27 March 2023
EMA/CHMP/47815/2023
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 27-30 March 2023

Vice-Chair: Bruno Sepodes, deputising for the Chair Harald Enzmann

27 March 2023, 13:00 – 19:30, virtual meeting/room 1C

28 March 2023, 08:30 – 19:30, virtual meeting/room 1C

29 March 2023, 08:30 – 19:30, virtual meeting/room 1C

30 March 2023, 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 27-30 March 2023. See March 2023 CHMP minutes (to be published post April 2023 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 27-30 March 2023.

1.3. Adoption of the minutes

CHMP minutes for 20-23 February 2023.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 20 March 2023.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

No items

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Epidyolex - cannabidiol - Orphan - EMEA/H/C/004675/II/0020

GW Pharma (International) B.V.

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include treatment with Epidyolex (monotherapy) as adjunctive therapy of seizures associated with Lennox Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients 2 years of age and older (without the restriction for use only in conjunction with clobazam), based on the previously generated data in patients treated without CLB in the LGS and DS pivotal studies re-evaluated in the context of the more recent evidence from study GWEP1521 in tuberous sclerosis complex (TSC). As a consequence, sections 4.1, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The

Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement editorial changes in the product information. Version 2.1 of the RMP has also been submitted."

Scope: Oral explanation

Action: Oral explanation to be held on 28 March 2023 at 16:00

Request for Supplementary Information adopted on 15.12.2022, 15.09.2022.

See 5.1

2.3.2. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0056

Orexigen Therapeutics Ireland Limited

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber

Scope: "Submission of updated study design and protocol synopsis for the CVOT-2 study, a category 1 study listed in Annex II.D (ANX/001.7) undertaken to assess the effect of naltrexone extended release (ER) / bupropion ER on the occurrence of major adverse cardiovascular events (MACE), as requested in the CHMP AR for ANX/001.6. The Annex II and the RMP version 13 are updated accordingly."

Scope: Oral explanation

Action: Oral explanation to be held on 27 March 2023 at 16:00

Request for Supplementary Information adopted on 26.01.2023, 15.09.2022, 24.03.2022.

See 9.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. COVID-19 vaccine - EMEA/H/C/006058

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

Scope: Opinion

Action: For adoption

3.1.2. ublituximab - EMEA/H/C/005914

treatment of relapsing forms of multiple sclerosis (RMS)

Scope: Opinion

Action: For adoption

List of Questions adopted on 22.04.2022.

3.1.3. dabigatran etexilate - EMEA/H/C/005639

prevention of venous thromboembolic events

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.01.2023, 15.09.2022, 23.06.2022, 24.02.2022. List of Questions adopted on 12.11.2020.

3.1.4. lacosamide - EMEA/H/C/006047

treatment of epilepsy

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 15.09.2022.

3.1.5. mirikizumab - EMEA/H/C/005122

treatment of moderately to severely active ulcerative colitis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.01.2023. List of Questions adopted on 15.09.2022.

3.1.6. sodium thiosulfate - PUMA - EMEA/H/C/005130

for the prevention of ototoxicity induced by cisplatin (CIS) chemotherapy in patients 1 month to < 18 years of age with localised, non-metastatic, solid tumours.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 13.10.2022, 16.12.2021, 24.06.2021. List of Questions adopted on 25.06.2020.

3.1.7. spironolactone - EMEA/H/C/005535

Management of refractory oedema

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 10.11.2022. List of Questions adopted on 24.03.2022.

3.1.8. eculizumab - EMEA/H/C/006036

treatment of paroxysmal nocturnal haemoglobinuria

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 10.11.2022.

3.1.9. sugammadex - EMEA/H/C/006046

reversal of neuromuscular blockade induced by rocuronium or vecuronium

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 15.09.2022.

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

3.2.1. recombinant respiratory syncytial virus pre-fusion f protein, adjuvanted with as01e - EMEA/H/C/006054

Accelerated assessment

indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.01.2023.

3.2.2. piflufolastat (18F) - EMEA/H/C/005520

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 10.11.2022.

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

Prevention of venous thromboembolic events

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.07.2022.

3.2.4. daprodustat - EMEA/H/C/005746

treatment of anaemia associated with chronic kidney disease (CKD) in adults

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 10.11.2022. List of Questions adopted on 23.06.2022.

3.2.5. 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 outstanding issues

Action: For adoption

List of Questions adopted on 21.07.2022.

3.2.6. sugammadex - EMEA/H/C/006083

Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.12.2022.

3.2.7. 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 outstanding issues

Action: For adoption

List of Questions adopted on 21.07.2022.

3.2.8. alpelisib - Orphan - EMEA/H/C/005468

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 10.11.2022.

3.2.9. atogepant monohydrate - EMEA/H/C/005871

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 10.11.2022.

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

3.3.1. arpraziquantel - Article 58 - EMEA/H/W/004252

treatment of schistosomiasis in children

Scope: List of questions

Action: For adoption

3.3.2. aumolertinib - EMEA/H/C/006069

treatment of non-small cell lung cancer

Scope: List of questions

Action: For adoption

3.3.3. ibuprofen - EMEA/H/C/006129

Treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age

Scope: List of questions

Action: For adoption

3.3.4. dopamine hydrochloride - PUMA - EMEA/H/C/006044

Treatment of hypotension in neonates, infants and children

Scope: List of questions

Action: For adoption

3.3.5. momelotinib - Orphan - EMEA/H/C/005768

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

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

3.3.7. rozanolixizumab - Orphan - EMEA/H/C/005824

UCB Pharma; Treatment of generalised myasthenia gravis (gMG)

Scope: List of questions

Action: For adoption

3.3.8. toripalimab - EMEA/H/C/006120

Combination treatment for metastatic or recurrent locally advanced nasopharyngeal carcinoma and for metastatic or recurrent oesophageal squamous cell carcinoma

Scope: List of questions

Action: For adoption

3.3.9. ustekinumab - EMEA/H/C/006101

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

Scope: List of questions

Action: For adoption

3.3.10. etrasimod - EMEA/H/C/006007

treatment of patients with moderately to severely active ulcerative colitis (UC)

Scope: List of questions

Action: For adoption

3.3.11. palopegteriparatide - Orphan - EMEA/H/C/005934

Ascendis Pharma Bone Diseases A/S; PTH replacement therapy indicated for the treatment of hypoparathyroidism in adults.

Scope: List of questions

Action: For adoption

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

3.4.1. enalapril maleate - PUMA - EMEA/H/C/005731

treatment of heart failure

Scope: Letter by the applicant dated 24 March 2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in February 2023.

Action: For adoption

List of Outstanding Issues adopted on 23.02.2023. List of Questions adopted on 21.07.2022.

3.4.2. trastuzumab - EMEA/H/C/005769

treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)

Scope: Letter by the applicant dated 24 March 2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in December 2022.

Action: For adoption

List of Outstanding Issues adopted on 15.12.2022. List of Questions adopted on 19.05.2022.

3.4.3. pegzilarginase - Orphan - EMEA/H/C/005484

Immedica Pharma AB; treatment of hyperargininemia

Scope: Letter by the applicant dated 21 February 2023 requesting an extension to the clock stop to respond to the list of questions adopted in December 2022.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in December 2022 via written procedure on 08 March 2023.

Action: For adoption

List of Questions adopted on 15.12.2022.

3.4.4. paclitaxel - EMEA/H/C/005997

treatment of metastatic breast cancer

Scope: Letter by the applicant dated 13 March 2023 requesting an extension to the clock

stop to respond to the list of outstanding issues adopted in October 2022.

Action: For adoption

List of Outstanding Issues adopted on 13.10.2022. List of Questions adopted on 19.05.2022.

3.4.5. GBP510 - EMEA/H/C/005998

prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older

Scope: Letter by the applicant dated 13 March 2023 requesting an extension to the clock stop to respond to the list of questions adopted in December 2022.

Action: For adoption

List of Questions adopted on 15.12.2022.

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

3.5.1. Sohonos - palovarotene - Orphan - EMEA/H/C/004867

Ipsen Pharma; treatment of fibrodysplasia ossificans progressiva

Scope: Adoption of timetable; intervention by a third party; Re-examination rapporteurs were appointed via written procedure on 09 March 2023.

Action: For adoption

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

Opinion adopted on 26.01.2023. List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 16.09.2021.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. ferumoxytol - EMEA/H/C/005974

intravenous treatment of iron deficiency anaemia (IDA)

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Questions adopted on 15.09.2022.

3.7.2. tocilizumab - EMEA/H/C/006256

treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), Giant Cell Arteritis (GCA), treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA) and COVID-19

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Questions adopted on 15.12.2022.

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

Novartis Europharm Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Anette Kirstine Stark

Scope: "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."

Action: For adoption

List of Questions adopted on 10.11.2022.

4.1.2. Neparvis - sacubitril / valsartan - EMEA/H/C/004343/X/0042/G

Novartis Europharm Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Anette Kirstine Stark

Scope: "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."

Action: For adoption

List of Questions adopted on 10.11.2022.

4.1.3. Sogroya - somapacitan - Orphan - EMEA/H/C/005030/X/0006/G

Novo Nordisk A/S

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber

Scope: "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."

Action: For adoption

List of Questions adopted on 10.11.2022.

4.1.4. 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 a 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

List of Outstanding Issues adopted on 26.01.2023, 13.10.2022. List of Questions adopted on 21.07.2022.

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. Adtralza - tralokinumab - EMEA/H/C/005255/X/0007

LEO Pharma A/S

Rapporteur: Jayne Crowe, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to add a new strength of 300 mg (150 mg/ml) tralokinumab solution for injection in pre-filled pen for subcutaneous administration.
The RMP (version 1.1) is updated accordingly."

Action: For adoption

4.3.2. Erleada - apalutamide - EMEA/H/C/004452/X/0028/G

Janssen-Cilag International N.V.

Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to add a new strength (240 mg) film-coated tablets grouped with the IB variation (C.I.z).
The RMP (version 6.1) has also been submitted.
C.I.z (IB): to align the SmPC/PL for Erleada 60 mg with the SmPC/PL proposed for the registration of the new Erleada film-coated tablet strength, 240 mg.
The PL for Erleada 60 mg is proposed to be updated to ensure consistency.
In addition, few minor revisions are proposed to the SmPC for Erleada 60 mg, to align the SmPC proposed for the 240 mg strength:
- SmPC sections 5.1 and 5.2: Orthographic corrections
- SmPC section 6.5: Further details on the description of the current packaging have been added, this change does not result from a change to the container.
- SmPC section 6.6: The title of the section has been aligned with the QRD template."

Action: For adoption

4.3.3. Takhzyro - lanadelumab - Orphan - EMEA/H/C/004806/X/0034/G

Takeda Pharmaceuticals International AG Ireland Branch

Rapporteur: Kristina Dunder, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension application to add a new strength of 150 mg for lanadelumab solution for injection in pre-filled syringe and to extend the indication to include paediatric use (2 to <12 years).

The new indication is only applicable to the new 150 mg strength presentations.
The RMP (version 3.0) is updated in accordance.
A type IB variation (C.I.z) has been submitted to update section 7 of the Package Leaflet (PL) for the 300 mg in 2 ml pre-filled syringe (EU/1/18/1340/004-006) in line with the proposed PL for the 150 mg in 1 ml pre-filled syringe (new strength).
In addition, the MAH has requested an extension of the Orphan Market Exclusivity from 10 to 12 years."

Action: For adoption

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

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Inês Ribeiro-Vaz

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

Action: For adoption

4.3.5. Veltassa - patiromer - EMEA/H/C/004180/X/0031/G

Vifor Fresenius Medical Care Renal Pharma France

Rapporteur: Jayne Crowe, PRAC Rapporteur: Kirsti Villikka

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

Action: For adoption

4.3.6. Vyvgart - efgartigimod alfa - Orphan - EMEA/H/C/005849/X/0003

Argenx

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

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (1000 mg) and a new route of administration (subcutaneous use)."

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. Apexxnar - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0012

Pfizer Europe MA EEIG

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of indication to include infants, children and adolescents from 6 weeks to less than 18 years of age for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae, based on final results from studies B7471003, B7471011, B7471012, B7471013 and B7471014. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted."

Action: For adoption

5.1.2. Bimzelx - bimekizumab - EMEA/H/C/005316/II/0010

UCB Pharma S.A.

Rapporteur: Finbarr Leacy, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension of indication to include treatment of adults with active axial spondyloarthritis (axSpA), including non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS, radiographic axial spondyloarthritis), based on interim results from two interventional and controlled phase III clinical studies: AS0010 (BE MOBILE 1) and AS0011 (BE MOBILE 2), which provide evidence of the efficacy and safety of bimekizumab in axSpA (nr-axSpA and AS), both compared to placebo treatment. Further supportive data is provided by the results of a phase 2a exploratory study (AS0013), a phase 2b, dose-ranging study (AS0008) and its ongoing follow-on phase 2b open-label extension (OLE)

study (AS0009). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev.1."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022.

5.1.3. Bimzelx - bimekizumab - EMEA/H/C/005316/II/0011

UCB Pharma S.A.

Rapporteur: Finbarr Leacy, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension of indication to include treatment of active psoriatic arthritis in adults patients who have had an inadequate response or who have been intolerant to one or more DMARDs for BIMZELX, based on interim results of a Phase III study in biological DMARD naïve study participants (PA0010; BE OPTIMAL) and the final results of the Phase III study in study participants who are inadequate responders (inadequate response or intolerant) to ≤2 prior TNF inhibitors (PA0011; BE COMPLETE). Both Phase III studies are interventional studies aimed to evaluate the efficacy and safety of bimekizumab. For PA0010, the Initial Treatment Period was placebo- and no inferential active reference (adalimumab)-controlled, while PA0011 was placebo-controlled. Further supportive data comprise the results of a Phase 1 study (PA0007), a Phase 2b dose-finding study (PA0008) and a Phase 2 open label extension study (PA0009). A Phase 3 open-label extension study is currently ongoing (PA0012). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 to the SmPC have been updated. The package leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev.1. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022.

5.1.4. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - ATMP - EMEA/H/C/004731/II/0005

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, CHMP Coordinator: Armando Genazzani, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of adult patients with Second-line (2L) Transplant Intended (TI) Large B-Cell Lymphoma (LBCL) for Breyanzi, based on interim analyses from pivotal study JCAR017-BCM-003; this is a global randomized multicentre Phase III Trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell Non-Hodgkin Lymphomas (TRANSFORM); As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 23.02.2023, 09.09.2022.

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

Albireo

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of cholestasis and pruritus in Alagille syndrome (ALGS) in patients from birth and older for BYLVAY, based on final results from study A4250-012 and interim results from study A4250-015. Study A4250-012 is a 24-week, randomised, double-blind, placebo-controlled Phase III study conducted in 52 patients with a genetically confirmed diagnosis of ALGS and presence of pruritus and high serum bile acid levels at baseline. Study A4250-015 is an ongoing 72-week open-label extension trial for patients who completed study A4250-012 and evaluates the long-term safety and efficacy of Bylvay in patients with ALGS. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.6. Cosentyx - secukinumab - EMEA/H/C/003729/II/0090

Novartis Europharm Limited

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension of indication to include treatment of Hidradenitis Suppurativa (HS) for Cosentyx, based on interim results from two Phase III studies CAIN457M2301 (SUNSHINE) and CAIN457M2302 (SUNRISE); These studies are ongoing, multi-centre, randomized, double-blind, placebo-controlled, parallel group Phase 3 studies conducted to assess the short (16 weeks) and long-term (up to 52 weeks) efficacy and safety of two secukinumab dose regimens (Q2W or Q4W) compared to placebo in adult subjects with moderate to severe HS; 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 11 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022, 15.09.2022.

5.1.7. Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0027

Daiichi Sankyo Europe GmbH

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Inês Ribeiro-Vaz

Scope: "Extension of indication to include the indication treatment of non-small cell lung cancer for Enhertu (trastuzumab deruxtecan), based on results from study DS8201-A-U204 (DESTINY-Lung01) and study DS8201-A-U206 (DESTINY-Lung02).

Study DESTINY-Lung01 is a phase 2, multicentre, open-label, 2-cohort study of trastuzumab deruxtecan (DS-8201a), an anti-HER2 antibody drug conjugate (ADC), for HER2-over-expressing or -mutated, unresectable and/or metastatic non-small cell lung cancer (NSCLC) conducted at sites in Japan, the United States and Europe.
Study DESTINY-Lung02 is an ongoing phase 2, multicentre, randomised study to evaluate the safety and efficacy of trastuzumab deruxtecan in subjects with HER2-mutated metastatic non-small cell lung cancer, conducted in North America, Europe and Asia-Pacific.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.2 of the RMP has also been submitted."

Action: For adoption

5.1.8. Epidyolex - cannabidiol - Orphan - EMEA/H/C/004675/II/0020

GW Pharma (International) B.V.

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include treatment with Epidyolex (monotherapy) as adjunctive therapy of seizures associated with Lennox Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients 2 years of age and older (without the restriction for use only in conjunction with clobazam), based on the previously generated data in patients treated without CLB in the LGS and DS pivotal studies re-evaluated in the context of the more recent evidence from study GWEP1521 in tuberous sclerosis complex (TSC). As a consequence, sections 4.1, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement editorial changes in the product information. Version 2.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022, 15.09.2022.

See 2.3

5.1.9. Foclivia - pandemic influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/001208/II/0081

Seqirus S.r.l

Rapporteur: Maria Grazia Evandri, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include children from 6 months to less than 18 years of age for Foclivia, based on final results from study V87_30; this is a phase 2, randomized, observer-blind, multicentre study to evaluate the immunogenicity and safety of several doses of antigen and MF59 adjuvant content in a monovalent H5N1 pandemic influenza vaccine in healthy paediatric subjects 6 months to less than 9 years of age. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.9 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template."

Action: For adoption

5.1.10. Gazyvaro - obinutuzumab - Orphan - EMEA/H/C/002799/II/0052

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include the pre-treatment to reduce the risk of cytokine release syndrome (CRS) induced by glofitamab for Gazyvaro, based on results from study NP30179; this is a multicentre, open-label, Phase I/II study evaluating the safety, efficacy, tolerability and pharmacokinetics of escalating doses of glofitamab as a single agent and in combination with obinutuzumab administered after a fixed, single dose pre-treatment of Gazyvaro in patients with relapsed/refractory B-cell NHL. As a consequence, sections 4.1, 4.2, 4.4, 5.1, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version."

Action: For adoption

5.1.11. Imfinzi - durvalumab - EMEA/H/C/004771/II/0057

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi as 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 (HIMALAYA). 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 9, Succession 1 of the RMP has also been submitted. In addition, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

5.1.12. Jardiance - empagliflozin - EMEA/H/C/002677/II/0074

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of chronic kidney disease (CKD) for Jardiance, based on final results from study EMPA-KIDNEY (1245-0137) listed as a category 3 study in the RMP; this is a Phase III, multicentre international randomised parallel group double-blind placebo controlled clinical trial of empagliflozin once daily to assess cardio-renal outcomes in patients with chronic kidney disease. 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 19.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

5.1.13. Olumiant - baricitinib - EMEA/H/C/004085/II/0037

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of paediatric patients (from 2 years of age and older) with moderate to severe atopic dermatitis for Olumiant, based on the final results from study I4V-MC-JAIP; this is a Phase III, multicentre, randomised, double blind, placebo controlled, parallel-group, outpatient study evaluating the pharmacokinetics, efficacy, and safety of baricitinib in paediatric patients with moderate-to-severe atopic dermatitis. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 17.1 of the RMP has also been submitted"

Action: For adoption

5.1.14. Orencia - abatacept - EMEA/H/C/000701/II/0152

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include the prophylaxis of acute Graft versus Host Disease (aGvHD) in the adult and paediatric population for Orencia, based on final results from studies IM101311 - Abatacept Combined With a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis and IM101841 - Overall Survival In 7/8 HLA-Matched Hematopoietic Stem Cell Transplantation Patients Treated With Abatacept Combined With A Calcineurin Inhibitor And Methotrexate - An Analysis Of The Center For International Blood And Marrow Transplant Research (Cibmtr) Database. 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 and Labelling are updated in accordance. Version 28.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

5.1.15. Pepaxti - melphalan flufenamide - EMEA/H/C/005681/II/0002

Oncopeptides AB

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Elita Poplavska, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include treatment of patients with Multiple Myeloma who have received at least two prior lines of therapies for Pepaxti, based on final results from study OP-103 OCEAN; this is a randomized, open-label phase III study in patients with relapsed or refractory multiple myeloma following two to four lines of prior therapies and who were refractory to lenalidomide and the last line of therapy. 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 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Action: For adoption

5.1.16. Refixia - nonacog beta pegol - EMEA/H/C/004178/II/0032

Novo Nordisk A/S

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment and prophylaxis of bleeding in children below 12 years of age with haemophilia B including previously untreated patients for Refixia, based on interim results from studies NN7999-3774 and NN7999-3895. NN7999-3774 is a multicentre, open-label, non-controlled study evaluating the safety, efficacy and pharmacokinetics of nonacog beta pegol in previously treated children with haemophilia B, while NN7999-3895 is a multicentre, open-label, single-arm, non-controlled trial evaluating the safety and efficacy of nonacog beta pegol in previously untreated patients with haemophilia B. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

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

Eli Lilly Nederland B.V.

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

Scope: "Extension of indication to include the treatment of adults and adolescents 12 years and older with advanced RET fusion-positive thyroid cancer in the first-line setting for Retsevmo based on interim data from studies LIBRETTO-001 (LOXO-RET-17001) and LIBRETTO-121; LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in patients with RET-altered advanced solid tumours. LIBRETTO-121 is a Phase 1/2 study of selpercatinib in paediatric patients with advanced RET-altered solid or primary central nervous system tumours. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been submitted."

Action: For adoption

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

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication for Retsevmo to include the treatment of adults with advanced or metastatic RET fusion-positive solid tumours with disease progression on or

after prior systemic therapies or who have no satisfactory therapeutic options, based on interim data from study LIBRETTO-001 (LOXO-RET-17001); LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in in adult and adolescent patients with advanced RET-altered tumours. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

5.1.19. Tenkasi - oritavancin - EMEA/H/C/003785/II/0037

Menarini International Operations Luxembourg S.A.

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of paediatric population, aged between 3 months and less than 18 years for Tenkasi (oritavancin) 400 mg based on interim results from study TMC-ORI-11-01; this is a multicentre, open-label, dose-finding study of oritavancin single dose infusion in paediatric subjects less than 18 years of age with suspected or confirmed bacterial infections. The purpose of this Phase 1 study is to evaluate the safety, tolerability and PK of oritavancin in paediatric subjects and determine the optimal dose for a Phase 2 trial in paediatric subjects with ABSSSI. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been submitted.
In addition, the MAH is taking this opportunity to update the contact details of the local representatives in the Package Leaflet.
Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev 1."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022.

5.1.20. Trodelvy - sacituzumab govitecan - EMEA/H/C/005182/II/0020

Gilead Sciences Ireland UC

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

Scope: "Extension of indication to include treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting, based on final results from study IMMU-132-09 (TROPiCS-02); this is an open-label, randomized, multicentre phase 3 study of sacituzumab govitecan (IMMU-132) versus treatment of physician's choice (TPC) in subjects with hormonal receptor-positive (HR+) human epidermal growth factor receptor 2 (HER2) negative metastatic breast cancer (mBC) who have failed at least two prior chemotherapy regimens. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.21. Ultomiris - ravulizumab - EMEA/H/C/004954/II/0032

Alexion Europe SAS

Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive, based on interim results from study ALXN1210-NMO-307; this is a phase 3, external placebo-controlled, open-label, multicentre study to evaluate the efficacy and safety of ravulizumab in adult patients with NMOSD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2022.

5.1.22. Voxzogo - vosoritide - Orphan - EMEA/H/C/005475/II/0006

BioMarin International Limited

Rapporteur: Martina Weise, PRAC Rapporteur: Zane Neikena

Scope: "Extension of indication to include treatment of children less than 2 years of age for Voxzogo, based on final results from the category 1 study BMN 111-206 and interim results from its open-label extension study 111-208. 111-206 is a phase 2 randomized, double-blind, placebo-controlled, multicentre study to assess the safety and efficacy of BMN 111 in infants and young children with achondroplasia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

5.1.23. Wegovy - semaglutide - EMEA/H/C/005422/II/0009

Novo Nordisk A/S

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include treatment of adolescents for weight management for Wegovy based on final results from study NN9536-4451; this trial was conducted to assess the effect and safety of semaglutide in the paediatric population in order to address the unmet need for treatment of adolescents ages 12 to <18 years with obesity.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.2."

Action: For adoption

Request for Supplementary Information adopted on 23.02.2023, 15.12.2022.

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. gentamicin sulfate / sargramostim / heparin sodium / insulin human - EMEA/H/D/006090

human assisted reproductive techniques including in-vitro fertilisation procedures

Scope: Opinion

Action: For adoption

List of Questions adopted on 13.10.2022.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. in vitro diagnostic medical device - EMEA/H/D/006233

To determine HER2 (Human Epidermal Growth Factor Receptor 2) oncoprotein status

Scope: Opinion

Action: For adoption

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. FRESH bulb and Citrus limon FRESH Fruit dry hydroethanolic extract of Theobroma cacao seed dry aqueous extract OF Paullinia cupana seed – H0004155

Treatment of hair loss, in particular androgenetic alopecia and telogen effluvium, in men and women; Treatment of androgenetic alopecia and telogen effluvium, in adults (men and women) from the age of 18 years old; Treatment of moderate to severe Alopecia Areata in children and adolescents (from 2- to 18-year-old).

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. WS2409 Lixiana-EMEA/H/C/002629/WS2409/0042 Roteas-EMEA/H/C/004339/WS2409/0029

Daiichi Sankyo Europe GmbH

Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Nathalie Gault

Scope: "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC with available paediatric data based on final results from study DU176b-D-U312; this is a phase 3, open-label, randomised, multicentre, controlled trial to evaluate the pharmacokinetics and pharmacodynamics of edoxaban and to compare the efficacy and safety of edoxaban with standard-of-care anticoagulant therapy in paediatric subjects from birth to less than 18 years of age with confirmed venous thromboembolism (VTE). The Package Leaflet and Labelling are updated accordingly. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to bring the PI in line with the latest QRD template version 10.3."

Action: For adoption

9.1.2. Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0038, Orphan

Advanz Pharma Limited

Rapporteur: Blanca Garcia-Ochoa

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from studies 747-302 and 747-401, listed as specific obligations in the Annex II, as well as results from real-world evidence (RWE) studies evaluating analyses of hepatic clinical outcomes. Study 747-302 is a confirmatory double-blind, randomised, placebo-controlled multicentre study investigating the clinical benefit associated with Ocaliva treatment in patients with PBC who are either unresponsive or intolerant to UDCA treatment based on clinical endpoints, while study 747-401 is a double-blind, randomised, placebo-controlled study evaluating the safety and pharmacokinetics of Ocaliva in patients with PBC and moderate to severe hepatic impairment. The Annex II and Package Leaflet are updated accordingly."

Action: For adoption

9.1.3. Lamivudine / Zidovudine Teva - Lamivudine / Zidovudine – EMEA/H/C/001236

Teva B.V.; treatment of HIV infection

Rapporteur: Jean-Michel Race

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.4. Pregabalin Zentiva k.s. – pregabalin – EMEA/H/C/004277

Zentiva k.s.; treatment of neuropathic pain, epilepsy and Generalised Anxiety Disorder (GAD)

Rapporteur: Alar Irs

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.5. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0056

Orexigen Therapeutics Ireland Limited

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber

Scope: "Submission of updated study design and protocol synopsis for the CVOT-2 study, a category 1 study listed in Annex II.D (ANX/001.7) undertaken to assess the effect of naltrexone extended release (ER) / bupropion ER on the occurrence of major adverse cardiovascular events (MACE), as requested in the CHMP AR for ANX/001.6. The Annex II and the RMP version 13 are updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 26.01.2023, 15.09.2022, 24.03.2022.

See 2.3

9.1.6. Pioglitazone Teva – Pioglitazone - EMEA/H/C/002297

Teva B.V.

Rapporteur: Finbarr Leacy, Co- Rapporteur: N/A

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.7. Jcovden - COVID-19 vaccine (Ad26.COV2-S [recombinant]) – EMEA/H/C/005737 Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) – EMEA/H/C/005675

Janssen-Cilag International N.V.; AstraZeneca AB

Jcovden: Rapporteur: Christophe Focke, Co-Rapporteur: Sol Ruiz, PRAC Rapporteur: Ulla Wändel Liminga

Vaxzevria: Rapporteur: Sol Ruiz, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné

Scope: Update on products and feedback from PRAC and ETF discussions

Action: For discussion

9.1.8. Beovu - brolucizumab - EMEA/H/C/004913/II/0018

Novartis Europharm Limited

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to introduce an alternative posology regimen for wet AMD and update information based on modelling and simulation studies; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 10.11.2022.

9.1.9. Budesonide/Formoterol Teva Pharma B.V. - budesonide / formoterol fumarate dihydrate - EMEA/H/C/004882/II/0012/G

Teva Pharma B.V., Duplicate of DuoResp Spiromax

Rapporteur: John Joseph Borg, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: quality variation

Action: For adoption

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

March 2023 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. Revision of EMA policy 0044 scientific committee members and experts

Update on EMA policy 0044

Action: For information

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

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

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

Draft agenda for the 28-31 March 2023 PDCO meeting

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry

Reports from BWP March 2023 meeting to CHMP for adoption:

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

Action: For adoption

14.3.2. Nomination of new BMWP members

Nomination of 3 new BMWP members to replace those members who resigned in December 2022. Follow-up discussion from the March 2023 PROM meeting.

Action: For endorsement

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 13-16 March 2023. Table of conclusions

Action: For information

Scientific advice letters:

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

14.3.4. Ad-hoc Influenza Working Group

Scope: EU Strain selection for the Influenza Vaccines for the Season 2023/2024: Report from the Ad Hoc Influenza working group to the BWP

Action: For adoption

Scope: EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2022/2023

Update of the Product Information Annex (description of influenza strains) of Guideline on influenza vaccines - submission and procedural requirements (europa.eu)

Action: For adoption

14.3.5. Election of Vice-Chairperson – Rheumatology and Immunology Working Party

A call for nominations was launched at the February 2023 PROM meeting.

Nomination(s) received

Action: For election

14.3.6. Rheumatology and Immunology Working Party - Q&A on replacement of propellants

Q&A on replacement of propellants (for public consultation)

Action: For adoption

14.3.7. Quality Working Party - Extension of the mandate of Vice-Chair (human)

The current mandate of the QWP human vice-chair Laivi Saaremael (EE) is expiring in April 2023. Follow-up discussion from the March 2023 PROM meeting.

Action: For adoption

14.3.8. Bisphenol A (BPA) EMA-EFSA joint document on divergent opinion (Art. 59)

EFSA has carried out a re-evaluation of risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA has suggested lowering the tolerable daily intake (TDI) for BPA from 4 µg/kg bw to 10 ng/kg bw. During the public consultation EMA provided

comments highlighting diverging views related to various aspects of the EFSA scientific assessment. No agreement was achieved and in line with Art. 59 of EMA founding regulations, EFSA and EMA have therefore drafted a joint document for the European Commission to outline the divergencies.

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. Update of the Business Pipeline report for the human scientific committees

Q1-2023 initial marketing authorisation application submissions with eligibility request to central procedure

Action: For information

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. Presentation on EMA/FDA collaboration and Liaison Programme

Action: For information

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)*

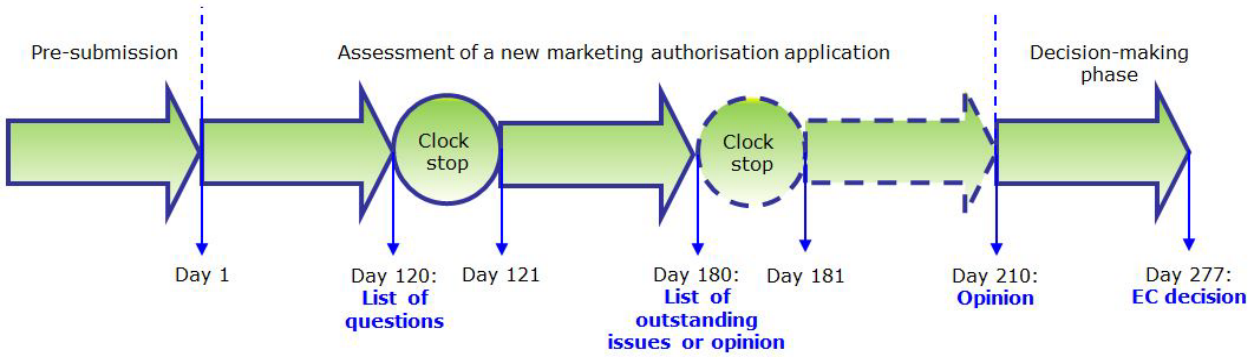
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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 *(section5.3)*

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 Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2023
EMA/CHMP/57111/2023

Annex to 27-30 March 2023 CHMP Agenda

Pre-submission and post-authorisations issues

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for
March 2023: **For adoption**

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

Final Outcome of Rapporteurship allocation for
March 2023: **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

Defitelio - defibrotide -
EMEA/H/C/002393/S/0060, Orphan
Gentium S.r.l., Rapporteur: Kristina Dunder,
PRAC Rapporteur: Mari Thorn

Obizur - susoctocog alfa -
EMEA/H/C/002792/S/0050
Baxalta Innovations GmbH, Rapporteur: Daniela
Philadelphy, PRAC Rapporteur: Gabriele Maurer

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

RXULTI - brexpiprazole -
EMEA/H/C/003841/R/0014
Otsuka Pharmaceutical Netherlands B.V.,
Rapporteur: Armando Genazzani, Co-
Rapporteur: Martina Weise, PRAC Rapporteur:
Lucia Kuráková
Request for Supplementary Information adopted

on 26.01.2023.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Defitelio - defibrotide -
EMEA/H/C/002393/R/0061, Orphan
Gentium S.r.l., Rapporteur: Kristina Dunder, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Hulio - adalimumab -
EMEA/H/C/004429/R/0041
Viatris Limited, Rapporteur: Christophe Focke, Co-Rapporteur: Christian Gartner, PRAC Rapporteur: Ulla Wändel Liminga

Ilumetri - tildrakizumab -
EMEA/H/C/004514/R/0042
Almirall S.A, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Adam Przybylkowski

Kigabeq - vigabatrin -
EMEA/H/C/004534/R/0012
ORPHELIA Pharma SAS, Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Kirsti Villikka

Lojuxta - lomitapide -
EMEA/H/C/002578/R/0054
Amryt Pharmaceuticals DAC, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst
Request for Supplementary Information adopted on 26.01.2023.

Mepsevii - vestronidase alfa -
EMEA/H/C/004438/R/0033, Orphan
Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Maria del Pilar Rayon

Nerlynx - neratinib -
EMEA/H/C/004030/R/0031
Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst
Request for Supplementary Information adopted on 26.01.2023.

Pelgraz - pegfilgrastim -
EMEA/H/C/003961/R/0040

Accord Healthcare S.L.U., Rapporteur: Sol Ruiz, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Menno van der Elst

Slenyto - melatonin - EMEA/H/C/004425/R/0021
RAD Neurim Pharmaceuticals EEC SARL, Rapporteur: Kristina Dunder, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins

Symkevi - tezacaftor / ivacaftor - EMEA/H/C/004682/R/0038, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Rhea Fitzgerald

Verzenios - abemaciclib - EMEA/H/C/004302/R/0025
Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Inês Ribeiro-Vaz

Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/R/0037, Orphan
Jazz Pharmaceuticals Ireland Limited, Rapporteur: Johanna Lähteenvuo, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Inês Ribeiro-Vaz
Request for Supplementary Information adopted on 23.02.2023.

B.2.3. Renewals of Conditional Marketing Authorisations

Kinpeygo - budesonide - EMEA/H/C/005653/R/0003, Orphan
STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Koselugo - selumetinib - EMEA/H/C/005244/R/0010, Orphan
AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga
Request for Supplementary Information adopted on 23.02.2023.

Rozlytrek - entrectinib - EMEA/H/C/004936/R/0015
Roche Registration GmbH, Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno

van der Elst

WAYLIVRA - volanesorsen - EMEA/H/C/004538/R/0022, Orphan
Akcea Therapeutics Ireland Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber
Request for Supplementary Information adopted on 26.01.2023.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 13-16 March 2023
PRAC:

Signal of drug interaction with flucloxacillin leading to subtherapeutic voriconazole levels

Vfend; Voriconazole Accord; Voriconazole Hikma (CAP) – voriconazole

Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Liana Gross-Martirosyan
PRAC recommendation on a variation
Action: For adoption

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

EMEA/H/C/PSUSA/00002253/202207
(oxybutynin)
CAPS:
Kentera (EMEA/H/C/000532) (oxybutynin), Teva B.V., Rapporteur: Karin Janssen van Doorn
NAPS:
NAPs - EU
PRAC Rapporteur: Jo Robays, "17/07/2017 To: 17/07/2022"

EMEA/H/C/PSUSA/00010544/202208 (palbociclib) CAPS: **IBRANCE** (EMEA/H/C/003853) (palbociclib), Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "03/08/2021 To: 02/08/2022"	
EMEA/H/C/PSUSA/00010715/202208 (patisiran) CAPS: **Onpattro** (EMEA/H/C/004699) (patisiran), Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "10/08/2021 To: 09/08/2022"	
EMEA/H/C/PSUSA/00010869/202208 (belantamab mafodotin) CAPS: **Blenrep** (EMEA/H/C/004935) (belantamab mafodotin), GlaxoSmithKline (Ireland) Limited, Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Ulla Wändel Liminga, "05/02/2022 To: 04/08/2022"	
EMEA/H/C/PSUSA/00010983/202208 (voxelotor) CAPS: **Oxbryta** (EMEA/H/C/004869) (voxelotor), Global Blood Therapeutics Netherlands B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jo Robays, "14/02/2022 To: 13/08/2022"	

B.4. EPARs / WPARs

Akeega - niraparib / abiraterone acetate - EMEA/H/C/005932 Janssen-Cilag International N.V., treatment of adult patients with prostate cancer, Fixed combination application (Article 10b of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
BEKEMV - eculizumab - EMEA/H/C/005652 Amgen Technology (Ireland) Unlimited Company, treatment of paroxysmal nocturnal haemoglobinuria, 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.
Elfabrio - pegunigalsidase alfa - EMEA/H/C/005618, Orphan Chiesi Farmaceutici S.p.A., treatment of Fabry	For information only. Comments can be sent to the PL in case necessary.

disease, New active substance (Article 8(3) of Directive No 2001/83/EC)	
HYFTOR - sirolimus - EMEA/H/C/005896, Orphan Plusultra pharma GmbH, Treatment of angiofibroma associated with tuberous sclerosis complex, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Opzelura - ruxolitinib - EMEA/H/C/005843 Incyte Biosciences Distribution B.V., treatment of non-segmental vitiligo, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Raltegravir Viatris - raltegravir potassium - EMEA/H/C/005813 Viatris Limited, treatment of human immunodeficiency virus (HIV-1), Generic, Generic of Isentress, Generic application (Article 10(1) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
Tibsovo - ivosidenib - EMEA/H/C/005936, Orphan Les Laboratoires Servier, treatment of acute myeloid leukaemia and treatment of metastatic cholangiocarcinoma, 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.
Tidhesco - ivosidenib - EMEA/H/C/006174, Orphan Les Laboratoires Servier, treatment of acute myeloid leukaemia, Duplicate, Duplicate of Tibsovo, 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.
Vafseo - vadadustat - EMEA/H/C/005131 AKEBIA EUROPE Limited, treatment of anaemia, 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

Adjupanrix - pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) -	Positive Opinion adopted by consensus on 23.03.2023.

EMEA/H/C/001206/II/0081/G GlaxoSmithkline Biologicals SA, Informed Consent of Pandemrix (EXP), Rapporteur: Johann Lodewijk Hillege Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 19.01.2023.	
Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0046/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 19.01.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Aranesp - darbepoetin alfa - EMEA/H/C/000332/II/0163 Amgen Europe B.V., Rapporteur: Martina Weise Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 02.02.2023.	Positive Opinion adopted by consensus on 09.03.2023.
Armisarte - pemetrexed - EMEA/H/C/004109/II/0030/G Actavis Group PTC ehf, Rapporteur: Alar Irs Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 15.12.2022, 22.09.2022.	Positive Opinion adopted by consensus on 23.03.2023.
Aybintio - bevacizumab - EMEA/H/C/005106/II/0016 Samsung Bioepis NL B.V., Rapporteur: Christian Gartner Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 12.01.2023.	Positive Opinion adopted by consensus on 09.03.2023.
Budesonide/Formoterol Teva Pharma B.V. - budesonide / formoterol fumarate dihydrate - EMEA/H/C/004882/II/0012/G Teva Pharma B.V., Duplicate, Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, PRAC Rapporteur: Marie Louise Schougaard Christiansen	See 9.1
CEVENFACTA - eptacog beta (activated) - EMEA/H/C/005655/II/0001 Laboratoire Francais du Fractionnement et des Biotechnologies, Rapporteur: Daniela Philadelphy Opinion adopted on 16.03.2023. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 16.03.2023.

on 24.11.2022.	
COMIRNATY - tozinameran - EMEA/H/C/005735/II/0167 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0025/G, Orphan GW Pharma (International) B.V., Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 23.03.2023.	Request for supplementary information adopted with a specific timetable.
EVUSHELD - tixagevimab / cilgavimab - EMEA/H/C/005788/II/0007/G AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus	
EXPAREL liposomal - bupivacaine - EMEA/H/C/004586/II/0011/G Pacira Ireland Limited, Rapporteur: Elita Poplavska Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Foclivia - pandemic influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/001208/II/0079 Seqirus S.r.l, Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 10.11.2022.	
Hemlibra - emicizumab - EMEA/H/C/004406/II/0033 Roche Registration GmbH, Rapporteur: Alexandre Moreau Opinion adopted on 02.03.2023. Request for Supplementary Information adopted on 12.01.2023.	Positive Opinion adopted by consensus on 02.03.2023.
Hepcludex - bulevirtide - EMEA/H/C/004854/II/0023/G, Orphan Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0143 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 16.02.2023.	Positive Opinion adopted by consensus on 23.03.2023.

Idacio - adalimumab - EMEA/H/C/004475/II/0018/G Fresenius Kabi Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 23.03.2023.	Request for supplementary information adopted with a specific timetable.
Idefirix - imlifidase - EMEA/H/C/004849/II/0010, Orphan Hansa Biopharma AB, Rapporteur: Martina Weise Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 19.01.2023.	Positive Opinion adopted by consensus on 23.03.2023.
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0084/G Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 09.02.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Instanyl - fentanyl - EMEA/H/C/000959/II/0075 Takeda Pharma A/S, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 02.03.2023.	Request for supplementary information adopted with a specific timetable.
Lunsumio - mosunetuzumab - EMEA/H/C/005680/II/0002/G, Orphan Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia	
Menveo - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/001095/II/0115/G GSK Vaccines S.r.l, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 02.03.2023. Request for Supplementary Information adopted on 12.01.2023.	Positive Opinion adopted by consensus on 02.03.2023.
Methylthioninium chloride Proveblue - methylthioninium chloride - EMEA/H/C/002108/II/0055/G Provepharm SAS, Rapporteur: Kristina Dunder	
Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0120/G Pfizer Europe MA EEIG, Rapporteur: Ingrid	

Wang Request for Supplementary Information adopted on 15.12.2022.	
Nucala - mepolizumab - EMEA/H/C/003860/II/0057/G GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 23.03.2023.	Request for supplementary information adopted with a specific timetable.
Nuceiva - botulinum toxin type a - EMEA/H/C/004587/II/0029 Evolus Pharma B.V., Rapporteur: Finbarr Leacy	
Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0035/G Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 12.01.2023.	
Padcev - enfortumab vedotin - EMEA/H/C/005392/II/0005/G Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 15.12.2022.	Positive Opinion adopted by consensus on 23.03.2023.
Privigen - human normal immunoglobulin - EMEA/H/C/000831/II/0195 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 16.02.2023.	Positive Opinion adopted by consensus on 23.03.2023.
QUVIVIQ - daridorexant - EMEA/H/C/005634/II/0007/G Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau	
Rapiscan - regadenoson - EMEA/H/C/001176/II/0041/G GE Healthcare AS, Rapporteur: Maria Concepcion Prieto Yerro Request for Supplementary Information adopted on 15.12.2022.	
Replagal - agalsidase alfa - EMEA/H/C/000369/II/0122 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Johann Lodewijk	Positive Opinion adopted by consensus on 23.03.2023.

Hillege Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 16.02.2023, 12.01.2023.	
Spikevax - elasomeran - EMEA/H/C/005791/II/0094/G Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Supemtek - influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0010/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 02.02.2023.	Positive Opinion adopted by consensus on 16.03.2023.
TachoSil - human thrombin / human fibrinogen - EMEA/H/C/000505/II/0119/G Corza Medical GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
TEPADINA - thiotepa - EMEA/H/C/001046/II/0046/G ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 09.02.2023.	
Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0115 MCM Vaccine B.V., Rapporteur: Christophe Focke Opinion adopted on 23.03.2023.	Positive Opinion adopted by consensus on 23.03.2023.
Vazkepa - icosapent ethyl - EMEA/H/C/005398/II/0009/G Amarin Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 15.12.2022, 01.09.2022.	Positive Opinion adopted by consensus on 16.03.2023.
Xenpozyme - olipudase alfa - EMEA/H/C/004850/II/0002/G, Orphan Genzyme Europe BV, Rapporteur: Johann	Positive Opinion adopted by consensus on 23.03.2023.

Lodewijk Hillege Opinion adopted on 23.03.2023. Request for Supplementary Information adopted on 02.02.2023.	
WS2359 **HyQvia-EMEA/H/C/002491/WS2359/0085** **Kiovig-EMEA/H/C/000628/WS2359/0120** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 02.03.2023. Request for Supplementary Information adopted on 08.12.2022.	Positive Opinion adopted by consensus on 02.03.2023.
WS2390 **Januvia-EMEA/H/C/000722/WS2390/0080** **Ristaben-EMEA/H/C/001234/WS2390/0074** **Steglujan-EMEA/H/C/004313/WS2390/0019** **TESAVEL-EMEA/H/C/000910/WS2390/0080** **Xelevia-EMEA/H/C/000762/WS2390/0088** Merck Sharp & Dohme B.V., Lead Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 16.02.2023.	

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

Amglidia - glibenclamide - EMEA/H/C/004379/II/0015, Orphan Ammtek, Rapporteur: Martina Weise, "Update of section 5.1 of the SmPC in order to update information regarding sulphonylurea effects on neurological abnormalities in children and adults with KCNJ11- and ABCC8-related neonatal diabetes based on literature." Request for Supplementary Information adopted on 23.03.2023, 09.02.2023.	Request for supplementary information adopted with a specific timetable.
Brintellix - vortioxetine - EMEA/H/C/002717/II/0038 H. Lundbeck A/S, Rapporteur: Karin Janssen van Doorn, "Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to include clinically relevant information on the efficacy, safety, tolerability and PK of vortioxetine in the paediatric population based on final results from studies 12709A, 12712A and 12712B. Study 12709A is an interventional, randomized,	

double-blind, placebo-controlled, active-reference (fluoxetine), fixed-dose study of vortioxetine in paediatric patients aged 7 to 11 years, with Major Depressive Disorder (MDD) to evaluate efficacy and safety. Whereas studies 12712A and 12712B are 2 open-label, long-term safety and efficacy studies in children and adolescents: one 6-month extension study (study 12712A) to studies 12709A and 12710A, and one 18-month extension study (study 12712B) to study 12712A. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 15.12.2022.	
Calquence - acalabrutinib - EMEA/H/C/005299/II/0015 AstraZeneca AB, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC based on the interim report of study ACE-CL-007; a randomized, multicentre, open-Label, 3-arm phase 3 study of obinutuzumab in combination with chlorambucil, ACP-196 in combination with obinutuzumab, and ACP-196 monotherapy in subjects with previously untreated chronic lymphocytic leukaemia." Request for Supplementary Information adopted on 23.03.2023, 15.12.2022.	Request for supplementary information adopted with a specific timetable.
Dovprela - pretomanid - EMEA/H/C/005167/II/0013, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, "Update of sections 4.8 and 5.1 of the SmPC in order to update frequency information of several adverse drug reactions (ADRs) as well as to update clinical efficacy information based on final results from study ZeNix (NC007) listed as a specific obligation (SOB/001) in the Annex II. This is a Phase III Partially-Blinded, Randomized Trial Assessing the Safety and Efficacy of Various Doses and Treatment Durations of Linezolid plus Bedaquiline and Pretomanid in Participants with Pulmonary Infection of Either Extensively DrugResistant Tuberculosis (XDRTB), pre-XDR-TB or Treatment Intolerant or NonResponsive Multi-Drug Resistant Tuberculosis (MDRTB)-ZeNix study. The Annex II and Package Leaflet are updated accordingly. 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."	
Evoltra - clofarabine - EMEA/H/C/000613/II/0077 Sanofi B.V., 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." Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 12.01.2023, 08.09.2022.	Positive Opinion adopted by consensus on 09.03.2023.
EVOTAZ - atazanavir / cobicistat - EMEA/H/C/003904/II/0044 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, "Update of section 4.5 of the SmPC in order to update drug-drug interaction (DDI) information related to the co-administration with antiplatelet therapies classified as P2Y12 platelet inhibitors as well as the co-administration with dexamethasone and other corticosteroids. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
IBRANCE - palbociclib - EMEA/H/C/003853/II/0040 Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to update efficacy and safety information based on final OS results from study A5481008 (PALOMA-2, "A Randomized, Multicenter, Double-blind Phase 3 Study of PD-0332991 (Oral CDK 4/6 Inhibitor) Plus Letrozole Versus Placebo Plus Letrozole for the Treatment of Postmenopausal Women with ER (+), HER2 (-) Breast Cancer Who Have Not Received Any Prior Systemic Anti-Cancer Treatment For Advanced Disease") to fulfil REC 2. In addition, the MAH took the opportunity to align Annex II with the current QRD template." Request for Supplementary Information adopted on 02.02.2023.	
Imnovid - pomalidomide - EMEA/H/C/002682/II/0050, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, "Update of section 5.1 of	

the SmPC in order to update efficacy and safety information following the assessment of II/0031/G based on OS results from study CC-4047-MM-007 listed as PAES in the Annex II; this is to further investigate the efficacy of pomalidomide in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide."	
Jevtana - cabazitaxel - EMEA/H/C/002018/II/0049 Sanofi Winthrop Industrie, Rapporteur: Alexandre Moreau, "Update of sections 4.6 and 5.3 of the SmPC in order to introduce a genotoxicity mechanism update and a contraception update based on the safety working party recommendations on the duration of contraception following the end of treatment with a genotoxic drug. The Package Leaflet is updated accordingly."	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0128 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "Update of section 5.1 of the SmPC in order to update information based on the final OS data for the overall population as well as for MMR subgroups from study 309/KEYNOTE-775 in order to fulfil the Recommendation: REC/033. This Recommendation was agreed to with the approval of study 309/KEYNOTE-775; this is a multicentre, open-label, randomized, phase 3 trial to compare the efficacy and safety of lenvatinib in combination with pembrolizumab versus treatment of physician's choice in participants with advanced endometrial cancer." Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 19.01.2023.	Positive Opinion adopted by consensus on 09.03.2023.
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0132 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "Update of section 4.8 of the SmPC in order to add optic neuritis to the list of adverse drug reactions (ADRs) with frequency rare based on literature review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to	Positive Opinion adopted by consensus on 16.03.2023.

introduce editorial changes to the PI." Opinion adopted on 16.03.2023.	
Lenvima - lenvatinib - EMEA/H/C/003727/II/0049 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "Update of section 5.1 of the SmPC in order to update the efficacy information of "Endometrial carcinoma" based on the final OS analysis data for the overall population as well as for MMR subgroups from study E7080-G000-309 / KEYNOTE-775. This is a Multicenter, Open-label, Randomized, Phase III study to compare the efficacy and safety of lenvatinib in combination with pembrolizumab versus treatment of physician's choice in participants with advanced endometrial cancer. In addition, the MAH took the opportunity to implement editorial changes in the SmPC." Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 19.01.2023.	Positive Opinion adopted by consensus on 09.03.2023.
Lupkynis - voclosporin - EMEA/H/C/005256/II/0005 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, "Update of sections 4.5 and 5.2 of the SmPC in order to update safety information based on final results from study AUR-VCS-2021-02 / Statin-DDI listed as REC in the Letter of Recommendation and study AUR-VCS-2016-02. AUR-VCS-2021-02 / Statin-DDI is an in-vivo DDI study, investigating the effects of voclosporin on simvastatin and its active metabolite simvastatin acid as substrates for OATP1B1/OATP1B3 and AUR-VCS-2016-02 was to show long-term (3 years) safety data from subjects receiving voclosporin and concomitant statins." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Lynparza - olaparib - EMEA/H/C/003726/II/0057 AstraZeneca AB, Rapporteur: Alexandre Moreau, "Update of sections 4.8 and 5.1 of the SmPC in order to update the long-term safety data and the final OS analysis from PAOLA-1 study (D0817C00003). This is a Randomized, Double-Blind, Phase III Trial of Olaparib vs. Placebo in Patients with Advanced FIGO Stage IIIB – IV	

High Grade Serous or Endometrioid Ovarian, Fallopian Tube, or Peritoneal Cancer Treated with Standard First Line Treatment, Combining Platinum-Taxane Chemotherapy and Bevacizumab Concurrent with Chemotherapy and in Maintenance. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 26.01.2023.	
Lynparza - olaparib - EMEA/H/C/003726/II/0059 AstraZeneca AB, Rapporteur: Alexandre Moreau, "Submission of the final report from study AME02164. This is a Genetic Toxicity Evaluation using a Bacterial Reverse Mutation Test with Salmonella typhimurium LT2 Strains TA1535, TA1537, TA98 and TA100, and Escherichia coli WP2 Strain uvrA/pKM101."	
Methylthioninium chloride Proveblue - methylthioninium chloride - EMEA/H/C/002108/II/0054 Provepharm SAS, Rapporteur: Kristina Dunder, "Submission of the final report from studies PVP-2016003 and HQF-METHB-2018001. PVP-2016003 is an Open-label clinical study to evaluate the safety and efficacy of ProvayBlue (methylene blue) for the treatment of acquired methemoglobinemia (MEBIPAM); while HQF-METHB-2018001 is a prospective, observational registry designed to collect real world data regarding the safety and efficacy of ProvayBlue." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Methylthioninium chloride Proveblue - methylthioninium chloride - EMEA/H/C/002108/II/0056 Provepharm SAS, Rapporteur: Kristina Dunder, "Update of section 4.5 of the SmPC in order to add information regarding potential increase of the risk of serotonin syndrome when used in combination with opioids, as well as, to add information regarding the potent reversible MAO Inhibitory activity of Methylthioninium chloride based on post-marketing data and literature; the Package Leaflet is updated accordingly."	
MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/II/0018/G	

Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, "Grouped application comprising three type II variations as follows: - Update of sections 4.8 and 5.1 of the SmPC in order to add crying, screaming and hyperhidrosis to the list of adverse drug reactions (ADRs) in children with frequency very common, common and common, respectively and to add immunogenicity data from study VAC52150EBL2004 (PREVAC), listed as a study 3 in the agreed PIP. This was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 study conducted at multiple sites in West Africa to investigate the immunogenicity and safety of 3 Ebola vaccine regimens versus placebo in adults (aged ≥18 years), adolescents (aged 12-17 years), and children (2 age strata: 5-11 years and 1-4 years) who never received a candidate Ebola vaccine (self-report) and had no history of Ebola virus disease (self-report). - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add interim safety and immunogenicity data from study VAC52150EBL2005, a study conducted by the MAH in infants 4-11 months of age. - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add final safety and immunogenicity data from study VAC52150EBL2011, a study in which an Ad26.ZEBOV booster dose was evaluated in children 1 to 11 years of age (at the time of first vaccination in EBL3001). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes and update the contact details of the local representatives in the Package Leaflet."	
Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0038, Orphan Advanz Pharma Limited, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from studies 747-302 and 747-401, listed as specific obligations in the Annex II, as well as results from real-world evidence (RWE) studies evaluating analyses of hepatic clinical outcomes. Study 747-302 is a confirmatory double-blind, randomised, placebo-controlled multicentre study investigating the clinical benefit associated with Ocaliva treatment in patients	See 9.1

with PBC who are either unresponsive or intolerant to UDCA treatment based on clinical endpoints, while study 747-401 is a double-blind, randomised, placebo-controlled study evaluating the safety and pharmacokinetics of Ocaliva in patients with PBC and moderate to severe hepatic impairment. The Annex II and Package Leaflet are updated accordingly."	
Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0036 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.4 and 4.5 of the SmPC in order to include a warning related to Immunosuppressants and to update the information regarding co-administration with Immunosuppressants following the assessment of procedure II/0010/G based on the cumulative review of the spontaneous reports of over-exposure/over-toxicity of immunosuppressants and literature review. In addition, the MAH took this opportunity to introduce minor editorial changes to the Package Leaflet."	
Plegridy - peginterferon beta-1A - EMEA/H/C/002827/II/0068 Biogen Netherlands B.V., Rapporteur: Johann Lodewijk Hillege, "Update of section 4.6 of the SmPC in order to update the information relating to secretion in human milk based on the results from study US-PEG-15-10936, a prospective, open label, post marketing study that measured Plegridy concentrations in breast milk in 6 lactating patients with Multiple Sclerosis. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Reblozyl - luspatercept - EMEA/H/C/004444/II/0016, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphy, "Update of section 5.1 of the SmPC in order to reflect the correct values of late-reported transfusions and modifications of previously reported transfusions based on final results from study ACE-536-B-THAL-001 (BELIEVE), A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study To Determine The Efficacy And Safety Of Luspatercept (Ace-536) Versus Placebo In Adults Who Require Regular Red Blood Cell	Request for supplementary information adopted with a specific timetable.

Transfusions Due To Beta-Thalassemia." Request for Supplementary Information adopted on 16.03.2023.	
Retsevmo - selpercatinib - EMEA/H/C/005375/II/0016 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to add chylothorax and chylous ascites to the list of adverse drug reactions (ADRs) based on a review of adverse events. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 19.01.2023, 06.10.2022.	
Rydapt - midostaurin - EMEA/H/C/004095/II/0029, Orphan Novartis Europharm Limited, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add "Acute febrile neutrophilic dermatosis (Sweet syndrome)" to the list of adverse drug reactions (ADRs) with frequency not known based on pre-clinical data, clinical trial datasets, scientific literature and safety databases. The Package Leaflet is updated accordingly."	
SARCLISA - isatuximab - EMEA/H/C/004977/II/0020 Sanofi Winthrop Industrie, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update an existing warning on 'second primary malignancies', update the list of adverse drug reactions (ADRs) and update the efficacy and safety information based on final OS analysis from ICARIA study (EFC14335), following a recommendation by the CHMP during the initial MAA. This is a phase 3 randomized, open-label, multicenter study designed to assess the efficacy, safety, and pharmacokinetics (PK) of isatuximab in combination with pomalidomide and low-dose dexamethasone (IPd) compared with pomalidomide and low-dose dexamethasone (Pd) in patients with refractory or relapsed and refractory multiple myeloma."	
Spectrila - asparaginase - EMEA/H/C/002661/II/0032/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian Gartner, "Grouped Variation (Type II & Type	Positive Opinion adopted by consensus on 09.03.2023.

IB): C.I.4: Update of sections 4.4 and 4.6 of the SmPC in order to include the recommendations from the SWP regarding genotoxic medicinal products and contraception duration period; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.6.b: Deletion of the indication lymphoblastic lymphoma (LBL) in section 5.3 of the SmPC, as Spectrila is not approved for LBL." Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 19.01.2023.	
Spikevax - elasomeran - EMEA/H/C/005791/II/0088 Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from study DMID 20-0003 listed as a category 3 study in the RMP. This is a Phase I, Open Label, Dose-ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults." Request for Supplementary Information adopted on 19.01.2023.	
Spikevax - elasomeran - EMEA/H/C/005791/II/0093 Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report 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'." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Symtuza - darunavir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004391/II/0048 Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, "Submission of the final report from study TMC114FD2HTX3002 (DIAMOND). This is a phase 3, single-arm, open-label study to evaluate the efficacy and safety of	Positive Opinion adopted by consensus on 16.03.2023.

darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once daily fixed-dose combination (FDC) regimen in newly diagnosed, antiretroviral treatment-naïve human immunodeficiency virus type 1 (HIV-1) infected subjects receiving care in a test and treat model of care." Opinion adopted on 16.03.2023.	
Synagis - palivizumab - EMEA/H/C/000257/II/0132 AstraZeneca AB, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.2 and 5.1 of the SmPC in order to update safety information based on results from safety data evaluations from multiple sources, including the clinical study W00-350, post-Marketing Clinical Surveillance Programme (REACH), literature searches and the AstraZeneca Global Patient Safety database."	
TAGRISSO - osimertinib - EMEA/H/C/004124/II/0050 AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to modify the posology recommendations in the case of toxic epidermal necrolysis (TEN), add it as a new warning and add it to the list of adverse drug reactions (ADRs) with frequency uncommon and to update the frequency of interstitial lung disease (ILD) based on an internal safety information review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/II/0003/G SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, "Grouped application consisting of the submission of the final reports from the following five non-clinical studies: 9603766 (SG2 material), 9603767 (SG2 Dimer material), 9603768 (SG1 material), 9603769 (SG1 exo-isomer material) and 9603770 (Maleic Anhydride material). These are genotoxicity studies for active drug substance impurities/degradants." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Tegsedi - inotersen -	Positive Opinion adopted by consensus on

EMEA/H/C/004782/II/0034, Orphan Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, "Submission of the final report from study ISIS 420915-CS3, listed as a category 3 in the RMP. This is an Open-Label Extension Study to Assess the Long-Term Safety and Efficacy of ISIS 420915 in Patients with Familial Amyloid Polyneuropathy (FAP)." Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 08.12.2022.	09.03.2023.
TEZSPIRE - tezepelumab - EMEA/H/C/005588/II/0004 AstraZeneca AB, Rapporteur: Finbarr Leacy, "Submission of the final report detailing the extended follow-up data from study D5180C00018 (DESTINATION) listed as a category 3 study in the RMP; this is a multicentre, randomised, double-blind, placebo-controlled, parallel group, long term extension study designed to evaluate the safety and efficacy of 210 mg Q4W subcutaneous of tezepelumab in adults and adolescents with severe uncontrolled asthma for up to 2 continuous years of treatment." Request for Supplementary Information adopted on 26.01.2023.	
Trajenta - linagliptin - EMEA/H/C/002110/II/0049 Boehringer Ingelheim International GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2, 4.8, 5.1, and 5.2 of the SmPC in order to update information on paediatric population based on final results from study DINAMO 1218-0091; this is a Phase III double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. The Package Leaflet is updated accordingly."	
Translarna - ataluren - EMEA/H/C/002720/II/0068, Orphan PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.1 of the SmPC in order to update efficacy information upon the request by the CHMP following the outcome of P46/026 based	Positive Opinion adopted by consensus on 16.03.2023.

on final results from study PTC124-GD-045-DMD (study 045); this is an open-label, single-arm, phase 2 study designed to evaluate the ability of ataluren treatment to increase dystrophin protein levels in muscle cells of subjects with nonsense mutation duchenne muscular dystrophy (nmDMD)." Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 08.12.2022, 06.10.2022.	
Ultomiris - ravulizumab - EMEA/H/C/004954/II/0034 Alexion Europe SAS, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study ALXN1210-PNH-302, a Phase III, randomised, open-label, active controlled study of ALXN1210 versus eculizumab in adult patients with paroxysmal nocturnal hemoglobinuria (PNH) currently treated with eculizumab, listed as a category 3 study in the RMP. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Vaxneuvance - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) - EMEA/H/C/005477/II/0011 Merck Sharp & Dohme B.V., Rapporteur: Johann Lodewijk Hillege, "To update sections 4.2 and 5.1 of the SmPC in order to update the information for immune response after subcutaneous administration based on final results from study V114-P033 (EudraCT: 2019-003644-68), in accordance with Article 46 of the paediatric regulation. V114-P033 is a phase 3 Active-Comparator controlled study to evaluate the Safety, Tolerability, and Immunogenicity of V114 in Healthy Japanese Infants. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 26.01.2023.	
Veklury - remdesivir - EMEA/H/C/005622/II/0045 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update clinical virology information based on results of the phenotypic analysis of	Positive Opinion adopted by consensus on 16.03.2023.

the nsp12 substitutions that emerged post-treatment in study GS-US-540-5773, including T76I, A526V, A554V, E665K and C697F." Opinion adopted on 16.03.2023.	
Velphoro - iron - EMEA/H/C/002705/II/0028 Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.1 of the SmPC, upon request by the PRAC following the assessment of PSUSA/00010296/202111, to include information on the effect on iron parameters and haemoglobin, based on results from the previously submitted post-hoc analysis of study PA-CL-05A; a Phase 3, open-label, randomised, active-controlled, parallel group, multicentre clinical study, and its extension study PA-CL-05B." Request for Supplementary Information adopted on 15.12.2022.	
Venclyxto - venetoclax - EMEA/H/C/004106/II/0045 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Submission of the final report from study M14-032 'A Phase 2 Open-Label Study of the Efficacy and Safety of Venetoclax ABT-199 (GDC-0199) in Chronic Lymphocytic Leukaemia Subjects with Relapse of Refractory to B-Cell Receptor Signalling Pathway Inhibitor Therapy' listed as a category 3 study in the RMP." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Vipidia - alogliptin - EMEA/H/C/002182/II/0035 Takeda Pharma A/S, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information following positive opinion of procedure P46/013 and confirmation of full compliance of PIP EMEA-000496-PIP01-08-M08 based on reports from studies SYR-322_104 and SYR-322_309. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes."	
VPRIV - velaglucerase alfa -	Request for supplementary information adopted

EMEA/H/C/001249/II/0054 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, "Submission of the final report from study SHP-GCB-402: a multicenter, open-label, single-arm, phase 4 study designed to prospectively evaluate the effects of VPRIV on bone-related pathology in treatment-naïve subjects with type 1 Gaucher disease." Request for Supplementary Information adopted on 23.03.2023, 12.01.2023, 28.04.2022.	with a specific timetable.
Xevudy - sotrovimab - EMEA/H/C/005676/II/0014 Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update sections 4.4 and 5.1 of the SmPC to update information on epitope conservation and activity of sotrovimab against pseudotyped virus encoding epitope variants as well as to update information on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron BA.4.6 spike variant, the Omicron BQ.1.1 spike variant and the Omicron BQ.1, BF.7, BA.2.75.2 and XBB.1 spike Variants based on final results from studies PC-7831-0143 v15, PC-22-0130, PC-22-0142, PC-22-0145. In addition, the MAH took the opportunity implement editorial changes in the SmPC."	
Xevudy - sotrovimab - EMEA/H/C/005676/II/0015 Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to update clinical information based on a systematic literature review of observational studies evaluating the real world effectiveness of sotrovimab for treatment of SARS-CoV-2 infection during the period when the SARS-CoV-2 Omicron BA.2 sub-variant was dominant."	
ZABDENO - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/II/0015/G Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, "Grouped application comprising three type II variations as follows: - Update of sections 4.8 and 5.1 of the SmPC in order to add crying, screaming and hyperhidrosis to the list of adverse drug reactions (ADRs) in children with frequency very	

common, common and common, respectively and to add immunogenicity data from study VAC52150EBL2004 (PREVAC), listed as a study 3 in the agreed PIP. This was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 study conducted at multiple sites in West Africa to investigate the immunogenicity and safety of 3 Ebola vaccine regimens versus placebo in adults (aged ≥18 years), adolescents (aged 12-17 years), and children (2 age strata: 5-11 years and 1-4 years) who never received a candidate Ebola vaccine (self-report) and had no history of Ebola virus disease (self-report). - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add interim safety and immunogenicity data from study VAC52150EBL2005, a study conducted by the MAH in infants 4-11 months of age. - Update of sections 4.2, 4.8 and 5.1 of the SmPC to add final safety and immunogenicity data from study VAC52150EBL2011, a study in which an Ad26.ZEBOV booster dose was evaluated in children 1 to 11 years of age (at the time of first vaccination in EBL3001). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes and update the contact details of the local representatives in the Package Leaflet."	
WS2377 **Jentadueto-** **EMEA/H/C/002279/WS2377/0067** **Synjardy-** **EMEA/H/C/003770/WS2377/0067** Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Vitamin B12 decrease or deficiency and to update the list of adverse drug reactions (ADRs) in accordance with the recent update of the PI for Glucophage, which is the reference label for the compound metformin, and following the request by MHRA on 20 June 2022 for all products containing metformin; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet." Opinion adopted on 02.03.2023.	Positive Opinion adopted by consensus on 02.03.2023.

Request for Supplementary Information adopted on 12.01.2023.	
WS2418 **Lyxumia-EMEA/H/C/002445/WS2418/0039** **Suliqua-EMEA/H/C/004243/WS2418/0030** Sanofi Winthrop Industrie, Lead Rapporteur: Kristina Dunder, "Update of section 4.4 of the SmPC in order to add a new special warning on acute gallbladder disease based on cumulative review of the pharmacovigilance databases, worldwide scientific literature, labelling documents of other GLP-1RAs, and biological plausibility. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	

B.5.3. CHMP-PRAC assessed procedures

AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0042 Sanofi Winthrop Industrie, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Submission of the final report from study EFC11759 listed as a category 3 study in the RMP. This is a two-year, multicentre, randomized, double-blind, placebo-controlled, parallel group trial to evaluate efficacy, safety, tolerability and pharmacokinetics of teriflunomide administered orally once daily in paediatric patients with relapsing forms of multiple sclerosis (MS) followed by an open-label extension. The RMP version 8.0 has also been submitted." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Beovu - brolucizumab - EMEA/H/C/004913/II/0018 Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 5.1 of the SmPC in order to introduce an alternative posology regimen for wet AMD and update information based on modelling and simulation studies; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted." Request for Supplementary Information adopted	See 9.1

on 10.11.2022.	
Carbaglu - carglumic acid - EMEA/H/C/000461/II/0045 Recordati Rare Diseases, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of sections 4.2, 4.4 and 5.2 of the SmPC in order to include a proposed dose adjustment for patients with impaired renal function based on final results from study RCD-P0-027; this is a Phase I, multicentre, 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 implement editorial changes in Annex II and Labelling, and to bring the PI in line with the latest QRD template version 10.3."	
Coagadex - human coagulation factor X - EMEA/H/C/003855/II/0046, Orphan BPL Bioproducts Laboratory GmbH, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst, "Submission of the final report from study TEN06 - NCT03161626 (REC EMEA/H/C/003855). This is a non-interventional, multicentre, post-marketing registry study in three patients with moderate or severe hereditary FX deficiency, to assess Coagadex administered peri-operatively for haemostatic cover in major surgery during routine post-marketing use. The primary objective is to collect additional surgical data on the clinical effectiveness of Coagadex, in a post-marketing environment, for peri-operative haemostatic cover during major surgery in patients with moderate or severe hereditary factor X (FX) deficiency. The RMP version 3.0 has also been submitted." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Evicel - human fibrinogen / human thrombin - EMEA/H/C/000898/II/0099 Omrix Biopharmaceuticals N. V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of adverse drug reactions (ADRs), add pseudomeningocele to the list of ADRs with	Positive Opinion adopted by consensus on 16.03.2023.

frequency uncommon and to update efficacy and safety information on paediatric population, following P46/0030 based on the final results from paediatric clinical study BIOS-13-006. This is a Prospective Randomised Controlled Study Evaluating the Safety and Efficacy of EVICEL used for Suture-Line Sealing in Dura-Mater Closure during Paediatric Neurosurgical Cranial Procedures. The Package Leaflet is updated accordingly. Editorial changes are proposed to sections of the product information. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3. The RMP version 15.0 has also been submitted." Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 12.01.2023.	
Fintepla - fenfluramine - EMEA/H/C/003933/II/0015, Orphan Zogenix ROI Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "To update sections 4.2 and 5.2 of the SmPC to update the safety information based on final results from study ZX008-1903 listed as a category 3 study in the RMP; this is a Phase 1, Open-Label, Single-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ZX008 (Fenfluramine Hydrochloride) in Subjects with Varying Degrees of Hepatic Impairment. The primary objective of this study was to compare the PK of a single dose of ZX008 (fenfluramine HCl) in subjects with varying degrees of hepatic impairment with that of healthy matched control subjects. The updated RMP version 2.7 has also been submitted." Request for Supplementary Information adopted on 12.01.2023, 29.09.2022.	
GAVRETO - pralsetinib - EMEA/H/C/005413/II/0012 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.4 and 4.5 of the SmPC in order to amend posology recommendations, warnings and drug-drug interaction information regarding the co-administration with CYP3A4 inhibitors, P-gp	

inhibitors and CYP3A4 inducers based on final results from the DDI study GP43162, listed as a category 3 study in the RMP, as well as results from the physiologically based pharmacokinetic (PBPK) analyses summarised in the PBPK Report 1120689. Study GP43162 is a phase 1, open-label, fixed-sequence study to evaluate the effect of a single dose of cyclosporine on the single dose pharmacokinetics of pralsetinib in healthy subjects. The RMP version 1.6 has also been submitted."	
Lumykras - sotorasib - EMEA/H/C/005522/II/0007 Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.2 and 5.2 of the SmPC in order to update recommendations for patients with moderate to severe hepatic impairment following final results from study 20200362 listed as a category 3 PASS study in the EU RMP; this is a Phase I clinical study to evaluate the pharmacokinetics (PK) of a single oral dose of sotorasib administered in subjects with moderate or severe hepatic impairment compared with subjects who have normal hepatic function. The EU RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
MINJUVI - tafasitamab - EMEA/H/C/005436/II/0008, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.4 of the SmPC in order to add a new warning on Progressive Multifocal Leukoencephalopathy (PML) based on post-marketing data; the Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to bring the PI in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.

Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0056 Orexigen Therapeutics Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "Submission of updated study design and protocol synopsis for CVOT-2 study, a category 1 study listed in Annex II.D (ANX/001.7) undertaken to assess the effect of naltrexone extended release (ER) / bupropion ER on the occurrence of major adverse cardiovascular events (MACE), as requested in the CHMP AR for ANX/001.6. The Annex II and the RMP version 13 are updated accordingly." Request for Supplementary Information adopted on 26.01.2023, 15.09.2022, 24.03.2022.	See 9.1 and 2.3
Natpar - parathyroid hormone - EMEA/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." Request for Supplementary Information adopted on 10.11.2022, 21.07.2022.	
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0057 MediWound Germany GmbH, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the 24-months' CSR addendum of the MW2010-03-02 (DETECT) category 1 study; a multicentre, multinational, randomized, controlled, assessor blinded study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to gel vehicle and compared to standard of care. The	

provision of the CSR addresses the post-authorisation measure ANX 001.7. An updated RMP version 8.0 was provided as part of the application." Request for Supplementary Information adopted on 23.02.2023, 10.11.2022.	
Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0034/G Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study BN29739 (VELOCE) listed as a category 3 study in the RMP. This is a phase 3b, multicentre, randomized, parallel-group, open-label study to evaluate the effectiveness of vaccinations in patients with relapsing forms of multiple sclerosis (RMS) undergoing treatment with ocrelizumab. Submission of the final report from studies MA30005 (CASTING) and MN30035 (CHORDS). These are prospective, multicenter, international, interventional, open-label phase 3b studies to assess the efficacy and safety of ocrelizumab in patients with relapsing multiple sclerosis who have a suboptimal response to an adequate course of disease-modifying treatment. The RMP version 8.0 has also been submitted." Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 01.12.2022.	Positive Opinion adopted by consensus on 16.03.2023.
Padcev - enfortumab vedotin - EMEA/H/C/005392/II/0007 Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Eva Jirsová, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to introduce new posology recommendations in case of pneumonitis/interstitial lung disease (ILD), add a new warning on 'pneumonitis/ILD' and add it to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Piqray - alpelisib - EMEA/H/C/004804/II/0018 Novartis Europharm Limited, Rapporteur: Blanca	Request for supplementary information adopted with a specific timetable.

Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.5 and 5.2 of the SmPC in order to update drug-drug interaction information, based on final results from study BYL719A2111; this is a phase 1, open-label, fixed-sequence, two-period drug-drug interaction (DDI) study evaluating the PK probe substrates for CYP3A4, CYP2B6, CYP2C8, CYP2C9 and CYP2C19 when administered either alone or in combination with repeated doses of alpelisib. The Annex II and Package Leaflet are updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 16.03.2023.	
Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0020, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga, "To submit the updated final OS CSR for study GO39942 - A Phase III, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of polatuzumab vedotin in combination with R-CHP versus R-CHOPin previously untreated patients with DLBCL (POLARIX) listed as a category 3 study in the RMP. This submission will address the missing information of "long-term safety" in patients treated with polatuzumab vedotin. An updated RMP version 4.0 has also been submitted to remove the commitment for this study along with the missing information of "long-term safety"." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Repatha - evolocumab - EMEA/H/C/003766/II/0061 Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola, "Update of sections 4.8 and 5.1 of the SmPC in order to update safety information and include long-term safety and efficacy data based on final results from study 20130295 and study 20160250 listed as category 3 studies in the RMP; these are phase 3b, multicentre, open-label extension (OLE) studies designed to assess the long-term safety of evolocumab in subjects	

who completed the FOURIER study (study 20110118). The RMP version 8.0 has also been submitted." Request for Supplementary Information adopted on 01.12.2022.	
Rydapt - midostaurin - EMEA/H/C/004095/II/0028, Orphan Novartis Europharm Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Inês Ribeiro-Vaz, "Update of sections 4.2 and 5.2 of the SmPC in order to update efficacy and safety information in elderly patients based on final results from study CPKC412A2408 - An open-label, multi-center, Phase IIIb study to assess the safety and efficacy of midostaurin (PKC412) in patients 18 years of age or older with newly diagnosed FLT3-mutated Acute Myeloid Leukaemia who are eligible for "7+3" or "5+2" chemotherapy, listed as a PAES in the Annex II. The RMP version 8.0 has also been submitted."	
TUKYSA - tucatinib - EMEA/H/C/005263/II/0010 Seagen B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final report from study SGNTUC-017 (MOUNTAINEER) listed as a category 3 study in the RMP. This is a Phase 2, open label study of tucatinib combined with trastuzumab in patients with HER2+ metastatic colorectal cancer. Primary objective is to determine the antitumor activity of tucatinib given in combination with trastuzumab. The RMP version 1.1 is approved." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
Vaxneuvance - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) - EMEA/H/C/005477/II/0013/G Merck Sharp & Dohme B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Gabriele Maurer, "Grouped application comprising two type II variations as follows: - To update sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to add safety data on recipients of haematopoietic stem cell transplant (HSCT) based on final results from study V114-022, listed as a category 3 study in the RMP; This is a Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of	

Vaxneuvance in Recipients of Allogeneic Hematopoietic Stem Cell Transplant. - To update sections 4.2 and 5.1 of the SmPC in order to update the information regarding a 3-dose regimen based on final results from study V114-026; a Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 3-dose Regimen of Vaxneuvance in Healthy Infants. The Package Leaflet is updated accordingly. The RMP version 2.1 has also been submitted." Request for Supplementary Information adopted on 26.01.2023.	
Veklury - remdesivir - EMEA/H/C/005622/II/0046 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy and breast-feeding based on final results from study IMPAACT 2032 listed as a category 3 study in the RMP; this is a phase 4, prospective, open-label, non-randomized study to address PK and safety of remdesivir in pregnant women. The Package Leaflet is updated accordingly. The RMP version 5.2 has also been submitted." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
Xenpozyme - olipudase alfa - EMEA/H/C/004850/II/0001/G, Orphan Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Grouped application comprising two type II variations as follows: - To update section 4.6 of the SmPC in order to include a recommendation to conduct a pregnancy test for women of childbearing potential (WOCP) prior to treatment initiation based on embryo-foetal study in mice (study TER0694). In addition, the MAH proposes an update of section 5.3 of the SmPC based on a re-calculation of exposure margins for the embryo-foetal study. The MAH also proposes to align the SmPC with the updated CCDS. - To update sections 4.6 and 5.3 of the SmPC in order to include data in lactating mice based on final results from study MSSM-1120 - Evaluation of Olipudase alfa Transfer Into Milk of Lactating Mice.	Positive Opinion adopted by consensus on 16.03.2023.

The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted." Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 01.12.2022.	
WS2409 **Lixiana-EMEA/H/C/002629/WS2409/0042** **Roteas-EMEA/H/C/004339/WS2409/0029** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Nathalie Gault, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC with available paediatric data based on final results from study DU176b-D-U312; this is a phase 3, open-label, randomised, multicentre, controlled trial to evaluate the pharmacokinetics and pharmacodynamics of edoxaban and to compare the efficacy and safety of edoxaban with standard-of-care anticoagulant therapy in paediatric subjects from birth to less than 18 years of age with confirmed venous thromboembolism (VTE). The Package Leaflet and Labelling are updated accordingly. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to bring the PI in line with the latest QRD template version 10.3."	See 9.1

B.5.4. PRAC assessed procedures

PRAC Led **Brukinsa - zanubrutinib - EMEA/H/C/004978/II/0008** BeiGene Ireland Ltd, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the updated RMP (Version 3.0) on the dates of submission of information to the ongoing study BGB-3111-LTE1." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
PRAC Led **Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0117** GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Christophe Focke, "Submission of the interim report from study EPI-HPV-099	Positive Opinion adopted by consensus on 16.03.2023.

(217743). This is an observational, retrospective database post-authorisation safety study (PASS) assessing trends and changes over time in incidence of anal cancer and feasibility for a case-control study in European countries that introduced Cervarix in their National Immunisation Programme. The study was set up to address the missing information on the impact and effectiveness of Cervarix against anal lesions and cancer in the Cervarix RMP. The RMP version 26 has also been submitted" Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 01.12.2022.	
PRAC Led **Deltyba - delamanid - EMEA/H/C/002552/II/0061, Orphan** Otsuka Novel Products GmbH, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Christophe Focke, "Update of sections 4.2 and 4.4 of the SmPC in order to update treatment duration based on final results from EU PASS (protocol no. 242-12-402), listed as a category 3 study in the RMP. This is a "A Multicentre, EU-wide, Non-Interventional Post-Authorisation Study to Assess the Safety and Usage of Delamanid in Routine Medical Practice in Multidrug-Resistant Tuberculosis (MDR-TB) Patients". This treatment registry was for monitoring and documenting Deltyba use in routine medical practice and aimed to assess compliance with the recommendations in the authorised product information when prescribed as part of an appropriate combination regimen (ACR) for the treatment of MDR-TB. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update Annex II section D of the SmPC. An updated RMP version 4.3 and SmPC/PIL have also been submitted. RMP v4.3 is considered acceptable. " Request for Supplementary Information adopted on 16.03.2023, 01.12.2022.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Entyvio - vedolizumab - EMEA/H/C/002782/II/0073** Takeda Pharma A/S, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa	Request for supplementary information adopted with a specific timetable.

Balkowiec Iskra, "Submission of the final report from study MLN0002_401 listed as a category 3 study in the RMP in order to fulfil MEA/001.2; this is an international observational prospective cohort study comparing vedolizumab to other biologic agents in patients with ulcerative colitis or Crohn's disease. The RMP version 8.0 has also been submitted." Request for Supplementary Information adopted on 16.03.2023, 29.09.2022.	
PRAC Led **IMVANEX - smallpox vaccine (live modified vaccinia virus ankara) - EMEA/H/C/002596/II/0081** Bavarian Nordic A/S, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 9.3 in order to update the safety specifications in line with an extension of indication to "active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in adults", update the missing information from the list of safety concerns, differentiate routine pharmacovigilance activities and additional pharmacovigilance activities, addition of non-BN sponsored clinical study SEMVAc to additional pharmacovigilance activities and deletion of paediatric study POX-MVA-035 upon request by PRAC following the assessment of procedure II/76." Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 12.01.2023.	Positive Opinion adopted by consensus on 16.03.2023.
PRAC Led **Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0093** Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final non-interventional Pompe Registry Report 2022 (MEA024 and MEA025)." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0039, Orphan** Advanz Pharma Limited, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison:	Positive Opinion adopted by consensus on 16.03.2023.

Johann Lodewijk Hillege, "Submission of an updated RMP version 2.0 in order to change to EU Qualified Person for Pharmacovigilance (QPPV), update the list of safety concerns and study data for 747-302 and 747-401." Opinion adopted on 16.03.2023.	
PRAC Led **OPDIVO - nivolumab - EMEA/H/C/003985/II/0127** Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from the post-authorisation safety study (PASS) CA209835: A registry study in patients who underwent post-nivolumab allogeneic haematopoietic stem-cell transplantation (HSCT). This study is listed as a category 3 study in the RMP. An updated RMP version 31.0 has also been submitted." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
PRAC Led **Ozurdex - dexamethasone - EMEA/H/C/001140/II/0044** AbbVie Deutschland GmbH & Co. KG, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of an updated Annex II and RMP version 11 in order to remove additional risk minimisation measure: Patient guide, audio CD (where required)." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Parsabiv - etelcalcetide - EMEA/H/C/003995/II/0021** Amgen Europe B.V., PRAC Rapporteur: Valentina Di Giovanni, PRAC-CHMP liaison: Armando Genazzani, "Submission of the final report from study 20170561 listed as a category 3 study in the RMP. This is an observational PASS to evaluate the potential association between Parsabiv and gastrointestinal bleeding." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0032**	Request for supplementary information adopted with a specific timetable.

Pfizer Europe MA EEIG, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.8 of the SmPC in order to add 'hypertension' to the list of adverse drug reactions (ADRs) with frequency 'uncommon', following procedure EMEA/H/C/005973/LEG/006, based on review of aggregate post-marketing data. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 16.03.2023, 12.01.2023.	
PRAC Led **Sialanar - glycopyrronium - EMEA/H/C/003883/II/0026** Proveca Pharma Limited, PRAC Rapporteur: Zane Neikena, PRAC-CHMP liaison: Elita Poplavska, "Submission of an updated RMP version 3.1 in order to remove a Drug Utilisation Study (DUS)." Request for Supplementary Information adopted on 16.03.2023, 12.01.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Simponi - golimumab - EMEA/H/C/000992/II/0111** Janssen Biologics B.V., PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from PASS study CNTO148ART4001 listed as a category 3 study in the RMP; this is an observational prospective cohort study to collect and analyse information pertaining to pregnancy outcomes of women exposed to golimumab during pregnancy. The RMP version 23.2 has also been submitted." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Simponi - golimumab - EMEA/H/C/000992/II/0112** Janssen Biologics B.V., PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study PO4480 (RABBIT) listed as a category 3 study in the RMP. This is an observational prospective cohort study to evaluate the long-term safety of treatment with biologics in rheumatoid arthritis. The RMP (version 24.2) has also been updated."	Positive Opinion adopted by consensus on 16.03.2023.

Opinion adopted on 16.03.2023.	
PRAC Led **Spikevax - elasomeran - EMEA/H/C/005791/II/0085/G** Moderna Biotech Spain, S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Grouped application comprising two type II variations as follows: C.I.11.b - To add Spikevax bivalent Original/ Omicron BA.4-5 vaccine (mRNA-1273.222), to update studies mRNA-1273-P904, mRNA-1273-P905 and mRNA-1273-P910 in the Pharmacovigilance Plan to include exposure to Spikevax bivalent vaccines, to update the INN to elasomeran/davesomeran, and to reclassify studies mRNA-1273-P205 from category 2 to category 3 studies in the Pharmacovigilance Plan. C.I.13 - To submit the final CSR from study mRNA-1273-P201, a Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults ≥= 18 Years listed as a category 3 study including addition of clinical trial exposure data for part C of the study mRNA-1273-P201. RMP version 6.0 will be updated accordingly." Request for Supplementary Information adopted on 16.03.2023, 12.01.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Stelara - ustekinumab - EMEA/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. As a consequence, section 4.4 has been updated to amend the warning on the risk of infections and malignancy, and to include a warning on the risk of major adverse cardiovascular events (MACE). The package leaflet is updated accordingly. The RMP version 23.2 has also been updated."	Positive Opinion adopted by consensus on 16.03.2023.

Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 01.09.2022.	
PRAC Led **Symkevi - tezacaftor / ivacaftor - EMEA/H/C/004682/II/0039, Orphan** Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of the final report from PASS study VX17-661-117 listed as a category 3 study in the RMP. This is an Observational Study to Evaluate the Utilization Patterns and Real-World Effects of Tezacaftor and Ivacaftor Combination Therapy (TEZ/IVA) in Patients With Cystic Fibrosis (CF). The RMP version 3.4 has also been submitted." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Synagis - palivizumab - EMEA/H/C/000257/II/0131** AstraZeneca AB, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of an updated RMP version 2.0 in order to remove from the list of safety concerns "Anaphylaxis, Anaphylactic shock, and Hypersensitivity" and "Medication error of mixing lyophilised and liquid palivizumab before injection". In addition, the MAH took the opportunity to apply the revised template." Request for Supplementary Information adopted on 16.03.2023, 01.12.2022.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Tarceva - erlotinib - EMEA/H/C/000618/II/0071** Roche Registration GmbH, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Aaron Sosa Mejia, "Update of section 4.8 of the SmPC in order to provide a single table listing all ADRs following PSUSA/00001255/202111. The Package Leaflet is updated accordingly." Opinion adopted on 16.03.2023. Request for Supplementary Information adopted on 12.01.2023.	Positive Opinion adopted by consensus on 16.03.2023.
PRAC Led **Vimizim - elosulfase alfa -**	Positive Opinion adopted by consensus on 16.03.2023.

EMEA/H/C/002779/II/0040, Orphan BioMarin International Limited, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of an updated RMP version 6.0 in order to correct the objectives of MARS in the RMP to be consistent with version 6 of the protocol and to update the "Method used to calculate exposure" due to GDPR restrictions following the assessment of procedures PSA/S/0062 and PSUSA/00010218/202102." Opinion adopted on 16.03.2023.	
PRAC Led **XOSPATA - gilteritinib - EMEA/H/C/004752/II/0012, Orphan** Astellas Pharma Europe B.V., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of the final report from study 2215-PV-0001 - Evaluation of the effectiveness of the Xospata Routine Risk Minimisation Measures (RMMs) and an additional Risk Minimisation Measure (aRMM): A Cross sectional study among Healthcare Professionals to assess awareness and knowledge, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Zavesca - miglustat - EMEA/H/C/000435/II/0076** Janssen-Cilag International N.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 15.1 in order to remove risks in line with GVP module V revision 2. The MAH has also taken the opportunity to introduce minor changes, such as update of the post marketing exposure data and alignment with the latest Company EU-RMP Template." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2402** **Advagraf- EMEA/H/C/000712/WS2402/0069** **Modigraf- EMEA/H/C/000954/WS2402/0045** Astellas Pharma Europe B.V., Lead PRAC	Request for supplementary information adopted with a specific timetable.

Rapporteur: Ronan Grimes, PRAC-CHMP liaison: Jayne Crowe, "C.I.11.z - To update the EU Risk Management Plan with the new TPRI final study submission milestone, related to procedure EMEA/H/C/000712/MEA030 and EMEA/H/C/000954/MEA022 (study F506-PV-0001)." Request for Supplementary Information adopted on 16.03.2023.	
PRAC Led **WS2430** **Exviera-EMEA/H/C/003837/WS2430/0056** **Viekirax-EMEA/H/C/003839/WS2430/0068** AbbVie Deutschland GmbH & Co. KG, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "C.I.11.z - To update the RMP for Viekirax and Exviera to include the completion of studies B16-959, B20-146, M14-423 (TOPAZ-I) and M14-222 (TOPAZ-II), following the outcome of EMEA/H/C/PSR/J/0038, EMEA/H/C/WS2216 and EMEA/H/C/WS2304, respectively. The MAH proposes to remove the emergence and recurrence of hepatocellular carcinoma as potential risks and update the related pharmacovigilance activities and other sections of the RMPs." Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
PRAC Led **WS2434** **Entresto-EMEA/H/C/004062/WS2434/0049** **Neparvis-EMEA/H/C/004343/WS2434/0047** Novartis Europharm Limited, Lead PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "C.I.11.z - To amend the RMP for Ernestro and its duplicate marketing authorisation Neparvis to update the milestones for MEA 002 (study CLCZ696B2014) and MEA 004 (study CLCZ696B2015) ." Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2435** **Entresto-EMEA/H/C/004062/WS2435/0048** **Neparvis-**	Positive Opinion adopted by consensus on 16.03.2023.

EMEA/H/C/004343/WS2435/0046 Novartis Europharm Limited, Lead PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report from study CLCZ696B2013 listed as a category 3 study in the RMP. Study CLCZ696B2013 is a non-interventional, post-authorization, database cohort study to assess the risk of serious angioedema in association with LCZ696 (sacubitril/valsartan; Entresto) use in Black patients with heart failure in the United States." Opinion adopted on 16.03.2023.	

B.5.5. CHMP-CAT assessed procedures

Abecma - idecabtagene vicleucel - EMEA/H/C/004662/II/0022/G, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang Request for Supplementary Information adopted on 17.02.2023.	
Abecma - idecabtagene vicleucel - EMEA/H/C/004662/II/0026, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang,	
Abecma - idecabtagene vicleucel - EMEA/H/C/004662/II/0027, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang	
CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0005, Orphan, ATMP Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted on 09.12.2022.	
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0057, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 24.03.2023, 20.01.2023.	
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0036/G, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege	
WS2426 **Tecartus-** **EMEA/H/C/005102/WS2426/0032** **Yescarta-** **EMEA/H/C/004480/WS2426/0061** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	

B.5.6. CHMP-PRAC-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0014, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Armando Genazzani, PRAC Rapporteur: Gabriele Maurer, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from studies 017001 and JCAR-017-BCM-001 listed as obligations in the Annex II. These studies aimed to further characterise the long-term efficacy and safety of Breyanzi in patients treated with relapsed or refractory DLBCL, PMBCL, FL3B after two or more lines of systemic therapy. Study 017001 is a phase 1, open-label, single-arm, multicohort, multicentre, seamless design trial, while study JCAR-017-BCM-001 is a phase 2, open-label, single-arm, multicohort, multicentre trial. The Annex II is updated accordingly. The RMP version 3.0 has also been submitted."	

B.5.7. PRAC assessed ATMP procedures

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

WS2363/G **Copalia-** **EMEA/H/C/000774/WS2363/0127/G** **Dafiro-**	Positive Opinion adopted by consensus on 02.03.2023.

EMEA/H/C/000776/WS2363/0131/G **Exforge-** **EMEA/H/C/000716/WS2363/0126/G** Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 02.03.2023. Request for Supplementary Information adopted on 26.01.2023, 01.12.2022.	
WS2392/G **Efficib-** **EMEA/H/C/000896/WS2392/0109/G** **Janumet-** **EMEA/H/C/000861/WS2392/0108/G** **Ristfor-** **EMEA/H/C/001235/WS2392/0097/G** **Velmetia-** **EMEA/H/C/000862/WS2392/0114/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Johann Lodewijk Hillege Opinion adopted on 09.03.2023. Request for Supplementary Information adopted on 12.01.2023.	Positive Opinion adopted by consensus on 09.03.2023.
WS2399/G **Mirapexin-** **EMEA/H/C/000134/WS2399/0104/G** **Sifrol-** **EMEA/H/C/000133/WS2399/0095/G** Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 19.01.2023.	
WS2410 **Glyxambi-** **EMEA/H/C/003833/WS2410/0050** **Jardiance-** **EMEA/H/C/002677/WS2410/0077** **Synjardy-** **EMEA/H/C/003770/WS2410/0069** Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
WS2411/G **Copalia HCT-** **EMEA/H/C/001159/WS2411/0104/G** **Dafiro HCT-** **EMEA/H/C/001160/WS2411/0106/G** **Exforge HCT-** **EMEA/H/C/001068/WS2411/0103/G**	

Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 23.02.2023.	
WS2412 **Hexacima-EMEA/H/C/002702/WS2412/0144** **Hexyon-EMEA/H/C/002796/WS2412/0148** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	
WS2413/G **Axura-EMEA/H/C/000378/WS2413/0083/G** **Memantine Merz-EMEA/H/C/002711/WS2413/0019/G** Merz Pharmaceuticals GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro Request for Supplementary Information adopted on 16.03.2023.	Request for supplementary information adopted with a specific timetable.
WS2417/G **Ongentys-EMEA/H/C/002790/WS2417/0055/G** **Ontilyv-EMEA/H/C/005782/WS2417/0010/G** Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
WS2420 **Nuwiq-EMEA/H/C/002813/WS2420/0052** **Vihuma-EMEA/H/C/004459/WS2420/0034** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
WS2422/G **Entresto-EMEA/H/C/004062/WS2422/0050/G** **Neparvis-EMEA/H/C/004343/WS2422/0048/G** Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege	
WS2423 **Infanrix hexa-EMEA/H/C/000296/WS2423/0324** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke,	Positive Opinion adopted by consensus on 09.03.2023.

Opinion adopted on 09.03.2023.	
WS2424/G **Infanrix hexa-** **EMEA/H/C/000296/WS2424/0323/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke, Opinion adopted on 16.03.2023.	Positive Opinion adopted by consensus on 16.03.2023.
WS2425/G **Infanrix hexa-** **EMEA/H/C/000296/WS2425/0325/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	
WS2428/G **Silodosin Recordati-** **EMEA/H/C/004964/WS2428/0010/G** **Silodyx-** **EMEA/H/C/001209/WS2428/0050/G** **Urorec-** **EMEA/H/C/001092/WS2428/0053/G** Recordati Ireland Ltd, Generic, Generic of Urorec, Lead Rapporteur: Margareta Bego	
WS2441/G **Exelon-** **EMEA/H/C/000169/WS2441/0142/G** **Prometax-** **EMEA/H/C/000255/WS2441/0143/G** Novartis Europharm Limited, Lead Rapporteur: Alexandre Moreau	
WS2443 **Ambirix-** **EMEA/H/C/000426/WS2443/0126** **Twinrix Adult-** **EMEA/H/C/000112/WS2443/0161** **Twinrix Paediatric-** **EMEA/H/C/000129/WS2443/0162** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	

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

WS2318/G **Ebymect-** **EMEA/H/C/004162/WS2318/0058/G** **Edistride-** **EMEA/H/C/004161/WS2318/0056/G** **Forxiga-** **EMEA/H/C/002322/WS2318/0077/G** **Qtern-**	The MAH withdrew the procedure on 24.02.2023

EMEA/H/C/004057/WS2318/0036/G **Xigduo-** **EMEA/H/C/002672/WS2318/0068/G** AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Mari Thorn, "C.I.4 Update of section 4.4 of the SmPC in order to remove the potential risk of Lower Limb Amputation (LLA) based on studies D1690C00018, D1690C00019, DECLARE, DAPA-HF, DAPA-CKD, and DELIVER. The Package Leaflets are 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. In addition, the MAH took the opportunity to update the list of local representatives in the Qtern Package Leaflet. C.I.11.z Submission of an updated RMP in order to align the EU RMPs for the FDCs Xigduo, Ebymect and Qtern, to recently approved updates to the Forxiga EU RMP. C.I.z Update of section 4.5 of the SmPC to include further PI harmonisation to address the consideration raised by PRAC and CHMP during the ongoing dapagliflozin procedure PSUSA/00010029/202110. The Forxiga RMP and Edistride RMP version 28 has been submitted. The Qtern RMP version 7 has been submitted. The Xigduo RMP and Ebymect RMP version 13 has been submitted." Request for Supplementary Information adopted on 29.09.2022.	
Ronapreve - casirivimab / imdevimab - EMEA/H/C/005814/II/0007 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.4, 5.1 and 5.2 of the SmPC in order to introduce the proposed dose for SARS-CoV-2 Omicron BA.2, BA.2.12.1, BA.4, and BA.5 subvariants along with dose preparation and infusion instructions for treatment of outpatients and post-exposure prophylaxis as well as to update efficacy and pharmacokinetic information based on pharmacokinetic (PK) modelling data from R10933-PK-21187-SR-01V2 and R10933-R10987-4800mgIV-KRM and in vitro viral	The MAH withdrew the procedure on 10.03.2023.

neutralization data from the updated virus neutralization report R10933-PH-20091-SR-01V7 and its addendum; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 13.10.2022. Withdrawal request submitted on 10.03.2023.	

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

NUVAXOVID - COVID-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0030 Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege, "Submission of 6-month efficacy and safety interim data from the ongoing randomized, observer-blinded, placebo-controlled clinical studies 2019nCoV-501, 2019nCoV-301 and 2019nCoV-302." Request for Supplementary Information adopted on 15.12.2022.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in December 2022. The CHMP agreed to the request by the applicant via written procedure on 21.03.2023.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

in vitro diagnostic medical device - EMEA/H/D/006255 is indicated as an aid in the selection of adult hemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered	
apremilast - EMEA/H/C/006208 treatment of psoriatic arthritis, psoriasis, Behçet's disease	
axitinib - EMEA/H/C/006206 treatment of adult patients with advanced renal cell carcinoma (RCC)	
COVID-19 vaccine - EMEA/H/C/006058 immunisation to prevent COVID-19 caused by SARS-CoV-2	See also 3.1
bimatoprost - EMEA/H/C/005916 indicated for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma (OAG) or ocular hypertension (OHT) who are unsuitable for topical IOP-lowering	

medications
serplulimab - EMEA/H/C/006170, Orphan Henlius Europe GmbH, first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)
pomalidomide - EMEA/H/C/006195 in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM)
flortaucipir (18f) - EMEA/H/C/006064 indicated for Positron Emission Tomography (PET) imaging of the brain
danicopan - EMEA/H/C/005517, Orphan Alexion Europe, Treatment of extravascular haemolysis (EVH) in patients with paroxysmal nocturnal haemoglobinuria
retifanlimab - EMEA/H/C/006194, Orphan Incyte Biosciences Distribution B.V., Treatment of Merkel cell carcinoma (MCC).

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

Skyrizi - risankizumab - EMEA/H/C/004759/X/0033 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Extension application to add a new strength of 90 mg solution for injection in pre-filled syringe, indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy."
Teriflunomide Accord - teriflunomide - EMEA/H/C/005960/X/0002 Accord Healthcare S.L.U., Generic, Generic of AUBAGIO, Rapporteur: Kristina Nadrah, PRAC Rapporteur: Martin Huber, "Extension application to add a new strength of 7 mg film-coated tablets. The bioequivalence study data were submitted."

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

aflibercept - EMEA/H/C/006022
treatment of age-related macular degeneration (AMD) and visual impairment
List of Questions adopted on 15.09.2022.

recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMEA/H/C/006054
indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV
List of Questions adopted on 24.01.2023.

degarelix acetate - EMEA/H/C/006048
treatment of prostate cancer
List of Questions adopted on 10.11.2022.

crisantaspase - EMEA/H/C/005917
Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL).
List of Questions adopted on 13.10.2022.

epcoritamab - EMEA/H/C/005985, Orphan
AbbVie Deutschland GmbH & Co. KG, treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)
List of Questions adopted on 23.02.2023.

Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/X/0016
Novo Nordisk A/S, Rapporteur: Daniela Philadelphy, "Extension application to add two new strengths of 4000 IU and 5000 IU powder and solvent for solution for injection."
List of Questions adopted on 26.01.2023.

sparsentan - EMEA/H/C/005783, Orphan
Vifor France, for the treatment of primary immunoglobulin A nephropathy (IgAN).
List of Questions adopted on 15.12.2022.

dabrafenib - EMEA/H/C/005885, Orphan
Novartis Europharm Limited, Treatment of glioma
List of Questions adopted on 26.01.2023.

decitabine / cedazuridine - EMEA/H/C/005823, Orphan
Otsuka Pharmaceutical Netherlands B.V., treatment of myeloid leukaemia

List of Questions adopted on 15.12.2022.

human albumin solution / gentamicin sulfate - EMEA/H/D/006141
human assisted reproductive techniques including in-vitro fertilisation procedures
List of Questions adopted on 10.11.2022.

ritlecitinib - EMEA/H/C/006025
is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.
List of Questions adopted on 15.12.2022.

pegfilgrastim - EMEA/H/C/005587
treatment of neutropenia
List of Questions adopted on 24.02.2022.

Ofev - nintedanib - EMEA/H/C/003821/X/0052/G
Boehringer Ingelheim International GmbH, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Nikica Mirošević Skvrce, "Extension application to add a new strength of 25 mg soft capsule grouped with a type II variation C.I.6.a to add a new indication of treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age, based on results from study 1199 0337 (InPedILD); a randomised, placebo-controlled, double-blind, multicentre, multinational, phase III clinical trial undertaken to evaluate dose-exposure and safety of nintedanib on top of standard of care in children and adolescents (6 to 17 years old) with clinically significant fibrosing ILD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes to the list of local representatives in the Package Leaflet. The updated RMP version 12.0 is also submitted."
List of Questions adopted on 26.01.2023.

Olumiant - baricitinib - EMEA/H/C/004085/X/0035/G
Eli Lilly Nederland B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, "Extension application to introduce a new strength (1 mg film-coated tablet), grouped with a type II variation (C.I.6.a) in order to extend the indication to

include treatment, as monotherapy or in combination with conventional synthetic disease modifying antirheumatic drugs (DMARDs), of active juvenile idiopathic arthritis (JIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs, based on final results from the pivotal study JAHV (I4V-MC-JAHV); this is a multicentre, double-blind, randomised, placebo-controlled, medication-withdrawal Phase 3 study in children from 2 years to less than 18 years of age with JIA who have had an inadequate response or intolerance to treatment with at least 1 cDMARD or bDMARD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance.
Version 15.1 of the RMP has also been submitted."
List of Questions adopted on 26.01.2023.

tocilizumab - EMEA/H/C/005781
treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), Giant Cell Arteritis (GCA), treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) and COVID-19
List of Questions adopted on 15.12.2022.

elacestrant - EMEA/H/C/005898
treatment of postmenopausal woman and men with breast cancer
List of Questions adopted on 15.12.2022.

trametinib - EMEA/H/C/005886, Orphan
Novartis Europharm Limited, Treatment of paediatric patients aged 1 year and older with glioma
List of Questions adopted on 26.01.2023.

sugammadex - EMEA/H/C/006115
reversal of neuromuscular blockade induced by rocuronium or vecuronium
List of Questions adopted on 15.12.2022.

tocilizumab - EMEA/H/C/005984
treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA),

juvenile idiopathic polyarthritis (pJIA), chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) and COVID-19
List of Questions adopted on 26.01.2023.

natalizumab - EMEA/H/C/005752
Therapy for active relapsing remitting multiple sclerosis (RRMS)
List of Questions adopted on 10.11.2022.

quizartinib - EMEA/H/C/005910, Orphan
Daiichi Sankyo Europe GmbH, Treatment of adult patients with diagnosed acute myeloid leukaemia (AML)
List of Questions adopted on 15.12.2022.

oteseconazole - EMEA/H/C/005682
treatment and prevention of recurrent vulvovaginal candidiasis (RVVC) including the acute episodes of RVVC in adult women
List of Questions adopted on 15.09.2022.

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

Evoltra - clofarabine - EMEA/H/C/000613/S/0078
Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Lamzede - velmanase alfa - EMEA/H/C/003922/S/0031, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jan Neuhauser

Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/S/0004
SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber

Voraxaze - glucarpidase - EMEA/H/C/005467/S/0013, Orphan
SERB S.A.S., Rapporteur: Ondřej Slanař, PRAC Rapporteur: Martin Huber

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

Abecma - idecabtagene vicleucel - EMEA/H/C/004662/R/0029, Orphan, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, Co-Rapporteur: Heli Suila, CHMP Coordinators: Ingrid Wang and Johanna Lähteenvuo, PRAC Rapporteur: Ulla Wändel Liminga

Alunbrig - brigatinib / brigatinib - EMEA/H/C/004248/R/0049
Takeda Pharma A/S, Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Inês Ribeiro-Vaz

Apealea - paclitaxel - EMEA/H/C/004154/R/0017
Inceptua AB, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Inês Ribeiro-Vaz

AYVAKYT - avapritinib - EMEA/H/C/005208/R/0025, Orphan
Blueprint Medicines (Netherlands) B.V., Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst

Blenrep - belantamab mafodotin - EMEA/H/C/004935/R/0017, Orphan
GlaxoSmithKline (Ireland) Limited, Rapporteur: Johanna Lähteenvuo, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Ulla Wändel Liminga

Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/R/0027
Sanofi Pasteur, Rapporteur: Christophe Focke, Co-Rapporteur: Sol Ruiz, PRAC Rapporteur: Sonja Hrabcik

Dovprela - pretomanid - EMEA/H/C/005167/R/0015, Orphan
Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Gross-Martirosyan

Emgality - galcanezumab - EMEA/H/C/004648/R/0023
Eli Lilly Nederland B.V., Rapporteur: Armando Genazzani, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka

Fortacin - lidocaine / prilocaine - EMEA/H/C/002693/R/0038
Recordati Ireland Ltd, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Johann

Lodewijk Hillege, PRAC Rapporteur: Maria del Pilar Rayon

Fulphila - pegfilgrastim - EMEA/H/C/004915/R/0042

Viatris Limited, Rapporteur: Martina Weise, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst

Hepcludex - bulevirtide - EMEA/H/C/004854/R/0024, Orphan

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Idefirix - imlifidase - EMEA/H/C/004849/R/0014, Orphan

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

Namuscla - mexiletine - EMEA/H/C/004584/R/0014, Orphan

Lupin Europe GmbH, Rapporteur: Bruno Sepodes, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Eva Jirsová

Ogivri - trastuzumab - EMEA/H/C/004916/R/0054

Viatris Limited, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer

Pelmeg - pegfilgrastim - EMEA/H/C/004700/R/0025

Mundipharma Corporation (Ireland) Limited, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Christian Gartner, PRAC Rapporteur: Menno van der Elst

ROCTAVIAN - valoctocogene roxaparvovec - EMEA/H/C/005830/R/0003, Orphan, ATMP

BioMarin International Limited, Rapporteur: Violaine Closson Carella, Co-Rapporteur: Silke Dorner, CHMP Coordinators: Jean-Michel Race and Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst

TAKHZYRO - lanadelumab - EMEA/H/C/004806/R/0035, Orphan

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, Co-Rapporteur: Jean-Michel Race, PRAC

Rapporteur: Kirsti Villikka

Tecvayli - teclistamab -
EMEA/H/C/005865/R/0002
Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Jana Lukacisinova

Translarna - ataluren -
EMEA/H/C/002720/R/0071, Orphan
PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Liana Gross-Martirosyan

Vaborem - meropenem / vaborbactam -
EMEA/H/C/004669/R/0019
Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Maria del Pilar Rayon

VITRAKVI - larotrectinib -
EMEA/H/C/004919/R/0031
Bayer AG, Rapporteur: Filip Josephson, PRAC Rapporteur: Rugile Pilviniene

Xofigo - radium-223 -
EMEA/H/C/002653/R/0049
Bayer AG, Rapporteur: Janet Koenig, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Rugile Pilviniene

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

Abecma - idecabtagene vicleucel -
EMEA/H/C/004662/II/0031, Orphan, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, Co-Rapporteur: Heli Suila, CHMP Coordinator: Ingrid Wang and Johanna Lähteenvuo, PRAC Rapporteur: Ulla Wändel Liminga, "Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38 antibody and have demonstrated disease progression on the last

therapy for Abecma (idecabtagene vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
ADCETRIS - brentuximab vedotin - EMEA/H/C/002455/II/0107, Orphan Takeda Pharma A/S, Rapporteur: Johann Lodewijk Hillege, "Extension of indication to include treatment of adult patients with previously untreated CD30+ advanced (including Stage III) Hodgkin lymphoma (HL), in combination with doxorubicin, vinblastine and dacarbazine (AVD), for ADCETRIS, based on the second interim analysis of OS data from ECHELON-1 study (C25003); this is a randomized, open-label, phase 3 trial of A+AVD versus ABVD as frontline therapy in patients with advanced classical HL. As a consequence, sections 4.1 and 5 of the SmPC are updated."	
HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0087 Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in adults for HyQvia, based on final results from studies 161403 and ABV-771-1001; and interim results from study 161505. 161403 and 161505 are interventional Phase III efficacy and safety studies respectively, while ABV-771-1001 is an interventional Phase I safety study. 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 and Labelling are updated in accordance.	

Version 14.0 of the RMP has also been submitted.”	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0133 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst, “Extension of indication to include in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy for treatment of locally advanced unresectable or metastatic HER2- positive gastric or gastro-oesophageal junction adenocarcinoma for Keytruda, based on interim results from study KEYNOTE-811, an ongoing Phase 3, double-blind trial comparing trastuzumab plus chemotherapy and pembrolizumab with trastuzumab plus chemotherapy and placebo as first-line treatment in participants with HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 40.1 of the RMP has also been submitted.”	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0134 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, PRAC Rapporteur: Menno van der Elst, “Extension of indication to include in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant, treatment of resectable stage II, IIIA, or IIIB (T3 4N2) non-small cell lung carcinoma in adults for Keytruda based on study KEYNOTE-671, a phase III, randomized, double-blind trial of platinum doublet chemotherapy +/- pembrolizumab as neoadjuvant/adjuvant therapy for participants with resectable stage II, IIIA, and resectable IIIB (T3-4N2) non-small cell lung cancer. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.1 of the RMP has also been submitted.”	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0135 Merck Sharp & Dohme B.V., Co-Rapporteur: Jan	

Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include in combination with chemotherapy the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastrooesophageal junction adenocarcinoma in adults based on study KEYNOTE-859, a randomized, double-blind phase 3 trial, evaluating KEYTRUDA in combination with chemotherapy compared to placebo in combination with chemotherapy for the first-line treatment of patients with HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 42.1 of the RMP has also been submitted."

Lonsurf - trifluridine / tipiracil - EMEA/H/C/003897/II/0026

Les Laboratoires Servier, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga, "Extension of indication to include treatment of patients with refractory metastatic colorectal cancer, for LONSURF in combination with bevacizumab based on results from study SUNLIGHT (CL3-95005-007); This is an open-label, randomised, phase III study comparing trifluridine/tipiracil in combination with bevacizumab to trifluridine/tipiracil monotherapy in patients with refractory metastatic colorectal cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. The updated RMP version 9.1 has also been submitted. In addition, the MAH took the opportunity to update section 4.6 of the SmPC and the package leaflet accordingly."

Mounjaro - tirzepatide - EMEA/H/C/005620/II/0007

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include chronic weight management, including weight loss and weight maintenance, for MOUNJARO, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial body mass index (BMI) of ≥ 30 kg/m2 (obesity), or ≥ 27 kg/m2

to < 30 kg/m2 (overweight) in the presence of at least one weight-related comorbid condition, based on a global, pivotal phase 3 study I8F-MC-GPHK (SURMOUNT-1) and five supportive phase 3 studies (SURPASS-1 to -5) in participants with T2DM and BMI ≥ 27 kg/m2. SURMOUNT-1 is a phase 3, randomized, double-blind, placebo-controlled trial to investigate the efficacy and safety of tirzepatide once weekly in participants without type 2 diabetes who have obesity or are overweight with weight related comorbidities. As a consequence, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
OPDIVO - nivolumab - EMEA/H/C/003985/II/0130 Bristol-Myers Squibb Pharma EEIG, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Extension of indication to include OPDIVO for the adjuvant treatment of adults and adolescents 12 years of age and older with stage IIB or IIC melanoma who have undergone complete resection, based on results from study CA20976K; This is a phase III, randomized, double-blind study of adjuvant immunotherapy with nivolumab versus placebo after complete resection of stage IIB/C melanoma. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 33.0 of the RMP has also been submitted."	
Praluent - alirocumab - EMEA/H/C/003882/II/0078 Sanofi Winthrop Industrie, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include treatment of paediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia (HeFH) as an adjunct to diet, alone or in combination with other LDL-C lowering therapies, based on final results from study	

EFC14643 listed as a category 3 study in the RMP; this is a randomized, double-blind, placebo-controlled study followed by an open-label treatment period to evaluate the efficacy and safety of alirocumab in children and adolescents with heterozygous familial hypercholesterolemia. 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 8.0 of the RMP is also submitted."

PREVYMIS - letermovir - EMEA/H/C/004536/II/0033/G, Orphan

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Kirsti Villikka, "Grouped application consisting of 1) Extension of indication to include treatment of prophylaxis of cytomegalovirus in kidney transplant recipients (KTR) for PREVYMIS, based on final results from study P002MK8228; this is a Phase III, randomized, double-blind, active comparator-controlled study to evaluate the efficacy and safety letermovir versus valganciclovir for the prevention of Human Cytomegalovirus (CMV) Disease in adult kidney transplant recipients. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes; 2) Update of section 4.2 of the SmPC in order to update duration of treatment recommendation based on final results from study P040MK8228; this is a Phase III randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of letermovir (LET) prophylaxis when extended from 100 days to 200 days post-transplant in cytomegalovirus (CMV) seropositive recipients (R+) of an allogeneic hematopoietic stem cell transplant (HSCT)."

Reblozyl - luspatercept - EMEA/H/C/004444/II/0021, Orphan

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jo Robays, "Extension of indication to include treatment of adult patients with anaemia due to very low,

low and intermediate-risk myelodysplastic syndromes (MDS), who may require RBC transfusions for Reblozyl, based on results from study ACE-536-MDS-002 (COMMANDS), an active-controlled, open-label, randomized Phase 3 study comparing the efficacy and safety of luspatercept vs epoetin alfa in adult subjects with anaemia due to IPSS-R very low, low or intermediate risk MDS, who are ESA naïve and require RBC transfusions, and studies ACE-536-MDS-001(MEDALIST), ACE-536-MDS-004 , A536-03, A536-05 and ACE-536-LTFU-001; 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 2.0 of the RMP has also been submitted."

SCENESSE - afamelanotide - EMEA/H/C/002548/II/0044, Orphan

Clinuvel Europe Limited, Rapporteur: Janet Koenig, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Martin Huber, "Extension of indication for the prevention of phototoxicity in adolescent patients (12 to under 18 years of age) with erythropoietic protoporphyria (EPP), based on the analysis of the safety and efficacy data available. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.4 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial correction to the PI."

Spikevax - elasomeran - EMEA/H/C/005791/II/0097/G

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Grouped variation:
- C.I.6.a (Type II): Extension of indication to include a 25 µg booster dose of Spikevax bivalent Original/Omicron BA.4-5 (12.5 µg elasomeran /12.5 µg davesomeran) in children aged 6 through 11 years of age; as a consequence, sections 2, 4.1, 4.2, 4.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 6.5 of the RMP has also been submitted.
- C.I.z (Type II): Update of sections 4.8 and 5.1 of the Spikevax bivalent Original/Omicron BA.1 SmPC to add median follow-up period and D91

persistence data, based on Parts F and G (mRNA- 1273.214) of study mRNA-1273-P205 (NCT04927065), an open-label Phase 2/3 study evaluating the immunogenicity and safety of variant-targeting booster candidate vaccines.
The Package Leaflet is updated accordingly.
- C.I.z (Type II): To update sections 4.8 and 5.1 of the Spikevax bivalent Original/Omicron BA.4-5 SmPC to add ADR details and clinical data, based on Part H (mRNA- 1273.222) of study mRNA-1273-P205 (NCT04927065), an open-label Phase 2/3 study evaluating the immunogenicity and safety of variant-targeting booster candidate vaccines.
In addition, the marketing authorisation holder took the opportunity to implement a number of editorial changes to the product information."

VEYVONDI - vonicog alfa - EMEA/H/C/004454/II/0030

Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Mari Thorn, "Extension of indication to include "prophylactic treatment to prevent or reduce the frequency of bleeding episodes" for VEYVONDI based on final results from study 071301 and interim results from study SHP677-304. Study 071301 is a prospective, phase 3, open-label, international multicenter study on efficacy and safety of prophylaxis with rVWF in severe von Willebrand disease; while study SHP677-304 is a phase 3B, prospective, open-label, uncontrolled, multicenter study on long term safety and efficacy of rVWF in paediatric and adult subjects with severe von Willebrand disease. As a consequence, sections 4.1, 4.2, 4.4, 5.1, 5.2, 6.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0037

Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski, "Extension of indication to include treatment of the paediatric population (1 to 18 years of age) for ZINPLAVA, based on final results from study MK-6072-001 (MODIFY III) listed as a category 3 study in the RMP; this is a phase 3, randomised, placebo-controlled,

parallel-group, multi-site, double-blind trial evaluating the safety, tolerability, pharmacokinetics (PK) and efficacy of a single infusion of bezlotoxumab in paediatric participants from 1 to <18 years of age receiving antibacterial drug treatment for Clostridioides difficile infection (CDI). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Advate - octocog alfa - EMEA/H/C/000520/II/0119/G
Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0036/G
Baxalta Innovations GmbH, Rapporteur: Daniela Philadelphy

Azacitidine Mylan - azacitidine - EMEA/H/C/004984/II/0014
Mylan Ireland Limited, Generic, Generic of Vidaza, Rapporteur: Hrefna Gudmundsdottir

CEVENFACTA - eptacog beta (activated) - EMEA/H/C/005655/II/0005
Laboratoire Francais du Fractionnement et des Biotechnologies, Rapporteur: Daniela Philadelphy

COMIRNATY - tozinameran - EMEA/H/C/005735/II/0174/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Elaprase - idursulfase - EMEA/H/C/000700/II/0109
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Johann Lodewijk Hillege

Eptifibatide Accord - eptifibatide - EMEA/H/C/004104/II/0015/G
Accord Healthcare S.L.U., Generic, Generic of Integrilin, Rapporteur: Jayne Crowe

Eptifibatide Accord - eptifibatide - EMEA/H/C/004104/II/0016/G
Accord Healthcare S.L.U., Generic, Generic of Integrilin, Rapporteur: Jayne Crowe

HEPLISAV B - hepatitis B surface antigen - EMEA/H/C/005063/II/0024
Dynavax GmbH, Rapporteur: Filip Josephson

Idefirix - imlifidase - EMEA/H/C/004849/II/0015, Orphan
Hansa Biopharma AB, Rapporteur: Martina Weise

Insulin aspart Sanofi - insulin aspart - EMEA/H/C/005033/II/0013/G
Sanofi Winthrop Industrie, Rapporteur: Johann Lodewijk Hillege

Kevzara - sarilumab - EMEA/H/C/004254/II/0036/G
Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus

LIVMARLI - maralixibat - EMEA/H/C/005857/II/0001/G, Orphan
Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise

Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0069
GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus

Mounjaro - tirzepatide - EMEA/H/C/005620/II/0006/G
Eli Lilly Nederland B.V., Rapporteur: Martina Weise

Naglazyme - galsulfase - EMEA/H/C/000640/II/0090
BioMarin International Limited, Rapporteur: Fátima Ventura

Nimenrix - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/002226/II/0125/G
Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang

Nucala - mepolizumab - EMEA/H/C/003860/II/0059/G
GlaxoSmithKline Trading Services Limited,

Rapporteur: Finbarr Leacy

Nulojix - belatacept -
EMEA/H/C/002098/II/0088/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson

Polivy - polatuzumab vedotin -
EMEA/H/C/004870/II/0021/G, Orphan
Roche Registration GmbH, Rapporteur: Alexandre Moreau

POTELIGEO - mogamulizumab -
EMEA/H/C/004232/II/0018, Orphan
Kyowa Kirin Holdings B.V., Rapporteur: Johann Lodewijk Hillege

POTELIGEO - mogamulizumab -
EMEA/H/C/004232/II/0019/G, Orphan
Kyowa Kirin Holdings B.V., Rapporteur: Johann Lodewijk Hillege

Ronapreve - casirivimab / imdevimab -
EMEA/H/C/005814/II/0010/G
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus

Truvelog Mix 30 - insulin aspart -
EMEA/H/C/005635/II/0003/G
Sanofi Winthrop Industrie, Rapporteur: Martina Weise

WS2365
Ambirix-
EMEA/H/C/000426/WS2365/0125
Bexsero-
EMEA/H/C/002333/WS2365/0119
Cervarix-
EMEA/H/C/000721/WS2365/0119
Fendrix-
EMEA/H/C/000550/WS2365/0081
Infanrix hexa-
EMEA/H/C/000296/WS2365/0326
Synflorix-
EMEA/H/C/000973/WS2365/0176
Twinrix Adult-
EMEA/H/C/000112/WS2365/0160
Twinrix Paediatric-
EMEA/H/C/000129/WS2365/0161
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2444
Lixiana-EMEA/H/C/002629/WS2444/0044

Roteas-EMEA/H/C/004339/WS2444/0031
Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro

WS2454
Fluenz Tetra-
EMEA/H/C/002617/WS2454/0127
Pandemic influenza vaccine H5N1
AstraZeneca-
EMEA/H/C/003963/WS2454/0062
AstraZeneca AB, Lead Rapporteur: Christophe Focke

WS2457/G
Riltrava Aerosphere-
EMEA/H/C/005311/WS2457/0005/G
Trixeo Aerosphere-
EMEA/H/C/004983/WS2457/0012/G
AstraZeneca AB, Lead Rapporteur: Finbarr Leacy

WS2461/G
Blitzima-
EMEA/H/C/004723/WS2461/0065/G
Truxima-
EMEA/H/C/004112/WS2461/0068/G
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Aimovig - erenumab -
EMEA/H/C/004447/II/0026/G
Novartis Europharm Limited, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update clinical efficacy and safety information based on final results from studies CAMG334A2301 (LIBERTY) and CAMG334ADE01 (HER-MES). The 'LIBERTY' study is a randomized, double-blind, parallel-group, placebo-controlled phase 3 study to assess the efficacy and tolerability of Aimovig in adult patients with episodic migraine who had previously failed 2- 4 prophylactic migraine treatments, while the 'HER-MES' study is a randomized, double-blind, double-dummy, multicenter, parallel group, phase 4 study to assess tolerability and efficacy of Aimovig against topiramate in adult patients with episodic and chronic migraine."

Ameluz - 5-aminolevulinic acid -

EMEA/H/C/002204/II/0055
Biofrontera Bioscience GmbH, Rapporteur: Janet Koenig, "Update of section sections 4.2, 4.8, 5.1 and 6.6 of the SmPC in order to include artificial daylight lamps as an additional light source for photodynamic therapy in combination with Ameluz for the treatment of actinic keratoses based on final results from non-clinical study PT-0042-A and literature (investigator-initiator trials). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Brukinsa - zanubrutinib - EMEA/H/C/004978/II/0013
BeiGene Ireland Ltd, Rapporteur: Aaron Sosa Mejia, "Update of section 5.1 of the SmPC in order to update efficacy information based on final efficacy results of 'progression-free survival' (PFS) analysis from study BGB-3111-305; this is a Phase III, randomized study of Zanubrutinib compared with Ibrutinib in patients with Relapsed/Refractory Chronic Lymphocytic Leukaemia or Small Lymphocytic Lymphoma. In addition, the MAH took the opportunity to update section 4.4 of the SmPC in order to align the wording with the approved Package Leaflet."

Cosentyx - secukinumab - EMEA/H/C/003729/II/0097
Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, "Update of section 4.8 of the SmPC in order to add pyoderma gangrenosum to the list of adverse drug reactions (ADRs) with frequency not known based on a systematic review of the MAH safety database, clinical trial data, literature search and epidemiological evaluation.
The Package Leaflet is updated accordingly.
In addition, the MAH took the opportunity to include a Notification 61(3)."

Darzalex - daratumumab - EMEA/H/C/004077/II/0066, Orphan
Janssen-Cilag International N.V., Rapporteur: Aaron Sosa Mejia, "Submission of the final report from subgroup analysis of subjects with body weight >120 kg in ongoing randomised studies (MMY1004, MMY3012, MMY2040, and AMY3001) to further characterise the impact of body weight >120 kg on exposure and efficacy

outcomes."

Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0030

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.8 and 5.1 of the SmPC in order to update transfusion data for subjects with human epidermal growth factor receptor 2 (HER2)-positive gastric/gastroesophageal junction adenocarcinoma (GC) and to update the overall response rate for study DS8201-A-J202 (following the assessment of procedure II/0012) based on studies DS8201-A-J101, DS8201-A-J202 (DESTINY-Gastric01) and DS8201-A-U205 (DESTINY-Gastric02).
DS8201-A-J101 is a phase 1, Two-part, Multicenter, Non-randomized, Open-label, Multiple Dose Firstin-Human Study in Advanced Solid Malignant Tumor.
DS8201-A-J202 is a phase 2, Multicenter, Open-label Study of DS-8201a in Subjects with HER2-Expressing Advanced Gastric or gastroesophagal junction Adenocarcinoma.
DS8201-A-U205 is a phase 2, Multicenter, Open-label, Single-arm Trial of Trastuzumab Deruxtecan in HER2-Positive, Unresectable or Metastatic Gastric or Gastro-esophagal junction (GEJ) Adenocarcinoma Subjects who have progressed on or after a Trastuzumab-containing Regimen.
In addition, the MAH took this opportunity to implement minor editorial changes to the SmPC."

Fasenra - benralizumab - EMEA/H/C/004433/II/0047

AstraZeneca AB, Rapporteur: Fátima Ventura, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric population information based on final results from study D3250C00025; this is an Open-label Study to Evaluate the Pharmacokinetics and Pharmacodynamics and Long-term Safety of Benralizumab Administered Subcutaneously in Children with Severe Eosinophilic Asthma."

Galafold - migalastat - EMEA/H/C/004059/II/0038, Orphan

Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2 and 5.2 of the SmPC in order to

modify administration instructions and to update the pharmacokinetic information based on study AT1001-045; a randomized, open-label, 6-way crossover study to evaluate the relative bioavailability of the 150-mg migalastat hydrochloride (HCl) capsule taken with caffeinated and sweetened beverages versus taken with water in healthy volunteers. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce some minor editorial changes and additional corrections to the SmPC referring to prior regulatory procedures II/0030 and II/0034."	
HEPLISAV B - hepatitis B surface antigen - EMEA/H/C/005063/II/0023 Dynavax GmbH, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to add 'injection site pruritus' to the list of adverse drug reactions (ADRs) with frequency 'uncommon', based on post-marketing surveillance. In addition, the MAH took the opportunity to introduce minor changes to the PI."	
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0136 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, "Update of sections 5.1 of the SmPC in order to provide the final OS data (including analyses/KM plots from favourable prognosis subgroups) following the assessment of procedure II/0104, based on results from study E7080-G000-307/KEYNOTE 581 (REC); A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Everolimus or Pembrolizumab Versus Sunitinib Alone in First-Line Treatment of Subjects with Advanced Renal Cell Carcinoma (CLEAR)."	
Kisplyx - lenvatinib - EMEA/H/C/004224/II/0055 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "Update of section 5.1 of the SmPC in order to update efficacy information in first-line treatment of patients with renal cell carcinoma (in combination with pembrolizumab), based on the OS final analysis for the overall population from study E7080-G000-307/KEYNOTE 581; this	

is a multicenter, randomized, open-label, phase 3 study comparing the efficacy and safety of lenvatinib in combination with either pembrolizumab or everolimus versus sunitinib alone in first-line treatment of subjects with advanced renal cell carcinoma (RCC)."

NUVAXOVID - covid-19 vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0045

Novavax CZ, a.s., Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen - adolescent boosting vaccination based on interim results from study 2019nCOV-301(IR) listed as a category 3 study in the RMP; this is a Phase 3, randomised, observer-blinded, placebo- controlled study to evaluate the efficacy, safety, and immunogenicity of SARS CoV-2 rS with Matrix-M adjuvant in adult participants ≥ 18 years of age with a paediatric expansion (12 to < 18 years of age). The Package Leaflet is updated accordingly."

Oxlumo - lumasiran - EMEA/H/C/005040/II/0014, Orphan

Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from study ALN-GO1; this is a 105 week Subcutaneous Carcinogenicity Study in Rats with Toxicokinetics. In addition, the MAH took the opportunity to implement editorial changes and to bring the PI in line with the latest QRD template version 10.3."

Paxlovid - nirmatrelvir / ritonavir - EMEA/H/C/005973/II/0037

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Submission of the updated population modelling analysis report (PMAR-EQDD-C467a-Other-1463): population pharmacokinetics of nirmatrelvir/ritonavir after oral administration in adults with/without COVID-19 - a pooled analysis of phase 1/2/3 data."

Perjeta - pertuzumab - EMEA/H/C/002547/II/0066

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "To update sections 4.8 and 5.1 to reflect updated overall survival data and cardiac safety data, based on interim results from study

BO25126 (APHINITY): A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer.
The Package Leaflet is updated accordingly.
In addition, the MAH took the opportunity to introduce editorial changes."

QUVIVIQ - daridorexant - EMEA/H/C/005634/II/0009/G

Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information with midazolam, dabigatran, rosuvastatin and warfarin, based on studies ID-078-125 and ID-078-126. Study ID-078-125 is a single-center, open-label, three-period, fixed-sequence design study to investigate the effect of daridorexant on the pharmacokinetics of dabigatran and rosuvastatin in healthy male subjects, while study ID-078-126 is a single-center, open-label study to investigate the effect of single- and multiple-dose daridorexant on the pharmacokinetics of midazolam and its metabolite 1-hydroxymidazolam, and the effect of single-dose daridorexant on the pharmacokinetics and pharmacodynamics of warfarin in healthy male subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI."

Reyataz - atazanavir - EMEA/H/C/000494/II/0137

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.3 and 4.5 in order to add drug-drug interaction information with antiplatelet therapies classified as P2Y12 platelet inhibitors (ticagrelor, clopidogrel and prasugrel), dexamethasone or other corticosteroids, antineoplastics encorafenib or ivosidenib, gonadotropin-releasing hormone (GnRH) receptor antagonist elagolix, kinase inhibitor fostamatinib and antineoplastic apalutamide based on the cumulative review of literature search.
The Package Leaflet is updated accordingly.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

RINVOQ - upadacitinib - EMEA/H/C/004760/II/0033

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Submission of the final report from study M16-098 listed as a category 3 study in the RMP. This is a multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of upadacitinib in subjects with active ankylosing spondylitis."

Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/II/0005

SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, "Update of section 4.2 of the SmPC in order to introduce a new posology regimen for those with a body weight of 120 kg and above based on final results from study SIGA-246-022 and study report 865, which is a PopPK modelling and simulation report. Study SIGA-246-022 is a multiple-dose, open-label, safety, tolerability, and pharmacokinetic study of tecovirimat in adults weighing more than 120 kg. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Tecvayli - teclistamab - EMEA/H/C/005865/II/0003

Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, "Update of sections 4.2, 4.6 and 5.2 of the SmPC in order to revise the dosing schedule, amend recommendations on contraception and breast-feeding and to update pharmacokinetic information, based on the latest data available; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet."

TEZSPIRE - tezepelumab - EMEA/H/C/005588/II/0008

AstraZeneca AB, Rapporteur: Finbarr Leacy, "Update of section 4.5 of the SmPC in order to include information relating to the humoral antibody responses induced by the seasonal influenza virus based on final results from study

VECTOR (D5180C00031); this is a multicenter, randomized, double-blind, parallel group, placebo-controlled, phase IIIb study to evaluate the potential effect of tezepelumab on the humoral immune response to seasonal quadrivalent influenza vaccination in adolescent and young adult participants with moderate to severe asthma. In addition, the MAH took the opportunity to implement editorial changes to section 5.1 of the SmPC."	
Twynsta - telmisartan / amlodipine - EMEA/H/C/001224/II/0046/G Boehringer Ingelheim International GmbH, Rapporteur: Martina Weise, "C.I.4: Update of section 4.8 of the SmPC in order to add 'hyponatraemia' to the list of adverse drug reactions (ADRs) with frequency 'rare'; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, update the list of local representatives in the Package Leaflet and bring the PI in line with the latest QRD template version 10.3. C.I.z: Update of section 4.9 of the SmPC in order to add the risk of non-cardiogenic pulmonary oedema for amlodipine in case of overdose; the Package Leaflet is updated accordingly."	
Veklury - remdesivir - EMEA/H/C/005622/II/0049 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update preclinical data on the antiviral activity of remdesivir against the Omicron subvariants BA.2.75, BA.4.6, BF.5, XBB, and BQ.1.1 based on results from study PC-540-2044."	
Victoza - liraglutide - EMEA/H/C/001026/II/0066 Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add Dysgeusia to the list of adverse drug reactions (ADRs) with frequency Uncommon based on the cumulative review of scientific literature. The Package Leaflet is updated accordingly."	
VITRAKVI - larotrectinib - EMEA/H/C/004919/II/0030	

Bayer AG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC in order to change posology recommendations in patients with liver function abnormalities, amend an existing warning on hepatotoxicity, update information on drug-drug interaction information with regards of effects CYP3A, P-gp and BCRP inhibitors and CYP3A and P-gp inducers, updates to the list of adverse drug reactions (ADRs), update efficacy data based on interim results from studies 20289 and 2090. The Package Leaflet is updated accordingly."

WS2415
Vfend-EMEA/H/C/000387/WS2415/0148
Pfizer Europe MA EEIG, Lead Rapporteur: Johann Lodewijk Hillege, "Update of section 4.4 of the SmPC to include increased risk of skin toxicity with concomitant use of voriconazole and methotrexate and potentially other drugs associated with ultraviolet (UV) reactivation to the current warning on photosensitivity skin reactions, based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to sections 4.4 and 4.5 of the SmPC."

WS2450/G
Glyxambi-
EMEA/H/C/003833/WS2450/0051/G
Synjardy-
EMEA/H/C/003770/WS2450/0070/G
Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to modify administration instructions to the elderly, amend an existing warning for the elderly and remove the warning for 'Cardiac Failure' in order to align with the Jardiance Product Information; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.
C.I.z: Update of section 4.4 of the SmPC in order to introduce a rewording related to use in patients with type 1 diabetes in order to align with the Jardiance Product Information; the Package Leaflet is updated accordingly."

WS2460

Elebrato Ellipta-
EMEA/H/C/004781/WS2460/0032
Trelegy Ellipta-
EMEA/H/C/004363/WS2460/0029
GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Anxiety', 'Tremor', 'Muscle spasms', 'Hyperglycaemia' and 'Palpitations' to the list of adverse drug reactions (ADRs) with frequency rare, based on an internal safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

WS2465
Entresto-
EMEA/H/C/004062/WS2465/0051
Neparvis-
EMEA/H/C/004343/WS2465/0049
Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Anette Kirstine Stark, "Submission of the final report from study CLCZ696B2320 listed as a category 3 study in the RMP in order to fulfil MEA/001. This is a multicenter, randomized, double-blind, active-controlled study to evaluate the effects of LCZ696 compared to valsartan on cognitive function in patients with chronic heart failure and preserved ejection fraction. The RMP version 6 has also been submitted."

B.6.10. CHMP-PRAC assessed procedures

Brineura - cerliponase alfa -
EMEA/H/C/004065/II/0039, Orphan
BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 9 of the SmPC in order to state that clinical data are available for patients aged 1 year and older and to include updates to the frequency of adverse reactions, immunogenicity, pharmacokinetic, and paediatric population sections based on the final results from studies 190-203, listed as a specific obligation and 190-202 (submitted in P46/013).
Study 190-203 was a Phase 2, open-label, multicenter study in pediatric patients < 18 years of age with CLN2 disease, confirmed by

deficiency of TPP1 enzyme activity and mutation of the CLN2 gene.
The Package Leaflet, Annex II and Annex IV are updated accordingly.
The RMP version 4.0 has also been submitted."

Bylvay - odevixibat - EMEA/H/C/004691/II/0013, Orphan
Albireo, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.4, 4.5 and 4.6 of the SmPC in order to update an existing warning, add drug-drug interaction (DDI) information with oral contraceptives and update information for women of childbearing potential, based on study A4250-022 listed as a category 3 study in the RMP; this is an open-label, phase 1 DDI study to evaluate the interaction of odevixibat with oral lipophilic contraceptives in healthy volunteers. The Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted."

Glivec - imatinib - EMEA/H/C/000406/II/0133
Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Monica Martinez Redondo, "Submission of the final report from study CSTI571I2201 - A European observational registry collecting efficacy and safety data in newly diagnosed pediatric Ph+ ALL patients treated with chemotherapy + imatinib ± HSCT, listed as an obligation in the Annex II of the Product Information. This study has been designed as an observational, multi-center registry to collect efficacy and safety data in Ph+ ALL pediatric patients (ages 1 to <18 years old) treated with chemotherapy + imatinib, with or without (± HSCT) primarily in European countries. The Annex II and the RMP (version 13.0) are updated accordingly."

Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0035, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber, "Update of sections 4.8 and 5.1 of the SmPC based on interim results from study VX19-445-107 (Study 107) listed as a category 3 study in the RMP; this is a Phase III, open-label study evaluating the long-

term safety and efficacy of VX445/TEZ/IVA combination therapy in subjects with cystic fibrosis who 6 years of age and older. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

LIVTENCITY - maribavir - EMEA/H/C/005787/II/0004, Orphan

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Submission of the final report from study SHP620-302 listed as a category 3 study in the RMP. This is a Phase III, multicenter, randomized, double-blind, double-dummy, active-controlled study of maribavir compared to valganciclovir for the treatment of asymptomatic Cytomegalovirus (CMV) Infection in Hematopoietic Stem Cell Transplant recipients. The RMP version 2.0 has also been submitted."

LUMYKRAS - sotorasib - EMEA/H/C/005522/II/0010/G

Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change in the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B. Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the

SmPC."

Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0094

Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, "Update of section 4.2 of the SmPC in order to add home infusion upon request by PRAC following the assessment of PSUSA/00000086/202109 I based on a cumulative search of the MAH Global Pharmacovigilance database and literature. The Package Leaflet and Annex II are updated accordingly.
The RMP version 10.0 has also been submitted."

Padcev - enfortumab vedotin - EMEA/H/C/005392/II/0007

Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Eva Jirsová, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to introduce new posology recommendations in case of pneumonitis/interstitial lung disease (ILD), add a new warning on 'pneumonitis/ILD' and add it to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Prolia - denosumab - EMEA/H/C/001120/II/0098

Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 5.1 and 5.2 in order to update efficacy, pharmacokinetic and safety information for paediatric population following the assessment of P46/043 and P46/044 based on final results from study 20130173, listed as a category 3 study in the RMP and study 20170534.
Study 20130173 was a prospective, multicenter, open-label, single-arm phase 3 study to evaluate the safety, efficacy, and PK of denosumab in children 2 to 17 years of age with OI.
Study 20170534 was an open-label, prospective, extension study of study 20130173.
The RMP version 31 has also been submitted.

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

Rekovelle - follitropin delta - EMEA/H/C/003994/II/0037/G

Ferring Pharmaceuticals A/S, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst, "Grouped application comprising two type II variations as follows:
- Update of sections 4.1, 4.2, 4.4, 4.5 and 5.1 of the SmPC to update the safety information following final results from study 000304 (BEYOND). This is a randomised, controlled, open label, parallel group, multicentre trial comparing the efficacy and safety of individualised FE 999049 (follitropin delta) dosing, using a long GnRH agonist protocol and a GnRH antagonist protocol in women undergoing controlled ovarian stimulation.
- Update of section 4.8 of the SmPC, including the tabulation of adverse drug reactions based on pooled safety data from studies ESTHER-1, ESTHER-2, 000273, 000145, BEYOND and RAINBOW.
The updated RMP version 8.0 has also been submitted.
In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Simponi - golimumab - EMEA/H/C/000992/II/0113

Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final report from study CNTO148UCO1001 (PURSUIT PEDS PK) listed as a category 3 study in the RMP. This is a phase 1b open-label study to assess the safety and pharmacokinetics of subcutaneously administered golimumab, a human anti-TNFα antibody, in pediatric subjects with moderately to severely active ulcerative colitis. The RMP version 24.1 has also been submitted."

Stelara - ustekinumab - EMEA/H/C/000958/II/0098/G

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

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0077/G

Roche Registration GmbH, Rapporteur: Aaron

Sosa Mejia, PRAC Rapporteur: Inês Ribeiro-Vaz, "Grouped application comprising two type II variations as follows: - Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add dose modification advice and new warning for two new important identified risks of immune-mediated myelitis and immune-mediated facial paresis and to add facial paresis and myelitis to the list of adverse drug reactions (ADRs) with frequency Rare following a safety signal based on the cumulative review of the MAH safety database and literature search. - Update of section 4.8 of the SmPC in order to add dry mouth to the list of adverse drug reactions (ADRs) with frequency Common, based on the results from study WO39210 (IMmotion010), a multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of atezolizumab versus placebo in patients with renal cell carcinoma (RCC) who are at high risk of disease recurrence following resection. The Annex II and Package Leaflet are updated accordingly. The RMP version 26.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet."	
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0082 Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on results from study 109MS402 - Tecfidera (dimethyl fumarate) Pregnancy Exposure Registry, listed as a category 3 study in the RMP; This is an observational study and aims to address the safety concern of effects on pregnancy outcome and prospectively evaluates pregnancy outcomes in women with MS who were exposed to a Registry-specified Biogen MS product during the eligibility window for that product. The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted. In addition, the MAH has taken the opportunity to introduce editorial changes to the Product	

Information."	
Vaxzevria - COVID 19 vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0089 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of 'dizziness' and 'abdominal pain' in the list of adverse drug reactions (ADRs) to common and to update safety and efficacy information, based on final results and final pooled analysis for studies COV001, COV002, COV003 and COV005 as well as the final manuscript for COV004, listed as category 3 studies in the RMP. Study COV001 is phase I/II, single-blind, randomised, active-controlled, multicenter study in healthy adults aged 18-55 years; Study COV002 is a phase II/III, single-blind, randomised, active-controlled, multicenter study in adults ≥ 18 years of age and at high risk of exposure to COVID-19; Study COV003 is a phase III, single-blind, randomised, controlled, multicenter study in adults ≥ 18 years of age at high risk of exposure to SARS-CoV-2; Study COV005 is a phase I/II, double-blind, randomised, placebo-controlled, multicenter study in adults 18 to 65 years of age with or without HIV. Study COV004 a phase IB/II single-blind, randomized controlled trial of the (AZD1222) vaccine in adults in Kenya. The Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted."	
WS2438/G **Relvar Ellipta- EMEA/H/C/002673/WS2438/0061/G** **Revinty Ellipta- EMEA/H/C/002745/WS2438/0058/G** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Monica Martinez Redondo, "Grouped application consisting of 1) Update sections 4.2 and 5.1 of the SmPC to include results from study HZA107116. This is a randomised, double-blind, parallel group, multicentre, stratified, study evaluating the efficacy and safety of once daily fluticasone furoate/vilanterol inhalation powder compared to once daily fluticasone furoate inhalation	

powder in the treatment of asthma in participants aged 5 to 17 years old (inclusive) currently uncontrolled on inhaled corticosteroids. The Package Leaflet and Labelling are updated accordingly. The RMP version 12.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC; 2) Submission of final report from Phase 2b study HZA106855 (FF dose ranging) which gives information regarding the dose selection for FF combination in study HZA107116; 3) Submission of final report from Phase 2b study HZA106853 (VI dose ranging) which gives information regarding the dose selection for VI combination in study HZA107116."

WS2451
Bondronat-
EMEA/H/C/000101/WS2451/0090
Bonviva-
EMEA/H/C/000501/WS2451/0075
Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Lead PRAC Rapporteur: Anette Kirstine Stark, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add information regarding the risk of "Atypical fractures of other long bones"; based on literature. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3."

B.6.11. PRAC assessed procedures

PRAC Led
AJOVY - fremanezumab -
EMEA/H/C/004833/II/0039
TEVA GmbH, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 4.0 in order to replace PASS TV48125-MH-50039 with PASS TV48125-MH-40217 following MEA/005.3 and MEA/005.4."

PRAC Led
Benlysta - belimumab -
EMEA/H/C/002015/II/0111
GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison:

Kristina Dunder, "Submission of the final report from year 5 Post-Treatment Follow-Up from study BEL 115467/HGS1006-C113 listed as a category 3 study in the RMP. This is a 52-week, global, multi-centre, randomized, placebo-controlled, double-blind study conducted to evaluate mortality and AESI in adults with active, autoantibody-positive SLE treated with belimumab plus standard therapy vs. placebo plus standard therapy. Following the 52-week controlled treatment period (Year 1), the study included a 4-year follow-up of each participant (Year 2-5). During the follow-up period, participants no longer received study intervention. The RMP version 44 has also been submitted."

PRAC Led

Skilarence - dimethyl fumarate - EMEA/H/C/002157/II/0032

Almirall S.A, Rapporteur: Janet Koenig, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study M-41008-44 listed as a category 3 study in the RMP. This is a non-interventional Post-Authorisation Safety Study titled 'A retrospective chart review to assess the effectiveness of the Skilarence risk minimisation activities in daily practice'. The RMP version 2.1 has also been submitted."

PRAC Led

Xeljanz - tofacitinib - EMEA/H/C/004214/II/0052

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from study A3921334 listed as a category 3 study in the RMP. This is a Non-Interventional Post Authorisation Safety Study to evaluate the effectiveness of additional risk minimisation measures materials for tofacitinib in Europe via a survey of healthcare professionals."

PRAC Led

WS2431

Tadalafil Mylan- EMEA/H/C/003787/WS2431/0023

Mylan Pharmaceuticals Limited, Generic, Generic of Cialis, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "To update the RMP

(version 3) to:
-develop follow-up forms in line with the reference product, Cialis, and to update Part III of RMP and Annex, Specific Adverse Drug Reaction Follow-up Forms accordingly, following CHMP and PRAC Rapporteurs Joint Assessment Report (EMEA/H/C/003787/R/0014, dated 15-Apr-2019).
-adopt the safety concerns in the RMP from the ones available on CMDh website (Revision 35, dated Sep-2022) for generic RMP version 1.1 dated 01 Apr 2020 approved via procedure PT/H/1982/001-002/DC.
-submit the updates in the new template (EMA/164014/2018 Rev.2.0.1 accompanying GVP Module V Rev.2).
The requested worksharing procedure proposed amendments to the None and to the Risk Management Plan (RMP).”

PRAC Led
WS2453
ProQuad-
EMEA/H/C/000622/WS2453/0160
Zostavax-
EMEA/H/C/000674/WS2453/0145
Merck Sharp & Dohme B.V., Lead PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, “Submission of updated RMPs for ProQuad and Zostavax versions 8.1 and 10.1 respectively, in order to remove the Varicella Zoster Virus Identification Program (VZVIP) as a routine pharmacovigilance activity beyond adverse reactions reporting and signal detection from the RMP Part III: pharmacovigilance plan.”

B.6.12. CHMP-CAT assessed procedures

Abecma - idecabtagene vicleucel - EMEA/H/C/004662/II/0032/G, Orphan, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Alofisel - darvadstrocel - EMEA/H/C/004258/II/0044/G, Orphan, ATMP
Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder, “Grouped application comprising one type II

variation and two type IB as follows: - Update of section 4.8 of the SmPC in order to update the Summary of the safety profile and to add anal abscess, proctalgia and anal fistula to the list of adverse drug reactions on post-marketing experience following the assessment of R/0036 based on a review of the MAH's Global Safety Database. - Update of section 4.2 of the SmPC in order to add the term Perilesional as an EDQM term, following the assessment of R/0036. - Update of sections 1, 2.2, 3, 4.2, 6.5 and 6.6 of the SmPC in order to replace the term "suspension for injection" for "dispersion for injection", following the assessment of R/0036. The Annex A, Package Leaflet and Labelling are updated in accordance."	
Alofisel - darvadstrocel - EMEA/H/C/004258/II/0045/G, Orphan, ATMP Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder	
Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0062/G, ATMP Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo	
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0069, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang	
ROCTAVIAN - valoctocogene roxaparvovec - EMEA/H/C/005830/II/0004/G, Orphan, ATMP BioMarin International Limited, Rapporteur: Violaine Closson Carella, CHMP Coordinator: Jean-Michel Race	

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS2433

Hexacima-
EMEA/H/C/002702/WS2433/0145
Hexyon-
EMEA/H/C/002796/WS2433/0149
Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

WS2439/G
Edistride-
EMEA/H/C/004161/WS2439/0060/G
Forxiga-
EMEA/H/C/002322/WS2439/0081/G
AstraZeneca AB, Lead Rapporteur: Kristina Dunder

WS2440/G
Riarify-
EMEA/H/C/004836/WS2440/0026/G
Trimbow-
EMEA/H/C/004257/WS2440/0032/G
Trydonis-
EMEA/H/C/004702/WS2440/0029/G
Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig

WS2452
CoAprovel-
EMEA/H/C/000222/WS2452/0213
Karvezide-
EMEA/H/C/000221/WS2452/0213
Sanofi Winthrop Industrie, Duplicate, Duplicate of Karvezide, Lead Rapporteur: Maria Concepcion Prieto Yerro

WS2455/G
Ongentys-
EMEA/H/C/002790/WS2455/0058/G
Ontilyv-
EMEA/H/C/005782/WS2455/0013/G
Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise

WS2459
Abseamed-
EMEA/H/C/000727/WS2459/0101
Binocrit-
EMEA/H/C/000725/WS2459/0100
Epoetin alfa Hexal-
EMEA/H/C/000726/WS2459/0100
Sandoz GmbH, Lead Rapporteur: Alexandre Moreau

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 27-30 March 2023 CHMP plenary:

G.2.2. List of procedures starting in March 2023 for April 2023 CHMP adoption of outcomes

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