



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 June 2024  
EMA/CHMP/259829/2024  
Human Medicines Division

## Committee for medicinal products for human use (CHMP)

### Draft agenda for the meeting on 24-27 June 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

24 June 2024, 13:00 – 19:45, virtual meeting/room 1C

25 June 2024, 08:30 – 19:45, virtual meeting/room 1C

26 June 2024, 08:30 – 19:45, virtual meeting/room 1C

27 June 2024, 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).



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## 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 24-27 June 2024. See June 2024 CHMP minutes (to be published post July 2024 CHMP meeting).

### 1.2. Adoption of agenda

CHMP agenda for 24-27 June 2024

### 1.3. Adoption of the minutes

CHMP minutes for 27-30 May 2024.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 17 June 2024.

## 2. Oral Explanations

### 2.1. Pre-authorisation procedure oral explanations

#### 2.1.1. Lecanemab - EMEA/H/C/005966

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

Scope: Oral explanation, intervention by a third party

**Action:** Oral explanation to be held on 25 June 2024 at 14:00

Participation of patient representatives.

List of Outstanding Issues adopted on 21.03.2024, 09.11.2023. List of Questions adopted on 25.05.2023.

#### 2.1.2. Pegcetacoplan - EMEA/H/C/005954

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Apellis Europe B.V.; Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: Oral explanation, intervention by a third party

**Action:** Oral explanation to be held on 25 June 2024 at 16:00

List of Outstanding Issues adopted on 25.04.2024, 12.10.2023. List of Questions adopted on 25.05.2023.



## 2.2. Re-examination procedure oral explanations

No items

## 2.3. Post-authorisation procedure oral explanations

### 2.3.1. Translarna - ataluren - EMEA/H/C/002720/R/0071 - Orphan

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PTC Therapeutics International Limited

Rapporteur: Peter Mol, Co-Rapporteur: Antonio Gomez-Outes

Scope: Oral explanation

**Action:** Oral explanation to be held on 25 June 2024 at 11:00

Participation of patient representatives.

Negative Opinion adopted on 25.01.2024. Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 25.05.2023.

See 9.1

### 2.3.2. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017

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Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: "Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and BMI  $\geq 27$  kg/m<sup>2</sup> for WEGOVY, based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Scope: Oral explanation

**Action:** Oral explanation to be held on 26 June 2024 at 09:00

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

See 5.1

## 2.4. Referral procedure oral explanations

### 2.4.1. Ocaliva - obeticholic acid - EMEA/H/A-20/1531

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Advanz Pharma Limited

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

Scope: Oral explanation

**Action:** Oral explanation to be held on 25 June 2024 at 09:00

Participation of patient representatives.

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed.

List of outstanding issues adopted on 25.01.2024. List of Questions adopted on 12.10.2023.

See 10.1

## 3. Initial applications

### 3.1. Initial applications; Opinions

#### 3.1.1. Erdafitinib - EMEA/H/C/006050

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treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC)

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

#### 3.1.2. Enzalutamide - EMEA/H/C/006299

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treatment of prostate cancer

Scope: Opinion

**Action:** For adoption

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

#### 3.1.3. Epinephrine - EMEA/H/C/006139

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Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 30.05.2024, 12.10.2023. List of Questions adopted on 23.02.2023.

#### 3.1.4. Masitinib - Orphan - EMEA/H/C/005897

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AB Science; in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS)

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 30.05.2024, 25.01.2024, 25.05.2023. List of Questions adopted on 15.12.2022.

#### 3.1.5. Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278

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

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 09.11.2023.

#### 3.1.6. Nilotinib - EMEA/H/C/006315

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treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 09.11.2023.

#### 3.1.7. Odronextamab - Orphan - EMEA/H/C/006215

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Regeneron Ireland Designated Activity Company; treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)

Scope: Opinion

**Action:** For adoption

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

#### 3.1.8. Crovalimab - EMEA/H/C/006061

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treatment of paroxysmal nocturnal haemoglobinuria

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on

09.11.2023.

### 3.1.9. Ustekinumab - EMEA/H/C/005918

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treatment of adult patients with moderately to severely active Crohn's disease, plaque psoriasis, paediatric plaque psoriasis and Psoriatic arthritis (PsA)

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 12.10.2023.

### 3.1.10. Flortaucipir (18F) - EMEA/H/C/006064

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

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 22.02.2024, 14.12.2023. List of Questions adopted on 20.07.2023.

### 3.1.11. Sotatercept - PRIME - Orphan - EMEA/H/C/005647

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

Scope: Opinion

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 23.01.2024.

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

### 3.2.1. Ustekinumab - EMEA/H/C/006585

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treatment of active plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA) and Crohn's disease.

Scope: List of outstanding issues

**Action:** For adoption

### 3.2.2. Aflibercept - EMEA/H/C/006150

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treatment of age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO), due to diabetic macular oedema (DME) and due to myopic choroidal neovascularisation (myopic CNV) or central RVO),

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 25.01.2024.

### 3.2.3. [Axitinib - EMEA/H/C/006206](#)

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treatment of adult patients with advanced renal cell carcinoma (RCC)

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 20.07.2023.

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

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treatment of alopecia areata in children and adolescents

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 12.10.2023.

### 3.2.5. [Bimatoprost - EMEA/H/C/005916](#)

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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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 20.07.2023.

### 3.2.6. [Mirvetuximab soravtansine - Orphan - EMEA/H/C/005036](#)

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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 22.02.2024.

### 3.2.7. [Vilobelimab - EMEA/H/C/006123](#)

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treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal

membrane oxygenation (ECMO).

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 14.12.2023.

### 3.2.8. Ustekinumab - EMEA/H/C/006221

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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 09.11.2023.

### 3.2.9. Temozolomide - Orphan - EMEA/H/C/006169

Orphelia Pharma; treatment of neuroblastoma

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 14.12.2023.

### 3.2.10. Meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165

indicated for active immunisation to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W, and Y

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 12.10.2023.

### 3.2.11. Aflibercept - EMEA/H/C/006056

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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 21.03.2024.

### 3.2.12. rdESAT-6 / rCFP-10 - EMEA/H/C/006177

Diagnosis of infection with *Mycobacterium tuberculosis*

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 22.06.2023.

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

#### 3.3.1. Tocilizumab - EMEA/H/C/006196

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treatment of rheumatoid arthritis (RA)

Scope: List of questions

**Action:** For adoption

#### 3.3.2. Datopotamab - EMEA/H/C/006547

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Treatment of adult patients with inoperable or metastatic HR-positive / HER2-negative breast cancer with disease progression following chemotherapy in the metastatic setting

Scope: List of questions

**Action:** For adoption

#### 3.3.3. Datopotamab - EMEA/H/C/006081

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treatment of adult patients with locally advanced or metastatic non squamous non-small cell lung cancer (NSCLC)

Scope: List of questions

**Action:** For adoption

#### 3.3.4. Pegfilgrastim - EMEA/H/C/006407

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treatment of neutropenia

Scope: List of questions

**Action:** For adoption

#### 3.3.5. Resminostat - Orphan - EMEA/H/C/006259

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

Scope: List of questions

**Action:** For adoption

#### 3.3.6. Seladelpar lysine dihydrate - PRIME - Orphan - EMEA/H/C/004692

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CymaBay Ireland, Ltd; treatment of primary biliary cholangitis (PBC) including pruritus in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with

ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA

Scope: List of questions

**Action:** For adoption

### 3.3.7. [Nirogacestat - Orphan - EMEA/H/C/006071](#)

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Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: List of questions

**Action:** For adoption

### 3.3.8. [Aflibercept - EMEA/H/C/006339](#)

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

Scope: List of questions

**Action:** For adoption

### 3.3.9. [Resmetirom - EMEA/H/C/006220](#)

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for the treatment of adults with nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis

Scope: List of questions

**Action:** For adoption

### 3.3.10. [Aflibercept - EMEA/H/C/006551](#)

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

Scope: List of questions

**Action:** For adoption

### 3.3.11. [Ustekinumab - EMEA/H/C/006444](#)

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for the treatment of Crohn's disease and ulcerative colitis

Scope: List of questions

**Action:** For adoption

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

### 3.4.1. [Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594](#)

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repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III



or IV

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of questions adopted in April 2024.

The CAT agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2024.

**Action:** For information

List of Questions adopted on 19.04.2024.

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

No items

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

No items

### **3.7. Withdrawals of initial marketing authorisation application**

#### **3.7.1. Dabigatran etexilate - EMEA/H/C/006023**

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Prevention of venous thromboembolic events

Scope: Withdrawal of marketing authorisation application

**Action:** For information

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 21.07.2022.

## **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. Betmiga - Mirabegron - EMEA/H/C/002388/X/0039/G**

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Astellas Pharma Europe B.V.;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (8 mg/ml prolonged-release granules for oral suspension), grouped with a type II variation (C.I.6.a) to include treatment of neurogenic detrusor overactivity (NDO) in paediatric patients aged 3 to less than 18 years.

The RMP (version 9.0) is updated in accordance."

**Action:** For adoption

List of Outstanding Issues adopted on 22.02.2024, 15.09.2022. List of Questions adopted on 22.04.2022.

#### 4.1.2. Cresemba - Isavuconazole - Orphan - EMEA/H/C/002734/X/0042/G

Basilea Pharmaceutica Deutschland GmbH;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 40 mg hard capsule to be used in paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and older for CRESEMBA 200 mg powder, based on final results from studies 9766-CL-0107 and 9766-CL-0046. Study 9766-CL-0046 is a Phase 1, open-label, multicentre study to evaluate the PK, safety and tolerability of intravenous and oral isavuconazonium sulfate in paediatric patients. This study was conducted in two sequential parts: Part 1 with three intravenous dosing cohorts, and Part 2 with two oral dosing cohorts. Study 9766-CL-0107 is a Phase 2, open-label, non-comparative, multicentre study to evaluate the safety and tolerability, efficacy, and PK of isavuconazole for the treatment of invasive aspergillosis or mucormycosis in paediatric patients aged 1 to < 18 years.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted."

**Action:** For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

#### 4.1.3. XALKORI - Crizotinib - EMEA/H/C/002489/X/0080/G

Pfizer Europe MA EEIG;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form (granules in capsules for opening) associated with new strengths (20, 50 and 150 mg), grouped with a type II variation (C.I.6.a) to include the treatment of paediatric patients with relapsed or refractory, systemic ALK-positive ALCL or unresectable, recurrent, or refractory ALK-positive IMT to change the lower end of the age range from  $\geq 6$  years to  $\geq 1$  year for Xalkori following the assessment of II/0072 based on final results from study ADVL0912. 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 9.1 of the RMP has also been submitted."

**Action:** For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 12.10.2023.

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

### 4.2.1. Opsumit - Macitentan - EMEA/H/C/002697/X/0051/G

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Janssen-Cilag International N.V.;

Rapporteur: Antonio Gomez-Outes, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

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

**Action:** For adoption

List of Questions adopted on 22.02.2024.

### 4.2.2. PHEBURANE - Sodium phenylbutyrate - EMEA/H/C/002500/X/0037

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Eurocept International B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 1.1) is updated in accordance."

**Action:** For adoption

List of Questions adopted on 25.01.2024.

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

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Proveca Pharma Limited;

Rapporteur: John Joseph Borg, PRAC Rapporteur: Mari Thorn

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

**Action:** For adoption

4.3.2. **BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/X/0014/G**

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Hipra Human Health S.L.;

Rapporteur: Beata Maria Jakline Ullrich, PRAC rapporteur: Zane Neikena

Extension application and Quality variation

**Action:** For adoption

4.3.3. **Uzpruvo - Ustekinumab - EMEA/H/C/006101/X/0001**

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STADA Arzneimittel AG;

Rapporteur: Christian Gartner, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (130 mg concentrate for solution for infusion) and a new route of administration (intravenous use). The RMP version 1.1 is updated in accordance."

**Action:** For adoption

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

No items

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

No items

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

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

5.1.1. **Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005**

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Sanofi Winthrop Industrie;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of children up to 24 months of age who remain vulnerable to severe Respiratory Syncytial Virus (RSV) disease through their second

RSV season for BEYFORTUS, based on interim results from studies D5290C00005 and D5290C00008.

Study D5290C00005 (MEDLEY) is a Phase II/III, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus in high-risk children. Study D5290C00008 (MUSIC) is a Phase II, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetics, and occurrence of antidrug antibody for Beyfortus in immunocompromised children ≤ 24 Months of Age.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

**Action:** For adoption

Request for Supplementary Information adopted on 30.05.2024, 25.04.2024, 25.01.2024, 12.10.2023, 20.07.2023.

### 5.1.2. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0072

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Janssen-Cilag International N.V.;

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: “Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the treatment of adult patients with newly diagnosed multiple myeloma, who are eligible for autologous stem cell transplant for Darzalex, based on the primary analysis results from the pivotal study 54767414MMY3014 (PERSEUS) and the results from study 54767414MMY2004 (GRIFFIN) and the D-VRd cohort of study 54767414MMY2040 (PLEIADES).

MMY3014 (PERSEUS) is a randomised, open-label, active-controlled, multicentre phase 3 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy (as required for autologous stem cell transplant). The primary objective is to compare the efficacy of (subcutaneous) daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd) in terms of progression free survival (PFS).

MMY2004 (GRIFFIN) is a randomised, open-label, active controlled, multicentre phase 2 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy and autologous stem cell transplant. The primary objective is to compare the efficacy of daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd), in terms of stringent complete response (sCR) rate.

MMY2040 (PLEIADES) is a randomised, open-label, multicentre phase 2 study to evaluate subcutaneous daratumumab in combination with standard multiple myeloma treatment regimens. The D-VRd cohort included adult subjects with newly diagnosed multiple myeloma, who were evaluated for clinical benefit in terms of very good partial response or better (VGPR) rate.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

**Action:** For adoption

### 5.1.3. Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0023

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Novo Nordisk A/S;

Rapporteur: Daniela Philadelphia, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include children below 12 years of age for treatment and prophylaxis of bleeding with haemophilia A for Esperoct, including previously untreated patients (PUPs) based on the final results from studies 3776, 4410, 3908, 3859, 3885, 3860, 4033 and 4595. As a consequence, section 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

**Action:** For adoption

### 5.1.4. Fasentra - Benralizumab - EMEA/H/C/004433/II/0052

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AstraZeneca AB;

Rapporteur: Fátima Ventura (PT) (MNAT with EL for Clinical Safety, EL for Clinical Efficacy, EL for Clinical Pharmacology), PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include treatment of eosinophilic granulomatosis with polyangiitis for Fasentra, based results from study D3253C00001 (Mandara); this was a randomised, double-blind, multicentre, parallel group, active-controlled, non-inferiority study that evaluated the efficacy and safety of benralizumab compared with mepolizumab in treatment of patients with EGPA on corticosteroid therapy with or without stable immunosuppressive therapy. 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 6.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes. 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 21.03.2024.

### 5.1.5. Hepcludex - Bulevirtide - Orphan - EMEA/H/C/004854/II/0031

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Gilead Sciences Ireland Unlimited Company;

Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease for Hepcludex, based on a modelling and simulation study and an extrapolation study to evaluate the use of Bulevirtide for the treatment of chronic hepatitis D infection in children from 3 to less than 18 years of age. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 4.1 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.”

**Action:** For adoption

Request for Supplementary Information adopted on 22.02.2024.

#### 5.1.6. [IMCIVREE - Setmelanotide - Orphan - EMEA/H/C/005089/II/0018](#)

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Rhythm Pharmaceuticals Netherlands B.V.,;

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

Scope: “Extension of indication to include the population of children aged 2 years and above for the treatment of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin Type 1 (PCSK1) deficiency or biallelic leptin receptor (LEPR) deficiency and Bardet-Biedl Syndrome (BBS) for IMCIVREE, based on the final results from study RM-493-033 “A Phase 3 Multicentre, One-Year, Open-Label Study of Setmelanotide in Paediatric Patients Aged 2 To <6 Years of Age with Rare Genetic Causes of Obesity”; this is an open label study to evaluate the weight-related parameters along with the safety and tolerability of setmelanotide in patients aged 2 to <6 years. 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 2.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI.”

**Action:** For adoption

Request for Supplementary Information adopted on 21.03.2024.

#### 5.1.7. [Infanrix hexa - Diphtheria, tetanus, pertussis \(acellular, component\), hepatitis B \(rDNA\), poliomyelitis \(inact.\) and haemophilus type B conjugate vaccine \(adsorbed\) - EMEA/H/C/000296/II/0340/G](#)

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GlaxoSmithkline Biologicals SA;

Rapporteur: Christophe Focke

Scope: “A grouped application consisting of two type II variations, as follows:

C.I.6.a: To modify the approved therapeutic indication to include treatment from the age of 6 weeks for the administration of the primary vaccination, section 4.1 of the SmPC is updated accordingly.

C.I.4: Update of section 4.2 of the SmPC for the use of mixed hexavalent/pentavalent primary vaccination schedule and vaccine interchangeability. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity implement editorial changes to the SmPC and the Package Leaflet.”

**Action:** For adoption

Request for Supplementary Information adopted on 25.04.2024.

#### 5.1.8. [Jaypirca - Pirtobrutinib - EMEA/H/C/005863/II/0002](#)

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Eli Lilly Nederland B.V.;

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

Scope: " Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)

**Action:** For adoption

#### 5.1.9. [Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0145](#)

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Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) the treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [Stage IB2-IIB (with node-positive disease) or Stage III-IVA based on FIGO 2014] for Keytruda, based on KEYNOTE-A18: A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.1 of the RMP has also been submitted."

**Action:** For adoption

Request for Supplementary Information adopted on 25.01.2024.

#### 5.1.10. [Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0153](#)

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Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication for KEYTRUDA in combination with carboplatin and paclitaxel to include first-line treatment of primary advanced or recurrent endometrial carcinoma in adults, based on final results from study KEYNOTE-868. This is a randomized Phase 3, placebo-controlled, double-blind study of pembrolizumab vs placebo in combination with chemotherapy (paclitaxel plus carboplatin) for newly diagnosed Stage III/Stage IVA, Stage IVB, or recurrent endometrial cancer.

As a consequence, sections 4.1 and 5.1 of the SmPC are updated. Version 46.1 of the RMP has also been submitted."

**Action:** For adoption



#### 5.1.11. Pegasys - Peginterferon alfa-2a - EMEA/H/C/000395/II/0119/G

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Pharmaand GmbH;

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Grouped application consisting of:

Extension of indication to include treatment of Polycythaemia Vera (PV) and Essential thrombocytopenia (ET) for PEGASYS, based on published data of clinical studies conducted in support of the efficacy and safety of Pegasys for the treatment of ET and PV. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 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

Request for Supplementary Information adopted on 30.05.2024, 22.02.2024.

#### 5.1.12. Pravafenix - Fenofibrate / Pravastatin sodium - EMEA/H/C/001243/II/0037

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Laboratoires SMB s.a.;

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

Scope: "Extension of indication to include treatment of mixed hyperlipidaemia in adult patients while on a treatment with pravastatin 40 mg monotherapy or on another moderate-intensity statin regimen for PRAVAFENIX, based on final results from the non-interventional PASS: POSE (Pravafenix Observational Study in Europe); this is a European, observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice. As a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

**Action:** For adoption

Request for Supplementary Information adopted on 21.03.2024.

#### 5.1.13. Tepkinly - Epcoritamab - Orphan - EMEA/H/C/005985/II/0001

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AbbVie Deutschland GmbH & Co. KG;

Rapporteur: Peter Mol, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Monica Martinez Redondo

Scope: " Extension of indication to include treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy for TEPKINLY, based on results from the indolent Non-Hodgkins Lymphoma (iNHL) expansion cohort of Study GCT3013-01, the First In Human (FIH) Phase 1/2 study in R/R B-NHL, with key supportive data from the Phase 1b/2 Study GCT3013-04 in Japanese subjects. Study GCT3013-01 is an ongoing global, single-arm, Phase 1/2 study designed to evaluate epcoritamab as monotherapy in R/R B-NHL. As a consequence, sections 1, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.4, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC)

726/2004)

**Action:** For adoption

Request for Supplementary Information adopted on 30.05.2024, 22.02.2024.

#### 5.1.14. [Vabysmo - Faricimab - EMEA/H/C/005642/II/0005](#)

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Roche Registration GmbH;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre

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

**Action:** For adoption

Request for Supplementary Information adopted on 21.03.2024, 09.11.2023.

#### 5.1.15. [Wegovy - Semaglutide - EMEA/H/C/005422/II/0017](#)

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Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: "Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and BMI  $\geq 27$  kg/m<sup>2</sup> for WEGOVY, based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

See 2.3

#### 5.1.16. [Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027/II/0035](#)

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Pfizer Ireland Pharmaceuticals;

Rapporteur: Ingrid Wang, Co-Rapporteur: Larisa Gorobets, PRAC Rapporteur: Rugile

Pilviniene

Scope: "Extension of indication to include treatment of paediatric patients from birth to less than 3-months of age in the following infections: complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI), including pyelonephritis, hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) and in the treatment of infections due to aerobic Gram-negative organisms in patients with limited treatment options, for ZAVICEFTA, based on final results from study C3591024 and the population PK modelling/simulation analyses. Study C3591024 is a Phase 2a, 2-part, open-label, non-randomized, multicentre, single and multiple dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in neonates and infants from birth to less than 3 months of age with suspected or confirmed infections due to gram-negative pathogens requiring intravenous antibiotic treatment. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 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 25.04.2024.

5.1.17. [WS2463](#)  
[Imfinzi - Durvalumab - EMEA/H/C/004771/WS2463/0063](#)  
[Lynparza - Olaparib - EMEA/H/C/003726/WS2463/0066](#)

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AstraZeneca AB;

Lead Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include Imfinzi (durvalumab) in combination with carboplatin and paclitaxel for the first line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR) or in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR) and to include Lynparze (olaparib) in combination with durvalumab for the maintenance treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch proficient (pMMR) whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel, based on the results from pivotal Phase III study, D9311C00001 (DUO-E). As a consequence sections 4.1, 4.2, 4.4, 4.5, 5.1 and 5.2 of the Imfinzi SmPC and sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the Lynparza SmPC are updated. The Annex II, the Package Leaflet and the Risk Management Plan (version 10.2 for Imfinzi and version 30.2 for Lynparza) are updated in accordance."

**Action:** For adoption

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

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

No items

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

No items

## **6. Medical devices**

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

No items

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

No items

### **6.3. Companion diagnostics - initial consultation**

#### **6.3.1. In vitro diagnostic medical device - EMEA/H/D/006536**

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to detect ITD and TKD mutations in the FLT3 gene in patients with acute myelogenous leukaemia (AML).

Scope: Opinion

**Action:** For adoption

#### **6.3.2. In vitro diagnostic medical device - EMEA/H/D/006530**

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to detect somatic alterations in human DNA and RNA isolated from formalin-fixed, paraffin-embedded (FFPE) solid tumour samples.

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. mirdametinib - H0006460

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Treatment of neurofibromatosis type 1-plexiform neurofibroma

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

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**Action:** For information

#### 8.2.2. Recommendation for PRIME eligibility

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**Action:** For adoption

## 9. Post-authorisation issues

### 9.1. Post-authorisation issues

#### 9.1.1. Erbitux - Cetuximab - EMEA/H/C/000558/II/0099

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Merck Europe B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to introduce every two-weeks (Q2W) dosing regimen as an alternative to the already approved every week (Q1W) dosing regimen for the indications of metastatic colorectal cancer (CRC) and the recurrent/metastatic squamous cell cancer of the head and neck (SCCHN) in combination with platinum-based chemotherapy, based on pharmacokinetic (PK)-TGI-OS modelling and simulations. The Package Leaflet is updated accordingly. The RMP version 19.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information."

**Action:** For adoption

#### 9.1.2. JCOVDEN – COVID-19 vaccine (Ad26.COV2-S [recombinant]) – EMEA/H/C/005737

Janssen-Cilag International N.V.; prevention of coronavirus disease-2019 (COVID-19)

Rapporteur: Christophe Focke, Co-Rapporteur: Sol Ruiz

Scope: Withdrawal of marketing authorisation

**Action:** For information

#### 9.1.3. Tremelimumab AstraZeneca (SRD) - tremelimumab – EMEA/H/C/004650

AstraZeneca; treatment of metastatic non-small cell lung cancer (NSCLC)

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Carolina Prieto Fernandez

Scope: Withdrawal of marketing authorisation

**Action:** For information

#### 9.1.4. COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0216

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

**Action:** For adoption

#### 9.1.5. Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0136

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

**Action:** For adoption

#### 9.1.6. Evicel - Human fibrinogen/Human thrombin – EMEA/H/C/000898

Omrix Biopharmaceuticals N. V.; supportive treatment in surgery, improvement of haemostasis and suture support for haemostasis in vascular surgery

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Withdrawal of marketing authorisation

**Action:** For information

#### 9.1.7. Translarna - ataluren - EMEA/H/C/002720/R/0071 - Orphan

PTC Therapeutics International Limited

Rapporteur: Peter Mol, Co-Rapporteur: Antonio Gomez-Outes

Scope: Renewal of conditional marketing authorization

**Action:** For adoption

Participation of patient representatives.

Negative Opinion adopted on 25.01.2024. Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 25.05.2023.

See 2.3

## 10. Referral procedures

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

#### 10.1.1. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065

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Orexigen Therapeutics Ireland Limited

Referral Rapporteur: Kristina Dunder, Referral Co-Rapporteur: Daniela Philadelphly

Scope: Revised timetable

**Action:** For adoption

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

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

CHMP list of outstanding issues adopted on 30.05.2024, 25.04.2024 and 14.12.2023. List of Questions adopted on 14.09.2023.

#### 10.1.2. Ocaliva - obeticholic acid - EMEA/H/A-20/1531

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Advanz Pharma Limited

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

Scope: Opinion

**Action:** For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed.

List of outstanding issues adopted on 25.01.2024. List of Questions adopted on 12.10.2023.

See 2.4

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

No items

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

No items

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

No items

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

**10.5.1. Havrix – Hepatitis A virus (inactivated, adsorbed) - EMEA/H/A-30/1527**

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GlaxoSmithKline Biologicals

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

Scope: List of outstanding issues / opinion

**Action:** For adoption

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

List of outstanding issues adopted on 21.03.2024. List of questions adopted on 09.11.2023.

**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**

### **10.11.1. Lorazepam Macure – lorazepam - EMEA/H/A-13/1536**

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Macure Pharma ApS

Referral Rapporteur: Peter Mol, Referral Co-Rapporteur: Kristina Dunder

Scope: Opinion

**Action:** For adoption

Variation number in decentralised procedure: NL/H/4353/001/II/004, notification sent by the Agency of The Netherlands dated 01 February 2024 notifying of the start of a referral under Article 13(1) of Regulation No 1234/2008.

List of questions adopted on 21.03.2024.

## **11. Pharmacovigilance issue**

### **11.1. Early Notification System**

June 2024 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. Timetable for August 2024 Written Procedure**

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**Action:** For adoption

## 14.2. Coordination with EMA Scientific Committees

### 14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

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List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for June 2024

**Action:** For adoption

### 14.2.2. Paediatric Committee (PDCO)

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Agenda of the June 2024 PDCO plenary meeting

**Action:** For information

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

### 14.3.1. Biologics Working Party (BWP)

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Chair: Sean Barry, Vice-Chair: Andreea Barbu

Reports from the BWP meeting for CHMP adoption

**Action:** For adoption

### 14.3.2. Name Review Group (NRG)

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Table of Decisions of the NRG meeting held on 18-19 June 2024.

**Action:** For adoption

### 14.3.3. Scientific Advice Working Party (SAWP)

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Chair: Paolo Foggi  
Report from the SAWP meeting held on 10-13 June 2024. 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.

## 14.4. 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**

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Q2-2024 initial marketing authorisation application submissions with eligibility request to central procedure

**Action:** For information

## **14.9. Others**

### **14.9.1. CHMP Learnings**

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CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

**Action:** For information

## **15. Any other business**

### **15.1. AOB topic**

No items

## Explanatory notes

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

### Oral explanations (section 2)

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

### Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

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

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

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

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

### **Re-examination procedures** (section 5.3)

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

### **Withdrawal of application** (section 3.7)

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

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

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

### **Pre-submission issues** (section 8)

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

### **Post-authorisation issues** (section 9)

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

### **Referral procedures** (section 10)

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

### **Pharmacovigilance issues** (section 11)

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

### **Inspections Issues** (section 12)

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

### **Innovation task force** (section 13)

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

### **Scientific advice working party (SAWP)** (section 14.3.1)

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

### **Satellite groups / other committees** (section 14.2)

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

### **Invented name issues** (section 14.3)

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

More detailed information on the above terms can be found on the EMA website: [www.ema.europa.eu/](http://www.ema.europa.eu/)



24 June 2024  
EMA/CHMP/259999/2024

## Annex to 24-27 June 2024 CHMP Agenda

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## **A. PRE-SUBMISSION ISSUES**

### **A.1. ELIGIBILITY REQUESTS**

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Report on Eligibility to Centralised Procedure for  
June 2024: **For adoption**

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

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Final Outcome of Rapporteurship allocation for  
June 2024: **For adoption**

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### **A.3. PRE-SUBMISSION ISSUES FOR INFORMATION**

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

## **B. POST-AUTHORISATION PROCEDURES OUTCOMES**

### **B.1. Annual re-assessment outcomes**

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

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##### **Evoltra - Clofarabine -**

**EMA/H/C/000613/S/0081**

Sanofi B.V., Rapporteur: Alexandre Moreau,  
PRAC Rapporteur: Tiphaine Vaillant

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##### **Lamzede - Velmanase alfa -**

**EMA/H/C/003922/S/0035, Orphan**

Chiesi Farmaceutici S.p.A., Rapporteur: Patrick  
Vrijlandt, PRAC Rapporteur: Jan Neuhauser

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### **B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES**

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

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##### **BAQSIMI - Glucagon -**

**EMA/H/C/003848/R/0015**

Amphastar France Pharmaceuticals, Rapporteur:  
Karin Janssen van Doorn, Co-Rapporteur:  
Martina Weise, PRAC Rapporteur: Eamon O  
Murchu

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##### **Quofenix - Delafloxacin -**

**EMA/H/C/004860/R/0026**

A. Menarini Industrie Farmaceutiche Riunite  
s.r.l., Rapporteur: Janet Koenig, Co-Rapporteur:  
Alar Irs, PRAC Rapporteur: Petar Mas

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**Rhokiinsa - Netarsudil -  
EMA/H/C/004583/R/0022**

Santen Oy, Rapporteur: Jayne Crowe, Co-  
Rapporteur: Ewa Balkowiec Iskra, PRAC  
Rapporteur: Maria del Pilar Rayon

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**B.2.2. Renewals of Marketing Authorisations for unlimited validity**

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**Cegfila - Pegfilgrastim -  
EMA/H/C/005312/R/0020**

Mundipharma Corporation (Ireland) Limited,  
Duplicate of Pelmeg, Rapporteur: Karin Janssen  
van Doorn, Co-Rapporteur: Christian Gartner,  
PRAC Rapporteur: Bianca Mulder

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**Clopidogrel/Acetylsalicylic acid Viatris -  
Clopidogrel / Acetylsalicylic acid -  
EMA/H/C/004996/R/0012**

Viatris Limited, Generic of DuoPlavin,  
Rapporteur: Kristina Nadrah, PRAC Rapporteur:  
Carla Torre

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**Evenity - Romosozumab -  
EMA/H/C/004465/R/0025**

UCB Pharma S.A., Rapporteur: Kristina Dunder,  
Co-Rapporteur: Christian Gartner, PRAC  
Rapporteur: Tiphaine Vaillant

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**Spravato - Esketamine -  
EMA/H/C/004535/R/0023**

Janssen-Cilag International N.V., Rapporteur:  
Martina Weise, Co-Rapporteur: Peter Mol, PRAC  
Rapporteur: Kirsti Villikka

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**B.2.3. Renewals of Conditional Marketing Authorisations**

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**Jaypirca - Pirtobrutinib -  
EMA/H/C/005863/R/0004**

Eli Lilly Nederland B.V., Rapporteur: Alexandre  
Moreau, Co-Rapporteur: Edward Laane, PRAC  
Rapporteur: Bianca Mulder

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**ROCTAVIAN - Valoctocogene roxaparvovec  
- EMA/H/C/005830/R/0011, Orphan,  
ATMP**

BioMarin International Limited, Rapporteur:  
Violaine Closson Carella, Co-Rapporteur: Silke  
Dorner, CHMP Coordinator: Jean-Michel Race,  
PRAC Rapporteur: Bianca Mulder  
Request for Supplementary Information adopted  
on 24.05.2024.

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**Translarna - Ataluren -  
EMA/H/C/002720/R/0071, Orphan**

See 9.1

PTC Therapeutics International Limited,  
Rapporteur: Peter Mol, Co-Rapporteur: Maria  
Concepcion Prieto Yerro, PRAC Rapporteur:  
Liana Martirosyan  
Request for Supplementary Information adopted  
on 25.05.2023.

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**B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES**

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**Signal detection**

PRAC recommendations on signals adopted at  
the PRAC meeting held on 10-13 June 2024  
PRAC:

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**Signal of secondary malignancy of T-cell  
origin**

Axicabtagene ciloleucel; idecabtagene  
vicleucel; lisocabtagene maraleucel;  
ciltabtagene autoleucel; tisagenlecleucel;  
brexucabtagene autoleucel - YESCARTA,  
ABECMA, BREYANZI, CARVYKTI, KYMRIAH,  
TECARTUS (CAP)

CAT Rapporteur: multiple, CHMP Coordinator:  
multiple, PRAC Rapporteur: multiple

PRAC recommendation on a variation; DHPC  
and communication plan

**Action:** For adoption

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PSUR procedures for which PRAC adopted a  
recommendation for variation of the terms of  
the MA at its June 2024 meeting:

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**EMA/H/C/PSUSA/0000102/202311**

(respiratory syncytial virus vaccine (bivalent,  
recombinant))

CAPS:

**Abrysvo** (EMA/H/C/006027) (Respiratory  
syncytial virus vaccine (bivalent,  
recombinant)), Pfizer Europe Ma EEIG,  
Rapporteur: Jayne Crowe, PRAC Rapporteur:  
Liana Martirosyan, "30/05/2023 To:  
30/11/2023"

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**EMA/H/C/PSUSA/00002014/202310**

(methotrexate)

CAPS:

**Jylamvo** (EMA/H/C/003756) (Methotrexate),

Therakind (Europe) Limited, Rapporteur:

Bruno Sepodes

**Nordimet** (EMA/H/C/003983)

(Methotrexate), Nordic Group B.V.,

Rapporteur: Bruno Sepodes

NAPS:

**NAPs** - EU

, PRAC Rapporteur: Martin Huber,

"31/10/2021 To: 31/10/2023"

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**EMA/H/C/PSUSA/00009253/202310**

(pasireotide)

CAPS:

**Signifor** (EMA/H/C/002052) (Pasireotide),

Recordati Rare Diseases, Rapporteur: Kristina

Dunder, PRAC Rapporteur: Mari Thorn,

"24/10/2020 To: 24/10/2023"

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**EMA/H/C/PSUSA/00010279/202310**

(obinutuzumab)

CAPS:

**Gazyvaro** (EMA/H/C/002799)

(Obinutuzumab), Roche Registration GmbH,

Rapporteur: Aaron Sosa Mejia, PRAC

Rapporteur: Ulla Wändel Liminga,

"31/10/2020 To: 31/10/2023"

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**EMA/H/C/PSUSA/00010301/202311**

(ibrutinib)

CAPS:

**Imbruvica** (EMA/H/C/003791) (Ibrutinib),

Janssen-Cilag International N.V., Rapporteur:

Filip Josephson, PRAC Rapporteur: Barbara

Kovacic Bytyqi, "13/11/2022 To: 12/11/2023"

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**EMA/H/C/PSUSA/00010535/202311**

(ixazomib)

CAPS:

**NINLARO** (EMA/H/C/003844) (Ixazomib),

Takeda Pharma A/S, Rapporteur: Paolo

Gasparini, PRAC Rapporteur: Ulla Wändel

Liminga, "19/05/2023 To: 19/11/2023"

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**EMA/H/C/PSUSA/00010577/202311**

(insulin glargine / lixisenatide)

CAPS:

**Suliqua** (EMA/H/C/004243) (Insulin glargine / Lixisenatide), Sanofi Winthrop Industrie,

Rapporteur: Kristina Dunder, PRAC

Rapporteur: Bianca Mulder, "21/11/2022 To: 21/11/2023"

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**EMA/H/C/PSUSA/00010974/202311**

(pegcetacoplan)

CAPS:

**ASPAVELI** (EMA/H/C/005553)

(Pegcetacoplan), Swedish Orphan Biovitrum

AB (publ), Rapporteur: Alexandre Moreau,

PRAC Rapporteur: Kimmo Jaakkola,

"14/05/2023 To: 13/11/2023"

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**EMA/H/C/PSUSA/00011019/202311**

(tirzepatide)

CAPS:

**Mounjaro** (EMA/H/C/005620) (Tirzepatide),

Eli Lilly Nederland B.V., Rapporteur: Martina

Weise, PRAC Rapporteur: Bianca Mulder,

"14/05/2023 To: 13/11/2023"

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**B.4. EPARs / WPARs**

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**ADZYNMA - rADAMTS13 -****EMA/H/C/006198, Orphan**

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

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**AKANTIOR - Polihexanide -****EMA/H/C/005858, Orphan**

SIFI SPA, treatment of acanthamoeba keratitis, 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.

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**Apexelsin - Paclitaxel - EMA/H/C/005997**

Whiteoak Pharmaceutical B.V., treatment of metastatic breast cancer, Generic, Generic of Abraxane, Generic application (Article 10(1) of Directive No 2001/83/EC)

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

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**Avzivi - Bevacizumab - EMA/H/C/005574**

FGK Representative Service GmbH, treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian

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

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tube or primary peritoneal cancer;  
first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer;  
first line treatment of patients with advanced and/or metastatic renal cell cancer., Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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**Cejemly - Sugemalimab -  
EMA/H/C/006088**

SFL Pharmaceuticals Deutschland GmbH,  
treatment of adults with metastatic non-small-cell lung cancer (NSCLC), 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.

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**Dasatinib Accord Healthcare - Dasatinib -  
EMA/H/C/006251**

Accord Healthcare S.L.U., indicated for the treatment of chronic myelogenous leukaemia (CML), indicated for the treatment of chronic myelogenous leukaemia (CML), Generic of Sprycel, Generic application (Article 10(1) of Directive No 2001/83/EC)

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

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**DURVEQTIX - Fidanacogene elaparvovec -  
EMA/H/C/004774, ATMP**

Pfizer Europe MA EEIG, indicated for the treatment of severe and moderately severe haemophilia B, 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.

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**Fluenz - Influenza vaccine (live attenuated, nasal) - EMA/H/C/006514**

AstraZeneca AB, Prophylaxis of influenza, 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.

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**GalliaPharm - Germanium (68Ge) chloride / Gallium (68Ga) chloride -  
EMA/H/C/006053**

Eckert & Ziegler Radiopharma GmbH, indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging, 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.

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**IXCHIQ - Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated -  
EMA/H/C/005797**

Valneva Austria GmbH, prevention of disease caused by chikungunya (CHIKV) virus, New

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

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

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**Nezglyal - Leriglitazone -  
EMA/H/C/005757, Orphan**

Minorix Therapeutics S.L., the treatment of cerebral progression and myelopathy in male patients with adrenoleukodystrophy (ALD)., 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.

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**Pomalidomide Accord - Pomalidomide -  
EMA/H/C/006273**

Accord Healthcare S.L.U., treatment of adult patients with multiple myeloma, Generic, Generic of Imnovid, Generic application (Article 10(1) of Directive No 2001/83/EC)

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

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**Pomalidomide Krka - Pomalidomide -  
EMA/H/C/006314**

KRKA, d.d., Novo mesto, treatment of multiple myeloma, Generic, Generic of Imnovid, Generic application (Article 10(1) of Directive No 2001/83/EC)

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

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**Pomalidomide Zentiva - Pomalidomide -  
EMA/H/C/006294**

Zentiva, k.s., treatment of adults with multiple myeloma, Generic, Generic of Imnovid, Generic application (Article 10(1) of Directive No 2001/83/EC)

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

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**Zegalogue - Dasiglucagon -  
EMA/H/C/006214**

Zealand Pharma A/S, treatment of severe hypoglycemia in patients with diabetes, 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.

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## **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**

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**AQUIPTA - Atogepant -  
EMA/H/C/005871/II/0001/G**

AbbVie Deutschland GmbH & Co. KG,  
Rapporteur: Janet Koenig  
Opinion adopted on 06.06.2024.

Positive Opinion adopted by consensus on 06.06.2024.

Request for Supplementary Information adopted

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on 04.04.2024.

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**BEKEMV - Eculizumab -**

**EMA/H/C/005652/II/0005**

Amgen Technology (Ireland) Unlimited  
Company, Rapporteur: Outi Mäki-Ikola

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**Besremi - Ropeginterferon alfa-2b -**

**EMA/H/C/004128/II/0033/G**

AOP Orphan Pharmaceuticals GmbH,  
Rapporteur: Janet Koenig  
Request for Supplementary Information adopted  
on 30.05.2024.

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**Braftovi - Encorafenib -**

**EMA/H/C/004580/II/0035/G**

Pierre Fabre Medicament, Rapporteur: Janet  
Koenig  
Opinion adopted on 20.06.2024.  
Request for Supplementary Information adopted  
on 14.03.2024.

Positive Opinion adopted by consensus on  
20.06.2024.

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**Buvidal - Buprenorphine -**

**EMA/H/C/004651/II/0025**

Camurus AB, Rapporteur: Finbarr Leacy  
  
Opinion adopted on 20.06.2024.  
Request for Supplementary Information adopted  
on 25.04.2024.

Positive Opinion adopted by consensus on  
20.06.2024.

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**Circadin - Melatonin -**

**EMA/H/C/000695/II/0071/G**

RAD Neurim Pharmaceuticals EEC SARL,  
Rapporteur: Bruno Sepodes  
Opinion adopted on 06.06.2024.  
Request for Supplementary Information adopted  
on 08.02.2024.

Positive Opinion adopted by consensus on  
06.06.2024.

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**COMIRNATY - COVID-19 mRNA vaccine -**

**EMA/H/C/005735/II/0216**

BioNTech Manufacturing GmbH, Rapporteur:  
Filip Josephson

See 9.1.

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**Cosentyx - Secukinumab -**

**EMA/H/C/003729/II/0116**

Novartis Europharm Limited, Rapporteur: Outi  
Mäki-Ikola  
Opinion adopted on 20.06.2024.

Positive Opinion adopted by consensus on  
20.06.2024.

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**Darzalex - Daratumumab -**

**EMA/H/C/004077/II/0073/G, Orphan**

Janssen-Cilag International N.V., Rapporteur:  
Aaron Sosa Mejia  
Request for Supplementary Information adopted  
on 06.06.2024.

Request for supplementary information adopted  
with a specific timetable.

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<p><b>Ebixa - Memantine / Memantine hydrochloride - EMEA/H/C/000463/II/0101</b>  H. Lundbeck A/S, Duplicate of Axura,  Rapporteur: Antonio Gomez-Outes</p> <p>Opinion adopted on 20.06.2024.  Request for Supplementary Information adopted on 25.04.2024, 11.01.2024.</p>	<p>Positive Opinion adopted by consensus on 20.06.2024.</p>
<p><b>Eylea - Aflibercept - EMEA/H/C/002392/II/0088</b>  Bayer AG, Rapporteur: Jean-Michel Race</p> <p>Opinion adopted on 20.06.2024.  Request for Supplementary Information adopted on 04.04.2024.</p>	<p>Positive Opinion adopted by consensus on 20.06.2024.</p>
<p><b>Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0045</b>  Seqirus Netherlands B.V., Rapporteur: Sol Ruiz</p>	
<p><b>Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0151/G</b>  CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus</p> <p>Opinion adopted on 20.06.2024.</p>	
<p><b>Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0155</b>  CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus</p>	<p>Positive Opinion adopted by consensus on 20.06.2024.</p>
<p><b>Ibandronic Acid Teva - Ibandronic acid - EMEA/H/C/001195/II/0021</b>  Teva B.V., Generic of Bondronat, Bonviva,  Rapporteur: Hrefna Gudmundsdottir</p> <p>Opinion adopted on 06.06.2024.  Request for Supplementary Information adopted on 11.04.2024, 29.02.2024, 16.11.2023.</p>	<p>Positive Opinion adopted by consensus on 06.06.2024.</p>
<p><b>Inhixa - Enoxaparin sodium - EMEA/H/C/004264/II/0109</b>  Techdow Pharma Netherlands B.V., Duplicate of Thorinane (EXP), Rapporteur: Christian Gartner</p> <p>Request for Supplementary Information adopted on 20.06.2024.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Kovaltry - Octocog alfa - EMEA/H/C/003825/II/0044/G</b>  Bayer AG, Rapporteur: Kristina Dunder</p> <p>Request for Supplementary Information adopted on 21.03.2024.</p>	

<p><b>Mounjaro - Tirzepatide - EMA/H/C/005620/II/0022</b> Eli Lilly Nederland B.V., Rapporteur: Martina Weise Request for Supplementary Information adopted on 20.06.2024.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMA/H/C/002246/II/0068</b> MediWound Germany GmbH, Rapporteur: Janet Koenig Opinion adopted on 20.06.2024.</p>	<p>Positive Opinion adopted by consensus on 20.06.2024.</p>
<p><b>Nucala - Mepolizumab - EMA/H/C/003860/II/0066/G</b> GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy Opinion adopted on 13.06.2024. Request for Supplementary Information adopted on 02.05.2024.</p>	<p>Positive Opinion adopted by consensus on 13.06.2024.</p>
<p><b>NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMA/H/C/005808/II/0070/G</b> Novavax CZ a.s., Rapporteur: Patrick Vrijlandt</p>	
<p><b>Ovaleap - Follitropin alfa - EMA/H/C/002608/II/0039</b> Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt  Request for Supplementary Information adopted on 11.04.2024, 07.12.2023.</p>	
<p><b>OXERVATE - Cenegermin - EMA/H/C/004209/II/0059, Orphan</b> Dompe farmaceutici S.p.A., Rapporteur: Antonio Gomez-Outes Opinion adopted on 06.06.2024. Request for Supplementary Information adopted on 02.05.2024.</p>	<p>Positive Opinion adopted by consensus on 06.06.2024.</p>
<p><b>Pelgraz - Pegfilgrastim - EMA/H/C/003961/II/0052/G</b> Accord Healthcare S.L.U., Rapporteur: Sol Ruiz Opinion adopted on 06.06.2024.</p>	<p>Positive Opinion adopted by consensus on 06.06.2024.</p>
<p><b>Privigen - Human normal immunoglobulin - EMA/H/C/000831/II/0202/G</b> CSL Behring GmbH, Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 18.04.2024.</p>	
<p><b>Skyclarys - Omaveloxolone -</b></p>	<p>Positive Opinion adopted by consensus on</p>

<p><b>EMA/H/C/006084/II/0003/G, Orphan</b>  Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher  Opinion adopted on 13.06.2024.</p>	13.06.2024.
<p><b>Spikevax - COVID-19 mRNA vaccine - EMA/H/C/005791/II/0123/G</b>  Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus  Request for Supplementary Information adopted on 25.04.2024.</p>	
<p><b>Spikevax - COVID-19 mRNA vaccine - EMA/H/C/005791/II/0132/G</b>  Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus</p>	
<p><b>Steen Solution - Human albumin solution - EMA/H/D/000002/II/0005</b>  XVIVO Perfusion AB, Rapporteur: Filip Josephson, "To reconfirm the Scientific opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745)."  Request for Supplementary Information adopted on 20.06.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p><b>Stimufend - Pegfilgrastim - EMA/H/C/004780/II/0007</b>  Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner  Request for Supplementary Information adopted on 20.06.2024, 16.05.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p><b>Supemtek - Influenza quadrivalent vaccine (rDNA) - EMA/H/C/005159/II/0015/G</b>  Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus  Request for Supplementary Information adopted on 06.06.2024, 08.02.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p><b>TEPADINA - Thiotepa - EMA/H/C/001046/II/0050/G</b>  ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau  Opinion adopted on 13.06.2024.  Request for Supplementary Information adopted on 04.04.2024.</p>	Positive Opinion adopted by consensus on 13.06.2024.
<p><b>TRODELVY - Sacituzumab govitecan - EMA/H/C/005182/II/0030/G</b>  Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus  Request for Supplementary Information adopted</p>	

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on 21.03.2024.

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**Tyenne - Tocilizumab -**

**EMA/H/C/005781/II/0003**

Fresenius Kabi Deutschland GmbH, Rapporteur:  
Kristina Dunder

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**Vabysmo - Faricimab -**

**EMA/H/C/005642/II/0011/G**

Roche Registration GmbH, Rapporteur: Jayne  
Crowe

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**Vaxelis - Diphtheria, tetanus, pertussis  
(acellular, component), hepatitis B (rDNA),  
poliomyelitis (inact.) and haemophilus type  
B conjugate vaccine (adsorbed) -**

**EMA/H/C/003982/II/0141**

MCM Vaccine B.V., Rapporteur: Christophe  
Focke  
Opinion adopted on 06.06.2024.

Positive Opinion adopted by consensus on  
06.06.2024.

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**Vaxneuvance - Pneumococcal  
polysaccharide conjugate vaccine (15  
valent, adsorbed) -**

**EMA/H/C/005477/II/0020**

Merck Sharp & Dohme B.V., Rapporteur: Patrick  
Vrijlandt  
Opinion adopted on 06.06.2024.

Positive Opinion adopted by consensus on  
06.06.2024.

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**Vyvgart - Efgartigimod alfa -**

**EMA/H/C/005849/II/0017, Orphan**

Argenx, Rapporteur: Thalia Marie Estrup Blicher  
Request for Supplementary Information adopted  
on 02.05.2024.

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**Ximluci - Ranibizumab -**

**EMA/H/C/005617/II/0010**

STADA Arzneimittel AG, Rapporteur: Jayne  
Crowe

Request for Supplementary Information adopted  
on 20.06.2024.

Request for supplementary information adopted  
with a specific timetable.

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**Zilbrysq - Zilucoplan -**

**EMA/H/C/005450/II/0002**

UCB Pharma S.A., Rapporteur: Kristina Dunder  
Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on  
13.06.2024.

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**Zometa - Zoledronic acid -**

**EMA/H/C/000336/II/0103/G**

Phoenix Labs Unlimited Company, Rapporteur:  
Thalia Marie Estrup Blicher  
Request for Supplementary Information adopted  
on 06.06.2024, 21.03.2024.

Request for supplementary information adopted  
with a specific timetable.

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**WS2652/G****Edistride-****Forxiga-**

AstraZeneca AB, Lead Rapporteur: Kristina Dunder

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**WS2663/G****Infanrix hexa-****EMA/H/C/000296/WS2663/0344/G**

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke  
Opinion adopted on 13.06.2024.

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Positive Opinion adopted by consensus on 13.06.2024.

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

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**AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMA/H/C/006054/II/0004**

GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, "Update of sections 4.8 and 5.1 of the SmPC in order to include data on persistence of protection over at least 2 RSV seasons following administration of a single dose of Arexvy based on final results from study RSV OA=ADJ-006 (A Phase 3, randomized, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above) and RSV OA=ADJ-004 (A phase 3, randomized, open-label, multi-country study to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above)."  
Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

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**Arixtra - Fondaparinux sodium - EMA/H/C/000403/II/0092**

Viartis Healthcare Limited, Rapporteur: Kristina Dunder, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study FDPX-IJS-7001; this

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Request for supplementary information adopted with a specific timetable.

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is a retrospective cohort study to evaluate long-term dosing, efficacy, and safety of fondaparinux for treatment of venous thromboembolism in paediatric patients. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 13.06.2024.

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**Biktarvy - Bictegravir / Emtricitabine / Tenofovir alafenamide - EMEA/H/C/004449/II/0059**

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, “Update of sections 4.4, 4.5, 4.6, 5.1 and 5.2 of the SmPC in order to update information on pregnancy and update the dosing recommendations with polyvalent caution-containing products for pregnant patients based on final results from GS-US-380-5310; A Phase 1b, Open-label study to Evaluate the Pharmacokinetics (PK), Safety and Efficacy of B/F/TAF in HIV-1 infected, Virologically Suppressed, Pregnant Women in their Second and Third Trimesters; study GS-US-380-3909 and the Antiretroviral Pregnancy Registry. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes.”

Request for Supplementary Information adopted on 25.04.2024.

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**BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0013**

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, “Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to change posology recommendations in individuals 16 years of age and older, amend an existing warning on hypersensitivity and anaphylaxis, delete insomnia and back pain from the list of adverse drug reactions (ADRs), change frequency of odynophagia, abdominal pain and injection site hypersensitivity from Uncommon to Rare and

Request for supplementary information adopted with a specific timetable.

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update immunogenicity information based on final results from study HIPRA-HH-2 (PART A and PART B) listed as a category 3 study in the RMP; HIPRA-HH-2 was a Phase IIb, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial in adults fully vaccinated against COVID-19. The objective was to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion heterodimer vaccine candidate (PHH-1V) against SARS-CoV-2 (Part A). An extension to the study was introduced to add a fourth dose as described below (Part B)."

Request for Supplementary Information adopted on 06.06.2024, 21.03.2024.

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**Bylvay - Odevixibat -**

**EMA/H/C/004691/II/0018, Orphan**

Ipsen Pharma, Rapporteur: Patrick Vrijlandt, "Update of section 4.2 of the SmPC in order to add instructions for odevixibat administration in liquids. The Package Leaflet is updated accordingly."

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**CAMZYOS - Mavacamten -**

**EMA/H/C/005457/II/0009**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Patrick Vrijlandt, "Update of section 4.2 of the SmPC in order to remove the sentence restricting the use of lower strength capsules to achieve higher prescribed dose, based on results from the bioequivalence study CV0271090; this is an open-label, randomized, single-dose, 2-way crossover study to establish bioequivalence of 1 × 15-mg mavacamten capsule to 3 × 5-mg mavacamten capsules in healthy participants. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the Product Information."

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**Cimzia - Certolizumab pegol -**

**EMA/H/C/001037/II/0110**

UCB Pharma S.A., Rapporteur: Kristina Dunder, "Update of sections 4.2 and 4.6 of the SmPC in order to update information on pregnancy based on final results from study UP0085, OTIS Phase I report and post marketing data. UP0085 is a Phase 1b,

Request for supplementary information adopted with a specific timetable.

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prospective, longitudinal, interventional, open-label study evaluating the impact of pregnancy on the PK of CZP. OTIS Phase I report presents the formal analysis of pregnancy outcome and infant and child follow-up data from the OTIS CZP Pregnancy Registry (RA0023). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.”  
Request for Supplementary Information adopted on 13.06.2024.

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**Clopidogrel Zentiva - Clopidogrel - EMEA/H/C/000975/II/0091**

Zentiva k.s., Duplicate of Clopidogrel BMS (SRD), Informed Consent of Iscover, Rapporteur: Bruno Sepodes, “Update of section 4.4 and 4.8 of the SmPC in order to update an existing warning on ‘Bleeding and haematological disorders’ by adding a statement on triple antiplatelet therapy (clopidogrel + aspirin + dipyridamole) for stroke secondary prevention based on the cumulative review of the MAH global safety database and scientific literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes.”  
Opinion adopted on 06.06.2024.

Positive Opinion adopted by consensus on 06.06.2024.

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**Constella - Linaclotide - EMEA/H/C/002490/II/0063**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Martina Weise, “Update of section 4.4 of the SmPC in order to update the statement relating to guanylate cyclase-C (GCC) receptor expression in the paediatric population to reflect current clinical data, including final results from study MCP-103-311; this is a non-interventional clinical research study to characterize GCC mRNA expression in duodenal and colonic mucosal biopsies in children aged 0 to 17 years. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to bring it in line with the latest QRD template.”  
Request for Supplementary Information

Request for supplementary information adopted with a specific timetable.

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adopted on 13.06.2024.

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**Cuprior - Trientine -**

**EMA/H/C/004005/II/0028**

Orphalan, Rapporteur: Jayne Crowe, "Submission of the final report from study TRIUMPH-2: Trientine dihydrochloride (Syprine capsules) vs. tetrahydrochloride (tablets): a Phase 1, single centre, randomised, interventional, open-label, 4-way crossover study in adult healthy male and female subjects to evaluate the pharmacokinetics and the safety and tolerability of 2 different oral formulations."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 11.04.2024.

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Positive Opinion adopted by consensus on 13.06.2024.

**Dengvaxia - Dengue tetravalent vaccine (live, attenuated) -**

**EMA/H/C/004171/II/0029**

Sanofi Pasteur, Rapporteur: Christophe Focke, "Submission of the final report from study CYD69 listed as a category 3 study in the RMP. This is an Observational study: Effectiveness of the tetravalent dengue vaccine, CYD-TDV (DENVAXIA) in the Philippines."

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**Erleada - Apalutamide -**

**EMA/H/C/004452/II/0037**

Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, "Update of section 5.1 of the SmPC in order to include information on Prostate Specific Antigen (PSA) reduction to undetectable levels, based on results from the TITAN (56021927PCR3002) and SPARTAN (ARN-509-003) studies. TITAN is a Phase 3 randomized, placebo-controlled, double-blind study of Apalutamide Plus Androgen Deprivation Therapy (ADT) versus ADT in subjects with Metastatic Hormone-sensitive Prostate Cancer (mHSPC). SPARTAN is a Phase 3, randomized, double-blind, placebo-controlled study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer."

Request for Supplementary Information adopted on 20.06.2024.

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Request for supplementary information adopted with a specific timetable.

**Evrydi - Risdiplam -**

**EMA/H/C/005145/II/0022**

Request for supplementary information adopted with a specific timetable.

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Roche Registration GmbH, Rapporteur:  
Bruno Sepodes, "Submission of the final  
report from study 'BP39055 (SUNFISH)'  
listed as a category 3 study in the RMP; this  
is a Two-Part Seamless, Multi-Centre  
Randomized, Placebo-Controlled, Double-  
blind Study to Investigate the Safety,  
Tolerability, Pharmacokinetics,  
Pharmacodynamics and Efficacy of  
RO7034067 in Type 2 and 3 Spinal Muscular  
Atrophy Patients."

Request for Supplementary Information  
adopted on 13.06.2024.

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**KIMMTRAK - Tebentafusp -  
EMA/H/C/004929/II/0005, Orphan**

Immunocore Ireland Limited, Rapporteur:  
Aaron Sosa Mejia, "Update of section 5.1 of  
the SmPC in order to include the updated  
Overall Survival (OS) data based on results  
from study IMCgp100-202; this is a phase III  
randomized, open-label, multi-centre study  
of the safety and efficacy of IMCgp100  
compared with investigator's choice in HLA-  
A\*0201 positive patients with previously  
untreated advanced uveal melanoma."

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**LIBTAYO - Cemiplimab -  
EMA/H/C/004844/II/0043**

Regeneron Ireland Designated Activity  
Company, Rapporteur: Aaron Sosa Mejia,  
"Update of section 4.8 of the SmPC in order  
to add 'uveitis' to the list of adverse drug  
reactions (ADRs) with frequency rare, based  
on a safety evaluation report. The Package  
Leaflet is updated accordingly. In addition,  
the MAH took the opportunity to introduce  
minor corrections to the efficacy data in  
section 5.1 of the SmPC based on an erratum  
for the interim report for study R2810-ONC-  
1620, as well as to introduce minor editorial  
and formatting changes to the PI and to  
update the list of local representatives in the  
Package Leaflet."

Opinion adopted on 20.06.2024.

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Positive Opinion adopted by consensus on  
20.06.2024.

**Mounjaro - Tirzepatide -  
EMA/H/C/005620/II/0021/G**

Eli Lilly Nederland B.V., Rapporteur: Martina  
Weise, "A grouped application consisting of  
two Type II variations, as follows:  
C.I.4: Update of sections 4.6, 4.8 and 5.1 of  
the SmPC in order to include information on

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Request for supplementary information adopted  
with a specific timetable.

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weight management (WM) based on final results from Phase 3 interventional WM studies (SURMOUNT-2, -3, and -4) and Phase 1 mechanism of action studies (GPGU and GPHH studies). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity implement editorial changes to the SmPC.

C.I.4: Update of section 5.1 of the SmPC in order to update the mechanism of action based on final results from in vitro studies ENDO123, QSB24, ENDO187, ENDO188 and ENDO190. The Package Leaflet is updated accordingly.”

Request for Supplementary Information adopted on 13.06.2024.

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**NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0069**

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, “Submission of the final report from study 2019nCoV-311 Part 1 listed as a category 3 study in the RMP. This is a 2-part, phase 3, randomized, observer blinded study to evaluate the safety and immunogenicity of Omicron subvariant and bivalent SARS-CoV-2 rS vaccines in adults previously vaccinated with other COVID-19 vaccines.”

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**Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0040/G**

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, “A grouped application comprised of three Type II Variations and one Type IA Variation, as follows:

3 Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to update clinical safety information based on final results from the three studies: study WA21092 (OPERA I), study WA21093 (OPERA II) and study WA25046 (ORATORIO). Study WA21092 (OPERA I) and study WA21093 (OPERA II) are randomized, double-blind, double-dummy, parallel-group studies to evaluate the efficacy and safety of ocrelizumab in comparison to interferon beta-1a (Rebif) in patients with relapsing multiple sclerosis (RMS), while study WA25046 (ORATORIO) is a phase 3, multicentre, randomized, parallel-group, double blinded, placebo controlled

Request for supplementary information adopted with a specific timetable.

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study to evaluate the efficacy and safety of ocrelizumab in adults with primary progressive multiple sclerosis (PPMS). In addition, the MAH took the opportunity to introduce minor editorial change to the Product Information.

Type IA (A.6): Change the ATC Code of ocrelizumab from L04AA36 to L04AG08.”  
Request for Supplementary Information adopted on 06.06.2024.

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**Orgovyx - Relugolix -**

**EMA/H/C/005353/II/0020**

Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt, “Update of sections 4.2 and 4.5 of the SmPC in order to add information on “Combination with other medicines for advanced hormone-sensitive prostate cancer” based on clinical studies and literature. In addition, the MAH took the opportunity to update section 5.1 of the SmPC.”

Request for Supplementary Information adopted on 23.05.2024.

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**Orladeyo - Berotralstat -**

**EMA/H/C/005138/II/0017/G**

BioCryst Ireland Limited, Rapporteur: Finbarr Leacy, “A grouped application comprised of two type II variations, as follows:

C.I.4: Update of section 4.5 of the SmPC in order to remove the recommendation for close monitoring for adverse events with concomitant use of P-gp and BCRP inhibitors based on final safety results from the drug-drug interaction study BCX7353-119, as well as to update the effects of cyclosporine on berotralstat. Study BCX7353-119 is a phase 1 drug-drug interaction study to evaluate the effect of cyclosporine on the pharmacokinetics of berotralstat in healthy subjects.

C.I.13: Submission of the final reports from parts 2 and 3 of study BCX7353-301; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of two dose levels of BCX7353 as an oral treatment for the suppression of events in subjects with hereditary angioedema.

In addition, the MAH took the opportunity to add additional wording for patients with

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severely reduced kidney function in the Package Leaflet and to introduce minor editorial changes to the PI, as per previous guidance.”

Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.

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**Pombiliti - Cipaglucosidase alfa -  
EMA/H/C/005703/II/0010**

Amicus Therapeutics Europe Limited,  
Rapporteur: Patrick Vrijlandt, “Update of sections 4.6 and 5.3 of the SmPC in order to provide information regarding pre-implantation loss based on the reassessment of non-clinical data. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and to introduce editorial changes.”

Request for Supplementary Information adopted on 18.04.2024.

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**RINVOQ - Upadacitinib -  
EMA/H/C/004760/II/0049**

Positive Opinion adopted by consensus on 13.06.2024.

AbbVie Deutschland GmbH & Co. KG,  
Rapporteur: Kristina Dunder, “Update of section 5.1 of the SmPC in order to include long term efficacy and safety information (up to week 104 data) from study SELECT-AXIS 2 (M19-944 (Study 2)); this is a phase 3, randomized, double-blind study evaluating the long-term safety, tolerability, and efficacy of upadacitinib 15 mg QD in subjects with nr-axSpA who completed the double-blind period on study drug. The MAH took also the opportunity to update the ATC code from L04AA44 into L04AF03.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 14.03.2024.

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**RINVOQ - Upadacitinib -  
EMA/H/C/004760/II/0050**

Positive Opinion adopted by consensus on 13.06.2024.

AbbVie Deutschland GmbH & Co. KG,  
Rapporteur: Kristina Dunder, “Update of section 5.1 of the SmPC in order to include long term efficacy and safety information (up to week 104 data) from study M19-944 (Study 1); this is a phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult subjects with axial spondyloarthritis followed by a remission-withdrawal period.”

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Opinion adopted on 13.06.2024.  
Request for Supplementary Information  
adopted on 04.04.2024.

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**Rystiggo - Rozanolixizumab -  
EMA/H/C/005824/II/0002, Orphan**  
UCB Pharma, Rapporteur: Thalia Marie  
Estrup Blicher, "Update of sections 4.4 and  
4.8 of the SmPC in order to amend a prior  
warning on aseptic meningitis to reflect the  
post-marketing cases and to add 'aseptic  
meningitis' to the list of adverse drug  
reactions (ADRs) with frequency 'not known'  
based on post-marketing data. The Package  
Leaflet is updated accordingly. In addition,  
the MAH took the opportunity to bring the PI  
in line with the latest QRD template version  
10.4."

Positive Opinion adopted by consensus on  
20.06.2024.

Opinion adopted on 20.06.2024.

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**Scemblix - Asciminib -  
EMA/H/C/005605/II/0013/G, Orphan**  
Novartis Europharm Limited, Rapporteur:  
Janet Koenig, "Grouped application  
comprising three type II variations as  
follows:

Positive Opinion adopted by consensus on  
13.06.2024.

C.I.4 - Update of sections 4.5 and 5.2 of the  
SmPC in order to add drug-drug interaction  
information with P-gp Substrates based on  
the final results from studies 2301078,  
CABL001A2301 and CABL001X2101, listed as  
a category 3 study in the RMP.

C.I.4 - Update of section 4.8 of the SmPC in  
order to update the Summary of the safety  
profile and safety information based on final  
results from study CABL001A2301 and  
CABL001X2101, listed as a category 3 study  
in the RMP.

C.I.4 - Update of section 5.1 of the SmPC in  
order to update safety information based on  
final results from study CABL001A2301.

The Package Leaflet is updated accordingly."  
Opinion adopted on 13.06.2024.

Request for Supplementary Information  
adopted on 02.05.2024.

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**Siklos - Hydroxycarbamide -  
EMA/H/C/000689/II/0061**

Theravia, Rapporteur: Karin Janssen van  
Doorn, "Update of section 4.5 of the SmPC in  
order to update information regarding the  
interference with certain Continuous Glucose  
Monitoring (CGM) sensors, based on a

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

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**Sivextro - Tedizolid phosphate -  
EMA/H/C/002846/II/0053**

Positive Opinion adopted by consensus on 06.06.2024.

Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, “Update of section 5.1 of the SmPC in order to implement the revised EUCAST MIC breakpoints of tedizolid. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”  
Opinion adopted on 06.06.2024.

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**Spravato - Esketamine -  
EMA/H/C/004535/II/0024**

Positive Opinion adopted by consensus on 20.06.2024.

Janssen-Cilag International N.V., Rapporteur: Martina Weise, “Update of section 4.8 of the SmPC in order to add ‘hypotension’ to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI.”

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**Sunlenca - Lenacapavir -  
EMA/H/C/005638/II/0013**

Request for supplementary information adopted with a specific timetable.

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, “Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from study TX-200-2046 entitled, “104 Week Subcutaneous Injection Carcinogenicity and Toxicokinetic Study of GS-6207 Administered Every 13 Weeks in Wistar-Han Rats”. In addition, the MAH took the opportunity introduce minor editorial changes to the PI.”  
Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 18.01.2024.

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**Tevimbra - Tislelizumab -  
EMA/H/C/005919/II/0009**

Positive Opinion adopted by consensus on 20.06.2024.

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, “Update of section 5.1 of the SmPC in order to update efficacy information based on the overall survival (OS) final analyses for study BGB-A317-302; this is a randomized, controlled, open-label, global phase 3 study comparing the efficacy

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of the anti-PD-1 antibody tislelizumab (BGB-A317) versus chemotherapy as second line treatment in patients with advanced unresectable/metastatic oesophageal squamous cell carcinoma.”

Opinion adopted on 20.06.2024.

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**Trulicity - Dulaglutide -**

**EMA/H/C/002825/II/0070**

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, “Update of section 4.4 of the SmPC in order to add a new warning on gastroparesis based on clinical data, post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC.”

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**Ultomiris - Ravulizumab -**

**EMA/H/C/004954/II/0043/G**

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, “A grouped application comprised of a Type II Variation and a Type IA Variation, as follows:

Type II (C.I.4): Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update clinical information regarding the atypical haemolytic uremic syndrome (aHUS) indication, based on final results from studies ALXN1210-aHUS-311 and ALXN1210-aHUS-312. ALXN1210-aHUS-311 is a phase 3, open-label, uncontrolled, multicentre, single treatment arm study in adolescent and adult patients with evidence of TMA who are naïve to complement inhibitor treatment, while ALXN1210-aHUS-312 is a phase 3, open-label, uncontrolled, multicentre, single treatment arm study in paediatric patients with evidence of TMA who are naïve to complement inhibitor treatment (Cohort 1) or are clinically stable after having been treated with eculizumab (Cohort 2). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Type IA (A.6): To change the ATC Code for ravulizumab from L04AA43 to L04AJ02.”

Request for Supplementary Information adopted on 20.06.2024, 14.03.2024.

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Request for supplementary information adopted with a specific timetable.

**Ultomiris - Ravulizumab -**

**EMA/H/C/004954/II/0045**

Alexion Europe SAS, Rapporteur: Carolina

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Prieto Fernandez, "Update of sections 4.8 and 5.1 of the SmPC in order to update the summary of safety profile and information in adult patients with Generalised Myasthenia Gravis based on final results from study ALXN1210-MG-306; this is a Phase 3, randomized, double-blind, parallel-group, placebo-controlled, multi-centre study with an ongoing Open-Label Extension Period of up to 2 years in adult patients with gMG who were naïve to complement inhibitor treatment. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

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**Xarelto - Rivaroxaban -  
EMA/H/C/000944/II/0110/G**

Bayer AG, Rapporteur: Kristina Dunder, "A grouped application consisting of:  
Type II (C.I.4): Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on in vitro study report PH-41585. In addition, the MAH took the opportunity to implement editorial changes in the SmPC.

Type IB (C.I.z): Update of sections 6.5 and 6.6 of the SmPC to mitigate the risk of misinterpretation regarding the volume of the suspension to be prepared. The Labelling and Package Leaflet are updated accordingly."

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**Xeljanz - Tofacitinib -  
EMA/H/C/004214/II/0059**

Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, "Update of section 4.4 of the SmPC in order to update serious infections section based on post marketing data and literature. In addition, the MAH has taken the opportunity to implement changes to improve readability and to update the list of local representatives in the Package Leaflet."

Request for Supplementary Information adopted on 13.06.2024, 14.03.2024.

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Request for supplementary information adopted with a specific timetable.

**Xevudy - Sotrovimab -  
EMA/H/C/005676/II/0028**

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC with new data on the in antiviral activity of sotrovimab against the Omicron variants named:

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Positive Opinion adopted by consensus on 13.06.2024.

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XBB.1.16.6, FL.1.5.1, JN.1, BA.2.86 variants and XBB.2.3.”

Opinion adopted on 13.06.2024.

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**WS2647**

**Mekinist-**

**EMA/H/C/002643/WS2647/0066**

**Tafinlar-**

**EMA/H/C/002604/WS2647/0071**

Novartis Europharm Limited, Lead Rapporteur: Peter Mol, “Update of section 5.1 of the SmPC for Tafinlar and Mekinist in order to update efficacy information based on final results from study CDRB436F2301 (COMBI-AD); this is a phase 3 randomized double blind study of dabrafenib in combination with trametinib versus two placebos in the adjuvant treatment of high-risk BRAF V600 mutation-positive melanoma after surgical resection. The RMP version 11.1 for Tafinlar and version 19.2 for Mekinist have also been submitted. In addition, MAH took the opportunity to introduce minor editorial changes to the Product Information.”

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**WS2658**

**Braftovi-**

**EMA/H/C/004580/WS2658/0039**

**Mektovi-**

**EMA/H/C/004579/WS2658/0031**

Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, “Update of sections 5.1 of the SmPC in order to update efficacy and safety information following the outcome of procedures 004579/0000 and R/0024 based on final results from study C4221004 (CMEK162B2301). This was a 2-part, multi-centre, randomized, open label, Phase III study comparing the efficacy and safety of encorafenib plus binimetinib to vemurafenib and encorafenib monotherapy in participants with locally advanced unresectable or metastatic melanoma with BRAF V600 mutation. In addition, the MAH took the opportunity to introduce editorial changes to the PI.”

Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 20.06.2024

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**WS2700**

**M-M-RvaxPro-**

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**EMA/H/C/000604/WS2700/0123**

**ProQuad-**

**EMA/H/C/000622/WS2700/0166**

Merck Sharp & Dohme B.V., Lead

Rapporteur: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on literature search. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI."

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### **B.5.3. CHMP-PRAC assessed procedures**

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**Byooviz - Ranibizumab -**

**EMA/H/C/005545/II/0016/G**

Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, PRAC Rapporteur: Ulla Wändel Liminga  
Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

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**Dapivirine Vaginal Ring 25 mg - Dapivirine - EMA/H/W/002168/II/0025/G**

International Partnership for Microbicides

Belgium AISBL, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jan Neuhauser, "A grouped application consisting of:

Type II (C.I.4): Update of section 4.6 of the SmPC in order to update information on breastfeeding based on final results from study MTN-043 (B-PROTECTED) listed as a category 3 study in the RMP (MEA/009). MTN-043 is a Phase 3b, randomized, open-label, safety, and drug detection study of dapivirine vaginal ring and oral truvada in breastfeeding mother-infant pairs. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI.

Type IB (C.I.11.z): Submission of an updated RMP version 1.4 in order to request a change on the due date for the MTN-034 (REACH) study."  
Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

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**Erbix - Cetuximab -**

**EMA/H/C/000558/II/0099**

Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.4 and 4.9 of the SmPC in

See 9.1

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order to introduce every two-weeks (Q2W) dosing regimen as an alternative to the already approved every week (Q1W) dosing regimen for the indications of metastatic colorectal cancer (CRC) and the recurrent/metastatic squamous cell cancer of the head and neck (SCCHN) in combination with platinum-based chemotherapy, based on pharmacokinetic (PK)-TGI-OS modelling and simulations. The Package Leaflet is updated accordingly. The RMP version 19.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information.”

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**Fintepla - Fenfluramine -  
EMA/H/C/003933/II/0022/G, Orphan**

UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, “A grouped application comprised of three Type II variations, as follows:

C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to modify the list of adverse drug reactions based on a revised safety ADR methodology for Dravet and Lennox-Gastaut syndromes, which includes pooled analyses encompassing studies ZX008-1503 and ZX008-1601 cohort B. The Package Leaflet is updated accordingly.

C.I.4: Update of section 5.1 of the SmPC in order to update clinical efficacy information for Dravet syndrome based on final results from study ZX008-1503 listed as a category 3 study in the RMP. This is an open-label extension trial to assess the long-term safety of ZX008 (fenfluramine hydrochloride) oral solution as an adjunctive therapy in children and young adults with Dravet syndrome.

C.I.4: Update of section 5.1 of the SmPC in order to update clinical efficacy information for Lennox-Gastaut syndrome based on final results from study ZX008-1601 Part 1 cohort B and interim results for study ZX008-1601 Part 2 cohort B. Study 1601 Part 1 was an international, randomized, double-blind, parallel-group, placebo-controlled study in subjects with LGS 2 to 35 years of age, while study 1601 Part 2 is a long-term, open-label, flexible-dose extension for subjects who completed study 1601 Part 1. The RMP version 3.0 has also been submitted.

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In addition, the MAH took the opportunity to introduce minor changes to the Product Information, including to section 4.2 of the SmPC”  
Request for Supplementary Information adopted on 21.03.2024.

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**Ilumetri - Tildrakizumab -  
EMA/H/C/004514/II/0055**

Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski  
Opinion adopted on 13.06.2024.  
Request for Supplementary Information adopted on 11.04.2024.

Positive Opinion adopted by consensus on 13.06.2024.

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**Kalydeco - Ivacaftor -  
EMA/H/C/002494/II/0126**

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo, “Submission of the final report from study VX15-770-126 (study 126) listed as a category 3 study in the RMP; this is a phase 3, 2-arm, multicentre open-label study to evaluate the safety and pharmacodynamics of long-term ivacaftor treatment in subjects with cystic fibrosis who are less than 24 months of age at treatment initiation and have an approved ivacaftor-responsive mutation. The RMP version 16.0 has also been submitted.”  
Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

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**Kuvan - Sapropterin -  
EMA/H/C/000943/II/0078**

BioMarin International Limited, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu, “Submission of the final report from study KOGNITO, listed as a category 3 study in the RMP. This is a Phase IV Open-Label, Single-Cohort Study of the Long-Term Neurocognitive Outcomes in 4-to 5-Year-Old Children with Phenylketonuria Treated with Sapropterin Dihydrochloride (Kuvan) for 7 Years. The RMP version 16.1 has also been submitted.”  
Opinion adopted on 13.06.2024.  
Request for Supplementary Information adopted on 07.03.2024, 11.01.2024, 28.09.2023.

Positive Opinion adopted by consensus on 13.06.2024.

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**Leqvio - Inclisiran -  
EMA/H/C/005333/II/0021**

Novartis Europharm Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Kimmo

Positive Opinion adopted by consensus on 13.06.2024.

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Jaakkola, "Submission of the final report from study ORION-8 - A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 11.04.2024.

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**Loargys - Pegzilarginase -  
EMA/H/C/005484/II/0002/G, Orphan**

Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "Grouped application comprising two type II variations as follows:

C.I.4 – Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-300A (SOB 003), listed as a specific obligation in Annex II. Study 300A was a Phase 3, randomized, double blind, placebo-controlled study of the efficacy and safety of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).

C.I.4 – Update of section 4.8 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-102A (SOB 004), listed as a specific obligation in Annex II.

Study 102A was an open label extension study to evaluate the long-term safety, tolerability, and efficacy of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).

The Package Leaflet and Annex II are updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes."

Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

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**Lupkynis - Voclosporin -  
EMA/H/C/005256/II/0013**

Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.6 and 5.2 of the SmPC in order to update breast-

Positive Opinion adopted by consensus on 13.06.2024.

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feeding information based on final results from study AUR-VCS-2021-04. This study is a single-centre, open-label, Phase 1, lactation study to investigate the amount of voclosporin excreted in breast milk following a single oral dose of 23.7 mg voclosporin in healthy, lactating, female volunteers. The Package Leaflet is updated accordingly. The updated RMP version 5.0 is agreed.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 11.04.2024.

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**MVABEA - Ebola vaccine (rDNA, replication-incompetent) -**

**EMA/H/C/005343/II/0021**

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

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**Retsevmo - Selpercatinib -**

**EMA/H/C/005375/II/0028**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, “Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study LIBRETTO-431 (JZJC) listed as a specific obligation in the Annex II (SOB/002); this is a randomized Phase 3 study comparing selpercatinib to platinum-based and pemetrexed therapy with or without pembrolizumab in patients with locally advanced or metastatic, RET-fusion-positive NSCLC. The Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II.”

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Request for Supplementary Information adopted on 07.03.2024.

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**RoActemra - Tocilizumab -  
EMA/H/C/000955/II/0121**

Positive Opinion adopted by consensus on 13.06.2024.

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study ZUMA-8 (PAM). This is a phase 1 multicentre study evaluating the safety and tolerability of KTE-X19 in adult subjects with Relapsed/Refractory Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma. The RMP version 29.0 has also been submitted." Opinion adopted on 13.06.2024.  
Request for Supplementary Information adopted on 07.03.2024.

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**Spikevax - COVID-19 mRNA vaccine -  
EMA/H/C/005791/II/0136**

See 9.1

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

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**VELSIPITY - Etrasimod -  
EMA/H/C/006007/II/0001**

Positive Opinion adopted by consensus on 13.06.2024.

Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of section 4.4 to modify the macular oedema warning based on the evaluation of the cases of MO/cystoid MO reported in the etrasimod clinical studies and other S1P labels in the EU. The Package Leaflet and Annex II are updated in accordance. RMP version 1.5 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI." Opinion adopted on 13.06.2024.

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**ZABDENO - Ebola vaccine (rDNA,  
replication-incompetent) -  
EMA/H/C/005337/II/0019**

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorisation vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity

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of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information.”

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**Zeposia - Ozanimod -**

**EMA/H/C/004835/II/0024/G**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, “Grouped application comprising two variations as follows:

Type II (C.I.4) – Update of sections 4.4 and 4.8 the SmPC in order to add a new warning on liver injury, to add Liver injury to the list of adverse drug reactions (ADRs) with frequency rare based on the cumulative review of the MAH safety database, clinical trials and literature search. The RMP version 8.0 also been submitted.

Type IA (A.6) – To change the ATC code from L04AA38 to L04AE02.”

Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

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**ZTALMY - Ganaxolone -**

**EMA/H/C/005825/II/0006, Orphan**

Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, “Update of section 5.1 of the SmPC in order to update open-label data based on the final report from study 1042-CDD-3001 OLE listed as a category 3 study in the RMP. This was the open-label portion of the pivotal study 1042-CDD-3001; a double-blind, randomized, placebo-controlled trial of adjunctive ganaxolone treatment in children and young adults with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) followed by long-term open-label treatment. The RMP version 1.4 has also been submitted.”

Request for Supplementary Information adopted on 11.04.2024.

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**WS2619/G**

**Invokana-**

**EMA/H/C/002649/WS2619/0066/G**

**Vokanamet-**

**EMA/H/C/002656/WS2619/0073/G**

Janssen-Cilag International N.V., Lead

Request for supplementary information adopted with a specific timetable.

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Rapporteur: Martina Weise, Lead PRAC  
Rapporteur: Martin Huber, "A grouped application consisting of two Type II variations, as follows:

C.I.4: Update of section 4.4 of the SmPC in order to amend an existing warning on Diabetic Ketoacidosis based on literature. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy based on literature.

The RMP version 11.1 has also been submitted." Request for Supplementary Information adopted on 13.06.2024, 11.04.2024.

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**WS2664**

**Ebymect-**

**EMA/H/C/004162/WS2664/0066**

**Qtern-EMA/H/C/004057/WS2664/0043**

**Xigduo-EMA/H/C/002672/WS2664/0076**

AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.5, 4.8, 5.1 and 6.1 of the SmPC in order to align dapagliflozin related information in Fixed Dose Combination with Forxiga. The Package Leaflet is updated accordingly. The RMPs version 15.1 (Xigduo and Wbymect) and 9.1 (Qtern) has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

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**B.5.4. PRAC assessed procedures**

PRAC Led

**BESPONSA - Inotuzumab ozogamicin - EMA/H/C/004119/II/0028, Orphan**

Pfizer Europe MA EEIG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from study B1931028; this is a non-interventional post-authorization safety study (PASS) of inotuzumab ozogamicin to characterize complications post-hematopoietic stem cell transplantation (HSCT) following inotuzumab ozogamicin treatment in adult and paediatric patients with B-cell precursor acute

Request for supplementary information adopted with a specific timetable.

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lymphoblastic leukaemia (ALL). The RMP version 3.0 has also been submitted.”

Request for Supplementary Information adopted on 13.06.2024.

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PRAC Led

**CAMZYOS - Mavacamten -  
EMA/H/C/005457/II/0008**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, “Submission of an updated RMP version 3.0 in order to revise the number of patients planned to be enrolled in DISCOVER-HCM US-registry study CV027012 (MEA 005). In addition, the MAH took this opportunity to update protocol title for MAVEL-HCM study (CV027013) and include reference to study protocol in Annex 3 of the RMP, following the assessment of PAM procedure MEA 001.”

Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on 13.06.2024.

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PRAC Led

**COMIRNATY - COVID-19 mRNA vaccine -  
EMA/H/C/005735/II/0206/G**

BioNTech Manufacturing GmbH, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Patrick Vrijlandt, “A grouped application comprised of 3 Type II variations as follows: C.I.13: Submission of the final report from study C4591012 listed as a category 3 study in the RMP. This is a non-interventional Post-Emergency Use Authorisation active safety surveillance study among individuals in the Veteran’s Affairs health system receiving Comirnaty. The RMP version 13.0 is approved. C.I.11.b: Update of RMP to version 13.0 in order to implement changes to an agreed post-authorisation study (C4591052 protocol amendments 1 & 2) in the RMP, where there is an impact on the description of the study. C.I.11.b: Update of RMP to version 13.0 in order to implement changes to an agreed post-authorisation study (C4591021 protocol amendment 4) in the RMP, where there is an impact on the description of the study. In addition, the MAH took the opportunity to update the milestones for the two studies C4591022 and C4591051 in the RMP.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted

Positive Opinion adopted by consensus on 13.06.2024.

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on 11.04.2024.

PRAC Led

**Gilenya - Fingolimod -  
EMA/H/C/002202/II/0090/G**

Novartis Europharm Limited, PRAC Rapporteur:  
Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre  
Moreau, "Grouped application comprising two  
variations as follows:

Type II (C.I.3.b) - Update of sections 4.3 and  
4.4 of the SmPC in order to add history of  
progressive multifocal leukoencephalopathy  
(PML) as a new contraindication and to amend  
an existing warning on PML and to update the  
educational material to improve the general  
readability of these documents and better  
address key messages and recommendations  
for healthcare professionals following the  
assessment of procedure  
PSUSA/00001393/202302. The Package Leaflet  
and Annex II are updated accordingly. The RMP  
version 20.0 has also been submitted.

Type IA (A.6) - To change the ATC Code of  
Fingolimod from L04AA27 to L04AE01."

Request for Supplementary Information adopted  
on 13.06.2024.

Request for supplementary information adopted  
with a specific timetable.

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PRAC Led

**MenQuadfi - Meningococcal Group A, C, W  
and Y conjugate vaccine -  
EMA/H/C/005084/II/0031**

Sanofi Pasteur, PRAC Rapporteur: Jean-Michel  
Dogné, PRAC-CHMP liaison: Karin Janssen van  
Doorn, "Update of section 4.8 of the SmPC in  
order to add 'Hypersensitivity' and 'Anaphylaxis'  
to the list of adverse drug reactions (ADRs) with  
frequency 'not known' and 'very rare'  
respectively, based on a cumulative review of  
cases of hypersensitivity/allergic reaction  
(including anaphylaxis) following the request by  
PRAC in the Assessment Report for  
PSUSA/00010044/202304. The Package Leaflet  
is updated accordingly."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted  
on 11.04.2024.

Positive Opinion adopted by consensus on  
13.06.2024.

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PRAC Led

**Olumiant - Baricitinib -  
EMA/H/C/004085/II/0047**

Eli Lilly Nederland B.V., PRAC Rapporteur: Adam  
Przybylkowski, PRAC-CHMP liaison: Ewa

Request for supplementary information adopted  
with a specific timetable.

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Balkowiec Iskra, "Submission of the final report from non-interventional Study I4V-MC-B012 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance of baricitinib in three European registries. The RMP version 23.1 has also been submitted."

Request for Supplementary Information adopted on 13.06.2024.

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PRAC Led

**Prolia - Denosumab -  
EMA/H/C/001120/II/0100**

Amgen Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from the post marketing observational study 20090522, listed as a category 3 study in the RMP. This is a denosumab global safety assessment among women with postmenopausal osteoporosis (PMO), men with osteoporosis, and men and women who receive Prolia with glucocorticoid exposure in multiple observational databases." Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 11.01.2024.

Request for supplementary information adopted with a specific timetable.

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PRAC Led

**Reyataz - Atazanavir -  
EMA/H/C/000494/II/0140**

Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Jean-Michel Race, "Update of section 4.4 of the SmPC in order to clarify and update the warning regarding dyslipidaemia in relation to other comparators, following the PRAC's recommendation in the outcome of the PSUSA/00000258/202106 procedure. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information." Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on 13.06.2024.

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PRAC Led

**Spikevax - COVID-19 mRNA vaccine -  
EMA/H/C/005791/II/0131**

Moderna Biotech Spain S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report from study mRNA-1273-919 - An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to Spikevax During Pregnancy, listed as a category 3 study in the RMP."

Request for supplementary information adopted with a specific timetable.

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Request for Supplementary Information adopted on 13.06.2024.

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PRAC Led

**Sprycel - Dasatinib -**

**EMA/H/C/000709/II/0090**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Aaron Sosa Mejia, "Update of the RMP (version 18.2) in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 11.04.2024, 30.11.2023.

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Positive Opinion adopted by consensus on 13.06.2024.

PRAC Led

**Stelara - Ustekinumab -**

**EMA/H/C/000958/II/0100**

Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on the final synoptic report from study CNTO1275PSO4037 (OTIS); this is a pregnancy exposure registry for Stelara. The Package Leaflet is updated accordingly. The RMP version 26.2 has also been submitted."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 11.01.2024, 31.08.2023.

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Positive Opinion adopted by consensus on 13.06.2024.

PRAC Led

**Stelara - Ustekinumab -**

**EMA/H/C/000958/II/0104**

Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of the final report from study RRA-20745 listed as a category 3 study in the RMP. This is an observational post-authorization safety study (PASS) to describe the safety of ustekinumab and other Crohn's disease treatments in a cohort of patients with Crohn's disease. The RMP version 27.2 has also been submitted."

Request for Supplementary Information adopted on 13.06.2024, 11.01.2024.

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Request for supplementary information adopted with a specific timetable.

PRAC Led

**TachoSil - Human thrombin / Human fibrinogen - EMA/H/C/000505/II/0124**

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Request for supplementary information adopted with a specific timetable.

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Corza Medical GmbH, PRAC Rapporteur:  
Gabriele Maurer, PRAC-CHMP liaison: Jan  
Mueller-Berghaus, "Submission of an updated  
RMP version 9.1 in order to reflect the extension  
of indication to include the paediatric population  
and to update the details of the planned non-  
interventional post-authorisation safety study:  
PASS-TachoSil Evaluation (PasTel)."  
Request for Supplementary Information adopted  
on 13.06.2024, 08.02.2024.

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PRAC Led

**Uptravi - Selexipag -  
EMA/H/C/003774/II/0045**

Janssen-Cilag International N.V., PRAC  
Rapporteur: Nathalie Gault, PRAC-CHMP liaison:  
Alexandre Moreau, "Submission of the final  
report from study 67896049PAH0002  
(EXTRACT) and interim report for study AC-  
065A401 (EXPOSURE), listed as a category 3  
study in the RMP. EXTRACT is a Retrospective  
Medical Chart Review of Patients with PAH newly  
treated with either Uptravi (selexipag) or any  
other PAH-specific therapy. EXPOSURE is an  
observational cohort study of PAH patients  
newly treated with either Uptravi (selexipag) or  
any other PAH-specific therapy, in clinical  
practice."  
Request for Supplementary Information adopted  
on 13.06.2024.

Request for supplementary information adopted  
with a specific timetable.

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PRAC Led

**Vyndaqel - Tafamidis -  
EMA/H/C/002294/II/0091/G, Orphan**

Pfizer Europe MA EEIG, PRAC Rapporteur:  
Tiphaine Vaillant, PRAC-CHMP liaison: Jean-  
Michel Race, "A grouped application comprised  
of two Type II Variations, as follows:

C.I.4: Update of the Annex II based on final  
results from study B3461001 (THAOS) listed as  
a category 3 study in the RMP. This is a global,  
multi-centre, longitudinal, observational survey  
of patients with documented transthyretin gene  
mutations or wild-type transthyretin  
amyloidosis.

C.I.13: Submission of the final report from  
study B3461042 listed as a category 3 study in  
the RMP. This is a post-marketing safety  
surveillance study in Japanese patients with  
AATR-PN.

Request for supplementary information adopted  
with a specific timetable.



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The RMP version 10.0 has also been submitted.  
In addition, the MAH took the opportunity to provide B3461028 Clinical Study Report (CSR) Errata.”

Request for Supplementary Information adopted on 13.06.2024, 11.04.2024.

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PRAC Led

**Xeljanz - Tofacitinib -  
EMA/H/C/004214/II/0062**

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol, “Submission of the final report from study A3921203 (Tofacitinib Pregnancy Exposure Registry OTIS Autoimmune Diseases in Pregnancy Project) listed as a category 3 study in the RMP; this is a prospective, observational cohort study of pregnancy outcomes in women with a disease for which tofacitinib had an approved indication.”

Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on 13.06.2024.

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PRAC Led

**Xeljanz - Tofacitinib -  
EMA/H/C/004214/II/0063**

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol, “Submission of an updated RMP version 32.0 in order to propose the removal of category 3 study A3921329 (A Long-Term, Observational Study within the CorEvitas [formerly Corrona] Inflammatory Bowel Disease (IBD) Registry to Characterize the Safety of Tofacitinib in Patients with Ulcerative Colitis in the Post-Approval Setting). In addition, the MAH took the opportunity to update the RMP with some other minor updates.”

Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on 13.06.2024.

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PRAC Led

**WS2571  
Glyxambi-  
EMA/H/C/003833/WS2571/0055  
Jardiance-  
EMA/H/C/002677/WS2571/0082  
Synjardy-  
EMA/H/C/003770/WS2571/0076**

Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, “Submission of the final report from study 1245-

Positive Opinion adopted by consensus on 13.06.2024.

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0201. This is an observational post-authorization safety study (PASS) to assess the risk of acute pancreatitis in type 2 diabetes mellitus (T2DM) patients newly initiating empagliflozin compared to other oral non-incretin/non-sodium glucose co-transporter-2 inhibitors (SGLT2i)-containing glucose lowering drugs. The RMP versions 22.0, 15.0 and 10.0 have also been submitted for Jardiance, Synjardy and Glyxambi, respectively.”  
Opinion adopted on 13.06.2024.  
Request for Supplementary Information adopted on 30.11.2023.

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PRAC Led

**WS2587**

**TECFIDERA-**

**EMA/H/C/002601/WS2587/0085**

**Vumerity-**

**EMA/H/C/005437/WS2587/0015**

Biogen Netherlands B.V., Lead PRAC  
Rapporteur: Martin Huber, PRAC-CHMP liaison:  
Martina Weise, “Submission of the final report from study 109MS401, a multicentre, global, observational study to collect information on safety and to document the drug utilization of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category 3 study in the RMP (MEA007.6). The RMPs version 16.1 for Tecfidera and version 2.1 for Vumerity, have also been submitted.”  
Request for Supplementary Information adopted on 13.06.2024, 08.02.2024.

Request for supplementary information adopted with a specific timetable.

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PRAC Led

**WS2686**

**Cinacalcet Accordpharma-**

**EMA/H/C/005236/WS2686/0011**

Accord Healthcare S.L.U., Generic of Mimpara, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “To update the RMP to make updated in following safety concerns (important identified risks) after approval of the same changes in the reference product, Mimpara (in procedure EMA/H/C/000570/IB/0069):  
-Update of "Hypocalcemia" to "Hypocalcemia in the paediatric population"  
-Removal of "QT prolongation and ventricular arrhythmias secondary to hypocalcaemia"  
-Removal of "Convulsions/seizures"

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Furthermore, the Marketing Authorisation Holder is taking the opportunity to consolidate into a single RMP the RMPs approved for Cinacalcet 30mg/60mg/90mg Film-coated tablets through CP (EMA/H/C/005236) and DCP (FI/H/869/01-03/DC) procedures.”

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#### **B.5.5. CHMP-CAT assessed procedures**

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##### **Abecma - Idecabtagene vicleucel - EMEA/H/C/004662/II/0048, Orphan, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang  
Request for Supplementary Information adopted on 21.06.2024.

Request for supplementary information adopted with a specific timetable.

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##### **Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0036/G, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini, “Grouped application comprising two variations as follows:

C.I.4 – Update of sections 4.4 of the SmPC in order to add immune effector cell-associated neurotoxicity syndrome (ICANS) and ICE scoring in the table for neurologic adverse reaction and update of section 4.8 of the SmPC to add immune effector cell-associated neurotoxicity syndrome (ICANS) as an adverse drug reaction (ADR) with a “not known” frequency based on the cumulative review of MAH safety database and literature. The Package Leaflet is updated accordingly. An updated RMP version 4.1 has been provided including the relevant changes in accordance with the scope of this procedure. In addition, the MAH took this opportunity to introduce editorial changes and administrative updates concerning the PIP product status in section 4.2 and 5.1 of the SmPC.

A.6 – To include the ATC Code L01XL08 in section 5.1 of the SmPC.”

Request for Supplementary Information adopted on 24.05.2024, 16.02.2024.

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##### **Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Request for supplementary information adopted with a specific timetable.

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Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini  
Request for Supplementary Information adopted on 21.06.2024, 15.03.2024.

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**Casgevvy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0003/G, Orphan, ATMP**

Vertex Pharmaceuticals (Ireland) Limited,  
Rapporteur: Jan Mueller-Berghaus  
Request for Supplementary Information adopted on 21.06.2024.

Request for supplementary information adopted with a specific timetable.

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**Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0066/G, ATMP**

Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo, "A grouped application consisting of two Type II variations, as follows:  
C.I.13: Submission of the final report from Study 5 (added in EMEA-001251-PIP01-11-M04) titled "Exposure-Response analysis of Talimogene Laherparepvec for adult subjects with melanoma from Study 20120324 and comparison to paediatric subjects' data from Study 20110261 in support of a paediatric investigational plan"  
C.I.13: Submission of the final report from Study 6 (added in EMEA-001251-PIP01-11-M04) titled "Efficacy Analysis of the Young Adult Melanoma Subgroup (from 18 to less than 36 years of age) From 4 Talimogene Laherparepvec Monotherapy Studies Using Bayesian Extrapolation With Data Collected From the Older Adult Melanoma Subgroup (from 36 years of age and older) to Support Extrapolation of Efficacy From Adult Patient With Advanced Melanoma to Adolescent Patients With Advanced Melanoma"."

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**WS2689 Tecartus- EMEA/H/C/005102/WS2689/0045 Yescarta- EMEA/H/C/004480/WS2689/0076**

Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus  
Request for Supplementary Information adopted on 21.06.2024.

Request for supplementary information adopted with a specific timetable.

### B.5.6. CHMP-PRAC-CAT assessed procedures

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**Yescarta - Axicabtagene ciloleucel -  
EMA/H/C/004480/II/0075/G, Orphan,  
ATMP**

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Erneholm, "Grouped application comprising two type II variations as follows:

C.I.13 - Submission of the final report from study KTE-C19-101 (ZUMA-1) listed as a category 3 study in the RMP. This is a Phase 1/2 Multicentre Study Evaluating the Safety and Efficacy of Kte-C19 In Subjects with Refractory Aggressive Non-Hodgkin Lymphoma.

C.I.13 - Submission of the final report from study KTE-C19-106 (ZUMA-6) listed as a category 3 study in the RMP. This is a Phase 1-2 Multi-Centre Study Evaluating the Safety and Efficacy of Kte-C19 In Combination with Atezolizumab in Subjects with Refractory Diffuse Large B-Cell Lymphoma (DLBCL).

The RMP version 9.2 has also been submitted." Request for Supplementary Information adopted on 21.06.2024.

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Request for supplementary information adopted with a specific timetable.

### B.5.7. PRAC assessed ATMP procedures

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

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**WS2645/G****Avamys-****EMA/H/C/000770/WS2645/0052/G****Elebrato Ellipta-****EMA/H/C/004781/WS2645/0039/G****Relvar Ellipta-****EMA/H/C/002673/WS2645/0066/G****Revinty Ellipta-****EMA/H/C/002745/WS2645/0063/G****Trelegy Ellipta-****EMA/H/C/004363/WS2645/0036/G**

GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy, Quality variation

Opinion adopted on 06.06.2024.

Request for Supplementary Information

adopted on 11.04.2024.

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Positive Opinion adopted by consensus on 06.06.2024.

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**WS2654****Aerius-****EMA/H/C/000313/WS2654/0106**

Positive Opinion adopted by consensus on 20.06.2024.

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**Azomyr-****EMA/H/C/000310/WS2654/0110****Neoclarityn-****EMA/H/C/000314/WS2654/0104**

Organon N.V., Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke, "To update section 4.4 of the SmPC and section 2 of the package leaflet to correct the content of benzyl alcohol from 0.75 mg to 0.375 mg and the content of propylene glycol from 100.75 mg to 100.19 mg to comply with the Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use".

Additionally, the MAH has taken the opportunity to update section 2 of the SmPC to state the excipient with known effect lactose quantitatively.

In addition, the MAH has taken the opportunity to update section 4.8 of the SmPC and section 4 of the package leaflet to correct the link to QRD Appendix V for the national reporting system.

Furthermore, the MAH has taken the opportunity to update the package leaflet with details of the local representative for Austria.

Lastly, the MAH has taken the opportunity to introduce minor editorial corrections to the PI in the following language: CS."

Opinion adopted on 20.06.2024.

Request for Supplementary Information adopted on 04.04.2024.

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**WS2656/G****Copalia HCT-****EMA/H/C/001159/WS2656/0112/G****Dafiro HCT-****EMA/H/C/001160/WS2656/0114/G****Exforge HCT-****EMA/H/C/001068/WS2656/0111/G**

Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher Quality Variation, Request for Supplementary Information adopted on 02.05.2024.

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**WS2665****Mircera-****EMA/H/C/000739/WS2665/0101****NeoRecormon-**

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**EMA/H/C/000116/WS2665/0125**

Roche Registration GmbH, Lead Rapporteur:  
Martina Weise, Quality Variation

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**WS2669****HyQvia-****EMA/H/C/002491/WS2669/0098****Kiovig-****EMA/H/C/000628/WS2669/0128**

Baxalta Innovations GmbH, Lead Rapporteur:

Jan Mueller-Berghaus, Quality variation

Opinion adopted on 13.06.2024.

Request for Supplementary Information

adopted on 02.05.2024.

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Positive Opinion adopted by consensus on  
13.06.2024.

**WS2681****Ambirix-****EMA/H/C/000426/WS2681/0133****Fendrix-****EMA/H/C/000550/WS2681/0086****Infanrix hexa-****EMA/H/C/000296/WS2681/0345****Twinrix Adult-****EMA/H/C/000112/WS2681/0168****Twinrix Paediatric-****EMA/H/C/000129/WS2681/0169**

GlaxoSmithkline Biologicals SA, Lead

Rapporteur: Christophe Focke, Quality

variation

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**WS2694/G****GONAL-f-****EMA/H/C/000071/WS2694/0170/G****Pergoveris-****EMA/H/C/000714/WS2694/0092/G**

Merck Europe B.V., Lead Rapporteur: Thalia

Marie Estrup Blicher, Quality Variation

Request for Supplementary Information

adopted on 06.06.2024.

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Request for supplementary information adopted  
with a specific timetable.

**WS2699****Adrovanse-****EMA/H/C/000759/WS2699/0054****FOSAVANCE-****EMA/H/C/000619/WS2699/0057****VANTAVO-****EMA/H/C/001180/WS2699/0044**

Organon N.V., Lead Rapporteur: Christian

Gartner, Quality variation

Opinion adopted on 06.06.2024.

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Positive Opinion adopted by consensus on  
06.06.2024.

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

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#### **Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0130**

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "To delete the following presentations (EU/1/20/1507/001; EU/1/20/1507/002; EU/1/20/1507/003; EU/1/20/1507/004; EU/1/20/1507/005; EU/1/20/1507/006; EU/1/20/1507/007; EU/1/20/1507/008; EU/1/20/1507/009; EU/1/20/1507/010) from the Spikevax marketing authorization. The SmPC, Package Leaflet and Labelling section of the Product Information are updated accordingly."  
Request for Supplementary Information adopted on 13.06.2024.  
Withdrawal request submitted on 18.06.2024.

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The MAH withdrew the procedure on 18.06.2024.

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

## **B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION**

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

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#### **L-Acetylleucine -**

**EMEA/H/C/006327** Intrabio Ireland Limited, is indicated in adults and children from birth for chronic treatment of Niemann-Pick Type C (NPC).

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**Denosumab - EMEA/H/C/006269** prevention of skeletal related events with advanced malignancies

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**Denosumab - EMEA/H/C/006268**, treatment of osteoporosis and bone loss

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#### **Delandistrogene moxeparvovec -**

**EMEA/H/C/005293, Orphan, ATMP**

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

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#### **Emtricitabine / Tenofovir alafenamide -**

**EMEA/H/C/006469**

, for the treatment of human immunodeficiency virus type 1 (HIV-1)

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**Influenza vaccine (surface antigen, inactivated, adjuvanted) -**

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**EMA/H/C/006538**

, Prophylaxis of influenza in adults 50 years of age and older

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**Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) -****EMA/H/C/006532, Article 28**

, Prophylaxis of influenza in adults and children from 2 years of age.

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**Sipavibart - EMA/H/C/006291****Accelerated review**

indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older

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**Bifikafusp alfa / Onfekafusp alfa -****EMA/H/C/005651**

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

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**Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded -****Accelerated review****EMA/H/C/005772, Orphan, ATMP**

Cordex Biologics International Limited, treatment of adult patients with haematological malignancies,

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**Zanidatamab - EMA/H/C/006380, Orphan**

Jazz Pharmaceuticals Ireland Limited, Treatment of biliary tract cancer

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

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**Adempas - Riociguat -****EMA/H/C/002737/X/0041**

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

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**Hukyndra - Adalimumab -****EMA/H/C/005548/X/0026**

STADA Arzneimittel AG, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Mari Thorn, "Extension application to add a new strength of 20 mg for

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adalimumab solution for injection in the pre-filled syringe administered by subcutaneous use.”

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**OPDIVO - Nivolumab -  
EMA/H/C/003985/X/0144**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:  
Carolina Prieto Fernandez, PRAC Rapporteur:  
Martin Huber, “Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use).

Version 40.0 of the RMP has also been submitted.”

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**REZOLSTA - Darunavir / Cobicistat -  
EMA/H/C/002819/X/0054/G**

Janssen-Cilag International N.V., Rapporteur:  
Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli, “Extension application to introduce a new strength (675 mg/150 mg film-coated tablets) grouped with an extension of indication (C.I.6.a) to include, treatment of HIV-1 infected paediatric patients (aged 6 years and older with body weight at least 25 kg) for REZOLSTA, based on the 48-week ad hoc interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of cobicistat-boosted darunavir in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1,4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.3, 6.5 and 8 of the SmPC and Annex II are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4.”

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**Rybrevant - Amivantamab -  
EMA/H/C/005454/X/0014**

Janssen-Cilag International N.V., Rapporteur:  
Filip Josephson, PRAC Rapporteur: Gabriele Maurer, “Extension application to introduce a new pharmaceutical form (solution for injection), two new strengths of 1600 mg and 2240 mg (160 mg/ml concentration) and a new route of administration (subcutaneous use).”

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**Taltz - Ixekizumab -  
EMA/H/C/003943/X/0051**

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Eli Lilly and Co (Ireland) Limited, Rapporteur:  
Kristina Dunder, Co-Rapporteur: Finbarr Leacy,  
PRAC Rapporteur: Gabriele Maurer, "Extension  
application to add a new strength of 40 mg for  
Taltz, Solution for injection"

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

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#### **In vitro diagnostic medical device - EMA/H/D/006530**

to detect somatic alterations in human DNA  
and RNA isolated from formalin-fixed, paraffin-  
embedded (FFPE) solid tumour samples.  
Request for Supplementary Information adopted  
on 30.05.2024.

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

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#### **EVKEEZA - Evinacumab - EMA/H/C/005449/S/0018**

Ultragenyx Germany GmbH, Rapporteur: Patrick  
Vrijlandt, PRAC Rapporteur: Mari Thorn

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

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#### **Azacitidine Accord - Azacitidine - EMA/H/C/005147/R/0019**

Accord Healthcare S.L.U., Generic of Vidaza,  
Rapporteur: Hrefna Gudmundsdottir, PRAC  
Rapporteur: Bianca Mulder

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#### **Azacitidine Mylan - Azacitidine - EMA/H/C/004984/R/0019**

Mylan Ireland Limited, Generic of Vidaza,  
Rapporteur: Hrefna Gudmundsdottir, PRAC  
Rapporteur: Bianca Mulder

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#### **Dexmedetomidine Accord - Dexmedetomidine - EMA/H/C/005152/R/0013**

Accord Healthcare S.L.U., Generic of Dexdor,  
Rapporteur: John Joseph Borg, PRAC  
Rapporteur: Ulla Wändel Liminga

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#### **GIVLAARI - Givosiran - EMA/H/C/004775/R/0020, Orphan**

Alnylam Netherlands B.V., Rapporteur: Patrick  
Vrijlandt, Co-Rapporteur: Fátima Ventura, PRAC  
Rapporteur: Martin Huber

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#### **Lyumjev - Insulin lispro -**

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**EMA/H/C/005037/R/0019**

Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Mari Thorn

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**Nilemdo - Bempedoic acid -****EMA/H/C/004958/R/0042**

Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

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**NUBEQA - Darolutamide -****EMA/H/C/004790/R/0021**

Bayer AG, Rapporteur: Alexandre Moreau, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Jan Neuhauser

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**Nustendi - Bempedoic acid / Ezetimibe -****EMA/H/C/004959/R/0047**

Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

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**Rybelsus - Semaglutide -****EMA/H/C/004953/R/0042**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

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**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**

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

Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Liana Martirosyan, "Extension of indication to include active immunization of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Substudy A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants  $\geq 18$  to  $< 60$  years of age at high risk of severe RSV disease due to certain chronic medical conditions. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in

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accordance. Version 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection.”

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

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**JEMPERLI - Dostarlimab -  
EMA/H/C/005204/II/0032**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre, “Extension of indication for JEMPERLI to include, in combination with carboplatin and paclitaxel, the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy based on Interim Analysis 1 and 2 from study RUBY Part 1 (213361). This is a phase 3, randomized, double-blind, controlled study evaluating the efficacy and safety of dostarlimab plus carboplatin and paclitaxel in primary advanced or recurrent EC versus placebo plus carboplatin and paclitaxel.

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 4.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to align the PI with the latest QRD template version 10.4.”

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**LUTATHERA - Lutetium (177Lu)  
oxodotreotide -  
EMA/H/C/004123/II/0052, Orphan**

Advanced Accelerator Applications, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, “Extension of indication to include the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (G2 and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) adult patients for LUTATHERA, based on primary analysis results from study CAAA601A22301 (NETTER-2); NETTER-2 study is a Phase III, multicentre, stratified, open-label, randomized, comparator-controlled study comparing treatment with Lutathera plus

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octreotide LAR 30 mg (Lutathera arm) to treatment with high-dose octreotide LAR 60 mg (control arm). The main purpose of the NETTER-2 study was to determine if treatment in the Lutathera arm prolongs PFS in subjects with newly diagnosed SSTR-positive, G2 and G3 advanced GEP-NET when compared with treatment in the control arm.

As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes in the SmPC. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.”

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

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**Ngenla - Somatrogon -  
EMA/H/C/005633/II/0016, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, “Extension of indication to include the long-term replacement of endogenous growth hormone of adults with growth hormone deficiency for Ngenla, based on supplemental results from study CP-4-005 and the Phase 2 supportive study CP-4-003. CP-4-005 is a Phase 3, multicentre study designed to evaluate the efficacy and safety of a Long Acting hGH Product (MOD-4023) in adult subjects with Growth Hormone Deficiency. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9 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 Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes.”

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**REKAMBYS - Rilpivirine -  
EMA/H/C/005060/II/0022**

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Martirosyan, “Extension of indication to include in combination with cabotegravir injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Rekambys,

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based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicentre, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. Consequently, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update a local representative in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4”

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**Slentyto - Melatonin -**

**EMA/H/C/004425/II/0028**

RAD Neurim Pharmaceuticals EEC SARL,  
Rapporteur: Kristina Dunder, Co-Rapporteur:  
Tomas Radimersky, PRAC Rapporteur: Ana Sofia  
Diniz Martins, “Extension of indication to include  
treatment of insomnia in children and  
adolescents aged 2-18 with Attention-Deficit  
Hyperactivity Disorder (ADHD), where sleep  
hygiene measures have been insufficient, based  
on results from phase III study NEU\_CH\_7911  
and literature. As a consequence, sections 4.1  
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. ”

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**Tremfya - Guselkumab -**

**EMA/H/C/004271/II/0044**

Janssen-Cilag International N.V., Rapporteur:  
Beata Maria Jakline Ullrich, PRAC Rapporteur:  
Gabriele Maurer, “Extension of indication for  
TREMIFYA to include treatment of adult patients  
with moderately to severely active Crohn's  
disease (CD) who have had an inadequate  
response, lost response, or were intolerant to  
either conventional therapy or a biologic  
treatment, based on results from GALAXI Phase  
2/3 program and the GRAVITI Phase 3 study.

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GALAXI is a Phase 2/3, randomized, double-blind, placebo- and active-controlled, parallel-group, multicentre protocol to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active CD who have demonstrated an inadequate response or failure to tolerate previous conventional or biologic therapy. GRAVITI is a Phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of guselkumab SC induction therapy in participants with moderately to severely active CD. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

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**Vocabria - Cabotegravir -  
EMA/H/C/004976/II/0022**

ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "Extension of indication to include in combination with rilpivirine injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Vocabria, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicentre, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing

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authorisation holder (MAH) took the opportunity to introduce editorial changes. Furthermore, the PI is brought in line with the latest QRD template version 10.4.”

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**Vyvgart - Efgartigimod alfa -**

**EMA/H/C/005849/II/0020, Orphan**

Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, “Extension of indication to include the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) with active disease despite treatment with corticosteroids or immunoglobulins for VYVGART, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP); and based on interim results from study ARGX-113-1902; this is an open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with (CIDP).

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC has been updated. The Package Leaflet has been updated in accordance with the SmPC. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”

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**B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects**

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**BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain**

**fusion homodimer / Selvacovatein -**

**EMA/H/C/006058/II/0016**

Hipra Human Health S.L., Co-Rapporteur:  
Daniela Philadelphly

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**IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) -**

**EMA/H/C/002596/II/0104/G**

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

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

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#### **B.6.10. CHMP-PRAC assessed procedures**

#### **B.6.11. PRAC assessed procedures**

#### **B.6.12. CHMP-CAT assessed procedures**

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##### **WS2613**

**Tecartus-**

**EMA/H/C/005102/WS2613/0046**

**Yescarta-**

**EMA/H/C/004480/WS2613/0078**

Kite Pharma EU B.V., Lead Rapporteur: Jan

Mueller-Berghaus, , Quality

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#### **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**

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##### **WS2688**

**Corlantor-**

**EMA/H/C/000598/WS2688/0063**

**Ivabradine Anpharm-**

**EMA/H/C/004187/WS2688/0023**

**Procoralan-**

**EMA/H/C/000597/WS2688/0062**

Les Laboratoires Servier, Lead Rapporteur:

Patrick Vrijlandt

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##### **WS2715**

**M-M-RvaxPro-**

**EMA/H/C/000604/WS2715/0125**

**ProQuad-**

**EMA/H/C/000622/WS2715/0167**

Merck Sharp & Dohme B.V., Lead Rapporteur:

Jan Mueller-Berghaus, "To introduce editorial changes in sections 3.2.S.4.1 and 3.2.S.4.5."

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##### **WS2725/G**

**Efficib-**

**EMA/H/C/000896/WS2725/0115/G**

**Janumet-**

**EMA/H/C/000861/WS2725/0113/G**

**Ristfor-**

**EMA/H/C/001235/WS2725/0102/G**

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**Velmetia-****EMA/H/C/000862/WS2725/0121/G**

Merck Sharp & Dohme B.V., Lead Rapporteur:  
Patrick Vrijlandt, Quality variation

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**WS2728****Blitzima-****EMA/H/C/004723/WS2728/0075****Truxima-****EMA/H/C/004112/WS2728/0078**

Celltrion Healthcare Hungary Kft., Lead  
Rapporteur: Sol Ruiz, Quality variation

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**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**

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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**

### **F.1. Parallel Distribution - Pursuant to Article 9 of Council Regulation (EC) No. 2743/98 of 14 December 1998, as amended**

### **F.2. Request for scientific opinion on justification of exceptional circumstance and for imperative grounds of public health**

## **G. ANNEX G**

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

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

### **G.2. PRIME**

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

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