refractory marginal zone lymphoma (MZL), New active substance (Article 8(3) of Directive No 2001/83/EC)

WPAR

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

**Pepaxti - melphalan flufenamide -
EMA/H/C/005681**

Oncopeptides AB, treatment of multiple myeloma, 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.

**Ranivisio - ranibizumab -
EMA/H/C/005019**

Midas Pharma GmbH, The treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation (CNV), Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

RAYVOW - lasmiditan - EMA/H/C/005332

Eli Lilly Nederland B.V., acute treatment of migraine with or without aura in adults, 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.

**ROCTAVIAN - valoctocogene roxaparvovec -
EMA/H/C/005830, Orphan, ATMP**

BioMarin International Limited, treatment of severe haemophilia A, 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.

**Scemblix - asciminib - EMA/H/C/005605,
Orphan**

Novartis Europharm Limited, treatment of Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-

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

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

**Sunlenca - lenacapavir -
EMA/H/C/005638**

Gilead Sciences Ireland Unlimited Company,
treatment of human immunodeficiency virus
type 1 (HIV-1) infection, 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.

**VEGZELMA - bevacizumab -
EMA/H/C/005534**

Celltrion Healthcare Hungary Kft., Treatment of
metastatic carcinoma of the colon or rectum,
metastatic breast cancer and recurrence of
platinum-sensitive epithelial ovarian, fallopian
tube or primary peritoneal cancer.
First-line treatment of patients with
unresectable advanced, metastatic or recurrent
non-small cell lung cancer.
First-line treatment of patients with advanced
and/or metastatic renal cell cancer., Similar
biological application (Article 10(4) of Directive
No 2001/83/EC)

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

**Vyvgart - efgartigimod alfa -
EMA/H/C/005849, Orphan**

Argenx, treatment of generalised Myasthenia
Gravis (gMG), New active substance (Article
8(3) of Directive No 2001/83/EC)

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

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

**Benepali - etanercept -
EMA/H/C/004007/II/0065/G**

Samsung Bioepis NL B.V., Rapporteur: Andrea
Laslop

**COMIRNATY - tozinameran -
EMA/H/C/005735/II/0134/G**

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson

**COMIRNATY - tozinameran -
EMA/H/C/005735/II/0135/G**

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson

COMIRNATY - tozinameran -
EMA/H/C/005735/II/0136

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson

Dupixent - dupilumab -
EMA/H/C/004390/II/0059/G

sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 30.06.2022.

Request for Supplementary Information adopted
on 07.04.2022.

Positive Opinion adopted by consensus on
30.06.2022.

Edarbi - azilsartan medoxomil -
EMA/H/C/002293/II/0031

Takeda Pharma A/S, Rapporteur: Johann
Lodewijk Hillege

Elaprase - idursulfase -
EMA/H/C/000700/II/0095

Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Johann Lodewijk
Hillege

Request for Supplementary Information adopted
on 07.07.2022, 24.03.2022.

Request for supplementary information adopted
with a specific timetable.

Elaprase - idursulfase -
EMA/H/C/000700/II/0098/G

Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Johann Lodewijk
Hillege

Request for Supplementary Information adopted
on 10.06.2022, 07.04.2022.

Entyvio - vedolizumab -
EMA/H/C/002782/II/0070/G

Takeda Pharma A/S, Rapporteur: Armando
Genazzani

Erelzi - etanercept -
EMA/H/C/004192/II/0040/G

Sandoz GmbH, Rapporteur: Johann Lodewijk
Hillege

Erelzi - etanercept -
EMA/H/C/004192/II/0042/G

Sandoz GmbH, Rapporteur: Johann Lodewijk
Hillege

**Ervebo - recombinant vesicular stomatitis
virus - Zaire ebolavirus vaccine (live) -**
EMA/H/C/004554/II/0022/G

Merck Sharp & Dohme B.V., Rapporteur:
Christophe Focke

**EVUSHELD - tixagevimab / cilgavimab -
EMA/H/C/005788/II/0002/G**

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus

**Firazyr - icatibant -
EMA/H/C/000899/II/0054/G, Orphan**

Takeda Pharmaceuticals International AG,
Rapporteur: Kristina Dunder

**Flucelvax Tetra - influenza vaccine surface
antigen inactivated prepared in cell
cultures - EMA/H/C/004814/II/0027**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Opinion adopted on 07.07.2022.

Positive Opinion adopted by consensus on
07.07.2022.

**Fluenz Tetra - influenza vaccine (live
attenuated, nasal) -
EMA/H/C/002617/II/0117**

AstraZeneca AB, Rapporteur: Christophe Focke
Opinion adopted on 07.07.2022.

Positive Opinion adopted by consensus on
07.07.2022.

**GONAL-f - follitropin alfa -
EMA/H/C/000071/II/0154/G**

Merck Europe B.V., Rapporteur: Johann
Lodewijk Hillege
Request for Supplementary Information adopted
on 22.04.2022.

**IMVANEX - smallpox vaccine (live modified
vaccinia virus Ankara) -
EMA/H/C/002596/II/0075/G**

Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

**Increlex - mecasermin -
EMA/H/C/000704/II/0076**

Ipsen Pharma, Rapporteur: Outi Mäki-Ikola
Opinion adopted on 30.06.2022.
Request for Supplementary Information adopted
on 28.04.2022.

Positive Opinion adopted by consensus on
30.06.2022.

**Increlex - mecasermin -
EMA/H/C/000704/II/0077/G**

Ipsen Pharma, Rapporteur: Outi Mäki-Ikola

**Jivi - damoctocog alfa pegol -
EMA/H/C/004054/II/0023**

Bayer AG, Rapporteur: Thalia Marie Estrup
Blicher
Opinion adopted on 30.06.2022.
Request for Supplementary Information adopted
on 07.04.2022.

Positive Opinion adopted by consensus on
30.06.2022.

Kadcyla - trastuzumab emtansine -**EMA/H/C/002389/II/0066/G**

Roche Registration GmbH, Rapporteur: Thalia

Marie Estrup Blicher

Lynparza - olaparib -**EMA/H/C/003726/II/0055/G**

AstraZeneca AB, Rapporteur: Alexandre Moreau

Opinion adopted on 30.06.2022.

Request for Supplementary Information adopted on 19.05.2022.

Positive Opinion adopted by consensus on 30.06.2022.

Mekinist - trametinib -**EMA/H/C/002643/II/0053/G**

Novartis Europharm Limited, Rapporteur: Paula

Boudewina van Hennik

Request for Supplementary Information adopted on 22.04.2022.

Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) -**EMA/H/W/002300/II/0061/G**

GlaxoSmithKline Biologicals SA, Rapporteur: Jan Mueller-Berghaus

Natpar - parathyroid hormone -**EMA/H/C/003861/II/0033/G, Orphan**

Takeda Pharmaceuticals International AG,

Rapporteur: Karin Janssen van Doorn

Request for Supplementary Information adopted on 17.03.2022, 02.12.2021.

Ngenla - somatogon -**EMA/H/C/005633/II/0001/G, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Jayne

Crowe

Request for Supplementary Information adopted on 19.05.2022.

Nuceiva - botulinum toxin type A -**EMA/H/C/004587/II/0025/G**

Evolus Pharma B.V., Rapporteur: Jayne Crowe

Opinion adopted on 07.07.2022.

Positive Opinion adopted by consensus on 07.07.2022.

OXERVATE - cenegermin -**EMA/H/C/004209/II/0038/G, Orphan**

Dompe farmaceutici S.p.A., Rapporteur: Maria

Concepcion Prieto Yerro

Padcev - enfortumab vedotin -**EMA/H/C/005392/II/0001**

Astellas Pharma Europe B.V., Rapporteur: Aaron

Sosa Mejia

**Pemetrexed Accord - pemetrexed -
EMA/H/C/004072/II/0020**

Accord Healthcare S.L.U., Generic, Generic of
Alimta, Rapporteur: John Joseph Borg

**Plegridy - peginterferon beta-1a -
EMA/H/C/002827/II/0067**

Biogen Netherlands B.V., Rapporteur: Johann
Lodewijk Hillege
Opinion adopted on 07.07.2022.

Positive Opinion adopted by consensus on
07.07.2022.

**Polivy - polatuzumab vedotin -
EMA/H/C/004870/II/0017/G, Orphan**

Roche Registration GmbH, Rapporteur:
Alexandre Moreau
Request for Supplementary Information adopted
on 23.06.2022.

**Privigen - human normal immunoglobulin -
EMA/H/C/000831/II/0185**

CSL Behring GmbH, Rapporteur: Jan Mueller-
Berghaus
Opinion adopted on 14.07.2022.
Request for Supplementary Information adopted
on 12.05.2022.

Positive Opinion adopted by consensus on
14.07.2022.

**Privigen - human normal immunoglobulin -
EMA/H/C/000831/II/0188**

CSL Behring GmbH, Rapporteur: Jan Mueller-
Berghaus

**Puregon - follitropin beta -
EMA/H/C/000086/II/0124**

Organon N.V., Rapporteur: Jayne Crowe
Request for Supplementary Information adopted
on 07.07.2022.

Request for supplementary information adopted
with a specific timetable.

**Pyramax - pyronaridine / artesunate -
EMA/H/W/002319/II/0031/G**

Shin Poong Pharmaceutical Co., Ltd.,
Rapporteur: Jean-Michel Race
Request for Supplementary Information adopted
on 07.07.2022.

Request for supplementary information adopted
with a specific timetable.

**Rekovelte - follitropin delta -
EMA/H/C/003994/II/0034**

Ferring Pharmaceuticals A/S, Rapporteur: Jean-
Michel Race

**Rhokiinsa - netarsudil -
EMA/H/C/004583/II/0010/G**

Santen Oy, Rapporteur: Jayne Crowe

**Rixubis - nonacog gamma -
EMA/H/C/003771/II/0044**

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop
Request for Supplementary Information adopted on 12.05.2022.

**SARCLISA - isatuximab -
EMA/H/C/004977/II/0015**

sanofi-aventis groupe, Rapporteur: Paula Boudewina van Hennik

**Sogroya - somapacitan -
EMA/H/C/005030/II/0004/G, Orphan**

Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege

**Spectrila - asparaginase -
EMA/H/C/002661/II/0031**

medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Andrea Laslop

**Stelara - ustekinumab -
EMA/H/C/000958/II/0094/G**

Janssen-Cilag International N.V., Rapporteur: Jayne Crowe

**Supemtek - quadrivalent influenza vaccine
(recombinant, prepared in cell culture) -
EMA/H/C/005159/II/0007/G**

Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 16.06.2022, 10.03.2022.

**TAKHZYRO - lanadelumab -
EMA/H/C/004806/II/0030/G, Orphan**

Takeda Pharmaceuticals International AG, Rapporteur: Kristina Dunder
Request for Supplementary Information adopted on 16.06.2022.

**Tigecycline Accord - tigecycline -
EMA/H/C/005114/II/0002/G**

Accord Healthcare S.L.U., Generic, Generic of Tygacil, Rapporteur: Daniela Philadelphia
Request for Supplementary Information adopted on 31.03.2022, 13.01.2022.

**Trogarzo - ibalizumab -
EMA/H/C/004961/II/0016/G**

Theratechnologies Europe Limited, Rapporteur: Johann Lodewijk Hillege
Request for Supplementary Information adopted on 17.02.2022, 25.11.2021.

Trulicity - dulaglutide - EMA/H/C/002825/II/0064/G Eli Lilly Nederland B.V., Rapporteur: Martina Weise Opinion adopted on 07.07.2022.	Positive Opinion adopted by consensus on 07.07.2022.
Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMA/H/C/003982/II/0097 MCM Vaccine B.V., Rapporteur: Christophe Focke Request for Supplementary Information adopted on 02.06.2022.	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMA/H/C/005675/II/0071 AstraZeneca AB, Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 02.06.2022.	
VPRIV - velaglucerase alfa - EMA/H/C/001249/II/0055, Orphan Takeda Pharmaceuticals International AG, Rapporteur: Martina Weise	
WS2264 Humalog- EMA/H/C/000088/WS2264/0194 Liprolog- EMA/H/C/000393/WS2264/0154 Eli Lilly Nederland B.V., Lead Rapporteur: Kristina Dunder Opinion adopted on 30.06.2022.	Positive Opinion adopted by consensus on 30.06.2022.
WS2275/G GONAL-f- EMA/H/C/000071/WS2275/0156/G Pergoveris- EMA/H/C/000714/WS2275/0078/G Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 07.07.2022.	Request for supplementary information adopted with a specific timetable.
WS2285/G Humalog- EMA/H/C/000088/WS2285/0195/G Liprolog- EMA/H/C/000393/WS2285/0155/G Eli Lilly Nederland B.V., Lead Rapporteur:	

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

Bydureon - exenatide -

EMA/H/C/002020/II/0074

AstraZeneca AB, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add cholelithiasis and cholecystitis to the list of adverse drug reactions (ADRs) with frequency (unknown) based on the cumulative review of pre-clinical and clinical study data, post-marketing data, medical/scientific literature and signal searches in internal and external databases on 'Gallbladder-related disorders' and exenatide.

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

BYETTA - exenatide -

EMA/H/C/000698/II/0078

AstraZeneca AB, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add cholelithiasis and cholecystitis to the list of adverse drug reactions (ADRs) with frequency (unknown) based on the cumulative review of pre-clinical and clinical study data, post-marketing data, medical/scientific literature and signal searches in internal and external databases on 'Gallbladder-related disorders' and exenatide.

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

Cibinqo - abrocitinib -

EMA/H/C/005452/II/0002

Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder, "Update of sections 4.2 and 4.5 of the SmPC based on results from Drug-Drug Interaction (DDI) study B7451061; A phase 1, randomised, crossover study to evaluate relative bioavailability of abrocitinib oral suspension and effect of an acid-reducing agent on the bioavailability of abrocitinib commercial tablet and to assess the taste of abrocitinib oral formulations in healthy adult participants aged 18 to 55 years of age. The Package Leaflet is updated in accordance."

Positive Opinion adopted by consensus on 07.07.2022.

Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted
on 07.04.2022.

Dificlir - fidaxomicin -

EMA/H/C/002087/II/0049

Tillotts Pharma GmbH, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to introduce a new posology regimen based on final results from EXTEND study - A Phase IIIb/IV Randomized, Controlled, Open-Label, Parallel Group Study to Compare the Efficacy of Vancomycin Therapy to Extended Duration Fidaxomicin Therapy in the Sustained Clinical Cure of Clostridium difficile Infection in an Older Population. The Package Leaflet is updated accordingly."

Enhertu - trastuzumab deruxtecan -

EMA/H/C/005124/II/0019

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, "Update of section 4.2 of the SmPC to add nausea/vomiting premedication prophylaxis information following procedure II/14 based on analyses from study DS8201-A-U302 (DESTINY-Breast03); this is a Phase 3, multicenter, randomized, open-label, 2-arm, active controlled study in subjects with unresectable and/or metastatic HER2-positive breast cancer previously treated with trastuzumab and a taxane.
The Package Leaflet is updated accordingly."

Esperoct - turoctocog alfa pegol -

EMA/H/C/004883/II/0013, Orphan

Novo Nordisk A/S, Rapporteur: Andrea Laslop, "Update of section 4.2 of the SmPC in order to delete the statement in reference to previously untreated patients (PUPs) and section 5.1 of the SmPC in order to update information based on final results from study NN7088-3908; this is an open-label single-arm multicentre non-controlled phase 3a trial investigating safety and efficacy of turoctocog alfa pegol (N8-GP) in prophylaxis and treatment of bleeding episodes in previously untreated paediatric patients with severe haemophilia A. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

GONAL-f - follitropin alfa -

EMA/H/C/000071/II/0155

Merck Europe B.V., Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.1, 4.2, 4.4, 5.1, 5.2 and 6.6 of the SmPC to revise the definition of severe LH and FSH deficiency, aligning with current medical guidelines and clinical practice, to clarify follicular development as the treatment target and selection of the most adequate Medically Assisted Reproduction procedure for healthcare providers, and the pharmacokinetic and pharmacodynamic properties of follitropin alfa; and to align with the Product Information of Pergoveris as previously assessed by the CHMP in procedure EMA/H/C/000714/II/0075.

The package leaflet is updated accordingly. In addition, the applicant has taken the opportunity to improve the Instructions for Use (IFU) layout and to implement the Medical Device Regulation in the IFU."

Request for Supplementary Information adopted on 10.06.2022.

**Hepcludex - bulevirtide -
EMA/H/C/004854/II/0011, Orphan**

Positive Opinion adopted by consensus on 07.07.2022.

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC in order to move the warnings for the ADRs 'Increase of bile salts' and 'Administration site reactions' to section 4.8 of the SmPC as additional describing information to the listed PTs, together with the addition of a new ADR: hypersensitivity reactions (including anaphylactic reaction). Further to a safety review based on pooled data from clinical trials and post-marketing experience, editing of existing ADRs in section 4.8 was also carried out. The Package Leaflet was updated accordingly.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the EU QRD template v10.2."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 31.03.2022.

**IBRANCE - palbociclib -
EMA/H/C/003853/II/0038/G**

Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "C.I.4: Update of section 5.3 of the SmPC in order to update the primary target

organ findings and development toxicity wording.

In addition, the MAH took the opportunity to update the list of local representatives (Belgium, Luxembourg, Germany and the Netherlands) in the Package Leaflet.

A.6: Update of Palbociclib ATC code based on the last revised classification of the Cyclin-dependent kinase (CDK) inhibitors made by the WHO.”

Request for Supplementary Information adopted on 02.06.2022.

**Imbruvica - ibrutinib -
EMA/H/C/003791/II/0074**

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the information related to Paediatrics following assessment done in procedure P46/035, based on results from the paediatric study LYM3003 “A Randomized, Open-label, Safety and Efficacy Study of Ibrutinib in Pediatric and Young Adult Patients With Relapsed or Refractory Mature B-cell non-Hodgkin Lymphoma”.

The Package Leaflet is updated accordingly.”

**Imbruvica - ibrutinib -
EMA/H/C/003791/II/0075**

Janssen-Cilag International N.V., Rapporteur: Filip Josephson, “Update of section 4.2 of the SmPC to incorporate information specific for dose modifications for non-cardiac events and events of cardiac failure or cardiac arrhythmias events based on data pool from clinical studies which included 4 Phase II (PCYC-1102-CA, PCYC-1104-CA, PCYC-1118E, PCYC-1142-CA) and 8 Phase III studies (PCYC-1112-CA, PCYC-1115-CA, CLL3001, PCYC-1130-CA, MCL3001, PCYC-1127-CA, CLL3011, and MCL3002).”

**Jardiance - empagliflozin -
EMA/H/C/002677/II/0062/G**

Boehringer Ingelheim International GmbH, Rapporteur: Johann Lodewijk Hillege, “Update of section 5.1 of the SmPC with the results of clinical study EMPULSE (1245-0204), a multicentre, randomised, double-blind, 90-day superiority trial to evaluate the effect on clinical benefit, safety and tolerability of once daily oral EMPagliflozin 10 mg compared to placebo, initiated in patients hospitalised for acUte heart

failLure (de novo or decompensated chronic HF) who have been StabilisEd (EMPULSE).
In addition, the MAH took the opportunity to implement editorial changes in the SmPC.”
Request for Supplementary Information adopted on 28.04.2022, 10.02.2022.

JCOVDEN - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0053/G See 9.1

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, “Update of section 4.2 of the SmPC to introduce a heterologous booster dose of JCOVDEN following priming with another adenoviral vector-based vaccine and an inactivated whole virion COVID-19 vaccine based on literature evidence from studies COV-BOOST and RHH-01 respectively. Update of sections 4.8 and 5.1 of the SmPC to include safety and immunogenicity data of JCOVDEN as homologous and heterologous booster dose based on data from studies COV2008, a randomised, double-blind Phase 2 study and literature evidence from studies COV-BOOST, RHH-001 and DMID 21-0012. The Package Leaflet is updated accordingly.”

JEMPERLI - dostarlimab - EMEA/H/C/005204/II/0007

GlaxoSmithKline (Ireland) Limited, Rapporteur: Blanca Garcia-Ochoa, “Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update dose modifications recommendations in immune related adverse reactions, amend existing warnings, and add further immune-related ADRs to the list of adverse drug reactions (ADRs), with different frequencies, based on data from company sponsored trials and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to remove information on Polysorbate 80 and update the list of local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 22.04.2022, 27.01.2022.

Jyseleca - filgotinib - EMEA/H/C/005113/II/0008

Positive Opinion adopted by consensus on 30.06.2022.

Galapagos N.V., Rapporteur: Kristina Dunder, “C.I.4 - Update of sections 4.4 and 4.8 of the SmPC in order to update the risk factors for viral reactivation, add recommendation of

prophylactic zoster vaccination prior to treatment, add lymphopenia to the list of adverse drug reactions (ADRs) with frequency common, update the information on serum phosphate and the experience from the long-term extension studies based on interim results from study GS-US-417-0304 (FINCH 4); this is a Multicenter, Double-Blind, Long Term Extension Study to Assess the Safety and Efficacy of Filgotinib in Subjects with Rheumatoid Arthritis; the Package Leaflet is updated accordingly.”

Opinion adopted on 30.06.2022.

Request for Supplementary Information adopted on 22.04.2022, 13.01.2022, 09.09.2021.

Koselugo - selumetinib -

EMA/H/C/005244/II/0006/G, Orphan

AstraZeneca AB, Rapporteur: Alexandre Moreau, “Submission of the reports for the long-term efficacy and safety updates from study D1532C00057: SPRINT Phase I and SPRINT Phase II Stratum 1 to fulfil the Specific Obligations SOB/003 and SOB/002, respectively, listed in the Annex II of the Product Information. This is a phase I/II study of the mitogen activated protein kinase kinase (MEK) 1 inhibitor selumetinib (AZD6244; HYD-Sulfate) in children with neurofibromatosis type 1 (NF1) and inoperable plexiform neurofibromas (PN).”

Lokelma - sodium zirconium cyclosilicate -

EMA/H/C/004029/II/0025

AstraZeneca AB, Rapporteur: Silvijus Abramavicius, “Update of section 4.5 of the SmPC in order to add drug-drug interaction information based on final report for interventional study D9480C00012, “A Two-Cohort, Randomised Sequence, Crossover, Open-label Study to Assess the Effect of a Single Dose of Sodium Zirconium Cyclosilicate (SZC) on the Pharmacokinetics of Tacrolimus and Cyclosporin in Healthy Subjects”. The Package Leaflet is updated accordingly. In addition, the MAH is taking this opportunity to update the contact details of the local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 10.06.2022.

**Methylthioninium chloride Proveblue -
methylthioninium chloride -**

EMA/H/C/002108/II/0052/G

Provepharm SAS, Rapporteur: Kristina Dunder,
"- Update of sections 4.2 and 5.2 of the SmPC
in order to change the posology
recommendations in patients with renal and
hepatic impairment and update the
pharmacokinetic information respectively, based
on results from: an open-label, parallel group,
population-matched, single-dose study to
investigate the influence of renal impairment on
the pharmacokinetics of ProvayBlue (Study
Report PVP-2016006). The package leaflet and
labelling are updated accordingly. The applicant
takes this opportunity to update the Product
Information according to the QRD template
v10.1 and v10.2.

- Update of sections 4.5 and 5.2 of the SmPC in
order to add drug-drug interaction information
with other medicinal products and update the
pharmacokinetic information respectively, based
on results from: an open-label, randomized,
two-period, crossover study to assess the effect
of a single dose of methylene blue 5 mg/ml on
the pharmacokinetics of the probe drugs
midazolam, caffeine, warfarin, omeprazole and
dextromethorphan in healthy subjects (Study
Report PVP-2016004). The package leaflet and
labelling are updated accordingly."

Request for Supplementary Information adopted
on 22.04.2022, 16.12.2021.

**NUVAXOVID - SARS-CoV-2, spike protein, See 9.1
recombinant, expressed in Sf9 cells derived
from Spodoptera frugiperda -**

EMA/H/C/005808/II/0011/G

Novavax CZ, a.s., Rapporteur: Johann Lodewijk
Hillege, "Grouped variation:

- C.I.4 (Type II): Update of section 5.1 of the
SmPC in order to introduce data on clinical
efficacy against the Omicron variant of concern,
based on data from study 2019nCoV-101 (Parts
1 and 2), a Phase 1/2, Randomized, Observer-
Blinded Study to Evaluate the Safety and
Immunogenicity of a SARS-CoV-2 Recombinant
Spike Protein Nanoparticle Vaccine (SARS-CoV-2
rS) With or Without Matrix-M Adjuvant in
Healthy Subjects (NCT04368988), study
2019nCoV-501, a Phase 2a/b, Randomized,
Observer-Blinded, Placebo-Controlled Study to

Evaluate the Efficacy, Immunogenicity, and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Matrix-M Adjuvant in South African Adult Subjects Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV (NCT04533399) and published literature. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial corrections throughout the product information.

- C.I.13 (Type II): Submission of the final clinical report from study 2019nCoV-101 (Part 1), a Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M Adjuvant in Healthy Subjects (NCT04368988). This submission addresses the post-authorisation measures MEA 009, REC 041 and REC 042."

**Oncaspar - pegaspargase -
EMA/H/C/003789/II/0048**

Les Laboratoires Servier, Rapporteur: Alexandre Moreau, "Update of sections 4.2 and 4.4 of the SmPC in order to add advice on premedication to reduce the cases of hypersensitivity reactions based on literature review and guidelines. The Package Leaflet is updated accordingly."

Paxlovid - (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-

**azabicyclo[3.1.0]hexane-2-carboxamide /
ritonavir - EMA/H/C/005973/II/0012/G**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "C.I.13 (type II): Submission of the whole body autoradiographic study report in rats with PF-07321332 (alone).

C.I.13 (type II): Update of section 5.3 of the SmPC to indicate that no adverse effects were observed during the pre-and postnatal development study based on final study report for the pre- and postnatal development (21GR149)."

Opinion adopted on 07.07.2022.

Positive Opinion adopted by consensus on 07.07.2022.

**Pegasys - peginterferon alfa-2a -
EMA/H/C/000395/II/0112**

Request for supplementary information adopted with a specific timetable.

Zr Pharma& GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.8 of the SmPC in order to include information on post-treatment recovery in growth based on final results from study YV25718 listed as a category 3 study in the RMP; this is a Phase IIIb parallel group, open label study of pegylated interferon alfa-2a monotherapy (PEG-IFN, RO0258310) compared to untreated control in children with HBeAg-Positive Chronic Hepatitis B in the immune active phase. The RMP version 9.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the Package Leaflet."

Request for Supplementary Information adopted on 07.07.2022.

Piqray - alpelisib -

EMA/H/C/004804/II/0012

Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with CYP3A4 inducers and inhibitors based on study BYL719A2110, a drug-drug interactions study that evaluated the PK of alpelisib when administered alone or with rifampin, a strong CYP3A4 inducer, in healthy participants."

Piqray - alpelisib -

EMA/H/C/004804/II/0013

Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, "Update of the SmPC sections 4.6 and 5.3 in order to add fertility data based on studies 2070119 "BYL719: Oral (Gavage) Study of Fertility in the Male Rat" and 2070120 "BYL719: Oral (Gavage) Study of Fertility and Early Embryonic Development in the Female Rat"."

Regkirona - regdanvimab -

EMA/H/C/005854/II/0005

Celltrion Healthcare Hungary Kft., Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to update the description of Phase 3 of study CT-P59 3.2 following finalisation of the clinical study report from study CT-P59 3.2 Part 2."

REKAMBYS - rilpivirine -

EMA/H/C/005060/II/0012

Janssen-Cilag International N.V., Rapporteur:
Johann Lodewijk Hillege, "Update of section 4.2 of the SmPC in order to expand oral bridging options for missed planned injections of cabotegravir and rilpivirine based on studies 201584 (FLAIR), 207966 (ATLAS-2M), 200056 (LATTE 2) and 201585 (ATLAS).
The Package Leaflet is updated accordingly.
In addition, the MAH is also taking this opportunity to introduce editorial changes."

**RYBREVANT - amivantamab -
EMA/H/C/005454/II/0001**

Positive Opinion adopted by consensus on
07.07.2022.

Janssen-Cilag International N.V., Rapporteur:
Filip Josephson, "Update of section 4.8 of the SmPC in order to add hypokalaemia and hypomagnesaemia to the list of adverse drug reactions (ADRs), with the frequency common, based on an updated analysis of data submitted during the marketing authorisation procedure.
The Package Leaflet is updated accordingly. In addition, the MAH proposed to update the current information in section 4.2 of the SmPC to improve clarity and provide more specific guidance. The MAH also took the opportunity to introduce editorial changes in section 4.8 of the SmPC."
Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted on 07.04.2022.

**Ryego - relugolix / estradiol /
norethisterone acetate -
EMA/H/C/005267/II/0009**

Positive Opinion adopted by consensus on
30.06.2022.

Gedeon Richter Plc., Rapporteur: Paula Boudewina van Hennik, "Update of sections 5.3 and 6.6 of the SmPC based on final results from MVT-601-9030_Relugolix_ZEOGRT_Study (Rec); this is a fish, full life cycle test performed in the context of the Environmental Risk Assessment of relugolix. The Package Leaflet is updated accordingly."
Opinion adopted on 30.06.2022.

**Spikevax - elasomeran -
EMA/H/C/005791/II/0057**

See 9.1

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, "Update of section 4.2 of the Spikevax SmPC to include a 50 µg booster dose for adolescents 12 to 18 years of age, based on the extrapolation of safety and efficacy data from young adults (18 to 24 years of age). The

package leaflet is updated accordingly.”
Request for Supplementary Information adopted
on 19.05.2022, 22.04.2022.

Spikevax - elasomeron -

See 9.1

EMA/H/C/005791/II/0066

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, “Update of sections 4.5 and 5.1 of the SmPC in order to introduce new clinical data regarding the co-administration of Spikevax with a high-dose quadrivalent influenza vaccine (QIV-HD), based on final results from study QHD00028 (NCT04969276), a Phase II, Open-label Study to ‘Assess the Safety and Immunogenicity of Fluzone High-Dose Quadrivalent (Influenza Vaccine), 2021-2022 Formulation and a Third Dose of Moderna COVID-19 Vaccine (mRNA-1273 Vaccine) Administered Either Concomitantly or Singly in Adults 65 Years of Age and Older Previously Vaccinated With a 2-dose Schedule of Moderna COVID-19 Vaccine’.”

Spikevax - elasomeron -

Positive Opinion adopted by consensus on
12.07.2022.

EMA/H/C/005791/II/0073

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, “C.I.11.b -To update Annex IIE of the Spikevax Product Information to delete SO3. Additional active substance and finished product stability data and review of the active substance and finished product specifications following further manufacturing experience have already been submitted and assessed in the context of previous procedures and are now considered fulfilled.”
Opinion adopted on 12.07.2022.

TAGRISSO - osimertinib -

Request for supplementary information adopted
with a specific timetable.

EMA/H/C/004124/II/0047

AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, “Update of section 5.2 of the SmPC based on final results from studies ODIN-BM and ODIN-HV; these are two phase I clinical pharmacology studies conducted in EGFRm+ NSCLC patients (ODIN-BM) and healthy volunteers (ODIN-HV) to determine osimertinib blood-brain barrier (BBB) penetration and brain distribution in patients with brain metastases and healthy volunteers with an intact BBB, respectively.”
Request for Supplementary Information adopted

on 07.07.2022.

**TECFIDERA - dimethyl fumarate -
EMA/H/C/002601/II/0078**

Positive Opinion adopted by consensus on
14.07.2022.

Biogen Netherlands B.V., Rapporteur: Martina Weise, "Submission of the final report from study 109MS408; upon request by the PRAC as per final PSUR assessment report of procedure EMA/H/C/PSUSA/00010143/20213. This is a Multicenter, Open-Label Study Evaluating the Effectiveness of Oral Tecfidera (Dimethyl Fumarate) on Multiple Sclerosis Disease Activity and Patient-Reported Outcomes in Subjects with Relapsing Remitting Multiple Sclerosis in the Real-World Setting (PROTEC)."
Opinion adopted on 14.07.2022.

**Vaxchora - cholera vaccine, oral, live -
EMA/H/C/003876/II/0013**

Emergent Netherlands B.V., Rapporteur: Ingrid Wang, "
Type II - C.I.4, to update section 6.6 of the SmPC to add the use of carbonated bottled water to reconstitute the vaccine in addition to non-carbonated bottled water. The package leaflet and labelling are updated accordingly. The applicant took the opportunity to submit a corrected Annex A in all languages, which currently presents an inconsistency in the way the strength was stated at MAA approval (as detailed in SmPC)."

**Vaxzevria - COVID 19 Vaccine (ChAdOx1 S
[recombinant]) -
EMA/H/C/005675/II/0031**

AstraZeneca AB, Rapporteur: Sol Ruiz, "
Submission of the final study report for MS1222-0002 "In Vitro Assay to Determine Release of Spike Protein From Transduced Cells" to fulfil the imposed study as reflected in Annex II of the product information and the RMP. As a result, Annex II of the product information is being updated to remove this study.
The MAH is taking the opportunity to provide two additional studies linked to support the investigation on the platelet activation: the final study report for MS1222-0001 "Computational Prediction of Spike Protein Interaction with Platelet Factor 4 (PF4)" which is the first report requested within the required studies for "in vitro interaction of AZD1222 or spike protein with PF4 and/or platelets" as reflected in the

RMP; and the study report for 520447
"Investigative Vaccine Study in the Mouse" to
evaluate spike protein levels and haematology
parameters."
Request for Supplementary Information adopted
on 23.06.2022, 13.01.2022, 23.09.2021.

**Vocabria - cabotegravir -
EMA/H/C/004976/II/0012**

ViiV Healthcare B.V., Rapporteur: Jean-Michel
Race, "Update of section 4.2 of the SmPC to
introduce an alternative oral therapy for
bridging between planned missed injections of
cabotegravir and rilpivirine (monthly and every
2 month), based on a retrospective safety
analysis of pooled data from 29 subjects in 3
clinical studies (Phase III studies: 201584,
207966, and 200056). In addition, the Package
Leaflet is updated accordingly."

**Vyxeos liposomal - daunorubicin /
cytarabine - EMA/H/C/004282/II/0030,
Orphan**

Jazz Pharmaceuticals Ireland Limited,
Rapporteur: Johanna Lähteenvuori, "Update of
sections 4.2, 4.4 and 5.2 of the SmPC to amend
information and delete the existing warning for
patients with renal impairment based on the
final results from study CPX351-102 (PMR2): a
phase 1, open-label, PK and safety study to
evaluate the potential impact of renal
impairment on the pharmacokinetics and safety
of CPX-351 (Daunorubicin and Cytarabine)
liposome for injection treatment in adult
patients with hematologic malignancies."
Request for Supplementary Information adopted
on 12.05.2022.

**Wegovy - semaglutide -
EMA/H/C/005422/II/0003/G**

Novo Nordisk A/S, Rapporteur: Johann Lodewijk
Hillege, "Update of section 5.1 of the SmPC in
order to update the description of the
pharmacodynamic effects and clinical efficacy
and safety based on final results from
interventional studies: Trial 4378 (STEP 5)
which compared the two-year effect of
semaglutide 2.4 mg once weekly versus
placebo; Trial 4576 (STEP 8) which compared
semaglutide s.c. 2.4 mg once weekly to
liraglutide s.c. 3.0 mg once daily and Trial 4373
extension (STEP 1ext) which explored the

change in body weight, cardiovascular risk factors and glucose metabolism in subjects who completed 68 weeks of treatment (semaglutide 2.4 mg or placebo) followed by a 52-week off-treatment period.”

Request for Supplementary Information adopted on 02.06.2022.

Xevudy - sotrovimab -

EMA/H/C/005676/II/0005

Glaxosmithkline Trading Services Limited,
Rapporteur: Thalia Marie Estrup Blicher,
“Update of sections 4.4 and 5.1 of the SmPC based on final results from study PC-7831-0157. This is a pharmacology study to determine the neutralisation activity of sotrovimab against SARS-CoV-2 pseudotyped virus expressing the Omicron BA.2.12.1, Omicron BA.4, or Omicron BA.5 spike proteins.”

WS2249

Delstrigo-

EMA/H/C/004746/WS2249/0029

Pifeltro-EMA/H/C/004747/WS2249/0022

Merck Sharp & Dohme B.V., Lead Rapporteur:
Filip Josephson, “Update of section 5.1 of the SmPC based on two non-clinical studies (study PD011: Assessment of in vitro antiviral activity against HIV-1 Resistant mutant, Y318F, alone and in combination with 12 other NNRTI mutants and study PD012: In vitro antiviral activity of doravirine (MK-1439) Against a panel of viruses bearing NNRTI resistance-associated Mutations). In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to update the list of local representatives in the Package Leaflet.”

WS2253

Eucreas-

EMA/H/C/000807/WS2253/0096

Galvus-EMA/H/C/000771/WS2253/0076

Icandra-

EMA/H/C/001050/WS2253/0100

Jalra-EMA/H/C/001048/WS2253/0078

Xiliarx-EMA/H/C/001051/WS2253/0077

Zomarist-

EMA/H/C/001049/WS2253/0098

Novartis Europharm Limited, Lead Rapporteur:
Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, “Update of section 4.8 of the SmPC in order to add the new ADRs 'cutaneous

Positive Opinion adopted by consensus on 07.07.2022.

vasculitis' with the frequency "not known". The Package Leaflet has been updated accordingly."
Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted on 05.05.2022.

WS2259

DuoPlavin-

EMA/H/C/001143/WS2259/0063

Iscover-

EMA/H/C/000175/WS2259/0149

Plavix-EMA/H/C/000174/WS2259/0147

sanofi-aventis groupe, Lead Rapporteur: Bruno Sepodes, "Update of section 4.4 of the SmPC in order to update an existing warning on 'Bleeding and haematological disorders' by adding a statement on triple antiplatelet therapy (clopidogrel + aspirin + dipyridamole) for stroke secondary prevention. The Package Leaflet is updated accordingly."

B.5.3. CHMP-PRAC assessed procedures

Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) -

EMA/H/C/005451/II/0002

Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphia, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.5, 4.8 and 5.1 of the SmPC to add information regarding the co-administration of Apexxnar with seasonal quadrivalent influenza vaccine (QIV) based on final study results from study B7471004, "A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20 valent Pneumococcal Conjugate Vaccine (20vPnC) When Coadministered with Seasonal Inactivated Influenza Vaccine (SIIV) in Adults ≥65 Years of Age." listed as a category 3 study in the RMP.

The Package Leaflet is updated accordingly.
The updated RMP version 1.1 has also been submitted."

Request for Supplementary Information adopted on 19.05.2022.

Cibinqo - abrocitinib -

EMA/H/C/005452/II/0001

Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of sections 4.4 and 4.8 of the

Request for supplementary information adopted with a specific timetable.

SmPC based on updated safety data from the Full Cumulative Pool (April 2021 data cut) from the ongoing long-term extension study B7451015. The RMP version v1.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to update the contact details of the local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 07.07.2022, 07.04.2022.

CRYSVITA - burosumab -

See 9.1

EMA/H/C/004275/II/0028, Orphan

Kyowa Kirin Holdings B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of the adverse drug reactions, to split immunogenicity data into paediatric and adult populations and to update clinical efficacy in paediatric patients, upon request by the CHMP following the assessment of PAM procedures P46/006 and P46/007 and type II variations II/04 and II/10/G, based on the final results from studies UX023-CL201, UX023-CL205 and UX023-CL301. As a consequence, the last remaining specific obligation, the provision of the final CSR for study UX023-CL205, was deleted from the Annex II. This was an open-label, phase 2 study undertaken to assess the safety, pharmacodynamics, and efficacy of KRN23 in paediatric patients between 1 and 4 years old with X-linked Hypophosphataemia (XLH). With the fulfilment of this specific obligation the MAH is requesting for the Crysvita MA to no longer be subject to specific obligations. The Package Leaflet was updated accordingly. The RMP version 5.0 was agreed during the procedure.”

Request for Supplementary Information adopted on 22.04.2022.

Descovy - emtricitabine / tenofovir alafenamide - EMA/H/C/004094/II/0057

Positive Opinion adopted by consensus on 07.07.2022.

Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, “Submission of the clinical study report and supporting modular summaries for study GS-US-311-1269 ‘Phase 2/3, Open Label, Multi-Cohort Switch Study to Evaluate

Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV 1 Infected Children and Adolescents Virologically Suppressed on a 2 NRTI Containing Regimen' in fulfilment of the milestone for the Category 3 additional pharmacovigilance activity to address the safety concern of long-term safety information in adolescents (missing information) as detailed in the Descovy EU Risk Management Plan (RMP). The RMP was amended as version 7 in line with this submission and to update the list of safety concerns."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 07.04.2022.

Esperoct - turoctocog alfa pegol -

EMA/H/C/004883/II/0010, Orphan

Novo Nordisk A/S, Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.4 and 4.8 of the SmPC to add a new warning and update the list of ADRs based on a validated safety signal concerning a lack of factor VIII activity in patients switching from a similar factor VIII product to Esperoct. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to align it with the latest QRD template version 10.2. The RMP version 2.0 has also been submitted."

Request for Supplementary Information adopted on 24.03.2022.

EXJADE - deferasirox -

EMA/H/C/000670/II/0082/G

Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "C.I.13: Submission of the final report from the Calypso study (CICL670F2202) listed as a category 3 study in the RMP. This is a randomized, openlabel, multicenter, two arm, Phase II study to evaluate treatment compliance, efficacy and safety of deferasirox (granules) in pediatric patients with iron overload. The RMP version 20.0 has also been submitted.

C.I.11.b: Submission of an updated RMP version 20.0 which the following changes: to remove the risk of 'medication error' from the Exjade RMP and to remove the information related to

the discontinuation of Exjade Dispersible Tablets in the EU.”

Request for Supplementary Information adopted on 07.04.2022.

Fintepla - fenfluramine -

EMA/H/C/003933/II/0010/G, Orphan

Zogenix ROI Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber,

“- Update of section 5.3 of the SmPC in order to update the non-clinical information following the study 20147822 (A 6-month Carcinogenicity Study of Fenfluramine Hydrochloride in Mice).

- Update of section 5.3 in order to update the non-clinical information following the study 8001993 (A 2-year Oral Gavage Carcinogenicity Study of Fenfluramine Hydrochloride in Rats).

- Submission of the final report of study 20147821 (Dose range finding study for 20147822).

- Submission of the final report of study 20166554 (Dose range finding study for 20147822).

- Submission of the final report of study 2021006-Z001-01 (In-vitro Evaluation of Potential Melanin Binding by Fenfluramine and Norfenfluramine).

An RMP version 2.4 has also been agreed.”

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 10.03.2022.

Positive Opinion adopted by consensus on 07.07.2022.

Fintepla - fenfluramine -

EMA/H/C/003933/II/0011/G, Orphan

Zogenix ROI Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber,

“- Update of sections 4.2 and 5.2 of the SmPC to include the relevant information regarding patients with renal impairment following the study 1902 (Pharmacokinetic study of fenfluramine hydrochloride in subjects with varying degrees of impaired and normal renal function)

- Update of sections 4.4 and 4.5 of the SmPC in order to reflect the relevant information on CYP1A2 or CYP2B6 or CYP2D6 inducers following the study 1904 (Pharmacokinetic drug-drug interaction study of fenfluramine hydrochloride with and without fluvoxamine (CYP1A2 inhibitor), paroxetine (CYP2D6 inhibitor) and rifampin (CYP2B6 inducer) in healthy subjects).

Request for supplementary information adopted with a specific timetable.

An RMP version 2.2 has also been submitted.”
Request for Supplementary Information adopted
on 07.07.2022, 10.03.2022.

**Gazyvaro - obinutuzumab -
EMA/H/C/002799/II/0047, Orphan**

Roche Registration GmbH, Rapporteur: Aaron
Sosa Mejia, PRAC Rapporteur: Annika Folin,
“Submission of the final report from study
BO21223/GALLIUM listed as a category 3 study
in the RMP. This is an open-label, international,
multicenter, randomized, Phase III study to
investigate the efficacy and safety of
obinutuzumab administration at standard
infusion rate plus chemotherapy followed by
obinutuzumab maintenance therapy for
responders (G-chemo arm) compared with
rituximab plus chemotherapy followed by
rituximab maintenance therapy for responders
(R-chemo arm) in patients with previously
untreated advanced indolent non-Hodgkin’s
lymphoma (iNHL).The RMP version 9.0 has also
been submitted.”

Request for Supplementary Information adopted
on 10.06.2022.

**HyQvia - human normal immunoglobulin -
EMA/H/C/002491/II/0078**

Baxalta Innovations GmbH, Rapporteur: Jan
Mueller-Berghaus, PRAC Rapporteur: Brigitte
Keller-Stanislawski, “Update of sections 4.8 and
5.1 of the SmPC in order to update safety data
in paediatric population based on final results
from study 161504 – Post-Authorisation Safety,
Tolerability and Immunogenicity Evaluation of
HyQvia in Pediatric Subjects With Primary
Immunodeficiency Diseases, listed as a category
3 study in the RMP. This is a paediatric
interventional Phase 4 study performed to
acquire additional data on safety, tolerability
and immunogenicity of HyQvia in pediatric (age
two to <18 years) patients with Primary
Immunodeficiency Diseases (PIDD).

In addition, the MAH is taking this opportunity
to update Annex II-D of the PI following
procedure EMA/H/C/002491/II/0070/G.
The RMP version 13.1 has also been submitted.”
Request for Supplementary Information adopted
on 07.07.2022.

Request for supplementary information adopted
with a specific timetable.

**Imbruvica - ibrutinib -
EMA/H/C/003791/II/0069**

Janssen-Cilag International N.V., Rapporteur:
Filip Josephson, PRAC Rapporteur: Nikica
Mirošević Skvrce, "Update of the SmPC section
4.4 to include information on fatal and serious
cardiac arrhythmias and cardiac failure, relevant
warnings and periodical monitoring of patients,
following a safety assessment for increased risk
of sudden death/cardiac death with the use of
ibrutinib. Section 2 of the PL has been updated
accordingly. Typographical errors have been
corrected throughout the PI. The revised RMP
version 11 has been submitted."
Request for Supplementary Information adopted
on 19.05.2022, 27.01.2022.

**Kadcyla - trastuzumab emtansine -
EMA/H/C/002389/II/0064**

Positive Opinion adopted by consensus on
07.07.2022.

Roche Registration GmbH, Rapporteur: Thalia
Marie Estrup Blicher, PRAC Rapporteur: Anette
Kirstine Stark, "Submission of the final report
from study BO28407 (KAITLIN): A randomized,
multicenter, open-label, Phase III trial
comparing trastuzumab plus pertuzumab plus a
taxane following anthracyclines versus
trastuzumab emtansine plus pertuzumab
following anthracyclines as adjuvant therapy in
patients with operable HER2-positive primary
breast cancer listed as a category 3 study in the
RMP.
The RMP version 15.0 has also been submitted."
Opinion adopted on 07.07.2022.

**Kaftrio - ivacaftor / tezacaftor /
elexacaftor -
EMA/H/C/005269/II/0017/G, Orphan**

Request for supplementary information adopted
with a specific timetable.

Vertex Pharmaceuticals (Ireland) Limited,
Rapporteur: Johann Lodewijk Hillege, PRAC
Rapporteur: Martin Huber, "C.I.4
Update of section 5.3 of the SmPC in order to
update the non-clinical information based on
final results from a 2-year oral carcinogenicity
study in rats (VX-445-TX-015) evaluating the
carcinogenic potential of up to 10 mg/kg/day of
elexacaftor. An updated RMP (version 6.0) has
also been submitted to include the completion
of the 2-year carcinogenicity study in rats as
well as to update the post-market pregnancy
safety information collection form following
EMA/H/C/WS2048.

C.I.13

To submit the final report of Tezacaftor Juvenile

Toxicity study (VX-661-TX-038)."
Request for Supplementary Information adopted
on 07.07.2022, 05.05.2022, 10.02.2022.

**Lamzede - velmanase alfa -
EMA/H/C/003922/II/0027, Orphan**

Chiesi Farmaceutici S.p.A., Rapporteur: Johann
Lodewijk Hillege, PRAC Rapporteur: Jan
Neuhauser, "Update of section 4.2 the SmPC in
order to include the home infusion statement,
following the assessment of
PSUSA/00010677/202009, based on results
from LAMAN-07, Sparkle and Italian Patient
Support Program (PSP).
The Package Leaflet and Annex II are updated
accordingly.
The RMP version 9.1 has also been submitted."

**Lorviqua - lorlatinib -
EMA/H/C/004646/II/0022**

Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa
Mejia, PRAC Rapporteur: Nikica Mirošević
Skvrce, "Submission of an updated RMP version
5.0 to revise plans for conduct of hepatic
impairment studies.
The RMP is updated to reflect the hepatic
impairment study B7461009 "A Phase 1 Study
to Evaluate the Effect of Hepatic Impairment on
the Pharmacokinetics and Safety of Lorlatinib in
Advanced Cancer Patients" termination and to
include new hepatic impairment study
B7461040 "A Phase 1, Open-label, Single-dose,
Parallel-group Study to Evaluate The Plasma
Pharmacokinetics and Safety of Lorlatinib in
Participants with Moderate and Severe Hepatic
Impairment Relative to Participants with Normal
Hepatic Function".

**Myalepta - metrelleptin -
EMA/H/C/004218/II/0025, Orphan**

Amryt Pharmaceuticals DAC, Rapporteur: Karin
Janssen van Doorn, PRAC Rapporteur: Adam
Przybylkowski, "Submission of an updated RPM
version 2.1. The applicant is proposing an
alternative study to the currently agreed
protocol for Specific Obligation SOB002 (AEGR-
734-002) due to the challenges of implementing
the existing protocol. Annex II is being updated
accordingly.
The MAH took the opportunity to update the
RMP in line with the outcome of previous
procedures and to include editorial changes."

Request for Supplementary Information adopted
on 24.03.2022.

**Natpar - parathyroid hormone -
EMA/H/C/003861/II/0042, Orphan**

Takeda Pharmaceuticals International AG,
Rapporteur: Karin Janssen van Doorn, PRAC
Rapporteur: Rhea Fitzgerald, "Submission of the
updated protocol from study SHP634-403 listed
as a Specific Obligation in the Annex II of the
Product Information with twice-daily (BID) as
the proposed alternative dosing regimen to be
evaluated. This is a Randomized, 2-Arm,
Double-Blind, Phase 4 Study to Evaluate Once
Daily (QD) Versus Twice Daily (BID)
Administration of Recombinant Human
Parathyroid Hormone (rhPTH[1-84]; NATPARA)
for the Treatment of Adults with
Hypoparathyroidism (HPT).
The Annex II and the RMP (submitted version
3.4) are updated accordingly."

**NUVAXOVID - SARS-CoV-2, spike protein,
recombinant, expressed in Sf9 cells derived
from Spodoptera frugiperda -
EMA/H/C/005808/II/0014**

See 9.1

Novavax CZ, a.s., Rapporteur: Johann Lodewijk
Hillege, PRAC Rapporteur: Brigitte Keller-
Stanislawski, "Update of sections 4.2, 4.8 and
5.1 of the SmPC in order to include a 0.5 mL
third dose for Nuvaxovid, to boost subjects that
have previously completed a primary
vaccination series with Nuvaxovid (homologous
booster dose) or with an authorised mRNA or
adenoviral vector vaccine (heterologous booster
dose), based on interim data from study
2019nCoV-101 (Part 2), a Phase 1/2,
Randomized, Observer-Blinded Study to
Evaluate the Safety and Immunogenicity of a
SARS-CoV-2 Recombinant Spike Protein
Nanoparticle Vaccine (SARS-CoV-2 rS) With or
Without Matrix-M Adjuvant in Healthy Subjects
(NCT04368988), final data from study
2019nCoV-501, a Phase 2a/b, Randomized,
Observer-Blinded, Placebo-Controlled Study to
Evaluate the Efficacy, Immunogenicity, and
Safety of a SARS-CoV-2 Recombinant Spike
Protein Nanoparticle Vaccine (SARS-CoV-2 rS)
With Matrix-M Adjuvant in South African Adult
Subjects Living Without HIV; and Safety and
Immunogenicity in Adults Living With HIV

(NCT04533399) and data from the COV-BOOST study (Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial); the Package Leaflet is updated accordingly. The RMP version 1.2 has also been submitted. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial corrections throughout the product information.”

**Ontozry - cenobamate -
EMA/H/C/005377/II/0009**

Positive Opinion adopted by consensus on 07.07.2022.

Angelini S.p.A., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Jean-Michel Dogné, “Update of section 5.3 of the SmPC in order to update information on toxicity to reproduction and development based on final results from non-clinical study “Effects of Cenobamate (YKP3089) on Embryo-Foetal Development in Rats after Twice Daily Oral Administration”. The RMP version 3.0 has been agreed.” Opinion adopted on 07.07.2022.

**Raxone - idebenone -
EMA/H/C/003834/II/0031, Orphan**

Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli, “Update of sections 4.2, 4.4, 4.9 and 5.1 of the SmPC based on the final study report from the PAROS study SNT-IV-003 (SOB003; listed as a cat 2 study in the RMP): “A non-interventional study of clinical experience in patients prescribed Raxone for the treatment of Leber's Hereditary Optic Neuropathy (LHON)”. Annex II is updated in accordance. A revised RMP version 1.14 was also submitted.” Request for Supplementary Information adopted on 24.03.2022.

**Replagal - agalsidase alfa -
EMA/H/C/000369/II/0117**

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, “Update of sections 4.2 and 6.6 of the SmPC in order to add self-administration by a trained patient and/or a caregiver as a new method of administration. The Package Leaflet

is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. The RMP version 0.1 has also been submitted.”

Request for Supplementary Information adopted on 23.06.2022, 24.03.2022.

**Rubraca - rucaparib -
EMA/H/C/004272/II/0029**

See 9.1

Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin, “Update of sections 4.4, 4.8 and 5.1 of the SmPC based on final results from study CO-338-043 (ARIEL4); this is a phase 3, multicentre, open-label, randomised study evaluating the efficacy and safety of rucaparib versus chemotherapy for treatment of relapsed ovarian cancer listed as a specific obligation in the Annex II; the Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. With this variation application, the MAH requests for the Rubraca marketing authorisation to no longer be subject to specific obligations. The SmPC, Annex II and PL are updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes and bring the PI in line with the latest QRD template version 10.2 Rev.1.”

Request for Supplementary Information adopted on 24.03.2022, 11.11.2021.

**Rydapt - midostaurin -
EMA/H/C/004095/II/0024, Orphan**

Request for supplementary information adopted with a specific timetable.

Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, “C.I.11.b Submission of the final report from study CPKC412E2301 listed as an obligation in the Annex II of the Product Information. This is a Phase III study to investigate the efficacy in elderly patients. A final pharmacogenomic report is also provided to fulfil MEA004. The Annex II and the RMP (submitted version 7.0) are updated accordingly.”

Request for Supplementary Information adopted on 07.07.2022, 10.03.2022.

**Trecondi - treosulfan -
EMA/H/C/004751/II/0012, Orphan**

Request for supplementary information adopted with a specific timetable.

medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Fátima Ventura, PRAC Rapporteur: Julia Pallos, “Update

of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with regards to CYP3A4, CYP2C19 and P-gp including physiologically based pharmacokinetic (PBPK) modelling. Version 1.0 of the RMP has also been submitted.”

Request for Supplementary Information adopted on 07.07.2022.

**Trecondi - treosulfan -
EMA/H/C/004751/II/0013, Orphan**

medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Fátima Ventura, PRAC Rapporteur: Julia Pallos, “Update of section 5.3 of the SmPC in order to update the description of non-clinical information regarding musculoskeletal and connective tissue disorders in form of lympho-histiocytic infiltration in the skeletal muscles and renal and urinary disorders which show up as haematuria. These new determinations are based on results from study LPT 37259. A revised RMP version 1.0 was also submitted.”

Request for Supplementary Information adopted on 07.07.2022.

Request for supplementary information adopted with a specific timetable.

**Veklury - remdesivir -
EMA/H/C/005622/II/0034/G**

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, “Grouping variation to update sections 5.1 and 5.2 of the SmPC as a consequence of the submission of the final component of the Specific Obligation 012 agreed in the renewal of the CMA (EMA/H/C/005622/R/0015) and listed in the Annex II of the Product Information. This submission includes the ACTT-1 final sequencing and phenotyping analysis and the full virology report including activity against variants. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted.”

Request for Supplementary Information adopted on 22.04.2022.

See 9.1

**Vyndaqel - tafamidis -
EMA/H/C/002294/II/0081, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Tiphaine Vaillant, “Update of section 5.1 of the SmPC in order to update information based on final results from study B3461029 listed as a Specific Obligation in the Annex II of the Product Information. This

is a non-interventional PASS sub-study evaluating effects of tafamidis on disease progression in patients with non-Val30Met mutations and symptomatic neuropathy. Consequently, the MAH proposes a switch from marketing authorisation under exceptional circumstances to full marketing authorisation given the fulfilment of the SOB. The Annex II and Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

WAYLIVRA - volanesorsen -

EMA/H/C/004538/II/0017/G, Orphan

Positive Opinion adopted by consensus on 07.07.2022.

Akcea Therapeutics Ireland Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "C.I.4: Update of sections 4.8 and 5.1 of the SmPC based on the final results from study (ISIS 304801 CS7), a multicentre open label extension study of Volanesorsen administered subcutaneously to patients with Familial Chylomicronemia Syndrome. The Package Leaflet has been updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI in order to align with the QRD template and to introduce minor linguistic update to Annex III of the product information to support product launch. C.I.11b. for RMP: Submission of an updated RMP version 2.1 based on the clinical study report addendum: A randomized, double blind, placebo-controlled Phase 3 study of ISIS 304801 administered subcutaneously to patients with Familial Chylomicronemia Syndrome (ISIS 304801 CS6 (APPROACH). C.I.11b. for RMP: Submission of an updated RMP version 2.1 in order to update section V.2 Additional Risk Minimisation Measures in the RMP to reflect a change in the distribution methodology of the educational materials (from a centralised model to a localised model of distribution) and to clarify what is meant by the prescriber kit. C.I.13: Submission of the final report from study ISIS 304801 (CS17). This is a Phase 2/3 double blind, randomized, placebo-controlled study, with an open label extension of ISIS 304801 administered subcutaneously to patients with familial partial lipodystrophy. The RMP

version 2.1 has also been submitted.”
Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted
on 10.03.2022.

WS2274
Relvar Ellipta-
EMA/H/C/002673/WS2274/0054
Revinty Ellipta-
EMA/H/C/002745/WS2274/0052

Request for supplementary information adopted
with a specific timetable.

GlaxoSmithKline (Ireland) Limited, Lead
Rapporteur: Maria Concepcion Prieto Yerro,
Lead PRAC Rapporteur: Maria del Pilar Rayon,
“Submission of the final report from study
HZA114971 listed as a category 3 study in the
RMP. This is a multicentre randomised, double-
blind, placebo-controlled, parallel-group study
to evaluate the effects of a one-year regimen of
orally inhaled fluticasone furoate 50 mcg once
daily on growth velocity in prepubertal,
paediatric subjects with asthma. The RMP
version 11.1 has also been submitted.”
Request for Supplementary Information adopted
on 07.07.2022.

B.5.4. PRAC assessed procedures

PRAC Led
Brintellix - vortioxetine -
EMA/H/C/002717/II/0037
H. Lundbeck A/S, PRAC Rapporteur: Jean-Michel
Dogné, PRAC-CHMP liaison: Karin Janssen van
Doorn, “Submission of the final report from
study PASS 16034N listed as a category 3 study
in the RMP. This is a non-interventional post-
authorisation safety study (PASS) of
vortioxetine in Europe - An analysis of European
automated healthcare databases. The RMP
version 4.0 has also been submitted.”
Request for Supplementary Information adopted
on 07.07.2022.

Request for supplementary information adopted
with a specific timetable.

PRAC Led
Defitelio - defibrotide -
EMA/H/C/002393/II/0058/G, Orphan
Gentium S.r.l., Rapporteur: Kristina Dunder,
PRAC Rapporteur: Ulla Wändel Liminga, PRAC-
CHMP liaison: Kristina Dunder, “Grouped
application including two type II variations as
follows:
C.I.13: Submission of the final study report of

Positive Opinion adopted by consensus on
07.07.2022.

the DEFIFrance registry: a national, post-registration observational study of the long-term safety and health outcome of patients treated with Defitelio, including patients with severe hepatic VOD after HSCT. This study is listed as a category 3 study in the RMP, and the submission of the study report addresses LEG/011.3. In addition, the MAH took the opportunity to provide two errata to the clinical study reports of studies #R09-1425 and #2006-05. Consequential changes to RMP version 9.2 have been implemented.

C.I.11: Submission of an updated RMP version 9.2 in order to remove reproductive toxicity as a potential risk.”

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 07.04.2022.

PRAC Led

**Duavive - estrogens conjugated /
bazedoxifene -**

EMA/H/C/002314/II/0032

Pfizer Europe MA EEIG, PRAC Rapporteur:
Martin Huber, PRAC-CHMP liaison: Martina
Weise, “Submission of an updated RMP version
3.2 in order to reflect the updated study
milestones and completion of the post-
authorisation safety study of CE/BZA in the
United States (US PASS, Study B2311060)
previously assessed as part of II/0030
(MEA002.15), as well as to update the post-
marketing data with the data lock point of 31
October 2021.”

Request for Supplementary Information adopted
on 07.07.2022.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

**JCOVDEN - adenovirus type 26 encoding
the SARS-CoV-2 spike glycoprotein -**

EMA/H/C/005737/II/0048/G

Janssen-Cilag International N.V., Rapporteur:
Christophe Focke, PRAC Rapporteur: Ulla
Wändel Liminga, PRAC-CHMP liaison: Kristina
Dunder, “Submission of the final reports from
four exploratory studies conducted to further
characterise the potential mechanisms
underlying the important identified risk of
thrombosis with thrombocytopenia syndrome
(TTS). These studies evaluated the levels of
anti-PF4 antibodies using clinical samples, both

Positive Opinion adopted by consensus on
07.07.2022.

from Ad26.COVS.2 and other non-COVID-19 Ad26-based vaccine clinical studies. Interim results from an additional exploratory study are provided and the submission milestone for the final results has been updated. The RMP version 4.1 has been submitted and updated in line with this procedure and the ongoing procedure EMEA/H/C/005737/II/0047/G. In addition, the MAH removed the important identified risk of anaphylaxis from the list of safety concerns (PSUSA/00010916/202108), updated the routine pharmacovigilance activities section and took the opportunity to implement other administrative updates in the RMP in alignment with procedure EMEA/H/C/005737/II/033. "

Opinion adopted on 07.07.2022.

PRAC Led

Kuvan - sapropterin -

EMA/H/C/000943/II/0073

BioMarin International Limited, Rapporteur:

Jayne Crowe, PRAC Rapporteur: Rhea

Fitzgerald, PRAC-CHMP liaison: Jayne Crowe,

"Submission of the final report from study BMN

162-501 KAMPER (formerly EMR700773-001)

listed as a category 3 study in the RMP. This is

an observational drug registry to assess the

long-term safety in subjects treated with Kuvan.

The submission of this study addresses the PAM

MEA 020. The RMP version 15.1 has also been

submitted."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 10.03.2022.

Positive Opinion adopted by consensus on 07.07.2022.

PRAC Led

Lemtrada - alemtuzumab -

EMA/H/C/003718/II/0041

Sanofi Belgium, Duplicate, Duplicate of

Lemtrada (WD), PRAC Rapporteur: Anette

Kirstine Stark, PRAC-CHMP liaison: Thalia Marie

Estrup Blicher, "Update of the RMP (last

approved version 9.0) to include a new

important identified risk "Autoimmune

encephalitis" following a signal on alemtuzumab

and autoimmune encephalitis raised in June

2021 and following the outcome of a cumulative

review in EMA/H/C/PSUSA/00010055/202109

procedure. Annex 6 is updated accordingly. In

addition, following the requests in procedure

EMA/H/C/003718/II/0038, the list of safety

Positive Opinion adopted by consensus on 07.07.2022.

concerns is revised to align with the GVP module V, and the safety concern "use during pregnancy" is removed. The agreed RMP version is v.10.1."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 05.05.2022.

PRAC Led

Moventig - naloxegol -

EMA/H/C/002810/II/0038

Kyowa Kirin Holdings B.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of an updated RMP version 7.2 proposing the cancellation of the cat. 3 study (D3820R00009: An Observational Drug Utilisation PASS of Moventig in selected European populations), following the assessment of MEA 006.11"

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 10.03.2022.

Positive Opinion adopted by consensus on 07.07.2022.

PRAC Led

Nucala - mepolizumab -

EMA/H/C/003860/II/0048

GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Submission of an updated RMP version 11 to reflect the proposal to stop the enrolment and to close the pregnancy registry "Mepolizumab Pregnancy Exposure Study 200870: a phase IV, prospective, observational, exposure cohort study of pregnancy outcomes in women (category 3 post authorisation measure in the RMP)" in 2024. The application also includes details of the proposed enhanced data collection for all pregnancies reported as an alternative."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 07.04.2022.

Positive Opinion adopted by consensus on 07.07.2022.

PRAC Led

PecFent - fentanyl -

EMA/H/C/001164/II/0054

Kyowa Kirin Holdings B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of an updated RMP (version 7.1) in line with the outcome of the last PSUR single assessment (PSUSA) procedure (PSUSA 00001369/202004)

Request for supplementary information adopted with a specific timetable.

finalised in January 2021 in order to update the key messages of the educational materials in line with Instanyl (fentanyl). As a result, Annex II-D on 'Conditions or restrictions with regard to the safe and effective use of the medicinal product' is updated accordingly. Finally, the MAH took the opportunity to bring the RMP in line with revision 2 of GVP module V on 'Risk management systems' and the product information in line with the latest quality review of documents (QRD) template (version 10.2). The requested variation proposed amendments to the Annex II and to the Risk Management Plan (RMP)."

Request for Supplementary Information adopted on 07.07.2022, 10.03.2022, 28.10.2021.

PRAC Led

Uptravi - selexipag -

EMA/H/C/003774/II/0035

Janssen-Cilag International N.V., PRAC

Rapporteur: Nathalie Gault, PRAC-CHMP liaison:

Alexandre Moreau, "Submission of an updated

RMP version 9.3 in order to include the amendment of the ongoing EXPOSURE study protocol, to add the EXTRACT study

(67896049PAH0002) as an additional pharmacovigilance activity (PASS) and to include the update of the PRAC-approved

EDUCATE PASS protocol (assessed in EMA/H/C/003774/MEA/003.4)."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 05.05.2022.

Positive Opinion adopted by consensus on 07.07.2022.

PRAC Led

Vargatef - nintedanib -

EMA/H/C/002569/II/0044

Boehringer Ingelheim International GmbH,

Rapporteur: Aaron Sosa Mejia, PRAC

Rapporteur: Georgia Gkegka, PRAC-CHMP

liaison: Konstantina Alexopoulou, "Submission

of an updated RMP version 10.0 in order to remove safety concerns that were classified as important identified risks, important potential risks and missing information, based on cumulative post-marketing experience. The MAH

is also proposing an update of the ATC code, an update of post-marketing exposure, the removal of adverse event follow-up forms and an update of search strategies."

Positive Opinion adopted by consensus on 07.07.2022.

Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted
on 05.05.2022, 10.02.2022.

PRAC Led
VPRIV - velaglucerase alfa -
EMA/H/C/001249/II/0049, Orphan
Takeda Pharmaceuticals International AG,
Rapporteur: Martina Weise, PRAC Rapporteur:
Martin Huber, PRAC-CHMP liaison: Martina
Weise, "Submission of final physician data study
results for PASS study "Evaluation of the
Effectiveness of Risk Minimisation Measures: A
Survey among Health Care Professionals and
Patient/Caregivers to Assess their Knowledge
and Attitudes on Prescribing and Home
Administration Conditions of Velaglucerase
Alpha (VPRIV) in 6 European Countries"
(EUPASS 14255). An updated RMP version 11.0
was agreed during the procedure, and Annex II
was updated accordingly to include new agreed
key elements for the educational material."
Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted
on 05.05.2022, 02.12.2021, 08.07.2021,
11.02.2021, 26.11.2020.

Positive Opinion adopted by consensus on
07.07.2022.

PRAC Led
Zepatier - elbasvir / grazoprevir -
EMA/H/C/004126/II/0033
Merck Sharp & Dohme B.V., Rapporteur: Johann
Lodewijk Hillege, PRAC Rapporteur: Ana Sofia
Diniz Martins, PRAC-CHMP liaison: Bruno
Sepodes, "Submission of the final report from
study B20-146 listed as a category 3 study in
the RMP. This is a non-imposed joint post-
authorisation safety study to evaluate the risk of
de novo hepatocellular carcinoma in patients
with compensated cirrhosis treated with direct-
acting antivirals for chronic hepatitis C (HCC De
Novo PASS)."
Opinion adopted on 07.07.2022.
Request for Supplementary Information adopted
on 10.03.2022.

Positive Opinion adopted by consensus on
07.07.2022.

PRAC Led
WS2212
Effentora-
EMA/H/C/000833/WS2212/0060
Teva B.V., Lead Rapporteur: Janet Koenig, Lead
PRAC Rapporteur: Martin Huber, PRAC-CHMP
liaison: Janet Koenig, "Submission of an

Request for supplementary information adopted
with a specific timetable.

updated RMP version 5.1 in order to reformat the RMP according to the revised guidance on GVP Module V (revision 2) and to implement PRAC comments arising from previous assessments as follows:

- Revision of the list of safety concerns;
- Implementation of key messages in educational materials adopted by PRAC for Instanyl;
- Revision of Annex 6 to include verbatim the text adopted by PRAC for Instanyl as presented in Annex 2 of the PRAC PSUSA AR;
- Revision of the use of digital access to educational material;
- Explanation of the role of the Health Products Regulatory Authority (HPRA)'s CAPA being no longer found to be a trigger of the current RMP update.

The 'additional risk minimisation measures' in the Annex II of the product information have been updated accordingly."

Request for Supplementary Information adopted on 07.07.2022, 10.03.2022.

PRAC Led

WS2216

Exviera-EMA/H/C/003837/WS2216/0052

Maviret-

EMA/H/C/004430/WS2216/0049

Viekirax-

EMA/H/C/003839/WS2216/0064

AbbVie Deutschland GmbH & Co. KG, Lead

Rapporteur: Filip Josephson, Lead PRAC

Rapporteur: Ana Sofia Diniz Martins, PRAC-

CHMP liaison: Bruno Sepodes, "Submission of

the final report from study B20-146 listed as a

category 3 study in the RMP. This is a non-

imposed joint post-authorisation safety study to

evaluate the risk of de novo hepatocellular

carcinoma in patients with compensated

cirrhosis treated with direct-acting antivirals for

chronic hepatitis C (HCC De Novo PASS)."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted on 10.03.2022.

Positive Opinion adopted by consensus on 07.07.2022.

PRAC Led

WS2222

Epclusa-

EMA/H/C/004210/WS2222/0064

Harvoni-

Positive Opinion adopted by consensus on 07.07.2022.

EMA/H/C/003850/WS2222/0104

Sovaldi-EMA/H/C/002798/WS2222/0077

Vosevi-EMA/H/C/004350/WS2222/0054

Gilead Sciences Ireland UC, Lead Rapporteur:
Filip Josephson, Lead PRAC Rapporteur: Ana
Sofia Diniz Martins, PRAC-CHMP liaison: Bruno
Sepodes, "Submission of the final report from
study B20-146 listed as a category 3 study in
the RMP. This is a non-imposed joint post-
authorisation safety study to evaluate the risk of
de novo hepatocellular carcinoma in patients
with compensated cirrhosis treated with direct-
acting antivirals for chronic hepatitis C (HCC De
Novo PASS)."

Opinion adopted on 07.07.2022.

Request for Supplementary Information adopted
on 10.03.2022.

B.5.5. CHMP-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel /

lisocabtagene maraleucel -

EMA/H/C/004731/II/0002, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Concetta Quintarelli, CHMP Coordinator:

Armando Genazzani

Breyanzi - lisocabtagene maraleucel /

lisocabtagene maraleucel -

EMA/H/C/004731/II/0003, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Concetta Quintarelli, CHMP Coordinator:

Armando Genazzani

Imlygic - talimogene laherparepvec -

EMA/H/C/002771/II/0053, ATMP

Amgen Europe B.V., Rapporteur: Maija

Tarkkanen, CHMP Coordinator: Johanna

Lähtenvuo

Kymriah - tisagenlecleucel -

EMA/H/C/004090/II/0058, Orphan,

ATMP

Novartis Europharm Limited, Rapporteur: Rune

Kjeken, CHMP Coordinator: Ingrid Wang

Kymriah - tisagenlecleucel -

EMA/H/C/004090/II/0059, Orphan,

ATMP

Novartis Europharm Limited, Rapporteur: Rune

Kjeken, CHMP Coordinator: Ingrid Wang,

"Update of section 5.1 of the SmPC based on a

subgroup analysis from CCTL019B2401 (B2401) disease registry listed as a PAES (ANX006) in the Annex II; this is a non-interventional study to evaluate the efficacy and safety of Kymriah in ALL patients below the age of 3 years. In addition, the MAH took the opportunity to update Annex II.D of the SmPC to reflect the fulfilment of the PAES.”

**Kymriah - tisagenlecleucel -
EMA/H/C/004090/II/0061/G, Orphan,
ATMP**

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

**Zolgensma - onasemnogene abeparvovec -
EMA/H/C/004750/II/0028/G, Orphan,
ATMP**

Novartis Gene Therapies EU Limited,
Rapporteur: Carla Herberts, CHMP Coordinator:
Johann Lodewijk Hillege

WS2247

Tecartus-

EMA/H/C/005102/WS2247/0020

Yescarta-

EMA/H/C/004480/WS2247/0050

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

Request for Supplementary Information adopted on 13.05.2022.

B.5.6. CHMP-PRAC-CAT assessed procedures

**Kymriah - tisagenlecleucel -
EMA/H/C/004090/II/0060, Orphan,
ATMP**

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Brigitte Keller-Stanislowski, “Update of section 4.2 of the SmPC in order to update the paediatric statement for the B-cell ALL indication and section 4.4 to update the warning on ‘prior treatment with anti-CD19 therapy’ as well as sections 4.4 and 4.8 in order to update safety data to reflect the pool of the 3 studies B2202, B2205J and B2001X. The proposed changes are in line with the request of the CHMP following the assessment of P46/012. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to

correct the Complete Response Rate (CRR) 95% Confidence Interval (CI) on Enrolled set for E2202 study presented in Table 8 in section 5.1 of the SmPC. The RMP version 5.0 has also been submitted.”

B.5.7. PRAC assessed ATMP procedures

PRAC Led

**Imlygic - talimogene laherparepvec -
EMA/H/C/002771/II/0051, ATMP**

Amgen Europe B.V., PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, “Submission of the final report from study 20180062; “Observational Research Study Report (ORSR)” listed as a category 3 study in the RMP. This is a multinational, non-interventional, cross-sectional survey study for the Patients aged $\geq$ 18 years who have received IMLYGIC at least once in the 3 months prior to completing the survey to evaluate the effectiveness of the patient-directed aRMMS. The primary objective of this study is to evaluate patients’ knowledge levels of the key messages included in the IMLYGIC Patient Safety Brochure among patients who receive IMLYGIC.”
Request for Supplementary Information adopted on 13.05.2022.

PRAC Led

**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/0033,
Orphan, ATMP**

Orchard Therapeutics (Netherlands) BV, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, “Submission of the final report from study STRIM-001
“Evaluation of referring healthcare providers’ and parents’/carers’ understanding of specific risks associated with Strimvelis treatment” listed as a category 3 study in the RMP. The RMP version 6.1 has also been submitted.”
Request for Supplementary Information adopted on 18.03.2022.

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

WS2219/G Fluenz Tetra- EMA/H/C/002617/WS2219/0116/G Pandemic influenza vaccine H5N1 AstraZeneca- EMA/H/C/003963/WS2219/0050/G AstraZeneca AB, Lead Rapporteur: Christophe Focke Opinion adopted on 07.07.2022.	Positive Opinion adopted by consensus on 07.07.2022.
---	--

WS2239/G Hexacima- EMA/H/C/002702/WS2239/0128/G Hexyon- EMA/H/C/002796/WS2239/0132/G Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 12.05.2022.	
--	--

WS2246 Tivicay-EMA/H/C/002753/WS2246/0080 Triumeq- EMA/H/C/002754/WS2246/0105 ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson	
--	--

WS2251/G Eucreas- EMA/H/C/000807/WS2251/0097/G Icandra- EMA/H/C/001050/WS2251/0101/G Zomarist- EMA/H/C/001049/WS2251/0099/G Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder Opinion adopted on 07.07.2022.	Positive Opinion adopted by consensus on 07.07.2022.
--	--

WS2255 Juluca-EMA/H/C/004427/WS2255/0043 Tivicay-EMA/H/C/002753/WS2255/0078 Triumeq- EMA/H/C/002754/WS2255/0103 ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson Opinion adopted on 30.06.2022.	Positive Opinion adopted by consensus on 30.06.2022.
--	--

WS2260 Stayveer- EMA/H/C/002644/WS2260/0036 Tracleer-	Positive Opinion adopted by consensus on 07.07.2022.
--	--

EMA/H/C/000401/WS2260/0101

Janssen-Cilag International N.V., Lead

Rapporteur: Alexandre Moreau

Opinion adopted on 07.07.2022.

WS2271/G

Erelzi-

EMA/H/C/004192/WS2271/0041/G

Rixathon-

EMA/H/C/003903/WS2271/0058/G

Riximyo-

EMA/H/C/004729/WS2271/0059/G

Sandoz GmbH, Lead Rapporteur: Jan Mueller-

Berghaus

WS2272/G

Hexacima-

EMA/H/C/002702/WS2272/0131/G

Hexyon-

EMA/H/C/002796/WS2272/0135/G

Sanofi Pasteur, Lead Rapporteur: Jan Mueller-

Berghaus

Opinion adopted on 07.07.2022.

WS2279/G

Ebymect-

EMA/H/C/004162/WS2279/0057/G

Xigduo-

EMA/H/C/002672/WS2279/0067/G

AstraZeneca AB, Lead Rapporteur: Kristina

Dunder

Opinion adopted on 07.07.2022.

WS2282

Hexacima-

EMA/H/C/002702/WS2282/0132

Hexyon-

EMA/H/C/002796/WS2282/0136

Sanofi Pasteur Europe, Duplicate, Duplicate of

Hexacima, Lead Rapporteur: Jan Mueller-

Berghaus

WS2287/G

Filgrastim Hexal-

EMA/H/C/000918/WS2287/0064/G

Zarzio-

EMA/H/C/000917/WS2287/0065/G

Sandoz GmbH, Lead Rapporteur: Johann

Lodewijk Hillege

WS2290

Prezista-

EMA/H/C/000707/WS2290/0117

Rezolsta-
EMA/H/C/002819/WS2290/0048

Symtuza-
EMA/H/C/004391/WS2290/0044

Janssen-Cilag International N.V., Lead
Rapporteur: Johann Lodewijk Hillege

WS2292

Abseamed-
EMA/H/C/000727/WS2292/0099

Binocrit-
EMA/H/C/000725/WS2292/0098

Epoetin alfa Hexal-
EMA/H/C/000726/WS2292/0098

Sandoz GmbH, Lead Rapporteur: Alexandre
Moreau

WS2293

Lyrica-EMA/H/C/000546/WS2293/0119

Pregabalin Pfizer-
EMA/H/C/003880/WS2293/0048

Upjohn EESV, Lead Rapporteur: Johann
Lodewijk Hillege, "To update sections 4.4 and
4.8 of the SmPC and sections 2, 3 and 4 of the
PL, to implement the wording related to the
cases of abuse and dependence in patients
without a history of substance disorder,
following procedures
EMA/H/C/000546/LEG/057 and
EMA/H/C/003880/LEG/009, resulting from
EMA/H/C/PSUSA/00002511/202101."

WS2295
Ongentys-
EMA/H/C/002790/WS2295/0048
Ontilyv-EMA/H/C/005782/WS2295/0002

Bial - Portela & Ca, S.A., Lead Rapporteur:
Martina Weise
Opinion adopted on 14.07.2022.

Positive Opinion adopted by consensus on
14.07.2022.

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

**Carbaglu - carglumic acid -
EMA/H/C/000461/II/0044**

The MAH withdrew the procedure on
06.07.2022.

Recordati Rare Diseases, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of sections 4.2 and 4.4 of the SmPC in order to include information on the impact of renal impairment on systemic exposures to Carbaglu following a FDA request, based on final results from study A Phase I, Multicenter, Open-Label, Parallel-Group Adaptive Pharmacokinetic Single Dose Study of Oral Carbaglu in Subjects with Normal and Varying Degrees of Impaired Renal Function. The Package Leaflet is updated accordingly. The RMP version 2.2 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 23.06.2022. Withdrawal request submitted on 06.07.2022.

**WS2254
HBVAXPRO-
EMA/H/C/000373/WS2254/0077
Vaxelis-EMA/H/C/003982/WS2254/0103**

The MAH withdrew the procedure on
01.07.2022.

Merck Sharp & Dohme B.V., Lead Rapporteur:
Jan Mueller-Berghaus
Withdrawal request submitted on 01.07.2022.

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

piflufolastat (18f) - EMA/H/C/005520

imaging in patients undergoing oncologic diagnostic procedures when increased expression of prostate specific membrane antigen is a diagnostic target

degarelix acetate - EMA/H/C/006048

treatment of prostate cancer

trastuzumab duocarmazine -**EMA/H/C/005654**

treatment of HER2 (Human Epidermal Growth Factor Receptor 2)-positive metastatic breast

cancer

human albumin solution / gentamicin sulfate - EMEA/H/D/006141

human assisted reproductive techniques
including in-vitro fertilisation procedures

eculizumab - EMEA/H/C/006036

treatment of paroxysmal nocturnal
haemoglobinuria

natalizumab - EMEA/H/C/005752

Therapy for active relapsing remitting multiple
sclerosis (RRMS)

**in vitro diagnostic medical device -
EMEA/H/D/006107**

In-vitro qualitative immunohistochemical
detection of programmed death-ligand 1 (PD-
L1)

alpelisib - EMEA/H/C/005468, Orphan

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

**atogepant monohydrate -
EMEA/H/C/005871**

Prophylaxis of migraine in adults who have at
least 4 migraine days per month.

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

**Entresto - sacubitril / valsartan -
EMEA/H/C/004062/X/0044/G**

Novartis Europharm Limited, Rapporteur:
Johann Lodewijk Hillege, PRAC Rapporteur:
Anette Kirstine Stark, "Extension application to
introduce a new pharmaceutical form associated
with two new strengths (6 mg/6 mg granules in
capsule for opening and 15 mg/16 mg granules
in capsule for opening), grouped with a type II
variation (C.I.6.a) in order to extend the
indication to include treatment of children and
adolescents aged one year or older with chronic
heart failure with left ventricular systolic
dysfunction, based on the results of study
PANORAMA-HF (CLCZ696B2319); a multicenter,
open-label, study to evaluate safety, tolerability,
pharmacokinetics and pharmacodynamics of
sacubitril/valsartan followed by a 52-week
randomized, double-blind, parallel group,

active-controlled study to evaluate the efficacy and safety of sacubitril/valsartan compared with enalapril in paediatric patients from 1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.2 of the SmPC are being updated and the Package Leaflet is updated accordingly. In addition, an updated RMP version 4.0 was provided as part of the application. Further, the MAH requested a one-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)

**Neparvis - sacubitril / valsartan -
EMA/H/C/004343/X/0042/G**

Novartis Europharm Limited, Rapporteur:
Johann Lodewijk Hillege, PRAC Rapporteur:
Anette Kirstine Stark, “Extension application to introduce a new pharmaceutical form associated with two new strengths (6 mg/6 mg granules in capsule for opening and 15 mg/16 mg granules in capsule for opening), grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of children and adolescents aged one year or older with chronic heart failure with left ventricular systolic dysfunction, based on the results of study PANORAMA-HF (CLCZ696B2319); a multicenter, open-label, study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of sacubitril/valsartan followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of sacubitril/valsartan compared with enalapril in paediatric patients from 1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.2 of the SmPC are being updated and the Package Leaflet is updated accordingly. In addition, an updated RMP version 4.0 was provided as part of the application. Further, the MAH requested a one-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)

**Sogroya - somapacitan -
EMA/H/C/005030/X/0006/G, Orphan**

Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Extension application to add a new strength of 15 mg/1.5 mL solution for injection in pre-filled pen grouped with a type II variation C.I.6 to add a new indication 'Replacement of endogenous growth hormone (GH) in children and adolescents with growth failure due to growth hormone deficiency (GHD)', based on results from the completed main 52-week period of the confirmatory phase 3 trial (4263), supported with long-term data from the phase 2 trial (4172), up to week 208 completed. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package Leaflet has been updated accordingly. A revised RMP version 3.0 was provided as part of the application."

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

Betmiga - mirabegron -

EMA/H/C/002388/X/0039/G

Astellas Pharma Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, "Extension application to introduce a new pharmaceutical form associated with new strength (8 mg/ml prolonged-release granules for oral suspension), grouped with a type II variation (C.I.6.a) to include treatment of neurogenic detrusor overactivity (NDO) in paediatric patients aged 3 to less than 18 years. The RMP (version 9.0) is updated in accordance."

List of Questions adopted on 22.04.2022.

tabelecleucel - EMA/H/C/004577, Orphan, ATMP

Atara Biotherapeutics Ireland Limited, treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLN)

List of Questions adopted on 18.03.2022.

miglustat - EMA/H/C/005695, Orphan

Amicus Therapeutics Europe Limited, treatment of adults aged 18 years and older with a confirmed diagnosis of Pompe disease

List of Questions adopted on 24.03.2022.

cipaglucosidase alfa - EMA/H/C/005703, Orphan

Amicus Therapeutics Europe Limited, treatment of adults aged 18 years and older with a confirmed diagnosis of Pompe disease
List of Questions adopted on 24.03.2022.

palovarotene - EMEA/H/C/004867, Orphan

Ipsen Pharma, Treatment of fibrodysplasia ossificans progressiva
List of Questions adopted on 16.09.2021.

sugammadex - EMEA/H/C/005935

reversal of neuromuscular blockade induced by rocuronium or vecuronium
List of Questions adopted on 24.03.2022.

vadadustat - EMEA/H/C/005131

Treatment of anaemia
List of Questions adopted on 24.03.2022.

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

Bylvay - odevixibat -

EMEA/H/C/004691/S/0008, Orphan

Albireo, Rapporteur: Johann Lodewijk Hillege,
PRAC Rapporteur: Adam Przybylkowski

MVABEA - ebola vaccine (rDNA, replication-incompetent) -

EMEA/H/C/005343/S/0015

Janssen-Cilag International N.V., Rapporteur:
Johann Lodewijk Hillege, PRAC Rapporteur:
Jean-Michel Dogné

Qarziba - dinutuximab beta -

EMEA/H/C/003918/S/0046, Orphan

EUSA Pharma (Netherlands) B.V., Rapporteur:
Paula Boudewina van Hennik, PRAC Rapporteur:
Brigitte Keller-Stanislowski

ZABDENO - ebola vaccine (rDNA, replication-incompetent) -

EMEA/H/C/005337/S/0012

Janssen-Cilag International N.V., Rapporteur:
Johann Lodewijk Hillege, PRAC Rapporteur:
Jean-Michel Dogné

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

COMIRNATY - tozinameran -

EMEA/H/C/005735/R/0137

BioNTech Manufacturing GmbH, Rapporteur:

Filip Josephson, PRAC Rapporteur: Menno van der Elst

**Enhertu - trastuzumab deruxtecan -
EMA/H/C/005124/R/0023**

Daiichi Sankyo Europe GmbH, Rapporteur:
Aaron Sosa Mejia, PRAC Rapporteur: Marcia
Sofia Sanches de Castro Lopes Silva

**Lamzede - velmanase alfa -
EMA/H/C/003922/R/0029, Orphan**

Chiesi Farmaceutici S.p.A., Rapporteur: Johann
Lodewijk Hillege, Co-Rapporteur: Janet Koenig,
PRAC Rapporteur: Jan Neuhauser

**Lokelma - sodium zirconium cyclosilicate -
EMA/H/C/004029/R/0027**

AstraZeneca AB, Rapporteur: Silvijus
Abramavicius, Co-Rapporteur: Ewa Balkowiec
Iskra, PRAC Rapporteur: Kirsti Villikka

**NUVAXOVID - SARS-CoV-2, spike protein,
recombinant, expressed in Sf9 cells derived
from Spodoptera frugiperda -
EMA/H/C/005808/R/0020**

Novavax CZ, a.s., Rapporteur: Johann Lodewijk
Hillege, PRAC Rapporteur: Brigitte Keller-
Stanislowski

**Riarify - beclometasone dipropionate /
formoterol fumarate dihydrate /
glycopyrronium -
EMA/H/C/004836/R/0022**

Chiesi Farmaceutici S.p.A., Informed Consent of
Trimbow, Rapporteur: Janet Koenig, Co-
Rapporteur: Jayne Crowe, PRAC Rapporteur:
Jan Neuhauser

**Semglee - insulin glargine -
EMA/H/C/004280/R/0040**

Viartis Limited, Rapporteur: Martina Weise, Co-
Rapporteur: Agnes Gyurasics, PRAC Rapporteur:
Menno van der Elst

**Shingrix - herpes zoster vaccine
(recombinant, adjuvanted) -
EMA/H/C/004336/R/0057**

GlaxoSmithkline Biologicals SA, Rapporteur:
Christophe Focke, Co-Rapporteur: Jan Mueller-
Berghaus, PRAC Rapporteur: Sonja Hrabcik

**Spikevax - elasomeran -
EMA/H/C/005791/R/0074**

Moderna Biotech Spain, S.L., Rapporteur: Jan

Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

**Tecartus - brexucabtagene autoleucel -
EMA/H/C/005102/R/0025, Orphan,
ATMP**

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Rune Kjekken, CHMP
Coordinators: Jan Mueller-Berghaus and Ingrid Wang, PRAC Rapporteur: Menno van der Elst

**Trydonis - beclometasone dipropionate /
formoterol fumarate dihydrate /
glycopyrronium -
EMA/H/C/004702/R/0025**

Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Rapporteur: Janet Koenig, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Jan Neuhauser

**Zessly - infliximab -
EMA/H/C/004647/R/0025**

Sandoz GmbH, Rapporteur: Eva Skovlund, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ulla Wändel Liminga

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

**Trulicity - dulaglutide -
EMA/H/C/002825/II/0065**

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Amelia Cupelli, "Extension of indication to include treatment of type 2 diabetes mellitus (T2DM) in children and adolescents aged 10 to less than 18 years based on final results from study H9X-MC-GBGC; this is a phase 3, double-blind, randomised, multi-centre, placebo-controlled superiority trial to evaluate PK, PD, safety and efficacy of dulaglutide in children from 10 to less than 18 years of age, with an open label extension to evaluate safety. 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 7.1 of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Adtralza - tralokinumab -**EMA/H/C/005255/II/0005**

LEO Pharma A/S, Rapporteur: Jayne Crowe

Alecensa - alectinib -**EMA/H/C/004164/II/0041**

Roche Registration GmbH, Rapporteur: Filip Josephson

Apexxar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) -**EMA/H/C/005451/II/0007/G**

Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy

Aranesp - darbepoetin alfa -**EMA/H/C/000332/II/0161**

Amgen Europe B.V., Rapporteur: Martina Weise

ARIKAYCE liposomal - amikacin -**EMA/H/C/005264/II/0008/G, Orphan**

Insmed Netherlands B.V., Rapporteur: Jayne Crowe

Elaprase - idursulfase -**EMA/H/C/000700/II/0101**Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Johann Lodewijk Hillege

Erbix - cetuximab -**EMA/H/C/000558/II/0094/G**

Merck Europe B.V., Rapporteur: Filip Josephson

Gazyvaro - obinutuzumab -**EMA/H/C/002799/II/0050, Orphan**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia

Grepid - clopidogrel -**EMA/H/C/001059/II/0054**Pharmathen S.A., Generic, Generic of Plavix,
Rapporteur: Nevenka Trsinar Brodt

Hizentra - human normal immunoglobulin -**EMA/H/C/002127/II/0139**

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

JCOVDEN - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein -**EMA/H/C/005737/II/0057**

Janssen-Cilag International N.V., Rapporteur:

Christophe Focke

**JCOVDEN - adenovirus type 26 encoding
the SARS-CoV-2 spike glycoprotein -
EMA/H/C/005737/II/0058/G**

Janssen-Cilag International N.V., Rapporteur:
Christophe Focke

**Jivi - damoctocog alfa pegol -
EMA/H/C/004054/II/0024/G**

Bayer AG, Rapporteur: Thalia Marie Estrup
Blicher

**Kovaltry - octocog alfa -
EMA/H/C/003825/II/0039**

Bayer AG, Rapporteur: Kristina Dunder

**Lyumjev - insulin lispro -
EMA/H/C/005037/II/0016**

Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-
Ikola

**Nuceiva - botulinum toxin type A -
EMA/H/C/004587/II/0027**

Evolus Pharma B.V., Rapporteur: Jayne Crowe

**Obizur - susoctocog alfa -
EMA/H/C/002792/II/0047/G**

Baxalta Innovations GmbH, Rapporteur: Andrea
Laslop

**Ogluo - glucagon -
EMA/H/C/005391/II/0005/G**

Tetris Pharma B.V., Rapporteur: Karin Janssen
van Doorn

**Onpattro - patisiran -
EMA/H/C/004699/II/0027/G, Orphan**

Alnylam Netherlands B.V., Rapporteur: Kristina
Dunder

**Phesgo - pertuzumab / trastuzumab -
EMA/H/C/005386/II/0012/G**

Roche Registration GmbH, Rapporteur: Aaron
Sosa Mejia

**Prasugrel Mylan - prasugrel -
EMA/H/C/004644/II/0013**

Mylan Pharmaceuticals Limited, Generic,
Generic of Efient, Rapporteur: Alar Irs

**Prevenar 13 - pneumococcal
polysaccharide conjugate vaccine (13-
valent, adsorbed) -
EMA/H/C/001104/II/0206/G**

Pfizer Europe MA EEIG, Rapporteur: Kristina

Dunder

PREVYMIS - Ietermovir -

EMA/H/C/004536/II/0028/G, Orphan

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson

Qarziba - dinutuximab beta -

EMA/H/C/003918/II/0045, Orphan

EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik

Respreeza - human alpha1-proteinase inhibitor - EMA/H/C/002739/II/0060

CSL Behring GmbH, Rapporteur: Kristina Dunder

RINVOQ - upadacitinib -

EMA/H/C/004760/II/0025/G

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder

Sialanar - glycopyrronium -

EMA/H/C/003883/II/0025/G

Proveca Pharma Limited, Rapporteur: Thalia Marie Estrup Blicher

Tecentriq - atezolizumab -

EMA/H/C/004143/II/0070/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia

Tysabri - natalizumab -

EMA/H/C/000603/II/0133

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus

Ultomiris - ravulizumab -

EMA/H/C/004954/II/0029

Alexion Europe SAS, Rapporteur: Blanca Garcia-Ochoa

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) -

EMA/H/C/003982/II/0104/G

MCM Vaccine B.V., Rapporteur: Christophe Focke

Vaxneuvance - pneumococcal polysaccharide conjugate vaccine (adsorbed) -

EMA/H/C/005477/II/0007/G

Merck Sharp & Dohme B.V., Rapporteur: Johann

**Vaxzevria - COVID 19 Vaccine (ChAdOx1 S
[recombinant]) -**

EMA/H/C/005675/II/0076/G

AstraZeneca AB, Rapporteur: Sol Ruiz

Vazkepa - icosapent ethyl -

EMA/H/C/005398/II/0009/G

Amarin Pharmaceuticals Ireland Limited,

Rapporteur: Martina Weise

Vectibix - panitumumab -

EMA/H/C/000741/II/0099

Amgen Europe B.V., Rapporteur: Eva Skovlund

Xenical - orlistat -

EMA/H/C/000154/II/0086

CHEPLAPHARM Arzneimittel GmbH, Rapporteur:

Jean-Michel Race

WS2283/G

Eucreas-

EMA/H/C/000807/WS2283/0098/G

Galvus-

EMA/H/C/000771/WS2283/0077/G

Icandra-

EMA/H/C/001050/WS2283/0103/G

Jalra-

EMA/H/C/001048/WS2283/0080/G

Xiliarx-

EMA/H/C/001051/WS2283/0078/G

Zomarist-

EMA/H/C/001049/WS2283/0100/G

Novartis Europharm Limited, Lead Rapporteur:

Kristina Dunder

WS2288

Humalog-

EMA/H/C/000088/WS2288/0196

Liprolog-

EMA/H/C/000393/WS2288/0156

Eli Lilly Nederland B.V., Lead Rapporteur:

Kristina Dunder

WS2296/G

Infanrix hexa-

EMA/H/C/000296/WS2296/0316/G

GlaxoSmithkline Biologicals SA, Lead

Rapporteur: Christophe Focke

WS2300/G

Infanrix hexa-

EMA/H/C/000296/WS2300/0317/G

GlaxoSmithkline Biologicals SA, Lead
Rapporteur: Christophe Focke

WS2313

Hexacima-

EMA/H/C/002702/WS2313/0133

Hexyon-

EMA/H/C/002796/WS2313/0137

Sanofi Pasteur Europe, Duplicate, Duplicate of
Hexacima, Lead Rapporteur: Jan Mueller-
Berghaus

WS2319

Nuwiq-EMA/H/C/002813/WS2319/0049

Vihuma-

EMA/H/C/004459/WS2319/0031

Octapharma AB, Lead Rapporteur: Jan Mueller-
Berghaus

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

Bavencio - avelumab -

EMA/H/C/004338/II/0035

Merck Europe B.V., Rapporteur: Filip Josephson,
"Update of sections 4.2, 5.1 and 5.2 of the
SmPC based on final results from study
MS100070-0306 following a P46 procedure
(EMA/H/C/004338/P46/009). This is a Phase I,
multi-centre, open-label, international study to
evaluate the dose, safety and tolerability,
antitumor activity, pharmacokinetic and
pharmacodynamics of avelumab in paediatric
subjects 0 to less than 18 years of age with
refractory or relapsed malignant solid tumours
(including central nervous system tumours) and
lymphoma for which no standard therapy is
available or for which the subject is not eligible
for the existing therapy. In addition, the MAH
took the opportunity to update Annex II section
D to be aligned with the EU Educational
materials (EM) and the EU Risk Management
Plan (RMP).

Furthermore, the MAH took the opportunity to
implement editorial changes."

CABOMETYX - cabozantinib -

EMA/H/C/004163/II/0029

Ipsen Pharma, Rapporteur: Ingrid Wang,
"Update of sections 4.4 and 4.8 of the SmPC in
order to update special warnings data and
information of adverse drug reactions (ADRs)
based on results from study XL184-311

(COSMIC-311); Study XL184-311 was a Phase 3 international, multicenter, randomized, double-blind, placebo-controlled study of cabozantinib in subjects with radioiodine (RAI)-refractory differentiated thyroid cancer (DTC) who had progressed during or after prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy.

In addition, the MAH is taking this opportunity to propose minor updates to the Package Leaflet.”

**Calquence - acalabrutinib -
EMA/H/C/005299/II/0013**

AstraZeneca AB, Rapporteur: Filip Josephson, “Update of section 5.1 of the SmPC in order to update efficacy and safety information based on final results from study ACE-CL-309 (A Phase 3 randomized open-label active-control study investigating Calquence for the Treatment of Subjects With Relapsed or Refractory Chronic Lymphocytic Leukaemia) listed as a category 3 study in the RMP.”

**Cervarix - human papillomavirus vaccine
[types 16, 18] (recombinant, adjuvanted,
adsorbed) - EMA/H/C/000721/II/0115**

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, “Submission of the final report from study HPV-027 listed as a category 3 study in the RMP to fulfil MEA 024.2; this is a long-term follow-up registry-based cohort study of HPV vaccine effectiveness against cervical pre-cancerous lesions and cervical cancer in a cohort of females previously enrolled from Finland in study HPV-008, as compared to an unvaccinated population-based reference cohort of females from Finland.”

**Cibinqo - abrocitinib -
EMA/H/C/005452/II/0005**

Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder, “Update of section 4.5 of the SmPC based on final results from Drug-Drug Interaction (DDI) study B7451092. This is a Phase I, open-label, fixed-sequence, 2-period study to estimate the effect of multiple dose abrocitinib on the pharmacokinetics of single doses of caffeine, efavirenz, and omeprazole in healthy participants.”

Darzalex - daratumumab -

EMA/H/C/004077/II/0062, Orphan

Janssen-Cilag International N.V., Rapporteur:
Aaron Sosa Mejia, "Update of section 4.8 of the SmPC in order to add COVID-19 to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a pooled dataset from the following interventional studies 4767414MMY2004, 54767414MMY3003, 54767414MMY3006, 54767414MMY3008, and 54767414MMY3013. The Package Leaflet is updated accordingly."

Evoltra - clofarabine -**EMA/H/C/000613/II/0077**

Genzyme Europe BV, Rapporteur: Alexandre Moreau, "Update of the Package Leaflet in order to update information regarding breast-feeding based on a comprehensive safety review. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

JCOVDEN - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein -**EMA/H/C/005737/II/0060**

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs) based on pooled analyses of clinical safety data from the following Phase III interventional studies: VAC31518COV3001 and VAC31518COV3009; and from the Phase I/II interventional studies: VAC31518COV1001, VAC31518COV1002, VAC31518COV1003 and VAC31518COV2001. The Package Leaflet is updated accordingly."

Keytruda - pembrolizumab -**EMA/H/C/003820/II/0126**

Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "To update sections 4.2 and 5.2 of the SmPC to include data for patients with moderate hepatic impairment based on KEYNOTE-240 (a double-blind, randomized, Phase 3 study of pembrolizumab in participants with previously systemically treated advanced HCC) and KEYNOTE-224 (a Phase 2 study of pembrolizumab as monotherapy in participants with advanced HCC). The MAH took the opportunity to make some editorial changes."

Legvio - inclisiran -

EMA/H/C/005333/II/0011

Novartis Europharm Limited, Rapporteur:
Martina Weise, "Submission of the final report from non-clinical study no. 2120284 in order to address a recommendation (REC). This is an in-silico assessment of the cross-tissue mRNA expression of the genes encoding for SULF1, INSYN2B (also referred to as FAM196B), ASGR1 and ASGR2 in tissues in man, monkey, rat and mouse."

Lumeblue - methylthioninium chloride -**EMA/H/C/002776/II/0004**

Alfasigma S.p.A., Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.2 and 5.2 of the SmPC in order to introduce a new posology regimen based on scientific literature."

Lumykras - sotorasib -**EMA/H/C/005522/II/0003**

Amgen Europe B.V., Rapporteur: Alexandre Moreau, "Update of section 4.2 of the SmPC based on results from the enteral feeding tube in vitro study (RPT-574024), undertaken to assess the feasibility of administration of sotorasib 120 mg film-coated tablets through an enteral feeding tube. The Package Leaflet was updated accordingly."

Lumykras - sotorasib -**EMA/H/C/005522/II/0004**

Amgen Europe B.V., Rapporteur: Alexandre Moreau, "Update of section 4.5 of the SmPC based on the results of study 2020042, a phase 1 clinical drug interaction study undertaken to assess the effect of concomitant sotorasib administration on the systemic exposure of breast cancer resistance protein (BCRP) transporter substrates. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet."

Lysodren - mitotane -**EMA/H/C/000521/II/0026**

HRA Pharma Rare Diseases, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.4 and 4.8 of the SmPC with new safety information regarding skin reactions (including rash, pruritus, urticaria...) and estrogenic effects in children based on post-marketing safety report and literature. The Package Leaflet is updated"

accordingly.”

Paxlovid - (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir - EMEA/H/C/005973/II/0015

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “Update of section 5.1 of the SmPC in order to add effect on lipids based on results from study C4671001;

In addition, the MAH took the opportunity to make an editorial clarification.”

Paxlovid - (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir - EMEA/H/C/005973/II/0016/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “Update of section 4.8 SmPC in order to include the adverse reactions nausea, abdominal pain and malaise based on global safety database of the MAH and Literature Review.

The Package Leaflet is updated accordingly.”

Paxlovid - (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide / ritonavir - EMEA/H/C/005973/II/0017

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “Submission of the final report from study In Vivo Efficacy Of Pf-07321332 As A Single Agent Or In Combination With Ritonavir In Balb/C Mouse-Adapted Sars-Cov-2 Model (PAM 023).

The objective of this study was to evaluate whether Ritonavir has in vivo antiviral activity against SARS-CoV-2 and whether combination of Ritonavir with PF-07321332 increased the exposure of PF-07321332 in the mouse model and further decreased viral lung replication.”

Qarziba - dinutuximab beta - EMEA/H/C/003918/II/0043, Orphan

EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik, “Update of

sections 4.1, 4.2 and 5.1 of the SmPC based on final results from study APN311-202V3 listed as a Specific Obligation in the Annex II of the Product Information. This is a Phase I/II dose schedule finding study of Ch14.18/CHO continuous infusion combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma. In addition, the MAH took the opportunity to update Annex II section E. The Package Leaflet is updated accordingly.”

**Qarziba - dinutuximab beta -
EMA/H/C/003918/II/0044, Orphan**

EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik, “Update of sections 4.2 and 4.8 of the SmPC with new safety information regarding central nervous system toxicity based on post-marketing safety report and literature.”

**QUVIVIQ - daridorexant -
EMA/H/C/005634/II/0004/G**

Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, “Submission of the final report from studies BA-17.030 (Validation of an analytical method for the determination of ACT-541468 and its metabolites ACT-776063, ACT-776537 and ACT-1016-3307 in rat plasma samples by LC-MS/MS) and study BA-18.023 (Validation of an analytical method for the determination of ACT-541468 and its metabolites ACT-776063, ACT-776537 and ACT-1016-3307 in rabbit plasma samples by LC-MS/MS). Both studies are part of the same post-authorisation measure evaluating the long-term stability of daridorexant and its metabolites (ACT-776063, ACT776537 and ACT-1016-3307) in rat and rabbit.”

**Reblozyl - luspaterecept -
EMA/H/C/004444/II/0011, Orphan**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphia, “Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to include new safety information about Extramedullary Hematopoietic Masses in transfusion-dependent beta-thalassemia patients based on the open-label phase of the ACE-536-B-THAL-001 Phase III study, the long-term follow-up study and post marketing data. The Package Leaflet is

updated accordingly.”

Rozlytrek - entrectinib -

EMA/H/C/004936/II/0012

Roche Registration GmbH, Rapporteur: Armando Genazzani, “Submission of the final integrated analysis report for cardiac risks, listed as a category 3 study in the RMP, in order to fulfil MEA/003. This is an integrated safety analysis report to assess cardiac risks based on GO40782 [STARTRK-2], CO40778 [STARTRK-NG], and BO41932 [TAPISTRY] studies (PAESs).”

Simponi - golimumab -

EMA/H/C/000992/II/0107

Janssen Biologics B.V., Rapporteur: Kristina Dunder, “Submission of the final report from study MK-8259-038 (Go-BACK) in order to fulfil MEA/30.2. This is a phase 4, randomized, double-blind, parallel-group, withdrawal, post-authorisation efficacy study (PAES) of golimumab in adult participants, aged 18 to 45 years, with active non-radiographic axial spondyloarthritis.”

Soliris - eculizumab -

EMA/H/C/000791/II/0122, Orphan

Alexion Europe SAS, Rapporteur: Blanca Garcia-Ochoa, “Submission of the final report from study ECU-NMO-302, a phase III, open-label, extension trial of ECU-NMO-301 to evaluate the safety and efficacy of eculizumab in subjects with neuromyelitis optica spectrum disorder (NMOSD) following procedure II/0105.”

Spikevax - elasmomeran -

See B.5.2

EMA/H/C/005791/II/0073

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, “C.I.11.b -To update Annex IIE of the Spikevax Product Information to delete SO3. Additional active substance and finished product stability data and review of the active substance and finished product specifications following further manufacturing experience have already been submitted and assessed in the context of previous procedures and are now considered fulfilled.”

Venclyxto - venetoclax -

EMA/H/C/004106/II/0042

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, “Update of section

5.1 of the SmPC in order to update data supporting the efficacy of the combined regimen of obinutuzumab and venetoclax (VEN+G; also known as GDC-0199 or ABT-199) versus obinutuzumab plus chlorambucil (GClb) in previously untreated CLL patients based on final results from study BO25323/CLL14; this is a prospective, open-label, multicenter randomized phase 3 trial to compare the efficacy and safety of a combined regimen of obinutuzumab and venetoclax (GDC-0199/ABT-199) versus obinutuzumab and chlorambucil in previously untreated patients with CLL and coexisting medical conditions. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Xarelto - rivaroxaban -

EMA/H/C/000944/II/0096

Bayer AG, Rapporteur: Kristina Dunder,
“Submission of the final report from study 15786 (COMPASS LTOLE). This is a phase 3, multicenter, randomized, double-blind, double-dummy, active comparator, event-driven study, in which subjects were randomized 1:1:1 to rivaroxaban 2.5 mg bid/ASA 100 mg od, or rivaroxaban 5 mg bid, or ASA 100 mg od.”

Xevudy - sotrovimab -

EMA/H/C/005676/II/0004

Glaxosmithkline Trading Services Limited,
Rapporteur: Thalia Marie Estrup Blicher,
“Submission of the final report from study PC-7831-0126 in order to fulfil the recommendation by the CHMP to submit an in vivo study in hamsters challenged with the UK (B.1.1.7) SARS-CoV-2 variant. This is a non-clinical study on the activity of sotrovimab against variants of concern from the UK, South Africa and Brazil.”

Xevudy - sotrovimab -

EMA/H/C/005676/II/0007

Glaxosmithkline Trading Services Limited,
Rapporteur: Thalia Marie Estrup Blicher,
“Update of sections 5.1 and 5.2 of the SmPC based on final results from study COMET-ICE (214367; VIR-7831-5001); this is a Phase II/III randomised, multi-centre, double-blind, placebo-controlled study to assess the safety and efficacy of monoclonal antibody VIR-7831 for the early treatment of coronavirus disease

2019 (COVID-19) in non-hospitalised patients.”

Zercepac - trastuzumab -

EMA/H/C/005209/II/0020

Accord Healthcare S.L.U., Rapporteur: Sol Ruiz,
“Submission of the final report from study
HLX02-BC01 in order to fulfil REC/006. This is a
double-blind, randomised, parallel-controlled,
multicentre, international, phase 3 study to
compare the efficacy, safety, and
immunogenicity of HLX02 versus EU-sourced
Herceptin in combination with docetaxel.”

WS2289

OPDIVO-

EMA/H/C/003985/WS2289/0122

Yervoy-EMA/H/C/002213/WS2289/0099

Bristol-Myers Squibb Pharma EEIG, Lead
Rapporteur: Blanca Garcia-Ochoa, “To update
sections 4.8 and 5.1 of the SmPC to include 7.5
years of minimum follow-up for all subjects
based on addendum 04 Clinical Study Report for
study CA209067; this is a phase 3 randomized,
double-blind study of nivolumab monotherapy
or nivolumab in combination with ipilimumab
versus ipilimumab monotherapy in subjects with
previously untreated, unresectable melanoma.
The MAH has taken the opportunity to introduce
minor editorial revisions in the SmPC.”

WS2304/G

Exviera-

EMA/H/C/003837/WS2304/0054/G

Viekirax-

EMA/H/C/003839/WS2304/0066/G

AbbVie Deutschland GmbH & Co. KG, Lead
Rapporteur: Filip Josephson, “Submission of the
final reports from studies M14-423 (TOPAZ-1)
and M14-222 (TOPAZ-II) listed as category 3
studies in the RMP for Viekirax and Exviera in
order to fulfil MEA/018 for Viekirax and
MEA/016 for Exviera. These are phase 3, open-
label, multicentre, post-authorisation safety
studies (PASS) to evaluate long-term outcomes
with ombitasvir/ paritaprevir/ritonavir and
dasabuvir with or without ribavirin (RBV) in
adults with GT1 chronic HCV infection.”

WS2312

Kisplyx-EMA/H/C/004224/WS2312/0053

Lenvima-

EMA/H/C/003727/WS2312/0048

Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn, "To update of SmPC sections 4.2 and 6.6 to include the option of administering the capsules as a suspension, including instructions for the administration and preparation of the suspension. The MAH also took the opportunity to include some editorial changes to the SmPC."

B.6.10. CHMP-PRAC assessed procedures

Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0006

Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphia, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.5, 4.8 and 5.1 of the SmPC based on final results from study B7471026 listed as a category 3 study in the RMP; this is a Phase III, randomized, double-blind trial to describe the safety and immunogenicity of 20-valent pneumococcal conjugate vaccine when coadministered with a booster dose of BNT162b2 in adults 65 years of age and older; the Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted."

JEMPERLI - dostarlimab - EMEA/H/C/005204/II/0013

GlaxoSmithKline (Ireland) Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of section 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study 4010-01-001 (GARNET) listed as a specific obligation in the Annex II; This is a single-arm, open-label, phase I trial of intravenous dostarlimab in advanced solid tumours. In addition, the MAH took the opportunity to update section E of Annex II. The RMP version 1.2 has also been submitted. "

Jyseleca - filgotinib - EMEA/H/C/005113/II/0018

Galapagos N.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of sections 4.4, 4.6 and 5.1 of the SmPC in order to update information on fertility based on interim results from studies GLPG0634-CL-227 (MANTA Ray) and GS-US-

418-4279 (MANTA) listed as a category 3 study in the RMP.

The Package Leaflet and Annex II are updated accordingly. The RMP version 4.1 has also been submitted.”

Leqvio - inclisiran -

EMA/H/C/005333/II/0013

Novartis Europharm Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Kimmo Jaakkola, “Submission of the final report from ORION-3 study (CKJX839A12201E1 or MDCO-PCS-16-01) listed as a category 3 study in the RMP. This is an open label, active comparator extension trial to assess the effect of long-term dosing of inclisiran and evolocumab given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C. The RMP version 2.0 has also been submitted.”

MenQuadfi - meningococcal group A, C, W135 and Y conjugate vaccine -

EMA/H/C/005084/II/0018/G

Sanofi Pasteur, Rapporteur: Andrea Laslop, PRAC Rapporteur: Jean-Michel Dogné, “Update of sections 4.2, 4.5, 4.8 and 5.1 of the SmPC in order to add long-term antibody persistence at least 3 years after primary vaccination, immunogenicity and safety of a booster dose of MenQuadfi in adolescents, adults, and older adults, as well as co-administration data with meningococcal serogroup B vaccine in adolescents and adults, in order to fulfil ANX/002 and ANX/003 based on final results from studies MET59 and MEQ00066, respectively, listed as specific obligations in the Annex II. MET59 is a phase 3b, open-label, partially randomized, parallel-group, active-controlled, multi-center study evaluating the immunogenicity and safety of a booster dose of an investigational quadrivalent MenACYW conjugate vaccine in adolescents and adults, while MEQ00066 is a phase 3, two-stage, randomized, open-label, multi-center trial evaluating the safety and immunogenicity of a single dose of MenACYW conjugate vaccine at least 3 years following initial vaccination with either Menomune vaccine or MenACYW conjugate vaccine in older adults. The Annex II and Package Leaflet are updated accordingly. The RMP version 1.1 has also been submitted.

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

**NUBEQA - darolutamide -
EMA/H/C/004790/II/0012**

Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser, “Submission of the final report of carcinogenicity study T104877-7 listed as a category 3 study in the RMP. This is a non-clinical study to assess the carcinogenic potential in mice. The study evaluates the effects of daily oral administration of darolutamide for a period of 6 months in tg-rasH2 transgenic mouse model. The updated RMP version 3.1 has also been submitted.”

**Symtuza - darunavir / cobicistat /
emtricitabine / tenofovir alafenamide -
EMA/H/C/004391/II/0045**

Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ana Sofia Diniz Martins, “Submission of the interim report from study GS-US-292-0106 listed as a category 3 study in the RMP. This is a Phase II/III, open-label study to evaluate of the pharmacokinetics, safety, tolerability, and antiviral activity of the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) single tablet regimen in HIV-1 infected antiretroviral treatment-naïve adolescents and virologically suppressed HIV-infected children. The RMP version 8.1 has also been submitted.”

**Vumerity - diroximel fumarate -
EMA/H/C/005437/II/0005**

Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, “Submission of the final report from study ALK8700-A301, A Phase 3 Open Label Study to Evaluate the Long-term Safety and Tolerability of ALKS 8700 in Adults with Relapsing Remitting Multiple Sclerosis listed as a category 3 study in the RMP. This is a multicentre, open-label study to evaluate the long-term safety, tolerability, and treatment effect over time of DRF administered for up to 96 weeks in adult participants with RRMS. The RMP version 1.1 has also been submitted.”

WS2187

OPDIVO-**EMA/H/C/003985/WS2187/0121****Yervoy-EMA/H/C/002213/WS2187/0098**

Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Blanca Garcia-Ochoa, Lead PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 4.8 of the SmPC in alignment with the recommendations made by the CHMP to revise the pooling approach used to describe irARs and tabulated summaries of ADRs following II/0096. Individual study data included within this application has been previously reviewed by the CHMP. The updated Opdivo RMP version 29.0 and Yervoy RMP version 37.0 have also been submitted. The MAH took the opportunity to introduce editorial changes. The Package Leaflet was updated accordingly."

WS2307**Rixathon-****EMA/H/C/003903/WS2307/0062****Riximyo-****EMA/H/C/004729/WS2307/0063**

Sandoz GmbH, Lead Rapporteur: Jan Mueller-Berghaus, Lead PRAC Rapporteur: Anette Kirstine Stark, "Update of section 4.1 of the SmPC in order to include the rapid infusion regimen (90 minutes) for second and subsequent infusions in the label for patients with non-Hodgkin's lymphoma (NHL) or chronic lymphocytic leukaemia (CLL) based on non-interventional PASS CGP2013ES01R and scientific literature. The RMP version 7.0 has also been submitted."

WS2323**Juluca-EMA/H/C/004427/WS2323/0045****Tivicay-EMA/H/C/002753/WS2323/0081****Triumeq-****EMA/H/C/002754/WS2323/0106**

ViiV Healthcare B.V., Lead Rapporteur: Janet Koenig, Lead PRAC Rapporteur: Nathalie Gault, "Submission of the final report from study 200336 listed as a category 3 study in the RMP. This is a prospective, interventional pharmacokinetic and safety study of DTG/ABC/3TC in pregnant women. The summary of objective of this PASS study is to investigate the use of DTG during pregnancy and address the safety concerns of pregnant/breastfeeding women. The RMP

versions 18.0, 20.0 and 4.0 for Tivicay, Triumeq and Juluca, respectively, have also been submitted.”

B.6.11. PRAC assessed procedures

PRAC Led

Besremi - ropeginterferon alfa-2b - EMA/H/C/004128/II/0025

AOP Orphan Pharmaceuticals GmbH, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, “Submission of an updated RMP version 1.1 for Besremi to revise safety concerns according to GVP Module V Rev.2.”

PRAC Led

Cancidas - caspofungin - EMA/H/C/000379/II/0078

Merck Sharp & Dohme B.V., PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, “Submission of an updated RMP version 4.1 in order to remove safety concerns and align it with the EU GVP Module V (Revision 2).”

PRAC Led

Cotellic - cobimetinib - EMA/H/C/003960/II/0027

Roche Registration GmbH, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, “Update of sections 4.4 and 5.1 of the SmPC in order to update information based on final results from study ML39302 listed as a category 3 study in the RMP in order to fulfil MEA/003.5; this is a non-interventional PASS study to investigate the effectiveness, safety and utilisation of cobimetinib and vemurafenib in patients with and without brain metastasis with BRAF V600 mutant melanoma under real world conditions. The RMP version 5.0 has also been submitted.”

PRAC Led

Gazyvaro - obinutuzumab - EMA/H/C/002799/II/0051, Orphan

Roche Registration GmbH, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, “Update of section 4.8 of the SmPC in line with the SmPC Guideline following the recommendation by PRAC in the outcome for the signal assessment of non-overt

disseminated intravascular coagulation (DIC) (EPITT no: 19711). The Package Leaflet is updated accordingly.”

PRAC Led

Mycamine - micafungin -

EMA/H/C/000734/II/0047

Astellas Pharma Europe B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, “To update Annex II and the RMP to version 23.0 to include the results of the non-interventional PASS as an Effectiveness Check of the Prescriber Checklist for Mycamine (micafungin) - 9463-PV-0002.”

PRAC Led

SCENESSE - afamelanotide -

EMA/H/C/002548/II/0042, Orphan

Clinuvel Europe Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, “Submission of an updated RMP version 9.1 in order to update the allergy and hypersensitivity risk from potential to identified, following reported cases of positive allergy test results, confirming the causal association between the allergies to afamelanotide. Consequently, the RMP has been revised to reclassify the important potential risk Allergy and hypersensitivity to important identified risk.”

PRAC Led

Stelara - ustekinumab -

EMA/H/C/000958/II/0095

Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, “Submission of the final report from study PSOLAR (C0168Z03) listed as a category 3 study in the RMP. This is a Multicenter, Open Registry of Patients with Psoriasis Who Are Candidates for Systemic Therapy Including Biologics: PSOLAR. The RMP version 22.2 has also been submitted.”

PRAC Led

WS2270

Vfend-EMA/H/C/000387/WS2270/0147

Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, “To update the Annex II and RMP to version 6.0 to include the results from final clinical study

report (CSR) following the completion of a non-interventional (NI) post-authorisation safety study (PASS), A1501103 "An Active Safety Surveillance Program to Monitor Selected Events in Patients with Long-term Voriconazole Use" - MEA091.

In addition, MAH is taking this opportunity to introduce editorial changes."

B.6.12. CHMP-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMA/H/C/004731/II/0004, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Concetta Quintarelli, CHMP Coordinator:
Armando Genazzani

Kymriah - tisagenlecleucel - EMA/H/C/004090/II/0062, Orphan, ATMP

Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang,
"Submission of the final report from study CCTL019B2401 listed as a category 1 study in the Annex II of the Product Information in order to fulfil ANX/007.3. This is a sub-analysis (PAES) to assess efficacy in patients with relapsed or refractory diffuse large B-cell lymphoma based on data from the registry study to assess the long-term safety of patients with B lymphocyte malignancies treated with tisagenlecleucel. The Annex II is updated accordingly."

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

PRAC Led

Imlygic - talimogene laherparepvec - EMA/H/C/002771/II/0056, ATMP

Amgen Europe B.V., PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from study 20120139 listed as a category 3 study in the RMP in order to fulfil MEA/004. This is a multicenter, observational registry study to evaluate the survival and long-term

safety of subjects who previously received talimogene laherparepvec in Amgen or BioVEX sponsored clinical trials.”

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

WS2277

Herceptin-

EMA/H/C/000278/WS2277/0182

MabThera-

EMA/H/C/000165/WS2277/0192

Roche Registration GmbH, Lead Rapporteur: Jan
Mueller-Berghaus

WS2291/G

Ambirix-

EMA/H/C/000426/WS2291/0122/G

Twinrix Adult-

EMA/H/C/000112/WS2291/0157/G

Twinrix Paediatric-

EMA/H/C/000129/WS2291/0158/G

GlaxoSmithKline Biologicals SA, Lead
Rapporteur: Christophe Focke

WS2301/G

M-M-RvaxPro-

EMA/H/C/000604/WS2301/0117/G

ProQuad-

EMA/H/C/000622/WS2301/0158/G

Merck Sharp & Dohme B.V., Lead Rapporteur:
Jan Mueller-Berghaus

WS2308/G

AZILECT-

EMA/H/C/000574/WS2308/0090/G

Rasagiline ratiopharm-

EMA/H/C/003957/WS2308/0022/G

Teva B.V., Lead Rapporteur: Bruno Sepodes

WS2310

Dovato-EMA/H/C/004909/WS2310/0033

Triumeq-

EMA/H/C/002754/WS2310/0107

ViiV Healthcare B.V., Lead Rapporteur: Filip
Josephson

WS2337/G

Copalia-

EMA/H/C/000774/WS2337/0126/G

Dafiro-

EMA/H/C/000776/WS2337/0130/G

Exforge-

EMA/H/C/000716/WS2337/0125/G

Novartis Europharm Limited, Lead Rapporteur:
Thalia Marie Estrup Blicher, "C.I.z - To update
section 4.9 of the SmPC, to implement the
wording related to the risk of non-cardiogenic
pulmonary oedema in amlodipine overdose,
following finalisation of procedure
PSUSA/00010434/202107.

C.I.11.a - To update Annex II to reflect the
fulfilment of Condition B, as set out by the
Commission Decision as an outcome of the
assessment for the impact of the Article 5(3)
scientific opinion on nitrosamines in human
medicinal products on the opinion adopted
pursuant to Article 31 of Directive 2001/83/EC
for angiotensin-II-receptor antagonists (sartans)
containing a tetrazole group."

WS2338

Copalia HCT-

EMA/H/C/001159/WS2338/0102

Dafiro HCT-

EMA/H/C/001160/WS2338/0104

Exforge HCT-

EMA/H/C/001068/WS2338/0101

Novartis Europharm Limited, Lead Rapporteur:
Thalia Marie Estrup Blicher, "C.I.z - To update
section 4.9 of the SmPC, to implement the
wording related to the risk of non-cardiogenic
pulmonary oedema in amlodipine overdose,
following finalisation of procedure
PSUSA/00010434/202107."

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.

G.2.1. List of procedures concluding at 18-21 July 2022 CHMP plenary

G.2.2. List of procedures starting in July 2022 for August 2022 CHMP adoption of outcomes

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