



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

08 December 2023  
EMA/CHMP/492427/2023  
Human Medicines Division

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

Minutes for the meeting on 09-12 October 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

### Disclaimers

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

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

### Note on access to documents

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



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## 1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

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

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

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

### 1.2. Adoption of agenda

CHMP agenda for 09-12 October 2023.

The CHMP adopted the agenda.

### 1.3. Adoption of the minutes

CHMP minutes for 11-14 September 2023.

The CHMP adopted the minutes for the 11-14 September 2023 plenary.

## 2. Oral Explanations

### 2.1. Pre-authorisation procedure oral explanations

#### 2.1.1. sparsentan - Orphan - EMEA/H/C/005783

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Vifor France; for the treatment of primary immunoglobulin A nephropathy (IgAN).

Scope: Oral explanation

**Action:** Oral explanation to be held on 11 October 2023 at 11:00

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



15.12.2022.

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

See 3.2

## 2.2. Re-examination procedure oral explanations

### 2.2.1. Albrioza - sodium phenylbutyrate / ursodoxicoltaurine - Orphan - EMEA/H/C/005901

Amylyx Pharmaceuticals EMEA B.V.; treatment of amyotrophic lateral sclerosis (ALS)

Scope: Oral explanation

**Action:** Oral explanation to be held on 10 October 2023 at 14:00

Participation of patient representatives.

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

Opinion on 22.06.2023. List of Outstanding Issues adopted on 23.02.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

An oral explanation was held on 10 October 2023. The presentation by the applicant focused on clinical aspects.

The CHMP noted the third-party interventions.

See 3.5

## 2.3. Post-authorisation procedure oral explanations

### 2.3.1. Imfinzi - durvalumab - EMEA/H/C/004771/II/0057

AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi as treatment of adults with unresectable hepatocellular carcinoma (uHCC), based on final results from study D419CC00002 (HIMALAYA); this was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma (HIMALAYA). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9, Succession 1 of the RMP has also been submitted. In addition, the PI is brought in line with the latest QRD template version 10.3."

Scope: Oral explanation

**Action:** Oral explanation to be held on 11 October 2023 at 16:00

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

An oral explanation was held on 11 October 2023. The presentation by the applicant focused on clinical aspects.

See 5.1

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

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Advanz Pharma Limited

Rapporteur: Carolina Prieto Fernandez

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

Scope: Oral explanation

**Action:** Oral explanation to be held on 10 October 2023 at 16:00

Request for Supplementary Information adopted on 30.03.2023.

An oral explanation was held on 10 October 2023. The presentation by the applicant focused on clinical aspects.

See 9.1 and 10.1

### 2.4. Referral procedure oral explanations

No items

## 3. Initial applications

### 3.1. Initial applications; Opinions

#### 3.1.1. Agamree - vamorolone - Orphan - EMEA/H/C/005679

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Santhera Pharmaceuticals (Deutschland) GmbH; treatment of Duchenne muscular dystrophy (DMD)

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 23.02.2023.

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

The Committee adopted a positive opinion recommending the granting of a marketing

authorisation by consensus together with the CHMP assessment report and translation timetable.

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

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

The CHMP noted the letter of recommendation dated 11 October 2023.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

### 3.1.2. [Elrexio - elranatamab - PRIME - Orphan - EMEA/H/C/005908](#)

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Pfizer Europe MA EEIG; Treatment of adult patients with relapsed or refractory multiple myeloma

Scope: Opinion

**Action:** For adoption

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

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

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

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

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

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

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 12 October 2023.

The CHMP adopted the similarity assessment report.

### 3.1.3. [Elucirem - gadopiclesol - EMEA/H/C/005626](#)

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Guerbet; for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate).

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 26.04.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

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

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

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

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

The summary of opinion was circulated for information.

#### 3.1.4. Loargys - pegzilarginase - Orphan - EMEA/H/C/005484

Immedica Pharma AB; treatment of hyperargininemia

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 15.12.2022.

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

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

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

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

The CHMP noted the letter of recommendation dated 11 October 2023.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

#### 3.1.5. Rezzayo - rezafungin - Orphan - EMEA/H/C/005900

Mundipharma GmbH; treatment of invasive candidiasis

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 15.12.2022.

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

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

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

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

The CHMP noted the letter of recommendation dated 10 October 2023.

The summary of opinion was circulated for information.

### 3.1.6. [Veozza - fezolinetant - EMEA/H/C/005851](#)

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Astellas Pharma Europe B.V.; treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 22.06.2023. List of Questions adopted on 26.01.2023.

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

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

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

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

The summary of opinion was circulated for information.

### 3.1.7. [Vueway - gadopiclesol - EMEA/H/C/006172](#)

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Bracco Imaging S.p.A.; for diagnostic: contrast-enhanced magnetic resonance imaging (MRI) to improve detection, visualisation and assist in characterisation of lesions in the central nervous system and in other body regions (including breast, liver and prostate).

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 26.04.2023, 10.11.2022.

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

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

timetable.

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

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

The summary of opinion was circulated for information.

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

### **3.2.1. concizumab - EMEA/H/C/005938**

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routine prophylaxis to prevent or reduce the frequency of bleeding in patients with: haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors  $\geq$  12 years of age; haemophilia B (congenital factor IX deficiency) with FIX inhibitors of any age

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 25.05.2023.

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

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

### **3.2.2. dabigatran etexilate - EMEA/H/C/005922**

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prevention of venous thromboembolic events

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 25.05.2023, 23.02.2023. List of Questions adopted on 23.06.2022.

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

The Committee adopted a 3<sup>rd</sup> list of outstanding issues with a specific timetable.

### **3.2.3. sparsentan - Orphan - EMEA/H/C/005783**

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Vifor France; for the treatment of primary immunoglobulin A nephropathy (IgAN).

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 25.05.2023. List of Questions adopted on 15.12.2022.

See 2.1

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

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

The Committee adopted a 2<sup>nd</sup> list of outstanding issues with a specific timetable.

#### 3.2.4. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165

indicated for in vitro labelling of kits for radiopharmaceutical preparation

Scope: List of outstanding issues; Letter by the applicant dated 05.10.2023 requesting an extension to the responses to the list of outstanding issues.

**Action:** For adoption

List of Questions adopted on 16.12.2021.

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

The Committee adopted a list of outstanding issues.

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

#### 3.2.5. epinephrine - EMEA/H/C/006139

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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 23.02.2023.

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

The Committee adopted a list of outstanding issues.

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

#### 3.2.6. dopamine hydrochloride - PUMA - EMEA/H/C/006044

Treatment of hypotension in neonates, infants and children

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 30.03.2023.

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

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

The CHMP agreed to consult the SAG CV and adopted a list of questions to this group.

### 3.2.7. [omaveloxolone - Orphan - EMEA/H/C/006084](#)

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Reata Ireland Limited; Treatment of Friedreich's ataxia

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 26.04.2023.

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

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

### 3.2.8. [pegcetacoplan - EMEA/H/C/005954](#)

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Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 25.05.2023.

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

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

The CHMP agreed to consult an ad-hoc expert group (AHEG) and adopted a list of questions to this group.

### 3.2.9. [toripalimab - EMEA/H/C/006120](#)

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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 30.03.2023.

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

The Committee adopted a list of outstanding issues.

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

### 3.2.10. [etrasimod - EMEA/H/C/006007](#)

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

Scope: List of outstanding issues

**Action:** For adoption



List of Questions adopted on 30.03.2023.

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

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

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

#### **3.3.1. 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 questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

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

#### **3.3.2. fruquintinib - EMEA/H/C/005979**

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treatment of metastatic colorectal cancer

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

#### **3.3.3. meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165**

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

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

### 3.3.4. ustekinumab - EMEA/H/C/005918

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treatment of adult patients with moderately to severely active Crohn's disease and active ulcerative colitis.

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

The CHMP agreed to consult the BMWP/PKWP and adopted a list of questions to these groups.

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

### 3.4.1. arpraziquantel - Article 58 - EMEA/H/W/004252

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treatment of schistosomiasis in children

Scope: Letter by the applicant dated 22.09.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

**Action:** For adoption

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

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

### 3.4.2. 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: Letter by the applicant dated 29.09.2023 requesting an extension to the clock stop to respond to the list of questions adopted in July 2023.

**Action:** For adoption

List of Questions adopted on 20.07.2023.

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

### 3.4.3. eribulin - EMEA/H/C/006134

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treatment of breast cancer and liposarcoma

Scope: Letter by the applicant dated 22.09.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

**Action:** For adoption

List of outstanding issues adopted on 14.09.2023. List of Questions adopted on 23.02.2023.

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

#### 3.4.4. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/006053

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

Scope: Letter by the applicant dated 29.09.2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

The CHMP agreed to the request by written procedure on 03 October 2023.

**Action:** For information

List of outstanding issues adopted on 14.09.2023. List of Questions adopted on 26.04.2023.

The CHMP noted the new timetable adopted via written procedure on 03 October 2023, agreeing to the applicant's request for an extension to the clock stop to respond to the list of outstanding issues adopted in September 2023.

#### 3.4.5. leniolisib - Orphan - EMEA/H/C/005927

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

Scope: Call for nominations for experts to the AHEG meeting

**Action:** For information

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

The CHMP noted the call for additional experts.

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

#### 3.5.1. Albriozza - sodium phenylbutyrate / ursodoxicoltaurine - Orphan - EMEA/H/C/005901

Amylyx Pharmaceuticals EMEA B.V.; treatment of amyotrophic lateral sclerosis (ALS)

Scope: Opinion

**Action:** For adoption

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

Opinion on 22.06.2023. List of Outstanding Issues adopted on 23.02.2023, 10.11.2022. List of Questions adopted on 23.06.2022.

See 2.2

Participation of patient representatives.

An oral explanation was held on 10 October 2023. The presentation by the applicant focused on clinical aspects.

The CHMP noted the third-party interventions.

The CHMP adopted a negative opinion by consensus, recommending the refusal of the granting of the conditional marketing authorisation. The CHMP adopted the CHMP assessment report.

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

### 3.5.2. Krazati - adagrasib - EMEA/H/C/006013

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

Scope: List of experts for SAG

**Action:** For adoption

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

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

The CHMP adopted the list of experts for the SAG.

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

No items

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

### 3.7.1. Jivadco - trastuzumab duocarmazine - EMEA/H/C/005654

medac Gesellschaft für klinische Spezialpräparate mbH; treatment of HER2 (Human Epidermal Growth Factor Receptor 2)-positive metastatic breast cancer

Scope: Withdrawal of marketing authorisation application

**Action:** For information

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

List of Outstanding Issues adopted on 20.07.2023. List of Questions adopted on 10.11.2022.

The CHMP noted the withdrawal of marketing authorisation application.

### 3.7.2. Sugammadex Lorien - sugammadex - EMEA/H/C/006115

LABORATORIOS LORIEN, S.L; reversal of neuromuscular blockade induced by rocuronium or vecuronium

Scope: Withdrawal of marketing authorisation application

**Action:** For information

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Bridion  
List of Outstanding Issues adopted on 25.05.2023. List of Questions adopted on  
15.12.2022.

The CHMP noted the withdrawal of marketing authorisation application.

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

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

#### **4.1.1. Vyepti - eptinezumab - EMEA/H/C/005287/X/0011**

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H. Lundbeck A/S

Rapporteur: Jan Mueller-Berghaus

Scope: "Line extension application to add a new strength (300 mg concentrate for solution for infusion)."

**Action:** For adoption

The Committee confirmed that all issues had been addressed.

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

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

#### **4.2.1. Entyvio - vedolizumab - EMEA/H/C/002782/X/0075**

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Takeda Pharma A/S

Rapporteur: Paolo Gasparini

Scope: quality

**Action:** For adoption

List of Questions adopted on 26.04.2023.

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

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

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

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Bayer AG

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

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

**Action:** For adoption

List of Questions adopted on 22.06.2023.

The Committee was reminded of the status of this application and its remaining outstanding issues relating to non-clinical and clinical aspects as well as the RMP.

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

#### 4.2.3. Kalydeco - ivacaftor - EMEA/H/C/002494/X/0115/G

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Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension application to introduce a new strength (13.4 mg of ivacaftor granules in sachet), grouped with a type II variation (C.I.6.a) in order to extend the indication of the granule presentations to include children with cystic fibrosis aged 1 to less than 4 months of age and weighing 3 kg or more who have an R117H CFTR mutation or one of the approved 9 gating (class III) mutations based on interim results from study VX15-770-124 (study 124); this is a phase 3, 2-part, open-label study to evaluate the safety, pharmacokinetics, and pharmacodynamics of ivacaftor (IVA) in subjects with CF who are less than 24 months of age at treatment initiation and have a CFTR gating mutation. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3 and 8 of the SmPC of the granules presentations and sections 4.2, 4.8, 5.1 and 5.2 of the SmPC of the tablets presentations are updated. The Labelling for the 13.4 mg granule presentation and the Package Leaflet of the granules and tablets presentations are updated in accordance. Version 15.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Type IA A.5.b

Type IA B.II.b.2."

**Action:** For adoption

List of Questions adopted on 25.05.2023.

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

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

#### 4.2.4. Skyrizi - risankizumab - EMEA/H/C/004759/X/0033

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AbbVie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy

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

**Action:** For adoption

List of Questions adopted on 20.07.2023.

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

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

#### 4.2.5. Talzenna - talazoparib - EMEA/H/C/004674/X/0015/G

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Pfizer Europe MA EEIG

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

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

**Action:** For adoption

List of Questions adopted on 22.06.2023.

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

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

#### 4.2.6. Viagra - sildenafil - EMEA/H/C/000202/X/0115

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Upjohn EESV

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible film)."

**Action:** For adoption

List of Questions adopted on 26.01.2023.

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

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

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

#### 4.3.1. [Amgevita - adalimumab - EMEA/H/C/004212/X/0036/G](#)

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Amgen Europe B.V.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new strength, 80 mg [0.8 ml (100 mg/ml)] solution for injection, grouped with quality variations  
The RMP (version 6.0) is updated in accordance."

**Action:** For adoption

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

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

#### 4.3.2. [Menveo - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/X/0119](#)

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GSK Vaccines S.r.l

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection). The RMP (version 11.0) is updated in accordance."

**Action:** For adoption

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

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

The CHMP agreed to the request by the MAH for an extension to the clock stop to respond to the list of questions.

#### 4.3.3. [Xalkori - crizotinib - EMEA/H/C/002489/X/0080/G](#)

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Pfizer Europe MA EEIG

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

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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

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

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

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

No items

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

No items

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

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

##### **5.1.1. Adcetris - brentuximab vedotin - Orphan - EMEA/H/C/002455/II/0109**

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Takeda Pharma A/S

Rapporteur: Peter Mol, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) treatment of adult patients with previously untreated CD30+ peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) for Adcetris based on the final overall survival results of Echelon-2 (SGN035-014), A randomized, double-blind, placebo-controlled, phase 3 study of brentuximab vedotin and CHP (A+CHP) versus CHOP in the frontline treatment of patients with CD30-positive mature T-cell lymphomas. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet

is updated in accordance. Version 19.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.”

**Action:** For adoption

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

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

The CHMP agreed to consult a SAG and adopted a list of questions to this group.

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

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Pfizer Europe MA EEIG

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

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

**Action:** For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

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

The Committee adopted 3<sup>rd</sup> request for supplementary information with a specific timetable.

### 5.1.3. [Beyfortus - nirsevimab - EMEA/H/C/005304/II/0005](#)

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AstraZeneca AB

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 and 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 20.07.2023.

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

The Committee adopted 2<sup>nd</sup> request for supplementary information with a specific timetable.

#### 5.1.4. [Bimzelx - bimekizumab - EMEA/H/C/005316/II/0020](#)

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UCB Pharma S.A.

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

Scope: "Extension of indication to include treatment of moderate to severe hidradenitis suppurativa (HS) in adults, based on final results from study HS0003 (BE HEARD I) and study HS0004 (BE HEARD II). These are phase 3, randomized, double blind, placebo controlled, multicenter, pivotal studies evaluating the efficacy and safety of bimekizumab in study participants with moderate to severe HS. Further supportive data are based on the results of phase 2 study HS0001 and phase 3 currently ongoing open-label extension study HS0005. 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 1.10 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

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

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

#### 5.1.5. [Brukinsa - zanubrutinib - EMEA/H/C/004978/II/0014](#)

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BeiGene Ireland Ltd

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include in combination with obinutuzumab treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic treatments for Brukinsa; based on results from studies BGB-3111-212 and BGB-3111-GA101-001. BGB-3111-212 is an ongoing international, Phase 2, open-label, randomized (2:1), active control study of zanubrutinib plus obinutuzumab (Arm A) versus obinutuzumab monotherapy (Arm B) in patients with R/R FL. The primary efficacy endpoint is overall response rate (ORR); while BGB-3111-GA101-001 is a Phase 1b Study to Assess Safety, Tolerability and Antitumor Activity of the Combination of BGB-3111 with Obinutuzumab in Subjects with B-Cell Lymphoid Malignancies. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

**Action:** For adoption

Request for Supplementary Information adopted on 22.06.2023.

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

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

The summary of opinion was circulated for information.

#### 5.1.6. Evkeeza - evinacumab - EMEA/H/C/005449/II/0011

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Ultragenyx Germany GmbH

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

Scope: "Extension of indication to include the treatment of paediatric patients with homozygous familial hypercholesterolaemia (HoFH) aged 5 years and older for Evkeeza, based on interim results from study R1500-CL-17100, as well as supportive information from an updated interim analysis of study R1500-CL-1719, and an extrapolation analysis (including population PK, population PK/PD, and simulation analyses). R1500-CL-17100 is an ongoing multicentre, three-part, single-arm, open-label study evaluating the efficacy, safety, and tolerability of evinacumab in paediatric patients aged  $\geq 5$  to 11 years with HoFH. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder took the opportunity to introduce minor editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

**Action:** For adoption

Request for Supplementary Information adopted on 14.09.2023.

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

The Committee adopted a 2<sup>nd</sup> request for supplementary information with a specific timetable.

#### 5.1.7. Imfinzi - durvalumab - EMEA/H/C/004771/II/0057

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AstraZeneca AB

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include Imfinzi as treatment of adults with unresectable hepatocellular carcinoma (uHCC), based on final results from study D419CC00002 (HIMALAYA); this was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma (HIMALAYA). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9, Succession 1 of the RMP has also been submitted. In addition, the PI is brought in line with the latest QRD template version 10.3."

**Action:** For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

See 2.3

An oral explanation was held on 11 October 2023. The presentation by the applicant

focused on clinical aspects.

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

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

The summary of opinion was circulated for information.

#### 5.1.8. Jemperli - dostarlimab - EMEA/H/C/005204/II/0023

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GlaxoSmithKline (Ireland) Limited

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include in combination with platinum-containing chemotherapy the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy, based on results from study 213361 (RUBY) Part 1, listed as a Specific Obligation in the Annex II; this is a phase 3, randomized, double-blind, multicenter study of dostarlimab (TSR-042) plus carboplatin-paclitaxel versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

Request for Supplementary Information adopted on 20.07.2023.

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

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

The summary of opinion was circulated for information.

#### 5.1.9. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0135

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Merck Sharp & Dohme B.V.

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

Scope: "Extension of indication to include in combination with chemotherapy the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS  $\geq$  1 based on study KEYNOTE-859, a randomised, double-blind phase 3 trial, evaluating Keytruda in combination with chemotherapy compared to placebo in combination with chemotherapy for the first-line treatment of patients with HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.

Version 40.0 of the RMP has also been submitted.”

**Action:** For adoption

Request for Supplementary Information adopted on 14.09.2023, 22.06.2023.

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

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

The summary of opinion was circulated for information.

#### 5.1.10. [Onivyde pegylated liposomal - irinotecan hydrochloride trihydrate - Orphan - EMEA/H/C/004125/II/0034](#)

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Les Laboratoires Servier

Rapporteur: Filip Josephson, PRAC Rapporteur: David Olsen

Scope: “Extension of indication to include first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas for Onivyde in combination with oxaliplatin, 5 fluorouracil (5 FU) and leucovorin (LV) based on final results from phase 3 study NAPOLI 3 (D-US-60010-001); this is an interventional study with a primary objective to evaluate the efficacy of the regimen of irinotecan liposome injection + oxaliplatin + 5-fluorouracil (5-FU)/leucovorin (LV) versus nab-paclitaxel + gemcitabine in improving overall survival (OS) in subjects who have not previously received chemotherapy for metastatic adenocarcinoma of the pancreas; As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. The updated RMP version 4.1 is also submitted.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

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

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

#### 5.1.11. [Orencia - abatacept - EMEA/H/C/000701/II/0152](#)

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Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Kimmo Jaakkola

Scope: “Extension of indication to include the prophylaxis of acute Graft versus Host Disease (aGvHD) in the adult and paediatric population for Orencia, based on final results from studies IM101311 - Abatacept Combined With a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis and IM101841 - Overall Survival In 7/8 HLA-Matched Hematopoietic Stem Cell Transplantation Patients Treated With Abatacept Combined With A Calcineurin Inhibitor And Methotrexate - An Analysis Of The Center For International Blood And Marrow Transplant Research (Cibmtr) Database. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 28.0 of the RMP has also been submitted. In

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

**Action:** For adoption

Request for Supplementary Information adopted on 30.03.2023.

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

The Committee adopted 2<sup>nd</sup> request for supplementary information with a specific timetable.

#### 5.1.12. Praluent - alirocumab - EMEA/H/C/003882/II/0078

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Sanofi Winthrop Industrie

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Gabriele Maurer

Scope: “Extension of indication to include treatment of paediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia (HeFH) as an adjunct to diet, alone or in combination with other LDL-C lowering therapies, based on final results from study EFC14643 listed as a category 3 study in the RMP; this is a randomized, double-blind, placebo-controlled study followed by an open-label treatment period to evaluate the efficacy and safety of alirocumab in children and adolescents with heterozygous familial hypercholesterolemia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP was agreed during the procedure. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP).”

**Action:** For adoption

Request for Supplementary Information adopted on 22.06.2023.

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

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

The summary of opinion was circulated for information.

#### 5.1.13. Prevymis - letermovir - Orphan - EMEA/H/C/004536/II/0033/G

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Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Kirsti Villikka

Scope: “C.I.6.a: Extension of indication to include prophylaxis of CMV disease in CMV-seronegative adults who have received a kidney transplant from a CMV-seropositive donor [D+/R-], based on the final results from study P002MK8228; this is Phase III, Randomized, Double-Blind, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of MK-8228 (Letermovir) Versus Valganciclovir for the Prevention of Human Cytomegalovirus (CMV) Disease in Adult Kidney Transplant Recipients. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

In addition, the MAH took the opportunity to introduce minor editorial changes to the product information.

C.I.4: Update of sections 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC to reflect a longer duration of treatment recommendation based on the final results from study P040MK8228; this is a Phase 3 randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of letermovir (LET) prophylaxis when extended from 100 days to 200 days post-transplant in cytomegalovirus (CMV) seropositive recipients (R+) of an allogeneic hematopoietic stem cell transplant (HSCT). 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 22.06.2023.

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

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

The summary of opinion was circulated for information.

#### 5.1.14. Reblozyl - luspatercept - Orphan - EMEA/H/C/004444/II/0021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Daniela Philadelphly, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jo Robays

Scope: “Extension of indication to include treatment of adult patients with anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS), who may require RBC transfusions for Reblozyl, based on results from study ACE-536-MDS-002 (COMMANDS), an active-controlled, open-label, randomized Phase 3 study comparing the efficacy and safety of luspatercept vs epoetin alfa in adult subjects with anaemia due to IPSS-R very low, low or intermediate risk MDS, who are ESA naïve and require RBC transfusions, and studies ACE-536-MDS-001(MEDALIST), ACE-536-MDS-004 , A536-03, A536-05 and ACE-536-LTFU-001; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.”

**Action:** For adoption

Request for Supplementary Information adopted on 22.06.2023.

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

The Committee adopted 2<sup>nd</sup> request for supplementary information with a specific timetable.

#### 5.1.15. Rubraca - rucaparib - EMEA/H/C/004272/II/0036

Pharmaand GmbH

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Ulla Wändel Liminga

Scope: “Extension of indication to include maintenance treatment of adult patients with advanced (FIGO Stages III and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first-line platinum-based chemotherapy



for Rubraca, based on interim results from study CO-338-087 (ATHENA); this is a Phase III, randomized, double-blind, dual placebo controlled study of rucaparib as monotherapy and in combination with nivolumab in patients with newly diagnosed EOC, FTC, or PPC who have responded to their first-line treatment (surgery and platinum-based chemotherapy). 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 6.3 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

Request for Supplementary Information adopted on 14.09.2023, 25.05.2023, 15.12.2022.

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

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

The summary of opinion was circulated for information.

#### 5.1.16. Veyvondi - vonicog alfa - EMEA/H/C/004454/II/0030

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Mari Thorn

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

**Action:** For adoption

Request for Supplementary Information adopted on 22.06.2023.

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

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

The summary of opinion was circulated for information.

#### 5.1.17. Zinplava - bezlotoxumab - EMEA/H/C/004136/II/0037

Merck Sharp & Dohme B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of the paediatric population (1 to 18

years of age) for Zinplava, based on final results from study MK-6072-001 (MODIFY III) listed as a category 3 study in the RMP; this is a phase 3, randomised, placebo-controlled, parallel-group, multi-site, double-blind trial evaluating the safety, tolerability, pharmacokinetics (PK) and efficacy of a single infusion of bezlotoxumab in paediatric participants from 1 to <18 years of age receiving antibacterial drug treatment for Clostridioides difficile infection (CDI). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.”

**Action:** For adoption

Request for Supplementary Information adopted on 22.06.2023.

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

The Committee adopted 2<sup>nd</sup> request for supplementary information with a specific timetable.

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

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/006340**

in vitro diagnostic device for laboratory use, intended for the qualitative detection of BRAF V600 mutations in DNA extracted from formalin-fixed, paraffin-embedded human tissue.

Scope: Opinion

**Action:** For adoption

Request for supplementary information adopted on 14.09.2023.

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

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

### **6.3.2. [in vitro diagnostic medical device - EMEA/H/D/006373](#)**

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detection of PD-L1 protein

Scope: Request for supplementary information

**Action:** For adoption

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

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

### **6.3.3. [in vitro diagnostic medical device - EMEA/H/D/006308](#)**

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detection of HER2 antigen

Scope: Opinion

**Action:** For adoption

Request for supplementary information adopted on 14.09.2023.

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

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

### **6.3.4. [in vitro diagnostic medical device - EMEA/H/D/006310](#)**

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

Scope: Request for supplementary information

**Action:** For adoption

Request for supplementary information adopted on 14.09.2023.

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

The Committee adopted a 2<sup>nd</sup> request for supplementary information with a specific timetable.

## **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. resmetirom – H0006220

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Treatment of adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with liver fibrosis

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

**Action:** For adoption

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

### 8.2. Priority Medicines (PRIME)

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

The CHMP adopted the recommendations for PRIME eligibility.

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

## 9. Post-authorisation issues

### 9.1. Post-authorisation issues

#### 9.1.1. Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/S/0004

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SIGA Technologies Netherlands B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber

Scope: "Annual reassessment of Marketing Authorisation for Tecovirimat SIGA (exceptional circumstances)."

**Action:** For adoption

Request for Supplementary Information adopted on 14.09.2023, 20.07.2023, 25.05.2023.

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

Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.

The Marketing Authorisation remains under exceptional circumstances.

### 9.1.2. [Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/II/0006](#)

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SIGA Technologies Netherlands B.V.

PRAC Led; PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise

Scope: "Submission of substantial updates to the protocol of study SIGA-246-021 listed as a specific obligation in the Annex II of the Product Information in order to reflect the transfer of sponsorship from SIGA Technologies, Inc. to the NIH Division of Microbiology and Infection Disease protocol. This is a phase 4, observational field study to evaluate safety and clinical benefit in tecovirimat-treated patients following exposure to variola virus and clinical diagnosis of smallpox disease. The Annex II and the RMP submitted version 1.2 are updated accordingly."

**Action:** For adoption

Request for Supplementary Information adopted on 14.09.2023, 25.05.2023, 14.04.2023.

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

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

### 9.1.3. [Ocaliva - obeticholic acid - EMEA/H/C/004093/II/0038, Orphan](#)

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Advanz Pharma Limited

Rapporteur: Carolina Prieto Fernandez

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

**Action:** For adoption

Request for Supplementary Information adopted on 30.03.2023.

See 2.3

An oral explanation was held on 10 October 2023. The presentation by the applicant focused on clinical aspects.

The CHMP adopted a negative opinion by consensus, recommending the refusal of the variation(s) to the terms of the marketing authorisation. The CHMP adopted the assessment report.

See 10.1

#### 9.1.4. [WS2409](#) [Lixiana-EMA/H/C/002629/WS2409/0042](#) [Roteas-EMA/H/C/004339/WS2409/0029](#)

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Daiichi Sankyo Europe GmbH

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

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

**Action:** For adoption

Request for Supplementary Information adopted on 30.03.2023.

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

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

#### 9.1.5. [Rebetol – ribavirin – EMA/H/C/000246](#)

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Merck Sharp & Dohme B.V.; Rebetol is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. Rebetol is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) for paediatric patients (children 3 years of age and older and adolescents) not previously treated and without liver decompensation.

Rapporteur: Jean-Michel Race, Co-Rapporteur: Bruno Sepodes

Scope: Withdrawal of marketing authorisation

**Action:** For information

The CHMP noted the withdrawal of marketing authorisation.

#### 9.1.6. [Qarziba - dinutuximab beta - EMA/H/C/003918/II/0043, Orphan](#)

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Recordati Netherlands B.V.

Rapporteur: Peter Mol

Scope: "Update of section 4.8 of the SmPC based on final results from study APN311-202V3 listed as a Specific Obligation in the Annex II of the Product Information. This is a Phase I/II dose schedule finding study of Ch14.18/CHO continuous infusion combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma. In addition, the MAH took the opportunity to update Annex II section E."

**Action:** For adoption

Request for Supplementary Information adopted on 26.04.2023, 15.09.2022.

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

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

#### 9.1.7. [Nuvaxovid - Covid-19 Vaccine \(recombinant, adjuvanted\) - EMEA/H/C/005808/II/0045](#)

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Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

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

**Action:** For adoption

Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

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

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

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

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Novavax CZ, a.s.

Rapporteur: Patrick Vrijlandt

Scope: quality variation

**Action:** For adoption

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

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

### 9.1.9. [Pepaxti - melphalan flufenamide - EMEA/H/C/005681/II/0002](#)

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Oncopeptides AB

Rapporteur: Peter Mol, Co-Rapporteur: Elita Poplavska, PRAC Rapporteur: Martin Huber

“Extension of indication to include treatment of patients with Multiple Myeloma who have received at least two prior lines of therapies for Pepaxti, based on final results from study OP-103 OCEAN; this is a randomized, open-label phase III study in patients with relapsed or refractory multiple myeloma following two to four lines of prior therapies and who were refractory to lenalidomide and the last line of therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC.”

Scope: Withdrawal of extension of indication application

**Action:** For information

Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 22.06.2023, 30.03.2023.

The CHMP noted the withdrawal of the extension of application.

### 9.1.10. [COVID-19 Vaccine \(inactivated, adjuvanted\) Valneva - SARS-CoV-2 virus, strain Wuhan hCoV-19/Italy/INMI1-isl/2020, inactivated - EMEA/H/C/006019](#)

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Valneva Austria GmbH; COVID-19 Vaccine (inactivated, adjuvanted) Valneva is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 to 50 years of age

Rapporteur: Daniela Philadelphly, Co-Rapporteur: Alar Irs

Scope: Notification to withdraw the marketing authorisation

**Action:** For information

The CHMP noted the notification to withdraw the marketing authorisation.

### 9.1.11. [Jakavi - ruxolitinib - EMEA/H/C/002464/II/0068](#)

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Novartis Europharm Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Peter Mol

Scope: “Update of sections 4.4 and 5.1 of the SmPC in order to add new warnings on ‘Major adverse cardiac events (MACE)’, ‘Thrombosis’, and ‘Second primary malignancies’, following an Art. 20 Class Referral involving JAK inhibitors approved to treat rheumatoid arthritis and to update efficacy information regarding the effects of ruxolitinib in relation to thromboembolic events based on recently published data from MAJIC-PV study (a randomized, controlled open-label study in polycythemia vera (PV)).”

**Action:** For discussion

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

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



The CHMP agreed to seek advice from the PRAC and adopted a list of questions to this Committee.

#### 9.1.12. Degarelix Accord - degarelix acetate - EMEA/H/C/006048

Accord Healthcare S.L.U.; treatment of prostate cancer

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Tiphaine Vaillant

Scope: Third-party intervention

**Action:** For information

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

Opinion adopted on 20.07.2023. List of Outstanding Issues adopted on 26.04.2023. List of Questions adopted on 10.11.2022.

The CHMP noted the third-party intervention.

#### 9.1.13. Pregabalin Sandoz GmbH – pregabalin – EMEA/H/C/004070

Sandoz GmbH; treatment of epilepsy and generalised anxiety disorder (GAD)

Rapporteur: Tomas Radimersky

Scope: Withdrawal of marketing authorisation

**Action:** For information

The CHMP noted the withdrawal of marketing authorisation.

#### 9.1.14. Integrilin – eptifibatide – EMEA/H/C/00230

GlaxoSmithKline (Ireland) Limited; prevention of early myocardial infarction

Rapporteur: Alexandre Moreau, Co-Rapporteur: Paolo Gasparini

Scope: DHPC and communication plan

**Action:** For adoption

CHMP noted the DHPC and communication plan.

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

PTC Therapeutics International Limited

Re-examination Rapporteur: TBC, Re-examination Co-Rapporteur: TBC

Scope: Draft Re-examination timetable, appointment of re-examination rapporteurs

**Action:** For adoption

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

The CHMP endorsed the draft timetable and noted the call for re-examination rapporteurs.

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

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GlaxoSmithKline (Ireland) Limited

Re-examination Rapporteur: TBC, Re-examination Co-Rapporteur: TBC

Scope: Draft Re-examination timetable, appointment of re-examination rapporteurs

**Action:** For adoption

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

The CHMP appointed a re-examination rapporteur and a re-examination co-rapporteur.

The CHMP endorsed the draft timetable.

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

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Ratiopharm GmbH

Rapporteur: Daniela Philadelphy

Scope: DHPC and communication plan

**Action:** For adoption

The CHMP noted the DHPC.

## 10. Referral procedures

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

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

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Advanz Pharma Limited

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

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

**Action:** For adoption

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

The CHMP appointed Carolina Prieto Fernandez as referral rapporteur and Paolo Gasparini

as referral Co-Rapporteur.

The CHMP agreed that no temporary measures were necessary at this stage. The CHMP considered at this point that a detailed assessment of all available data from study 747-302 (and 747-401) in the context of all available data on Ocaliva was necessary, before making recommendations on its authorised use.

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

Notification: 12 October 2023

Start of the procedure (CHMP): October 2023 CHMP

List of questions: 12 October 2023

Submission of responses: 01 December 2023

Re-start of the procedure: 26 December 2023

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 03 January 2024

Comments: 10 January 2024

Updated Rapporteur/co-rapporteur ARs circulated to CHMP: 16 January 2024

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

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

# **11. Pharmacovigilance issue**

## **11.1. Early Notification System**

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

**Action:** For information

The CHMP noted the information.

# **12. Inspections**

## **12.1. GMP inspections**

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

## **12.2. GCP inspections**

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

such inspections

### **12.3. Pharmacovigilance inspections**

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

### **12.4. GLP inspections**

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

## **13. Innovation Task Force**

### **13.1. Minutes of Innovation Task Force**

No items

### **13.2. Innovation Task Force briefing meetings**

No items

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

No items

### **13.4. Nanomedicines activities**

No items

## **14. Organisational, regulatory and methodological matters**

### **14.1. Mandate and organisation of the CHMP**

#### **14.1.1. Vote by PROXY**

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No items

#### **14.1.2. CHMP membership**

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No items

### 14.1.3. Strategic review and learning meeting (SRLM) under Spanish EU presidency

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Update on the SRLM, to be held 17-18 October 2023 in Madrid

CHMP: Maria Conception Prieto Yerro

**Action:** For information

The CHMP noted the update on the strategic review and learning meeting.

## 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 October 2023

**Action:** For adoption

The CHMP adopted the EURD list.

### 14.2.2. Paediatric Committee (PDCO)

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Agenda of the October 2023 PDCO plenary meeting

**Action:** For information

The CHMP noted the PDCO agenda.

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

### 14.3.1. Biologics Working Party (BWP)

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Chair: Sean Barry, Vice-chair: Francesca Luciani

Reports from BWP October 2023 meeting to CHMP for adoption:

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

**Action:** For adoption

The CHMP adopted the BWP reports.

### 14.3.2. Name Review Group (NRG)

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Table of Decisions of the NRG meeting held on 18-19 September 2023.

**Action:** For adoption

The CHMP adopted the NRG table of decisions.

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

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Chair: Paolo Foggi

Report from the SAWP meeting held on 25-28 September 2023. Table of conclusions

**Action:** For information

Scientific advice letters:

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

The CHMP noted the update.

#### 14.3.4. Oncology Working Party (ONCWP)

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Chair: Pierre Demolis

Guideline (Rev. 6) on the clinical evaluation of anticancer medicinal products following GCG review and adoption of the ONCWP.

**Action:** For adoption

The CHMP adopted the guideline (Rev. 6) on the clinical evaluation of anticancer medicinal products.

### 14.4. Cooperation within the EU regulatory network

No items

### 14.5. Cooperation with International Regulators

No items

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

No items

### 14.7. CHMP work plan

No items

### 14.8. Planning and reporting

No items

## 14.9. Others

### 14.9.1. CHMP Learnings

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CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

**Action:** For information

The CHMP noted the CHMP learnings.

## 15. Any other business

### 15.1. AOB topic

#### 15.1.1. Health Threats and ETF Update

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**Action:** For information

The CHMP noted the update.



## List of Participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 09-12 October 2023 CHMP meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in final deliberations and voting on:	concizumab - EMEA/H/C/005938
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	Praluent - alirocumab - EMEA/H/C/003882 /II/0078
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Grzegorz Cessak	Alternate	Poland	No participation in final deliberations and voting on:	COVID-19 vaccines
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	COVID-19 vaccines
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Carolina Prieto Fernandez	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No participation in discussion, final deliberations and voting on:	Imfinzi - durvalumab - EMEA/H/C/004771 /II/0057 Beyfortus - nirsevimab - EMEA/H/C/005304 /II/0005
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Vincent Gazin	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Nicolas Camhaji	Expert	France	No participation in discussion, final deliberations and voting on:	Jakavi - ruxolitinib - EMEA/H/C/002464 /II/0068

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Nathalie Dumarcet	Expert	France	No interests declared	
Kairi Rooma	Expert	Estonia	No interests declared	
Daiana Vasilcanu	Expert	Sweden	No interests declared	
Charlotte Anderberg	Expert	Sweden	No interests declared	
Sandra Holt	Expert	Sweden	No interests declared	
Ieva Rutkovska	Expert	Latvia	No interests declared	
Maria Victoria Tudanca Pacios	Expert	Spain	No restrictions applicable to this meeting	
Paula Contreras Alarcón	Expert	Spain	No participation in discussion, final deliberations and voting on:	Rezzayo - rezafungin - Orphan - EMEA/H/C/005900  bimatoprost - EMEA/H/C/005916  Skyrizi - risankizumab - EMEA/H/C/004759 /X/0033
Marta Lafuente Gonzalez	Expert	Spain	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Beatriz Gutiérrez Eugenio	Expert	Spain	No interests declared	
Teresa Llacer Delicado	Expert	Spain	No interests declared	
Julia Ruiz Gutierrez	Expert	Spain	No interests declared	
Antonio Gomez-Outes	Expert	Spain	No interests declared	
Ferrán Torres	Expert	Spain	No restrictions applicable to this meeting	
Riitta Niittyvuopio	Expert	Finland	No participation in discussion, final deliberations and voting on:	Jakavi - ruxolitinib - EMEA/H/C/002464 /II/0068
Antero Kallio	Expert	Finland	No restrictions applicable to this meeting	
Maija Tarkkanen	Expert	Finland	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Luca Santi	Expert	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert	Italy	No restrictions applicable to this meeting	
Cristina Migali	Expert	Italy	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Federico De Angelis	Expert	Italy	No interests declared	
Michela Piezzo	Expert	Italy	No interests declared	
Serena Zamponi	Expert	Italy	No interests declared	
Sara Galluzzo	Expert	Italy	No interests declared	
Luca Massacesi	Expert	Italy	No restriction against giving the SAG report on Albriozza	
Olga Kholmanskikh	Expert	Belgium	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Stefan Bonné	Expert	Belgium	No interests declared	
Nicolas Nyssen	Expert	Belgium	No interests declared	
Valérie Lescrainier	Expert	Belgium	No interests declared	
Lisa Nika	Expert	Austria	No restrictions applicable to this meeting	
Walter Johannes Beiersdorf	Expert	Austria	No restrictions applicable to this meeting	
Melanie Ramberger	Expert	Austria	No interests declared	
Maximilian Koblishcke	Expert	Austria	No restrictions applicable to this meeting	
Bojana Divkovic	Expert	Austria	No interests declared	
Ulrike Heissenberger	Expert	Austria	No interests declared	
Bernhard Majer	Expert	Austria	No interests declared	
Marte Fergestad	Expert	Norway	No interests declared	
Maja Sommerfelt Grønvold	Expert	Norway	No interests declared	
Catherine Byrne	Expert	Ireland	No interests declared	
Larissa Higgins	Expert	Ireland	No interests declared	
Brian Aylward	Expert	Ireland	No interests declared	
Olive Smyth	Expert	Ireland	No restrictions applicable to this meeting	
Agnieszka Przybyszewska	Expert	Ireland	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Friederike Marei Feldmann	Expert	Germany	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Erich Schneider	Expert	Germany	No interests declared	
Anna Krueger	Expert	Germany	No interests declared	
Gabriele Schlosser-Weber	Expert	Germany	No interests declared	
Elmer Schabel	Expert	Germany	No interests declared	
Dalia Akramienė	Expert	Lithuania	No restrictions applicable to this meeting	
Silvijus Abramavičius	Expert	Lithuania	No restrictions applicable to this meeting	
Ludivine Martin	Expert	France	No interests declared	
Sandrine Chiappini	Expert	France	No interests declared	
Lama Caizergues Sargi	Expert	France	No interests declared	
Céline Jumeau	Expert	France	No interests declared	
Norontsoa Rasolondramanitra	Expert	France	No interests declared	
Roxane Fornacciari	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Susanne Høpner Rasmussen	Expert	Denmark	No interests declared	
Trine S. Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Nanna Borup Johansen	Expert	Denmark	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ann-Cathrine Bach Dunvald	Expert	Denmark	No interests declared	
Kristin Skougaard	Expert	Denmark	No interests declared	
Thadeus Bao Quan Nguyen	Expert	Denmark	No interests declared	
Torsten Holm Nielsen	Expert	Denmark	No interests declared	
Kinga Nowicka-Matus	Expert	Denmark	No interests declared	
Sine Buhl Næss-Schmidt	Expert	Denmark	No restrictions applicable to this meeting	
Charlotte Hejl	Expert	Denmark	No restrictions applicable to this meeting	
Emilie Birch Kristensen	Expert	Denmark	No restrictions applicable to this meeting	
Boje Kvorning Pires Ehmsen	Expert	Denmark	No interests declared	
Michal Zwiewka	Expert	Germany	No interests declared	
Irene Nowotny	Expert	Germany	No participation in discussion, final deliberations and voting on:	Praluent - alirocumab - EMEA/H/C/003882 /II/0078
Hilke Zander	Expert	Germany	No interests declared	
Susanne Mueller	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Sara Tognarelli	Expert	Germany	No restrictions applicable to this meeting	
Yasmin Molter	Expert	Germany	No interests declared	
Frank Holtkamp	Expert	Netherlands	No interests declared	
Marika van Leeuwen	Expert	Netherlands	No interests declared	
Elizabeth Jacoba Johanna Berm	Expert	Netherlands	No restrictions applicable to this meeting	
Susanne Breedijk-van den Ende	Expert	Netherlands	No interests declared	
Hannelore Samyn	Expert	Netherlands	No interests declared	
Robine Donken	Expert	Netherlands	No interests declared	
Elly Vereyken	Expert	Netherlands	No interests declared	
Jacqueline van Kuijk	Expert	Netherlands	No interests declared	
Jens Stegers	Expert	Netherlands	No interests declared	
Nienke Rodenhuis	Expert	Netherlands	No interests declared	
Nicole Jaspers	Expert	Netherlands	No interests declared	
Quirine Fillekes	Expert	Netherlands	No interests declared	
Lies Van Vlijmen	Expert	Netherlands	No interests declared	
Femke Geers	Expert	Netherlands	No interests declared	
Chiara Acone	Expert	Netherlands	No restrictions applicable to this meeting	
Cornelis Frank Tuinenburg	Expert	Netherlands	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Elisabeth Johanne Rook	Expert	Netherlands	No interests declared	
Nynke Zandstra-Hosper	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Chantal van de Schootbrugge	Expert	Netherlands	No interests declared	
Illiana Meurs	Expert	Netherlands	No interests declared	
Melanie Diane Klok	Expert	Netherlands	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Pierre Demolis	Expert	France	No interests declared	
Juha Kolehmainen	Expert	Finland	No interests declared	
Mair Powell	Expert	Ireland	No interests declared	
Armin Koch	Expert	Germany	No restrictions applicable to this meeting	
Ebru Karakoc Madsen	Expert	Denmark	No interests declared	
Maria Di Marzo	Expert	Italy	No interests declared	
Yseult Brun	Expert	France	No interests declared	
Michal Pirozynski	Expert	Malta	No interests declared	
Matthew Camilleri	Expert	Malta	No interests declared	
Robert Nistico	Expert	Malta	No interests declared	
Gunnar Thor Gunnarsson	Expert	Iceland	No interests declared	
Anna Vikerfors	Expert	Sweden	No interests declared	
Edwige Haelterman Brenneisen	Expert	Belgium	No interests declared	
Violette Dirix	Expert	Belgium	No interests declared	
Inne Crevecoeur	Expert	Belgium	No participation in discussion, final deliberations and voting on:	arpraziquantel - Article 58 - EMEA/H/W/004252  Keytruda - pembrolizumab - EMEA/H/C/003820 /II/0135  Prevymis - letermovir - Orphan - EMEA/H/C/004536 /II/0033/G  Zinplava - bezlotoxumab - EMEA/H/C/004136 /II/0037  Rebetol – ribavirin – EMEA/H/C/000246
Olli Tenhunen	Expert	Finland	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with the help of EMA staff.				

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

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

## Explanatory notes

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

### Oral explanations (section 2)

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

### Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



08 December 2023  
EMA/CHMP/461666/2023

## Annex to 09-12 October 2023 CHMP Minutes

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## A. PRE-SUBMISSION ISSUES

### A.1. ELIGIBILITY REQUESTS

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Report on Eligibility to Centralised Procedure for October 2023: <b>For adoption</b>	Adopted
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### A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

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Final Outcome of Rapporteurship allocation for October 2023: <b>For adoption</b>	Adopted
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### A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

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

## B. POST-AUTHORISATION PROCEDURES OUTCOMES

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

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

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<b>Mvabea - ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/S/0019</b> Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	Positive Opinion adopted by consensus together with the CHMP assessment report.  The Marketing Authorisation remains under exceptional circumstances.
<b>Qarziba - dinutuximab beta - EMEA/H/C/003918/S/0053, Orphan</b> Recordati Netherlands B.V., Rapporteur: Peter Mol, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Gabriele Maurer	Positive Opinion adopted by consensus together with the CHMP assessment report.  The Marketing Authorisation remains under exceptional circumstances.
<b>Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248/S/0004</b> SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 14.09.2023, 20.07.2023, 25.05.2023.	Positive Opinion adopted by consensus together with the CHMP assessment report.  The Marketing Authorisation remains under exceptional circumstances.  See 9.1
<b>Zabdeno - ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/S/0017</b> Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	Positive Opinion adopted by consensus together with the CHMP assessment report.  The Marketing Authorisation remains under exceptional circumstances.

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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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**Ghryvelin - macimorelin -  
EMA/H/C/004660/R/0020**

Atnahs Pharma Netherlands B.V., Rapporteur:  
Martina Weise, Co-Rapporteur: Jean-Michel  
Race, PRAC Rapporteur: Liana Gross-  
Martirosyan,  
Request for Supplementary Information adopted  
on 14.09.2023.

Positive Opinion adopted by consensus together  
with the CHMP assessment report.

Based on the review of the available  
information, the CHMP was of the opinion that  
the renewal of the marketing authorisation can  
be granted with unlimited validity.

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

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**Atazanavir Krka - atazanavir -  
EMA/H/C/004859/R/0004**

KRKA, d.d., Novo mesto, Generic, Generic of  
Reyataz, Rapporteur: Tomas Radimersky, PRAC  
Rapporteur: Nathalie Gault

Positive Opinion adopted by consensus together  
with the CHMP assessment report.

Based on the review of the available  
information, the CHMP was of the opinion that  
the renewal of the marketing authorisation can  
be granted with unlimited validity.

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**Besremi - ropeginterferon alfa-2b -  
EMA/H/C/004128/R/0031**

AOP Orphan Pharmaceuticals GmbH,  
Rapporteur: Janet Koenig, Co-Rapporteur:  
Alexandre Moreau, PRAC Rapporteur: Ana Sofia  
Diniz Martins  
Request for Supplementary Information adopted  
on 20.07.2023.

Positive Opinion adopted by consensus together  
with the CHMP assessment report and  
translation timetable.

Based on the review of the available  
information, the CHMP was of the opinion that  
the renewal of the marketing authorisation can  
be granted with unlimited validity.

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**Flucelvax Tetra - influenza vaccine (surface  
antigen, inactivated, prepared in cell  
cultures) - EMA/H/C/004814/R/0040**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz,  
Co-Rapporteur: Jean-Michel Race, PRAC  
Rapporteur: Gabriele Maurer

Positive Opinion adopted by consensus together  
with the CHMP assessment report and  
translation timetable.

Based on the review of the available  
information, the CHMP was of the opinion that  
the renewal of the marketing authorisation can  
be granted with unlimited validity.

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**Febuxostat Krka - febuxostat -  
EMA/H/C/004773/R/0008**

KRKA, d.d., Novo mesto, Generic, Generic of  
Adenuric, Rapporteur: John Joseph Borg, PRAC  
Rapporteur: Jan Neuhauser

Positive Opinion adopted by consensus together  
with the CHMP assessment report and  
translation timetable.

Based on the review of the available  
information, the CHMP was of the opinion that  
the renewal of the marketing authorisation can  
be granted with unlimited validity.

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**Vizimpro - dacomitinib -  
EMA/H/C/004779/R/0011**

Pfizer Europe MA EEIG, Rapporteur: Carolina

Positive Opinion adopted by consensus together  
with the CHMP assessment report and  
translation timetable.

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Prieto Fernandez, Co-Rapporteur: Eva Skovlund, PRAC Rapporteur: Menno van der Elst	Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
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### **B.2.3. Renewals of Conditional Marketing Authorisations**

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<b>Hemgenix - etranacogene dezaparvovec - EMEA/H/C/004827/R/0007, Orphan, ATMP</b>	Positive Opinion adopted by consensus together with the CHMP assessment report.
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CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst	The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.
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The Marketing Authorisation remains conditional.

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<b>Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP</b>	Request for supplementary information adopted with a specific timetable.
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Holostem Therapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Concetta Quintarelli, CHMP Coordinators: Jan Mueller- Berghaus and Paolo Gasparini, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 06.10.2023.
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<b>Retsevmo - selpercatinib - EMEA/H/C/005375/R/0026</b>	Positive Opinion adopted by consensus together with the CHMP assessment report.
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Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst	The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.
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The Marketing Authorisation remains conditional.

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<b>Sirturo - bedaquiline - EMEA/H/C/002614/R/0054, Orphan</b>	Positive Opinion adopted by consensus together with the CHMP assessment report.
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Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga	The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.
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The Marketing Authorisation remains conditional.

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<b>Tecartus - brexucabtagene autoleucel - EMEA/H/C/005102/R/0034, Orphan, ATMP</b>	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.
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Kite Pharma EU B.V., Rapporteur: Jan Mueller- Berghaus, Co-Rapporteur: Rune Kjekken, CHMP Coordinators: Jan Mueller-Berghaus and Ingrid	The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can
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Wang, PRAC Rapporteur: Menno van der Elst

be granted.

The Marketing Authorisation remains conditional.

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

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#### **Post-authorisation safety studies**

PRAC recommendations on PASS results adopted at the PRAC meeting held on 25-28 September 2023 PRAC:

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#### **Intrarosa (CAP) – EMEA-H-C-PSR-S-0044**

Adopted

(prasterone)

PRAC Rapporteur: Menno van der Elst

Scope: Final study report for a drug utilisation study (DUS) to describe the baseline

characteristics and utilisation patterns of EU postmenopausal women initiating treatment

with Intrarosa and to assess whether EU

prescribers abide by the contraindications stated in the EU SmPC

PRAC recommendation to CHMP

**Action:** For adoption

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#### **Signal detection**

PRAC recommendations on signals adopted at the PRAC meeting held on 25-28 September 2023 PRAC:

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#### **Signal of cutaneous vasculitis**

Adopted

Azacitidine Accord, Azacitidine Betapharm, Azacitidine Mylan, Onureg, Vidaza (CAP) - azacitidine

Rapporteur: multiple, Co-Rapporteur: multiple,

PRAC Rapporteur: Menno van der Elst

PRAC recommendation on a variation

**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 October 2023 meeting:

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#### **EMEA/H/C/PSUSA/00002511/202301**

(pregabalin)

CAPS:

**Lyrica** (EMEA/H/C/000546) (pregabalin),

Upjohn EESV, Rapporteur: Peter Mol

**Pregabalin Pfizer** (EMEA/H/C/003880)

(pregabalin), Upjohn EESV, Rapporteur: Peter

Mol, PRAC Rapporteur: Liana Gross-Martirosyan,

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

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<p>"01/02/2021 To: 31/01/2023"</p>	<p>Update of sections 4.4 and 4.8 of the SmPC to include suicidal ideation as part of the observed withdrawal symptoms.</p>
<p><b>EMA/H/C/PSUSA/0002667/202302</b> (rotigotine) CAPS: <b>Neupro</b> (EMA/H/C/000626) (rotigotine), UCB Pharma S.A., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, "16/02/2020 To: 15/02/2023"</p>	<p>Based on the PRAC Rapporteur review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing rotigotine remains unchanged but recommends that the terms of the marketing authorisation(s) should be varied as follows: Update of section 4.4 of the SmPC to add a warning regarding the possibility for Parkinson Disease patients to experience dystonic events. The package leaflet is updated accordingly.</p>
<p><b>EMA/H/C/PSUSA/0009204/202301</b> (ivacaftor) CAPS: <b>Kalydeco</b> (EMA/H/C/002494) (ivacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Monica Martinez Redondo, "24/01/2020 To: 23/01/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add a warning regarding Depression and to add the adverse reaction Depression with a frequency "not known". The package leaflet is updated accordingly. Update of section 4.6 of the SmPC to amend the wording regarding breast-feeding. The package leaflet is updated accordingly.</p>
<p><b>EMA/H/C/PSUSA/00010730/202302</b> (tezacaftor / ivacaftor) CAPS: <b>Symkevi</b> (EMA/H/C/004682) (tezacaftor / ivacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Rhea Fitzgerald, "12/02/2022 To: 11/02/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add "depression" as an adverse drug reaction with a frequency not known and introduce a warning to inform prescribers about the risk of depression. The package leaflet is updated accordingly. Update of section 4.6 of the SmPC to amend wording regarding breast-feeding. The</p>



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package leaflet is updated accordingly.

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**EMA/H/C/PSUSA/00010745/202302**

(apalutamide)

CAPS:

**Erleada** (EMA/H/C/004452) (apalutamide),  
Janssen-Cilag International N.V., Rapporteur:  
Carolina Prieto Fernandez, PRAC Rapporteur:  
Tiphaine Vaillant, "14/02/2022 To: 13/02/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

- Update of section 4.4 of the SmPC to add a warning regarding interstitial lung disease. The package leaflet is updated accordingly.
- Update of section 4.8 of the SmPC to add the adverse drug reaction "restless legs syndrome" (RLS) with a frequency "uncommon" and add the adverse reaction "interstitial lung disease" with a frequency "not known". The package leaflet is updated accordingly.

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**EMA/H/C/PSUSA/00010795/202302**

(etanercept)

CAPS:

**Benepali** (EMA/H/C/004007) (etanercept),  
Samsung Bioepis NL B.V., Rapporteur: Christian  
Gartner

**Enbrel** (EMA/H/C/000262) (etanercept), Pfizer  
Europe MA EEIG, Rapporteur: Maria Concepcion  
Prieto Yerro

**Erelzi** (EMA/H/C/004192) (etanercept),  
Sandoz GmbH, Rapporteur: Peter Mol

**Nepexto** (EMA/H/C/004711) (etanercept),  
Biosimilar Collaborations Ireland Limited,  
Rapporteur: Martina Weise, PRAC Rapporteur:  
Monica Martinez Redondo, "02/02/2020 To:  
02/02/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

Update of section 4.8 of the SmPC to add Glomerulonephritis (frequency >not known<).  
The package leaflet is updated accordingly.

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**EMA/H/C/PSUSA/00010823/202302**

(upadacitinib)

CAPS:

**Rinvoq** (EMA/H/C/004760) (upadacitinib),  
AbbVie Deutschland GmbH & Co. KG,  
Rapporteur: Kristina Dunder, PRAC Rapporteur:  
Nikica Mirošević Skvrce, "14/08/2022 To:  
14/02/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

Update of section 4.4 of the SmPC to add a warning regarding hypoglycaemia in patients treated for diabetes. The package leaflet is

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	updated accordingly.
<p><b>EMA/H/C/PSUSA/00011000/202302</b> (ciltacabtagene autoleucl) CAPS: <b>Carvykti</b> (EMA/H/C/005095) (ciltacabtagene autoleucl), Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays, "27/08/2022 To: 27/02/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add information regarding a T-cell malignancy case and update of section 6.6 to include additional information on product handling issues (leak from bags of CARVYKTI). The package leaflet is updated accordingly.</p>
<p><b>EMA/H/C/PSUSA/00011010/202302</b> (teclistamab) CAPS: <b>Tecvayli</b> (EMA/H/C/005865) (teclistamab), Janssen-Cilag International N.V., Rapporteur: Johanna Lähtenvuo, PRAC Rapporteur: Jana Lukacisinova, "23/08/2022 To: 22/02/2023"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add new symptoms of ICANS and Grade 3 and higher ICANS. The Package leaflet is updated accordingly. The RMP version 3.2 has also been submitted.</p>
<b>B.4. EPARs / WPARs</b>	
<p><b>Aqumeldi - enalapril maleate - EMA/H/C/005731, PUMA</b> Proveca Pharma Limited, treatment of heart failure, Hybrid application (Article 10(3) of Directive No 2001/83/EC)</p>	For information only. Comments can be sent to the PL in case necessary.
<p><b>Catiolanze - latanoprost - EMA/H/C/005933</b> Santen Oy, Reduction of elevated intraocular pressure (IOP), Hybrid application (Article 10(3) of Directive No 2001/83/EC)</p>	For information only. Comments can be sent to the PL in case necessary.
<p><b>Ebglyss - lebrikizumab - EMA/H/C/005894</b> Almirall, S.A., treatment of moderate-to-severe atopic dermatitis in adults and adolescents, New active substance (Article 8(3) of Directive No</p>	For information only. Comments can be sent to the PL in case necessary.

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2001/83/EC)

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**Finlee - dabrafenib - EMEA/H/C/005885, Orphan**

Novartis Europharm Limited, Treatment of glioma, Known active substance (Article 8(3) of Directive No 2001/83/EC)

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

**Herwenda - trastuzumab - EMEA/H/C/005769**

Sandoz GmbH, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC), Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

**Sugammadex Lorien (WD) - sugammadex - EMEA/H/C/006115**

LABORATORIOS LORIEN, S.L, reversal of neuromuscular blockade induced by rocuronium or vecuronium, Generic, Generic of Bridion, Generic application (Article 10(1) of Directive No 2001/83/EC)

**WPAR**

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

**Vanflyta - quizartinib - EMEA/H/C/005910**

Daiichi Sankyo Europe GmbH, Treatment of adult patients with diagnosed acute myeloid leukaemia (AML), New active substance (Article 8(3) of Directive No 2001/83/EC)

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

**Yorvipath - palopegteriparatide - EMEA/H/C/005934, Orphan**

Ascendis Pharma Bone Diseases A/S, PTH replacement therapy indicated for the treatment of hypoparathyroidism in adults., New active substance (Article 8(3) of Directive No 2001/83/EC)

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

**Zilbrysq - zilucoplan - EMEA/H/C/005450, Orphan**

UCB Pharma S.A., treatment of generalised myasthenia gravis in adults, New active substance (Article 8(3) of Directive No 2001/83/EC)

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

**Zoonotic Influenza Vaccine Seqirus - zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006375**

Seqirus S.r.l., active immunisation against H5 subtype of Influenza A virus, Informed Consent of Aflunov, Informed consent application (Article 10c of Directive No 2001/83/EC)

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

## B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

### B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

<b>Afstyla - lonococog alfa - EMA/H/C/004075/II/0050</b> CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.09.2023.	Positive Opinion adopted by consensus on 21.09.2023.
<b>Bimervax - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMA/H/C/006058/II/0005/G</b> Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Request for Supplementary Information adopted on 28.09.2023.	Request for supplementary information adopted with a specific timetable.
<b>Bimervax - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMA/H/C/006058/II/0007/G</b> Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich Request for Supplementary Information adopted on 05.10.2023.	Request for supplementary information adopted with a specific timetable.
<b>Byooviz - ranibizumab - EMA/H/C/005545/II/0012/G</b> Samsung Bioepis NL B.V., Rapporteur: Christian Gartner Opinion adopted on 05.10.2023. Request for Supplementary Information adopted on 31.08.2023.	Positive Opinion adopted by consensus on 05.10.2023.
<b>DaTSCAN - ioflupane (123I) - EMA/H/C/000266/II/0066/G</b> GE Healthcare B.V., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 12.10.2023.	Request for supplementary information adopted with a specific timetable.
<b>Erleada - apalutamide - EMA/H/C/004452/II/0032/G</b> Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez Opinion adopted on 21.09.2023. Request for Supplementary Information adopted on 13.07.2023.	Positive Opinion adopted by consensus on 21.09.2023.

<p><b>Esperoct - turoctocog alfa pegol - EMEA/H/C/004883/II/0020/G</b>  Novo Nordisk A/S, Rapporteur: Daniela Philadelphia  Opinion adopted on 05.10.2023.  Request for Supplementary Information adopted on 20.07.2023.</p>	<p>Positive Opinion adopted by consensus on 05.10.2023.</p>
<p><b>Hemangioli - propranolol - EMEA/H/C/002621/II/0025</b>  Pierre Fabre Medicament, Rapporteur: Jean-Michel Race  Request for Supplementary Information adopted on 05.10.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Herceptin - trastuzumab - EMEA/H/C/000278/II/0189</b>  Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus  Opinion adopted on 21.09.2023.  Request for Supplementary Information adopted on 20.07.2023.</p>	<p>Positive Opinion adopted by consensus on 21.09.2023.</p>
<p><b>Iasibon - ibandronic acid - EMEA/H/C/002025/II/0025</b>  Pharmathen S.A., Generic, Generic of Bondronat, Rapporteur: Thalia Marie Estrup Blicher  Request for Supplementary Information adopted on 21.09.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Idelvion - albutrepenonacog alfa - EMEA/H/C/003955/II/0064, Orphan</b>  CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus  Opinion adopted on 28.09.2023.  Request for Supplementary Information adopted on 29.06.2023.</p>	<p>Positive Opinion adopted by consensus on 28.09.2023.</p>
<p><b>IVF Media G5 Series - human albumin solution - EMEA/H/D/000003/II/0008</b>  Vitrolife Sweden AB, Rapporteur: Filip Josephson  Request for Supplementary Information adopted on 12.10.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Kadcyla - trastuzumab emtansine - EMEA/H/C/002389/II/0069/G</b>  Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia  Request for Supplementary Information adopted on 05.10.2023, 13.07.2023.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Kaftrio - ivacaftor / tezacaftor /</b></p>	<p>Positive Opinion adopted by consensus on</p>

<p><b>elexacaftor -</b>  <b>EMA/H/C/005269/II/0042/G, Orphan</b>  Vertex Pharmaceuticals (Ireland) Limited,  Rapporteur: Peter Mol  Opinion adopted on 12.10.2023.</p>	12.10.2023.
<p><b>Kanjinti - trastuzumab -</b>  <b>EMA/H/C/004361/II/0023</b>  Amgen Europe B.V., BREDA, Rapporteur: Jan  Mueller-Berghaus  Opinion adopted on 21.09.2023.  Request for Supplementary Information adopted  on 06.07.2023.</p>	Positive Opinion adopted by consensus on 21.09.2023.
<p><b>Lacosamide Accord - lacosamide -</b>  <b>EMA/H/C/004443/II/0023/G</b>  Accord Healthcare S.L.U., Generic, Generic of  Vimpat, Rapporteur: John Joseph Borg  Request for Supplementary Information adopted  on 05.10.2023.</p>	Request for supplementary information adopted with a specific timetable.
<p><b>Lokelma - sodium zirconium cyclosilicate -</b>  <b>EMA/H/C/004029/II/0032</b>  AstraZeneca AB, Rapporteur: Larisa Gorobets  Request for Supplementary Information adopted  on 31.08.2023.</p>	Positive Opinion adopted by consensus on 12.10.2023.
<p><b>Metalyse - tenecteplase -</b>  <b>EMA/H/C/000306/II/0069/G</b>  Boehringer Ingelheim International GmbH,  Rapporteur: Martina Weise  Opinion adopted on 21.09.2023.  Request for Supplementary Information adopted  on 20.07.2023.</p>	Positive Opinion adopted by consensus on 21.09.2023.
<p><b>Minjuvi - tafasitamab -</b>  <b>EMA/H/C/005436/II/0012/G, Orphan</b>  Incyte Biosciences Distribution B.V.,  Rapporteur: Aaron Sosa Mejia  Request for Supplementary Information adopted  on 05.10.2023.</p>	Request for supplementary information adopted with a specific timetable.
<p><b>Orencia - abatacept -</b>  <b>EMA/H/C/000701/II/0158/G</b>  Bristol-Myers Squibb Pharma EEIG, Rapporteur:  Outi Mäki-Ikola  Request for Supplementary Information adopted  on 21.09.2023.</p>	Request for supplementary information adopted with a specific timetable.
<p><b>Orencia - abatacept -</b>  <b>EMA/H/C/000701/II/0158/G</b>  Bristol-Myers Squibb Pharma EEIG, Rapporteur:  Outi Mäki-Ikola  Request for Supplementary Information adopted</p>	Request for supplementary information adopted with a specific timetable.

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on 21.09.2023.

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**Orencia - abatacept -**

**EMA/H/C/000701/II/0161/G**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:

Outi Mäki-Ikola

Request for Supplementary Information adopted

on 12.10.2023.

Request for supplementary information adopted with a specific timetable.

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**Ovitrelle - choriogonadotropin alfa -**

**EMA/H/C/000320/II/0089**

Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Request for Supplementary Information adopted

on 05.10.2023.

Request for supplementary information adopted with a specific timetable.

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**Pemetrexed Accord - pemetrexed -**

**EMA/H/C/004072/II/0025**

Accord Healthcare S.L.U., Generic, Generic of

Alimta, Rapporteur: John Joseph Borg

Opinion adopted on 28.09.2023.

Positive Opinion adopted by consensus on 28.09.2023.

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**Perjeta - pertuzumab -**

**EMA/H/C/002547/II/0068/G**

Roche Registration GmbH, Rapporteur: Aaron

Sosa Mejia

Request for Supplementary Information adopted

on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**PreHevri - hepatitis B surface antigen (rDNA) - EMA/H/C/005466/II/0006**

VBI Vaccines B.V., Rapporteur: Jan Mueller-

Berghaus

Opinion adopted on 12.10.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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**Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) -**

**EMA/H/C/001104/II/0215/G**

Pfizer Europe MA EEIG, Rapporteur: Kristina

Dunder

Opinion adopted on 05.10.2023.

Request for Supplementary Information adopted

on 31.08.2023.

Positive Opinion adopted by consensus on 05.10.2023.

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**Raniviso - ranibizumab -**

**EMA/H/C/005019/II/0005**

Midas Pharma GmbH, Rapporteur: Jan Mueller-

Berghaus

Opinion adopted on 05.10.2023.

Request for Supplementary Information adopted

on 29.06.2023.

Positive Opinion adopted by consensus on 05.10.2023.

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**Raniviso - ranibizumab -**

**EMA/H/C/005019/II/0006**

Positive Opinion adopted by consensus on 05.10.2023.

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Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus  
Opinion adopted on 05.10.2023.  
Request for Supplementary Information adopted on 29.06.2023.

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**Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0066/G** Positive Opinion adopted by consensus on 28.09.2023.  
CSL Behring GmbH, Rapporteur: Kristina Dunder  
Opinion adopted on 28.09.2023.  
Request for Supplementary Information adopted on 13.07.2023.

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**Ryeqo - relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267/II/0019/G** Request for supplementary information adopted with a specific timetable.  
Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt  
Request for Supplementary Information adopted on 28.09.2023.

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**Ryeqo - relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267/II/0020/G** Request for supplementary information adopted with a specific timetable.  
Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt  
Request for Supplementary Information adopted on 28.09.2023.

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**Skytrofa - lonapegsomatropin - EMEA/H/C/005367/II/0019/G, Orphan** Request for supplementary information adopted with a specific timetable.  
Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt  
Request for Supplementary Information adopted on 12.10.2023.

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**Tavneos - avacopan - EMEA/H/C/005523/II/0010, Orphan** Positive Opinion adopted by consensus on 12.10.2023.  
Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder  
Opinion adopted on 12.10.2023.

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**Tezspire - tezepelumab - EMEA/H/C/005588/II/0009/G** Request for supplementary information adopted with a specific timetable.  
AstraZeneca AB, Rapporteur: Finbarr Leacy  
Request for Supplementary Information adopted on 12.10.2023.

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**Uptravi - selexipag - EMEA/H/C/003774/II/0039** Positive Opinion adopted by consensus on 12.10.2023.  
Janssen-Cilag International N.V., Rapporteur: Martina Weise  
Opinion adopted on 12.10.2023.

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Request for Supplementary Information adopted on 07.09.2023.

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**Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0131**

MCM Vaccine B.V., Rapporteur: Christophe Focke

Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**Vyepti - eptinezumab - EMEA/H/C/005287/II/0012**

H. Lundbeck A/S, Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 21.09.2023.

Positive Opinion adopted by consensus on 21.09.2023.

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**WS2526/G Infanrix hexa- EMEA/H/C/000296/WS2526/0335/G**

GlaxoSmithkline Biologicals SA, Lead

Rapporteur: Christophe Focke

Opinion adopted on 12.10.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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**WS2542/G Ongentys- EMEA/H/C/002790/WS2542/0059/G**

**Ontilyv- EMEA/H/C/005782/WS2542/0014/G**

Bial - Portela & C<sup>a</sup>, S.A., Lead Rapporteur: Martina Weise

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 14.09.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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

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**Ameluz - 5-aminolevulinic acid - EMEA/H/C/002204/II/0055**

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

Request for supplementary information adopted with a specific timetable.

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the SmPC.”

Request for Supplementary Information adopted on 12.10.2023, 25.05.2023.

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**Bimervax - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0006**

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, “Submission of the final report from study HAN-01 listed as a category 3 study in the RMP (MEA/006). This is a phase IIb, randomised, controlled, observer-blinded study to evaluate safety and immunogenicity of a recombinant protein RBD fusion dimer candidate vaccine against SARS-CoV-2 in adult healthy volunteers.”

Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0008**

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, “Submission of the final report from study HIPRA-HH-10 listed as a category 3 study in the RMP. This is a phase 2b, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion dimer candidate (PHH-1V) against SARS-CoV-2, in adults fully vaccinated with adenovirus vaccine against COVID-19.”

Opinion adopted on 12.10.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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**Braftovi - encorafenib - EMEA/H/C/004580/II/0031**

Pierre Fabre Medicament, Rapporteur: Janet Koenig, “Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information on effect of encorafenib in combination with binimetinib on the single oral dose PK of specific CYP isozymes substrates, and effect of multiple doses of modafinil, a moderate CYP3A4 inducer, on the multiple oral dose PK of encorafenib administered with binimetinib based on final results from arm 1 and 3 of clinical study ARRAY-818-103/C4221003 (REC). ARRAY-818-103/C4221003 study is a Phase 1, 3-arm, open-label

Request for supplementary information adopted with a specific timetable.

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DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours.”

Request for Supplementary Information adopted on 21.09.2023.

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**Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0037**

Positive Opinion adopted by consensus on 12.10.2023.

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, “Submission of the final clinical study report addendum for study DS8201-A-U303 (DESTINY-Breast04) in order to fulfil the recommendation to submit the final OS analysis. U303 is a phase 3, multicentre, randomised, open-label, active-controlled trial of trastuzumab deruxtecan (T-DXd), an anti-HER2-antibody drug conjugate (ADC), versus treatment of physician’s choice for HER2-low, unresectable and/or metastatic breast cancer subjects.”

Opinion adopted on 12.10.2023.

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**Fetcroja - cefiderocol - EMEA/H/C/004829/II/0016**

Positive Opinion adopted by consensus on 05.10.2023.

Shionogi B.V., Rapporteur: Filip Josephson, “Update of sections 4.2 and 6.2 of the SmPC in order to update the information on incompatibility in line with the PRAC recommendation adopted for EMEA/H/C/PSUSA/00010849/202211. The package leaflet was revised accordingly, to introduce information intended for healthcare professionals.”

Opinion adopted on 05.10.2023.

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**Filsuvez - birch bark extract - EMEA/H/C/005035/II/0006, Orphan**

Request for supplementary information adopted with a specific timetable.

Amryt Pharmaceuticals DAC, Rapporteur: Kristina Dunder, “Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study EASE (BEB-13); this is a double-blind, randomised, placebo (vehicle) controlled trial to evaluate efficacy and safety of birch bark extract on top of standard of care in children from birth to less than 18 years of age (and adults) with epidermolysis bullosa. In addition, the MAH took the opportunity to introduce minor changes to the PI.”

Request for Supplementary Information adopted

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on 12.10.2023.

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**Inrebic - fedratinib -**

**EMA/H/C/005026/II/0017, Orphan**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.5 of the SmPC in order to update drug-drug interaction information with dual inhibitors of CYP3A4 and CYP2C19, based on final results from study FEDR-CP-004; this is a phase 1, open-label study to evaluate the effect of a dual CYP2C19 and CYP3A4 inhibitor, fluconazole, on the pharmacokinetics of fedratinib in healthy adult subjects."

Request for Supplementary Information adopted on 05.10.2023, 31.08.2023.

Request for supplementary information adopted with a specific timetable.

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**Jakavi - ruxolitinib -**

**EMA/H/C/002464/II/0068**

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.4 and 5.1 of the SmPC in order to add new warnings on 'Major adverse cardiac events (MACE)', 'Thrombosis', and 'Second primary malignancies', following an Art. 20 Class Referral involving JAK inhibitors approved to treat rheumatoid arthritis and to update efficacy information regarding the effects of ruxolitinib in relation to thromboembolic events based on recently published data from MAJIC-PV study (a randomized, controlled open-label study in polycythemia vera (PV))."

Request for Supplementary Information adopted on 12.10.2023.

Request for supplementary information adopted with a specific timetable.

See 9.1

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**Jcovden - COVID-19 Vaccine Janssen (ad26.cov2.s) -**

**EMA/H/C/005737/II/0074/G**

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "Grouped application comprising two type II variations (C.I.13) as follows:

- Submission of the final report from study TOX15258 - Ad26.COVID.S (Prophylactic COVID-19 Vaccine): A Transcriptomics Exploratory Study in Cambodian Cynomolgus Monkey.
  - Submission of the report from study TV-TEC-236300 - Biophysical studies on interactions between human platelet 4 and Ad26.COVID.S."
- Opinion adopted on 12.10.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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**Jivi - damoctocog alfa pegol -**

Positive Opinion adopted by consensus on

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**EMA/H/C/004054/II/0028**

28.09.2023.

Bayer AG, Rapporteur: Thalia Marie Estrup Blicher, "Submission of the final report from study 19764 (PMI) listed as a category 3 study in the RMP as well as pooled data from phase 3 studies 13024 (PROTECT VIII) and 15912 (PROTECT Kids). Study 19764 is a multicenter, single group, uncontrolled, open-label interventional post-marketing investigation (PMI) to assess safety and efficacy of Jivi treatment in patients with hemophilia A." Opinion adopted on 28.09.2023.

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**Kisqali - ribociclib -****EMA/H/C/004213/II/0041/G**

Request for supplementary information adopted with a specific timetable.

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Grouped application comprising two type II variations as follows:

- Update of section 5.2 of the SmPC in order to update absorption information based on final results from study CLEE011A2117, a Phase I, single center, two-period, two-treatment, open label, randomized crossover study to investigate the absolute bioavailability of a single oral dose of 600 mg of ribociclib relative to an intravenous (i.v.) infusion of 150 mg ribociclib in healthy subjects.
- Update of sections 4.2 and 4.5 of the SmPC in order to update the recommended dose modification when ribociclib is administered in combination with CYP3A4 inhibitors and update the drug-drug interaction information on substances that may increase ribociclib plasma concentrations based on the updated PBPK modelling.

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

Request for Supplementary Information adopted on 12.10.2023, 22.06.2023.

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**Mektovi - binimetinib -****EMA/H/C/004579/II/0027**

Request for supplementary information adopted with a specific timetable.

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of the final report from study ARRAY 818-103 on Arms 1 and 3. This is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours, to assess drug drug interactions between

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encorafenib + binimetinib combination and midazolam (CYP3A4 substrate), caffeine (CYP1A2 substrate), omeprazole (CYP2C19 substrate), losartan (CYP2C9 substrate), dextromethorphan (CYP2D6 substrate) and modafinil (moderate CYP3A4 inducer).”  
Request for Supplementary Information adopted on 21.09.2023.

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**Mozobil - plerixafor -  
EMA/H/C/001030/II/0051**

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

Request for supplementary information adopted with a specific timetable.

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**Mylotarg - gemtuzumab ozogamicin -  
EMA/H/C/004204/II/0030, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa Mejia, “Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy, pharmacokinetic and safety information based on interim results from study WI203680 - MyeChild 01-International Randomised Phase III Clinical Trial in Children With Acute Myeloid Leukaemia – Incorporating an Embedded Dose Finding Study for Gemtuzumab Ozogamicin in Combination With Induction Chemotherapy. This is a dose finding sub-study aimed to identify the optimum tolerated number of doses of GO 3 mg/m<sup>2</sup> (up to a maximum of 3 doses) which can be combined safely with AraC plus mitoxantrone or liposomal DAUNO in induction therapy.”  
Opinion adopted on 12.10.2023.  
Request for Supplementary Information adopted on 31.08.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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**Nuvaxovid - Covid-19 Vaccine  
(recombinant, adjuvanted) -  
EMA/H/C/005808/II/0045**

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt, “Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen - adolescent boosting vaccination based on interim results from study 2019nCOV-301(IR) listed as a category 3 study in the RMP;

Positive Opinion adopted by consensus on 12.10.2023.

See 9.1

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this is a Phase 3, randomised, observer-blinded, placebo- controlled study to evaluate the efficacy, safety, and immunogenicity of SARS CoV-2 rS with Matrix-M adjuvant in adult participants  $\geq$  18 years of age with a pediatric expansion (12 to < 18 years of age). The Package Leaflet is updated accordingly.”  
Opinion adopted on 12.10.2023.  
Request for Supplementary Information adopted on 20.07.2023, 30.03.2023.

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**Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0058/G**

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

Request for supplementary information adopted with a specific timetable.

See 9.1

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

Advanz Pharma Limited, Rapporteur: Carolina Prieto Fernandez, “Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from studies 747-302 and 747-401, listed as specific obligations in the Annex II, as well as results from real-world evidence (RWE) studies evaluating analyses of hepatic clinical outcomes. Study 747-302 is a confirmatory double-blind, randomised, placebo-controlled multicentre study investigating the clinical benefit associated with Ocaliva treatment in patients with PBC who are either unresponsive or intolerant to UDCA treatment based on clinical endpoints, while study 747-401 is a double-blind, randomised, placebo-controlled study evaluating the safety and pharmacokinetics of Ocaliva in patients with PBC and moderate to severe hepatic impairment. The Annex II and Package Leaflet are updated accordingly.”  
Opinion adopted on 12.10.2023.  
Request for Supplementary Information adopted on 30.03.2023.

Negative Opinion adopted by consensus on 12.10.2023.

See 9.1

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**Qarziba - dinutuximab beta - EMEA/H/C/003918/II/0043, Orphan**

Recordati Netherlands B.V., Rapporteur: Peter Mol, “Update of sections 4.1, 4.2 and 5.1 of the SmPC based on final results from study APN311-202V3 listed as a Specific Obligation in the Annex II of the Product Information. This is a Phase I/II dose schedule finding study of

Positive Opinion adopted by consensus on 12.10.2023.

See 9.1

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Ch14.18/CHO continuous infusion combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma.

In addition, the MAH took the opportunity to update Annex II section E. The Package Leaflet is updated accordingly. "

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 26.04.2023, 15.09.2022.

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**Scemblix - asciminib -  
EMA/H/C/005605/II/0008, Orphan**

Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add interaction information between asciminib and OATP1B and BCRP substrates, based on results from three PBPK simulation reports: DMPK-R2001088, DMPK-R2270328 and DMPK-R2300226. The Package Leaflet is updated accordingly."

Request for Supplementary Information adopted on 21.09.2023.

Request for supplementary information adopted with a specific timetable.

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**Scemblix - asciminib -  
EMA/H/C/005605/II/0009, Orphan**

Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of section 5.3 of the SmPC in order to update preclinical safety data based on final results from study R1570226: this is a 2-year rat carcinogenicity study. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Request for Supplementary Information adopted on 21.09.2023.

Request for supplementary information adopted with a specific timetable.

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**Skyrizi - risankizumab -  
EMA/H/C/004759/II/0035**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Update of sections 4.8 and 5.1 of the SmPC for 150 mg solution for injection in pre-filled pen and pre-filled syringe and 75 mg solution for injection in pre-filled syringe based on final results from study M15-997; this is a Phase 3, single-arm, multicenter, open label study to assess the safety and efficacy of risankizumab for maintenance in moderate to severe plaque type psoriasis. In addition, the MAH took the opportunity to implement editorial changes to the SmPC for all strengths / pharmaceutical forms."

Opinion adopted on 21.09.2023.

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Positive Opinion adopted by consensus on 21.09.2023.

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Request for Supplementary Information adopted on 29.06.2023.

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

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update non-clinical information based on results from the non-clinical studies PC-540-2045 and PC-540-2046. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Request for Supplementary Information adopted on 05.10.2023.

Request for supplementary information adopted with a specific timetable.

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

Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC in order to add a new warning on "arterial thromboembolic events", based on a safety review. The Package Leaflet is updated accordingly."

Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMA/H/C/005754/II/0006**

Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC in order to add 'Hypersensitivity and anaphylactic reactions' 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 introduce minor changes to the PI."

Opinion adopted on 21.09.2023.

Positive Opinion adopted by consensus on 21.09.2023.

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**Zaltrap - aflibercept -  
EMA/H/C/002532/II/0070**

Sanofi Winthrop Industrie, Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update information regarding the duration of contraceptive use after cessation of treatment. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Opinion adopted on 05.10.2023.

Positive Opinion adopted by consensus on 05.10.2023.

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**WS2544**

Request for supplementary information adopted

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**Ebymect-**  
**EMA/H/C/004162/WS2544/0064**

with a specific timetable.

**Komboglyze-**  
**EMA/H/C/002059/WS2544/0057**  
**Xigduo-EMA/H/C/002672/WS2544/0074**

AstraZeneca AB, Lead Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Vitamin B12 decrease/deficiency' and to change the frequency of 'Vitamin B12 decrease/deficiency' in the list of adverse drug reactions (ADRs) from frequency 'very rare' to 'common'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."  
Request for Supplementary Information adopted on 21.09.2023.

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

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**Brineura - cerliponase alfa -**  
**EMA/H/C/004065/II/0039, Orphan**

Request for supplementary information adopted with a specific timetable.

BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 9 of the SmPC in order to state that clinical data are available for patients aged 1 year and older and to include updates to the frequency of adverse reactions, immunogenicity, pharmacokinetic and paediatric population sections based on the final results from studies 190-203, listed as a specific obligation and 190-202 (submitted in P46/013).  
Study 190-203 was a Phase 2, open-label, multicenter study in pediatric patients < 18 years of age with CLN2 disease, confirmed by deficiency of TPP1 enzyme activity and mutation of the CLN2 gene.  
The Package Leaflet, Annex II and Annex IV are updated accordingly.  
The RMP version 4.0 has also been submitted."  
Request for Supplementary Information adopted on 12.10.2023, 25.05.2023.

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**Evusheld - tixagevimab / cilgavimab -**  
**EMA/H/C/005788/II/0009/G**

Positive Opinion adopted by consensus on 12.10.2023.

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising two type II variations (REC 23) as follows:  
C.I.4 - Update of sections 4.4, 4.8 and 5.1 of

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the SmPC in order to update efficacy and safety information based on final results from study TACKLE (D8851C00001).

C.I.4 - Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety information based on final results from studies PROVENT (D8850C00002) and STORM CHASER (D8850C00003). In addition, the MAH took the opportunity to add some editorial changes. The RMP version 4.2 is also updated.”  
Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 20.07.2023.

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

BioMarin International Limited, Rapporteur:  
Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, “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 16.0 has also been submitted.”  
Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**Livtency - maribavir -  
EMA/H/C/005787/II/0004, Orphan**

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, “Submission of the final report from study SHP620-302 listed as a category 3 study in the RMP. This is a Phase III, multicenter, randomized, double-blind, double-dummy, active-controlled study of maribavir compared to valganciclovir for the treatment of asymptomatic Cytomegalovirus (CMV) Infection in Hematopoietic Stem Cell Transplant recipients. The RMP version 2.0 has also been submitted.”  
Opinion adopted on 12.10.2023.  
Request for Supplementary Information adopted on 25.05.2023.

Positive Opinion adopted by consensus on 12.10.2023.

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**Lynparza - olaparib -  
EMA/H/C/003726/II/0061**

AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Amelia Cupelli, “Update of sections 4.8 and 5.1 of the SmPC in order to

Positive Opinion adopted by consensus on 05.10.2023.

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update the overall survival and safety information, based on the final results from study D081SC00001 (PROpel), listed as a PAES in the Annex II; this is a randomised, double-blind, placebo-controlled, multicentre phase III study of olaparib plus abiraterone relative to placebo plus abiraterone as first-line therapy in men with metastatic castration resistant prostate cancer; the Annex II is updated in accordance. The RMP version 27.1 is approved. In addition, the MAH took the opportunity to revise the list of local representatives in the package leaflet”

Opinion adopted on 05.10.2023.

Request for Supplementary Information adopted on 31.08.2023, 06.07.2023.

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**Myozyme - alglucosidase alfa -  
EMA/H/C/000636/II/0094**

Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Nathalie Gault, “Update of section 4.2 of the SmPC in order to add home infusion upon request by PRAC following the assessment of PSUSA/00000086/202109 I based on a cumulative search of the MAH Global Pharmacovigilance database and literature.

The Package Leaflet and Annex II are updated accordingly.

The RMP version 10.0 has also been submitted.”

Request for Supplementary Information adopted on 12.10.2023, 26.04.2023.

Request for supplementary information adopted with a specific timetable.

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**Onpattro - patisiran -  
EMA/H/C/004699/II/0034, Orphan**

Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, “Submission of the final report from study ALN-TTR02-006 (study 006), listed a category 3 study in the RMP. This is a multicenter, open-label, extension study to evaluate the long-term safety and efficacy of patisiran in patients with familial amyloidotic polyneuropathy who have completed a prior clinical study with patisiran. The RMP version 2.2 has also been submitted.”

Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**Tagrisso - osimertinib -  
EMA/H/C/004124/II/0052**

AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst, “Update of section 5.1 of the SmPC in

Positive Opinion adopted by consensus on 28.09.2023.

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order to update efficacy information (final OS data) based on final results from study D5164C00001 (ADAURA) listed as a PAES in the Annex II; this is a Phase III, double-blind, randomised, placebo-controlled study, designed to assess the efficacy and safety of osimertinib versus placebo in patients with stage IB-IIIa epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC) who have undergone complete tumour resection, with or without postoperative adjuvant chemotherapy. The RMP version 15 has also been submitted. In addition, the MAH took the opportunity to update Annex II section D of the PI and to implement editorial changes to the SmPC."

Opinion adopted on 28.09.2023.

Request for Supplementary Information adopted on 31.08.2023.

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**Tegsedi - inotersen -  
EMA/H/C/004782/II/0038, Orphan**

Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.8 of the SmPC in order to modify the warning on liver monitoring and drug-induced liver injury and to add 'drug-induced liver injury' to the list of adverse drug reactions (ADRs) with frequency not known, following the request in the Assessment Report for PAM procedure EMA/H/C/004782/LEG/008. The Annex II and Package Leaflet are updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI."

Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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**Vaborem - meropenem / vaborbactam -  
EMA/H/C/004669/II/0020**

Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Maria del Pilar Rayon, "Submission of the final reports from Global Microbiology Surveillance Study and Molecular Surveillance Report, listed as a category 3 study in the RMP. Version 2.1 of the RMP has been approved."

Opinion adopted on 28.09.2023.

Positive Opinion adopted by consensus on 28.09.2023.

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**Vemlidy - tenofovir alafenamide -  
EMA/H/C/004169/II/0043/G**

Request for supplementary information adopted with a specific timetable.

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Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Valentina Di Giovanni, "Grouped application consisting of: C.I.13: Submission of the final report from study GS-US-320-0108 listed as category 3 studies in the RMP. This is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Negative, Chronic Hepatitis B. The RMP version 10.1 has also been submitted. C.I.13: Submission of the final report from study GS-US-320-0110 listed as category 3 studies in the RMP. This is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Positive, Chronic Hepatitis B. The RMP version 10.1 has also been submitted." Request for Supplementary Information adopted on 28.09.2023.

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**Vyvgart - efgartigimod alfa - EMEA/H/C/005849/II/0006, Orphan**  
Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.5 of the SmPC in order to amend an existing warning on use of vaccination and update drug-drug interaction information on vaccines based on final results from study ARGX-113-2102; this is a phase 1, randomized, open-label, placebo-controlled, parallel-group study to evaluate the immune response to PNEUMOVAX 23 in healthy participants receiving efgartigimod IV 10 mg/kg or placebo. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 28.09.2023. Request for Supplementary Information adopted on 06.07.2023.

Positive Opinion adopted by consensus on 28.09.2023.

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**Xospata - gilteritinib - EMEA/H/C/004752/II/0013, Orphan**  
Astellas Pharma Europe B.V., Rapporteur: Ingrid Wang, PRAC Rapporteur: Martin Huber, "Update of sections 4.2, 4.4 and 5.2 in order to update the information on renal impairment based on

Positive Opinion adopted by consensus on 12.10.2023.

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final results from study 2215-CL-0114, listed as a category 3 study in the RMP. Study 2215-CL-0114 is a phase 1, single-dose, open-label study to investigate the effect of renal impairment on gilteritinib pharmacokinetics, safety and tolerability in 9 participants with severe renal impairment compared to 8 participants with normal renal function.

The RMP version 5.0 has also been agreed during the procedure and submitted.

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

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 22.06.2023.

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**WS2409**

**Lixiana-EMA/H/C/002629/WS2409/0042**

**Roteas-EMA/H/C/004339/WS2409/0029**

Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC

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

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 30.03.2023.

Positive Opinion adopted by consensus on 12.10.2023.

See 9.1

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**WS2451**

**Bondronat-**

**EMA/H/C/000101/WS2451/0090**

**Bonviva-**

**EMA/H/C/000501/WS2451/0075**

Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Lead PRAC Rapporteur: Karin Erneholm, “Update of

Request for supplementary information adopted with a specific timetable.

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sections 4.2, 4.4 and 4.8 of the SmPC in order to add information regarding the risk of "Atypical fractures of other long bones"; based on literature. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3."

Request for Supplementary Information adopted on 12.10.2023, 12.05.2023.

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#### **B.5.4. PRAC assessed procedures**

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PRAC Led

**Arixtra - fondaparinux sodium -  
EMA/H/C/000403/II/0087**

Mylan Ire Healthcare Limited, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To update section 4.8 of the SmPC to update the ADR table following the assessment of PSUSA

(EMA/H/C/PSUSA/00001467/202112). The Package Leaflet is updated accordingly."

Opinion adopted on 28.09.2023.

Request for Supplementary Information adopted on 06.07.2023, 14.04.2023.

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Positive Opinion adopted by consensus on 28.09.2023.

PRAC Led

**Cabometyx - cabozantinib -  
EMA/H/C/004163/II/0033**

Ipsen Pharma, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Peter Mol, "Submission of the final report from study F-FR-60000-001 (CASSIOPE) listed as a category 3 study in the RMP. This is a prospective, non-imposed and non-interventional study of cabozantinib tablets in adults with advanced renal cell carcinoma (RCC) following prior vascular endothelial growth factor (VEGF)-targeted therapy. The RMP version 7.0 has also been submitted."

Opinion adopted on 28.09.2023.

Request for Supplementary Information adopted on 08.06.2023.

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Positive Opinion adopted by consensus on 28.09.2023.

PRAC Led

**Caelyx pegylated liposomal - doxorubicin -  
EMA/H/C/000089/II/0107**

Baxter Holding B.V., PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata,

"Submission of an updated RMP version 6.1 in

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Request for supplementary information adopted with a specific timetable.



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order to align to GVP Module V Revision 2 requirements, following a request received within the Assessment Report for procedure EMEA/H/C/PSUSA/00001172/202111.”  
Request for Supplementary Information adopted on 28.09.2023.

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PRAC Led  
**Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0036**  
Daiichi Sankyo Europe GmbH, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, “Submission of the final report from study ‘EU survey of relevant healthcare professionals on understanding of key risk minimisations measures pertaining to ILD/pneumonitis’ listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS.”  
Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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PRAC Led  
**Eurartesim - piperazine tetraphosphate / arteminol - EMEA/H/C/001199/II/0040/G**  
Alfasigma S.p.A., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, “C.I.13: Submission of the final report from the effectiveness evaluation survey for Eurartesim (protocol no. 3366) listed as a category 3 study in the RMP. This is a European multi-centre online survey to assess physician understanding of the revised edition of the educational material. Consequential changes to RMP version 16.1 have been implemented.  
C.I.11.b: Submission of an updated RMP version 16.1 in order to delete “Severe Malaria” from the Missing Information.”  
Request for Supplementary Information adopted on 28.09.2023, 08.06.2023.

Request for supplementary information adopted with a specific timetable.

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PRAC Led  
**Exjade - deferasirox - EMEA/H/C/000670/II/0085**  
Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, “Submission of an updated RMP version 21.2 in order to include the physician survey CICL670A2429 as a PASS category 3, based on the submission of a draft version of the protocol for the physician survey CICL670A2429. The Annex IID is updated to remove one sentence

Positive Opinion adopted by consensus on 28.09.2023.

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related to 'surveillance programme' and to introduce a minor correction to the guide for healthcare professionals."  
Opinion adopted on 28.09.2023.  
Request for Supplementary Information adopted on 08.06.2023.

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PRAC Led  
**Fasenra - benralizumab -  
EMA/H/C/004433/II/0049/G**  
AstraZeneca AB, PRAC Rapporteur: David Olsen,  
PRAC-CHMP liaison: Ingrid Wang, "Grouped application consisting of:  
1) Submission of an updated RMP version 5 in order to remove the safety concern of missing information on use in pregnant and lactating women. Consequently, the MAH proposes to remove study D3250R00026 as an additional pharmacovigilance activity, and to remove the commitment to conduct additional pharmacovigilance for the use of benralizumab in pregnant and lactating women with severe eosinophilic asthma.  
2) Submission of an updated RMP version 5 in order to remove the safety concern of important potential risk of serious infections."  
Opinion adopted on 28.09.2023.  
Request for Supplementary Information adopted on 06.07.2023.

Positive Opinion adopted by consensus on 28.09.2023.

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PRAC Led  
**Intuniv - guanfacine -  
EMA/H/C/003759/II/0033/G**  
Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of the final reports from the Drug Utilisation Study of Intuniv (guanfacine extended release) in European countries: a prescriber survey (EUPAS18739) and a retrospective database study (EUPAS18735), listed as category 3 studies in the RMP. The RMP version 4.0 has also been submitted."  
Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

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PRAC Led  
**Plenadren - hydrocortisone -  
EMA/H/C/002185/II/0043**  
Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn,

Positive Opinion adopted by consensus on 28.09.2023.

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PRAC-CHMP liaison: Kristina Dunder,  
"Submission of the final report from study  
SHP617-400 (EU AIR) listed as a category 3  
PASS in the RMP; this is a European multi-  
centre, multi-country, post-authorisation,  
observation study (registry) of patients with  
chronic adrenal insufficiency. The RMP version  
4.0 has also been submitted."  
Opinion adopted on 28.09.2023.

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PRAC Led  
**Reblozyl - luspatercept -  
EMA/H/C/004444/II/0023, Orphan**  
Bristol-Myers Squibb Pharma EEIG, PRAC  
Rapporteur: Jo Robays, PRAC-CHMP liaison:  
Karin Janssen van Doorn, "Submission of the  
final report from study ACE-536-MDS-005 listed  
as a category 3 study in the RMP. This is a non-  
interventional post-authorisation safety study  
(PASS) to evaluate the effectiveness of the  
additional risk minimisation measure (aRMM) for  
Reblozyl among Healthcare Providers (HCPs) in  
the EU/EEA. The RMP version 3.0 has been  
submitted in order to reflect the completion of  
the study and to remove the HCP checklist as  
routine aRMM. The Annex II is updated  
accordingly."  
Request for Supplementary Information adopted  
on 28.09.2023.

Request for supplementary information adopted  
with a specific timetable.

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PRAC Led  
**Rekambys - rilpivirine -  
EMA/H/C/005060/II/0019**  
Janssen-Cilag International N.V., PRAC  
Rapporteur: Liana Gross-Martirosyan, PRAC-  
CHMP liaison: Patrick Vrijlandt, "Submission of  
an updated RMP version 4.2 in order to update  
the risk characterisation information for the  
missing information "use in pregnancy" based  
on interim data of the Antiretroviral Pregnancy  
Register (APR), listed as a category 3 study in  
the RMP; and to align the milestones and due  
dates of this study following the outcome of  
procedure EMA/H/C/PSUSA/00010901/202209.  
In addition, the MAH took the opportunity to  
update the status and the interim report  
milestones for the studies DUS and COMBINE-  
2."  
Opinion adopted on 28.09.2023.

Positive Opinion adopted by consensus on  
28.09.2023.

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PRAC Led  
**Revlimid - lenalidomide -**

Positive Opinion adopted by consensus on

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**EMA/H/C/000717/II/0126**

28.09.2023.

Bristol-Myers Squibb Pharma EEIG, PRAC  
Rapporteur: Tiphaine Vaillant, PRAC-CHMP  
liaison: Alexandre Moreau, "Submission of the final report from study CC-5013-MDS-010 listed as an obligation in the Annex II of the Product Information. This is a prospective non-interventional post-authorisation safety study (PASS), designed as a disease registry of patients with transfusion dependent IPSS low or intermediate-1-risk myelodysplastic syndromes (MDS) and isolated del(5q). Section 4.8 of the SmPC is updated with the adverse drug reaction of anaemia in patients with myelodysplastic syndromes. Section D of the Annex II and the RMP (version 39.1) are updated accordingly."  
Opinion adopted on 28.09.2023.  
Request for Supplementary Information adopted on 08.06.2023.

PRAC Led

**Stelara - ustekinumab -****EMA/H/C/000958/II/0101/G**

Janssen-Cilag International N.V., PRAC  
Rapporteur: Rhea Fitzgerald, PRAC-CHMP  
liaison: Jayne Crowe, "Update of section 4.4 of the SmPC in order to remove a warning on cardiovascular events based on final results from non-interventional PASS studies NDI-MACE (CNTO1275PSO4005) and Quantify MACE (PCSIMM004697), listed as category 3 studies in the RMP (MEA/053 and MEA/054). NDI-MACE is a Nordic Database Initiative for Exposure to Ustekinumab: A Review and Analysis of Major Adverse Cardiovascular Events from the Swedish and Danish National Registry Systems; Quantify MACE is an Observational Longitudinal Post-authorisation Safety Study of STELARA in the Treatment of Psoriasis and Psoriatic Arthritis: Analysis of Major Adverse Cardiovascular Events (MACE) using Swedish National Health Registers. The Package Leaflet is updated accordingly. The RMP version 27.1 has also been submitted."  
Request for Supplementary Information adopted on 28.09.2023.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Tecovirimat SIGA - tecovirimat -****EMA/H/C/005248/II/0006**

SIGA Technologies Netherlands B.V., PRAC

Positive Opinion adopted by consensus on 12.10.2023.

See 9.1

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Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of substantial updates to the protocol of study SIGA-246-021 listed as a specific obligation in the Annex II of the Product Information in order to reflect the transfer of sponsorship from SIGA Technologies, Inc. to the NIH Division of Microbiology and Infection Disease protocol. This is a phase 4, observational field study to evaluate safety and clinical benefit in tecovirimat-treated patients following exposure to variola virus and clinical diagnosis of smallpox disease. The Annex II and the RMP submitted version 1.2 are updated accordingly."

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 14.09.2023, 25.05.2023, 14.04.2023.

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PRAC Led

**Vpriv - velaglucerase alfa -  
EMA/H/C/001249/II/0061**

Takeda Pharmaceuticals International AG  
Ireland Branch, Rapporteur: Martina Weise,  
PRAC Rapporteur: Martin Huber, PRAC-CHMP  
liaison: Martina Weise, "Submission of an  
updated RMP version 12 in order to remove  
certain risks from the list of safety concerns."

Request for Supplementary Information adopted  
on 28.09.2023, 06.07.2023, 14.04.2023,  
09.02.2023.

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Request for supplementary information adopted  
with a specific timetable.

PRAC Led

**WS2270**

**Vfend-EMA/H/C/000387/WS2270/0147**

Pfizer Europe MA EEIG, Lead Rapporteur:  
Patrick Vrijlandt, Lead PRAC Rapporteur: Liana  
Gross-Martirosyan, PRAC-CHMP liaison: Patrick  
Vrijlandt, "Update of Annex II and RMP to  
include the results from final clinical study  
report (CSR) following the completion of a non-  
interventional (NI) post-authorisation safety  
study (PASS): A1501103 "An Active Safety  
Surveillance Program to Monitor Selected Events  
in Patients with Long-term Voriconazole Use".  
MEA091 is fulfilled with this procedure. In  
addition, the MAH took this opportunity to  
introduce editorial changes to the RMP and  
transition from the EMA GVP 1 template to the  
new template GVP 2.1.

The frequency categories for the ADRs  
'periostitis', 'phototoxicity' and 'squamous cell

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Positive Opinion adopted by consensus on  
28.09.2023.

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carcinoma (SCC)' of the skin in the ADR table in section 4.8 of the Vfend SmPC and section 4 of the Vfend Package Leaflet were amended.  
Version 6.3 of the RMP is approved with this procedure."

Opinion adopted on 28.09.2023.

Request for Supplementary Information adopted on 12.05.2023, 12.01.2023, 01.09.2022.

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PRAC Led

**WS2517**

**Edistride-**

**EMA/H/C/004161/WS2517/0063**

**Forxiga-**

**EMA/H/C/002322/WS2517/0084**

AstraZeneca AB, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 30 in order to remove the potential important risk for Lower Limb Amputation."

Opinion adopted on 28.09.2023.

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Positive Opinion adopted by consensus on 28.09.2023.

PRAC Led

**WS2546**

**Brimica Genuair-**

**EMA/H/C/003969/WS2546/0039**

**Duaklir Genuair-**

**EMA/H/C/003745/WS2546/0040**

Covis Pharma Europe B.V., Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "C.I.11.z - To provide a new version of the RMP to update the milestone for PASS study D6560R00004 regarding Arrhythmia final report ."

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted on 14.09.2023.

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Positive Opinion adopted by consensus on 12.10.2023.

PRAC Led

**WS2548**

**Bretaris Genuair-**

**EMA/H/C/002706/WS2548/0051**

**Eklira Genuair-**

**EMA/H/C/002211/WS2548/0052**

Covis Pharma Europe B.V., Lead PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "C.I.11.z - To provide a new version of the RMP to update the milestone for PASS study D6560R00004 regarding Arrhythmia final report ."

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted

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Positive Opinion adopted by consensus on 12.10.2023.

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on 14.09.2023.

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

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**Breyanzi - lisocabtagene maraleucel /  
lisocabtagene maraleucel -  
EMA/H/C/004731/II/0019, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:  
Concetta Quintarelli, CHMP Coordinator: Paolo  
Gasparini

Opinion adopted on 12.10.2023, 06.10.2023.

Request for Supplementary Information adopted  
on 16.06.2023.

Positive Opinion adopted by consensus on  
12.10.2023.

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**Breyanzi - lisocabtagene maraleucel /  
lisocabtagene maraleucel -  
EMA/H/C/004731/II/0028/G, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:  
Concetta Quintarelli, CHMP Coordinator: Paolo  
Gasparini

Opinion adopted on 12.10.2023, 06.10.2023.

Positive Opinion adopted by consensus on  
12.10.2023.

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**Carvykti - ciltacabtagene autoleucel -  
EMA/H/C/005095/II/0023, Orphan,  
ATMP**

Janssen-Cilag International NV, Rapporteur: Jan  
Mueller-Berghaus, CHMP Coordinator: Jan  
Mueller-Berghaus

Request for Supplementary Information adopted  
on 06.10.2023.

Request for supplementary information adopted  
with a specific timetable.

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**Upstaza - eladocagene exuparvovec -  
EMA/H/C/005352/II/0014/G, Orphan,  
ATMP**

PTC Therapeutics International Limited,  
Rapporteur: Maura O'Donovan, CHMP  
Coordinator: Finbarr Leacy, "Update of sections  
4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order  
to update information on safety and efficacy,  
based on final results from studies NTUH-AADC-  
010 and NTUH-AADC-011. NTUH-AADC-010 is  
an open-label, single arm, externally controlled  
trial to evaluate safety, efficacy,  
pharmacodynamics and immunogenicity of  
AGIL-AADC in children from 18 months to less  
than 18 years of age with severe AADC  
deficiency, while NTUH-AADC-011 is an open-  
label, single arm, externally controlled trial to  
evaluate efficacy and safety of AGIL-AADC in  
children from 18 months to less than 6 years of  
age with severe AADC deficiency. In addition,  
sections 4.5, 4.9 and 6.6 of the SmPC are

Request for supplementary information adopted  
with a specific timetable.

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updated in order to provide better clarification and guidance for the medical practice. The Package Leaflet is updated accordingly. The MAH also took the opportunity to update the due date of the final report of study AADC-1602 in the Annex II, considering the 10-year follow up of the last patient in study AADC-011, and to introduce minor editorial changes to the PI.”  
Request for Supplementary Information adopted on 06.10.2023.

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

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, , “Update of section 5.1 of the SmPC in order to include new clinical data based on Overall Survival (OS) Primary Analysis from study KTE-C19-107 (ZUMA-7); this is a phase 3, randomized, open-label study evaluating the efficacy of axicabtagene ciloleucel versus standard of care therapy in subjects with relapsed/refractory diffuse large B cell lymphoma (DLBCL) in the 2nd line setting. In addition, the MAH took the opportunity to submit a consolidated Environmental Risk Assessment (ERA) document.”  
Request for Supplementary Information adopted on 06.10.2023.

Request for supplementary information adopted with a specific timetable.

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**WS2558/G Tecartus- EMEA/H/C/005102/WS2558/0036/G Yescarta- EMEA/H/C/004480/WS2558/0064/G**

Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus  
Opinion adopted on 05.10.2023.

Positive Opinion adopted by consensus on 05.10.2023.

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

**B.5.7. PRAC assessed ATMP procedures**

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

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**WS2408 Riarify-EMEA/H/C/004836/WS2408/0027 Trydonis-**

Request for supplementary information adopted with a specific timetable.



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**EMA/H/C/004702/WS2408/0030**

Chiesi Farmaceutici S.p.A., Informed Consent of  
Trimbow, Lead Rapporteur: Janet Koenig  
Request for Supplementary Information adopted  
on 12.10.2023.

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

CSL Behring GmbH, Lead Rapporteur: Jan  
Mueller-Berghaus

Request for Supplementary Information adopted  
on 05.10.2023.

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Request for supplementary information adopted  
with a specific timetable.

**WS2524****Galvus-EMA/H/C/000771/WS2524/0079****Jalra-EMA/H/C/001048/WS2524/0082****Xiliarx-EMA/H/C/001051/WS2524/0080**

Novartis Europharm Limited, Lead Rapporteur:  
Kristina Dunder<sup>C.I.z</sup> - To provide an updated  
Environmental Risk Assessment (ERA) report for  
OECD TG308 and OECD TG218 studies."

Opinion adopted on 12.10.2023.

Request for Supplementary Information adopted  
on 31.08.2023.

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Positive Opinion adopted by consensus on  
12.10.2023.

**WS2527/G****Infanrix hexa-****EMA/H/C/000296/WS2527/0334/G**

GlaxoSmithkline Biologicals SA, Lead  
Rapporteur: Christophe Focke

Opinion adopted on 21.09.2023.

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Positive Opinion adopted by consensus on  
21.09.2023.

**WS2528/G****Eucreas-****EMA/H/C/000807/WS2528/0101/G****Icandra-****EMA/H/C/001050/WS2528/0106/G****Zomarist-****EMA/H/C/001049/WS2528/0103/G**

Novartis Europharm Limited, Lead Rapporteur:  
Kristina Dunder<sup>C.I.z</sup> - To provide the  
Environmental Risk Assessment (ERA) report for  
vildagliptin to add data from OECD TG308 and  
OECD TG218 studies.

C.I.z - To provide the Environmental Risk

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Request for supplementary information adopted  
with a specific timetable.

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Assessment (ERA) report for metformin to add FOCUS\_DEGKINv2 SFO calculated DT50 values.”  
Request for Supplementary Information adopted on 12.10.2023, 31.08.2023.

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**WS2532/G**

**Hexacima-**

**EMA/H/C/002702/WS2532/0152/G**

**Hexyon-**

**EMA/H/C/002796/WS2532/0156/G**

Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 28.09.2023.”

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Positive Opinion adopted by consensus on 28.09.2023.

**WS2540**

**Biktarvy-**

**EMA/H/C/004449/WS2540/0057**

**Descovy-**

**EMA/H/C/004094/WS2540/0064**

**Genvoya-**

**EMA/H/C/004042/WS2540/0088**

**Odefsey-**

**EMA/H/C/004156/WS2540/0062**

**Vemlidy-**

**EMA/H/C/004169/WS2540/0044**

Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes

Request for Supplementary Information adopted on 28.09.2023.

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Request for supplementary information adopted with a specific timetable.

**WS2553/G**

**Delstrigo-**

**EMA/H/C/004746/WS2553/0036/G**

**Pifeltro-**

**EMA/H/C/004747/WS2553/0028/G**

Merck Sharp & Dohme B.V., Lead Rapporteur:

Filip Josephson

Opinion adopted on 28.09.2023.

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Positive Opinion adopted by consensus on 28.09.2023.

**WS2555/G**

**Kisplyx-**

**EMA/H/C/004224/WS2555/0057/G**

**Lenvima-**

**EMA/H/C/003727/WS2555/0052/G**

Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn

Opinion adopted on 05.10.2023.

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Positive Opinion adopted by consensus on 05.10.2023.

**WS2561/G**

**Olanzapine Glenmark-**

**EMA/H/C/001085/WS2561/0041/G**

**Olanzapine Glenmark Europe-**

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Request for supplementary information adopted with a specific timetable.

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**EMA/H/C/001086/WS2561/0038/G**

**Olazax-**

**EMA/H/C/001087/WS2561/0033/G**

**Olazax Disperzi-**

**EMA/H/C/001088/WS2561/0035/G**

Glenmark Arzneimittel GmbH, Generic, Generic

of Olasek (SRD), Zyprexa, Zyprexa Velotab,

Lead Rapporteur: Alexandre Moreau

Request for Supplementary Information adopted  
on 12.10.2023.

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**WS2562**

**Nilemdo-**

**EMA/H/C/004958/WS2562/0032**

**Nustendi-**

**EMA/H/C/004959/WS2562/0036**

Daiichi Sankyo Europe GmbH, Lead Rapporteur:

Patrick Vrijlandt

Opinion adopted on 21.09.2023.

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Positive Opinion adopted by consensus on  
21.09.2023.

**WS2565**

**Blitzima-**

**EMA/H/C/004723/WS2565/0069**

**Truxima-**

**EMA/H/C/004112/WS2565/0072**

Celltrion Healthcare Hungary Kft., Lead

Rapporteur: Sol Ruiz

Opinion adopted on 21.09.2023.

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Positive Opinion adopted by consensus on  
21.09.2023.

**WS2567**

**Glyxambi-**

**EMA/H/C/003833/WS2567/0054**

**Synjardy-**

**EMA/H/C/003770/WS2567/0075**

Boehringer Ingelheim International GmbH, Lead

Rapporteur: Patrick Vrijlandt

Opinion adopted on 05.10.2023.

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Positive Opinion adopted by consensus on  
05.10.2023.

**WS2568**

**Nuwiq-EMA/H/C/002813/WS2568/0055**

**Vihuma-**

**EMA/H/C/004459/WS2568/0037**

Octapharma AB, Lead Rapporteur: Jan Mueller-

Berghaus

Opinion adopted on 21.09.2023.

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Positive Opinion adopted by consensus on  
21.09.2023.

**WS2570**

**Lantus-EMA/H/C/000284/WS2570/0131**

**Suliqua-EMA/H/C/004243/WS2570/0036**

**Toujeo-EMA/H/C/000309/WS2570/0126**

Sanofi-Aventis Deutschland GmbH, Lead

Rapporteur: Patrick Vrijlandt

Request for Supplementary Information adopted

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Request for supplementary information adopted  
with a specific timetable.

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on 05.10.2023.

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

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**Amyvid - Florbetapir (18F) -  
EMA/H/C/002422/II/0044**

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber "Update of section 4.4 of the SmPC in order to remove the limitation regarding monitoring response to therapy based on available information in the scientific literature. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to update section 4.8 to the SmPC to align the clinical trial exposures with the RMP."

Withdrawal request submitted on 26.09.2023.

The MAH withdrew the procedure on 26.09.2023.

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**Ozurdex - dexamethasone -  
EMA/H/C/001140/II/0045**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 4.8 of the SmPC in order to add "Central serous chorioretinopathy" to the list of adverse drug reactions (ADRs) with frequency "uncommon" based on a safety signal and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and design changes to the Package Leaflet; and to bring the PI in line with the latest QRD template version 10.3."

Withdrawal request submitted on 22.09.2023.

The MAH withdrew the procedure on 22.09.2023.

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

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**WS2507  
Bondronat-  
EMA/H/C/000101/WS2507/0092  
Bonviva-  
EMA/H/C/000501/WS2507/0076**

Atnahs Pharma Netherlands B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Request for Supplementary Information adopted on 07.09.2023, 06.07.2023.

Request by the applicant for an extension to the clock stop to respond to the RSI adopted in September 2023.

The CHMP agreed to the request for an extension to the clock stop to respond to the RSI adopted in September 2023.

## **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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**aflibercept - EMEA/H/C/006150**

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)

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**erdafitinib - EMEA/H/C/006050**

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

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**insulin lispro - EMEA/H/C/006158**

treatment of diabetes mellitus

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**insulin aspart - EMEA/H/C/006187**

treatment of diabetes mellitus

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**amino acids - EMEA/H/C/005557, Orphan**

Recordati Rare Diseases, treatment of decompensation episodes in MSUD patients

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**pomalidomide - EMEA/H/C/006273**

treatment of adult patients with multiple myeloma

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**pomalidomide - EMEA/H/C/006314**

treatment of multiple myeloma

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**pomalidomide - EMEA/H/C/006302**

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

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**pomalidomide - EMEA/H/C/006294**

treatment of adults with multiple myeloma

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**imetelstat - EMEA/H/C/006105, Orphan**

Geron Netherlands B.V., treatment of adult patients with transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS) with ring sideroblasts

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**ustekinumab - EMEA/H/C/005805**

treatment of Crohn's Disease and Ulcerative colitis

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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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**Bimzelx - bimekizumab -**

**EMA/H/C/005316/X/0021**

UCB Pharma S.A., Rapporteur: Finbarr Leacy,  
PRAC Rapporteur: Liana Gross-Martirosyan,  
"Extension application to add a new strength of 320 mg (160 mg/ml) for bimekizumab solution for injection in pre-filled syringe or pre-filled pen, for subcutaneous (SC) administration."

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**Cresemba - isavuconazole -**

**EMA/H/C/002734/X/0042/G, Orphan**

Basilea Pharmaceutica Deutschland GmbH,  
Rapporteur: Patrick Vrijlandt, PRAC Rapporteur:  
Adam Przybylkowski, "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, multicenter 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, multicenter 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."

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**Eurartesim - piperazine tetraphosphate / arteminol - EMA/H/C/001199/X/0041**

Alfasigma S.p.A., Rapporteur: Janet Koenig,  
"Extension application to introduce a new pharmaceutical form associated with 2 new strengths (80 mg/10 mg and 160 mg/20 mg dispersible tablets)."

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**Mektovi - binimetinib -**

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**EMA/H/C/004579/X/0029**

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Extension application to add a new strength of 45 mg (film-coated tablets)."

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**Ocrevus - ocrelizumab -****EMA/H/C/004043/X/0039**

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (920 mg) and new route of administration (subcutaneous use).

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

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**Pheburane - sodium phenylbutyrate -****EMA/H/C/002500/X/0037**

Eurocept International B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "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."

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**Skyrizi - risankizumab -****EMA/H/C/004759/X/0043/G**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Gross-Martirosyan, "Extension application to a new strength of 180 mg of risankizumab (solution for injection in cartridge) grouped with a type II variation extension of indication (C.I.6.a) to include treatment of adult patients with moderately to severely active ulcerative colitis, for SKYRIZI, based on final results from studies M16-067 substudy 2: a phase 2b/3 multicenter, randomized, double-blind, placebo-controlled induction study to evaluate the efficacy and safety of risankizumab in subjects with moderately to severely active ulcerative colitis, and M16-066 substudy 1: a multicenter, randomized, double-blind, placebo controlled 52-week maintenance and an open-label extension study of the efficacy and safety of risankizumab in subjects with ulcerative colitis, as well as DDI study M19-974. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC for the Skyrizi 600 mg concentrate for solution for infusion, and sections 1, 2, 4.1, 4.2, 4.8, 5.1, 5.2, 5.3, 6.5

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and 6.6 of the SmPC for the Skyrizi 360 mg solution for injection in cartridge are updated. The Annex II, Labelling and Package Leaflets are updated in accordance. Version 5.0 of the RMP has also been submitted.”

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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/006340**

in vitro diagnostic device for laboratory use, intended for the qualitative detection of BRAF V600 mutations in DNA extracted from formalin-fixed, paraffin-embedded human tissue. Request for Supplementary Information adopted on 14.09.2023.

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#### **in vitro diagnostic medical device - EMA/H/D/006308**

detection of HER2 antigen  
Request for Supplementary Information adopted on 14.09.2023.

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#### **in vitro diagnostic medical device - EMA/H/D/006310**

immunohistochemical assay utilising an anti-PD-L1 monoclonal primary antibody  
Request for Supplementary Information adopted on 14.09.2023.

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

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#### **Brineura - cerliponase alfa - EMA/H/C/004065/S/0042, Orphan**

BioMarin International Limited, Rapporteur:  
Martina Weise, Co-Rapporteur: Maria  
Concepcion Prieto Yerro, PRAC Rapporteur: Mari  
Thorn

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#### **Imvanex - smallpox vaccine (live modified vaccinia virus ankara) - EMA/H/C/002596/S/0095**

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

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#### **Increlex - mecaseprin - EMA/H/C/000704/S/0081**

Ipsen Pharma, Rapporteur: Outi Mäki-Ikola,  
PRAC Rapporteur: Kirsti Villikka

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#### **Lojuxta - lomitapide - EMA/H/C/002578/S/0057**

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Amryt Pharmaceuticals DAC, Rapporteur:  
Patrick Vrijlandt, Co-Rapporteur: Paolo  
Gasparini, PRAC Rapporteur: Menno van der Elst

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**Strensiq - asfotase alfa -**  
**EMA/H/C/003794/S/0066, Orphan**  
Alexion Europe SAS, Rapporteur: Paolo  
Gasparini, PRAC Rapporteur: Rhea Fitzgerald

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**Upstaza - eladocagene exuparvovec -**  
**EMA/H/C/005352/S/0017, Orphan,**  
**ATMP**  
PTC Therapeutics International Limited,  
Rapporteur: Maura O'Donovan, CHMP  
Coordinator: Finbarr Leacy, PRAC Rapporteur:  
Gabriele Maurer

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**Vyndaqel - tafamidis -**  
**EMA/H/C/002294/S/0090, Orphan**  
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel  
Race, Co-Rapporteur: Bruno Sepodes, PRAC  
Rapporteur: Tiphaine Vaillant

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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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**Ambrisentan Mylan - ambrisentan -**  
**EMA/H/C/004985/R/0009**  
Mylan Pharmaceuticals Limited, Generic,  
Generic of Volibris, Rapporteur: Anastasia  
Mountaki, PRAC Rapporteur: Maria del Pilar  
Rayon

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**Doptelet - avatrombopag -**  
**EMA/H/C/004722/R/0018**  
Swedish Orphan Biovitrum AB (publ),  
Rapporteur: Aaron Sosa Mejia, Co-Rapporteur:  
Daniela Philadelphia, PRAC Rapporteur: Monica  
Martinez Redondo

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**Esperoct - turoctocog alfa pegol -**  
**EMA/H/C/004883/R/0022**  
Novo Nordisk A/S, Rapporteur: Daniela  
Philadelphia, Co-Rapporteur: Ewa Balkowicz  
Iskra, PRAC Rapporteur: Gabriele Maurer

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**Grasustek - pegfilgrastim -**  
**EMA/H/C/004556/R/0014**  
Juta Pharma GmbH, Rapporteur: Karin Janssen  
van Doorn, Co-Rapporteur: Martina Weise,  
PRAC Rapporteur: Menno van der Elst

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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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### **Kisqali - ribociclib -**

#### **EMA/H/C/004213/II/0045**

Novartis Europharm Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, stage II or stage III early breast cancer, irrespective of nodal status, in combination with an AI for Kisqali based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

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### **Palforzia - defatted powder of arachis**

#### **hypogaea L., semen (peanuts) -**

#### **EMA/H/C/004917/II/0014/G**

Aimmune Therapeutics Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kirsti Villikka, "Grouped variation consisting of:

C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomized, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON) to evaluate the safety and efficacy of peanut powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling were updated accordingly. Version 1.1 of the

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RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet. As part of the application the MAH is requesting a 1-year extension of the market protection.

B.II.e.5.a: Introduction of a new pack-size “ Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

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**Tagrisso - osimertinib -  
EMA/H/C/004124/II/0053**

AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Menno van der Elst, “Extension of indication to include TAGRISSO in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations, based on final results from study FLAURA2 (D5169C00001); this is a Phase III, open-label, randomized study of osimertinib with or without platinum plus pemetrexed chemotherapy, multicentre study to assess the efficacy and safety of TAGRISSO as first-line treatment in patients with EGFR mutation-positive, locally advanced or metastatic NSCLC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 16 of the RMP has also been submitted.”

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**Tecentriq - atezolizumab -  
EMA/H/C/004143/II/0081**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, “Extension of indication to include, in combination with bevacizumab, adjuvant treatment of adult patients with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation for TECENTRIQ, based on final results from study WO41535 (IMbrave050); this is a phase III, randomized, multi-centre, international, open-label study, conducted to evaluate the efficacy and safety of adjuvant therapy of atezolizumab in combination with bevacizumab in patients with

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completely resected or ablated HCC who were at high risk for disease recurrence. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 28.0 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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**Tecentriq - atezolizumab -  
EMA/H/C/004143/II/0082**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ana Sofia Diniz Martins, “Extension of indication to include first-line treatment of adult patients with non-small cell lung cancer (NSCLC) who are ineligible for platinum-based chemotherapy and who do not have EGFR mutant or ALK-positive disease, who have: locally advanced unresectable NSCLC not amenable for definitive chemoradiotherapy, or metastatic NSCLC, for TECENTRIQ, based on final results from study MO29872 (IPSOS); this is a phase 3, open-label, multicenter, randomized study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment naive advanced or recurrent (stage IIIB not amenable for multimodality treatment) or metastatic (stage IV) non-small cell lung cancer who are deemed unsuitable for platinum-containing therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. Version 29.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

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**Xtandi - enzalutamide -  
EMA/H/C/002639/II/0063**

Astellas Pharma Europe B.V., Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Maria del Pilar Rayon, “Extension of indication to include treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy, for Xtandi, based on final results from study MDV3100-13 (EMBARK); this is a phase 3, randomized, efficacy and safety study of

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enzalutamide plus leuprolide, enzalutamide monotherapy, and placebo plus leuprolide in men with high-risk nonmetastatic prostate cancer progressing after definitive therapy. 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 18.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet.”

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

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##### **Briumvi - ublituximab -**

**EMA/H/C/005914/II/0003**

Propharma Group The Netherlands B.V.,  
Rapporteur: Ewa Balkowiec Iskra

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##### **Diacomit - stiripentol -**

**EMA/H/C/000664/II/0045/G**

BIOCODEX, Rapporteur: Alar Irs

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##### **Ibandronic Acid Teva - ibandronic acid -**

**EMA/H/C/001195/II/0021**

Teva B.V., Generic, Generic of Bondronat,  
Bonviva, Rapporteur: Hrefna Gudmundsdottir

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##### **Ilumetri - tildrakizumab -**

**EMA/H/C/004514/II/0052**

Almirall S.A, Rapporteur: Jan Mueller-Berghaus

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##### **Keytruda - pembrolizumab -**

**EMA/H/C/003820/II/0143**

Merck Sharp & Dohme B.V., Rapporteur: Paolo  
Gasparini

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##### **Livmarli - maralixibat -**

**EMA/H/C/005857/II/0008/G, Orphan**

Mirum Pharmaceuticals International B.V.,  
Rapporteur: Martina Weise

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##### **NexoBrid - concentrate of proteolytic enzymes enriched in bromelain -**

**EMA/H/C/002246/II/0066**

MediWound Germany GmbH, Rapporteur: Janet  
Koenig

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##### **Orgalutran - ganirelix -**

**EMA/H/C/000274/II/0057/G**

Organon N.V., Rapporteur: Outi Mäki-Ikola

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##### **Ovaleap - follitropin alfa -**

**EMA/H/C/002608/II/0039**

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Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt

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**Pluvicto - lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483/II/0010**  
Novartis Europharm Limited, Rapporteur: Janet Koenig

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**Polivy - polatuzumab vedotin - EMEA/H/C/004870/II/0026, Orphan**  
Roche Registration GmbH, Rapporteur: Alexandre Moreau

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**Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0069**  
GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke

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**Trodelyv - sacituzumab govitecan - EMEA/H/C/005182/II/0029**  
Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus

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**Xofigo - radium-223 - EMEA/H/C/002653/II/0053**  
Bayer AG, Rapporteur: Janet Koenig

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**Yselyt - linzagolix choline - EMEA/H/C/005442/II/0009**  
Theramex Ireland Limited, Rapporteur: Finbarr Leacy

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**Ziextenzo - pegfilgrastim - EMEA/H/C/004802/II/0030/G**  
Sandoz GmbH, Rapporteur: Christian Gartner

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**WS2574**  
**Nilemdo-**  
**EMEA/H/C/004958/WS2574/0033**  
**Nustendi-**  
**EMEA/H/C/004959/WS2574/0037**  
Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt

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

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**Epidyolex - cannabidiol - EMEA/H/C/004675/II/0028/G, Orphan**  
Jazz Pharmaceuticals Ireland Limited,  
Rapporteur: Thalia Marie Estrup Blicher,  
"Grouped application comprising three type II variations (C.I.13) as follows:  
- Submission of the final report from study

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GWTX21068 – Genotoxicity study with 7-OH-CBD (Bacterial Reverse Mutation Assay). The objective of this study was to evaluate the ability of GWP4200370 (also known as 7-COOH-CBD) to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolising system (S-9).

- Submission of the final report from study GWTX21028 – Genotoxicity study with 7-COOH-CBD (Bacterial Reverse Mutation Assay). The objective of this study was to evaluate the ability of GWP4200307 to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolising system (S-9).

- Submission of the final report from GWTX18015 – Genotoxicity study with 7-COOH-CBD (Rat Micronucleus and Alkaline Comet Assay). The objective of this study was to evaluate the ability of GWP4200370 (also known as 7-COOH-CBD) to induce reverse mutations in five histidine-requiring strains of Salmonella typhimurium in the absence and presence of a rat liver metabolising system (S-9).”

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**Epidyolex - cannabidiol -  
EMA/H/C/004675/II/0029, Orphan**

Jazz Pharmaceuticals Ireland Limited,  
Rapporteur: Thalia Marie Estrup Blicher,  
“Submission of the final report from study GWCP18055. This is a randomized, double-blind, placebo- and positive-controlled, parallel group trial to investigate the effects of multiple therapeutic and suprathreshold doses of cannabidiol (GWP42003-P) in the fed state on the QT/QTc interval in healthy subjects.”

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**Ervebo - recombinant vesicular stomatitis virus - zaire ebolavirus vaccine (live) -  
EMA/H/C/004554/II/0034**

Merck Sharp & Dohme B.V., Rapporteur:  
Christophe Focke, “Update of section 5.1 of the SmPC in order to update long-term of immunogenicity information and safety results based on final results from study V920-009 (Partnership for Research on Ebola Vaccines in Liberia). In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”

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**Evrysdi - risdiplam -****EMA/H/C/005145/II/0017**

Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC in order to add information on cardiac electrophysiology based on final results from study BP42817 (QTc Study), listed as a category 3 PASS in the RMP. This is a Phase 1, double-blind, placebo and positive controlled crossover study to investigate the effects of risdiplam on QTc interval in healthy subjects."

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**Evrysdi - risdiplam -****EMA/H/C/005145/II/0018**

Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of section 5.3 of the SmPC in order to update carcinogenicity information based on final results from study 8447237. This is a 104 Week Oral (Gavage) Administration Carcinogenicity Study in the Wistar Rat to investigate the tumorigenic potential of Evrysdi. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

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**Livtency - maribavir -****EMA/H/C/005787/II/0008, Orphan**

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, "Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on the updated Population PK analysis data. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

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**Maviret - glecaprevir / pibrentasvir -****EMA/H/C/004430/II/0056**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Jean-Michel Race, "Update of section 5.1 of the SmPC in order to add a statement regarding concordance of SVR4 and SVR12, based on post-hoc analysis of the data from the Phase 2 and 3 clinical trials."

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**Rinvoq - upadacitinib -****EMA/H/C/004760/II/0045**

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Submission of the final report from study M15-555, listed as a category 3 study in the RMP. This is phase 3, randomized, double-blind study comparing upadacitinib (ABT-494) monotherapy to

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methotrexate (MTX) in subjects with moderately to severely active rheumatoid arthritis with inadequate response to MTX.”

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**Vokanamet - canagliflozin / metformin -  
EMA/H/C/002656/II/0072**

Janssen-Cilag International N.V., Rapporteur: Martina Weise, “Update of section 4.6 of the SmPC in order to update information on pregnancy based on literature and post-marketing data.”

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**Xultophy - insulin degludec / liraglutide -  
EMA/H/C/002647/II/0050**

Novo Nordisk A/S, Rapporteur: Kristina Dunder, “Update of section 4.8 of the SmPC in order to add Dizziness and Delayed gastric emptying to the list of adverse drug reactions (ADRs) with frequency common and unknown, respectively, based on the cumulative review of clinical studies data, post-marketing data, class labels and biological plausibility. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI.”

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**Zinforo - ceftaroline fosamil -  
EMA/H/C/002252/II/0063**

Pfizer Ireland Pharmaceuticals, Rapporteur: Alar Irs, “Update of section 4.8 of the SmPC in order to add ‘Kounis Syndrome’ to the list of adverse drug reactions (ADRs). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet.”

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**WS2502**

**CoAprovel-**

**EMA/H/C/000222/WS2502/0214**

**Karvezide-**

**EMA/H/C/000221/WS2502/0214**

Sanofi Winthrop Industrie, Lead Rapporteur: Maria Concepcion Prieto Yerro, “Update of section 5.3 of the SmPC in order to update information on hydrochlorothiazide monocomponent based on literature review.”

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**2573/G**

**Kinzalkomb-**

**EMA/H/C/000415/WS2573/0122/G**

**MicardisPlus-**

**EMA/H/C/000413/WS2573/0129/G**

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**PritorPlus-****EMA/H/C/000414/WS2573/0132/G**

Boehringer Ingelheim International GmbH, Lead Rapporteur: Paolo Gasparini, "Grouped application consisting of:

C.I.4 (Type II): Update of section 4.8 of the SmPC in accordance with the "Guideline on fixed combination medicinal products, Doc. Ref. CPMP/EWP/240/95 Rev. 1". The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Annex II of the PI, as well as, to update the list of local representatives in the Package Leaflet.

Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3.

C.I.4 (Type II): Update of sections 4.2, 4.3, 4.4, 4.5 and 5.2 of the SmPC in order to align with reference labels for both active substances. The Package is updated accordingly.

C.I.z (type IB unforeseen): Update of section 4.7 of the SmPC to replace the term "drowsiness" by "syncope or vertigo" to align it with adverse reactions table in section 4.8 of SmPC. The Package Leaflet is updated accordingly.

C.I.3.a (type IAIN): Update of section 5.3 of the SmPC based on the EMA request dated 31 Jan 2023 for the HCTZ containing medicinal products to remove the sentence "...the extensive human experience with hydrochlorothiazide has failed to show an association between its use and an increase in neoplasms" in order to address an inconsistency in the PI."

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**B.6.10. CHMP-PRAC assessed procedures**

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**Isturisa - osilodrostat -****EMA/H/C/004821/II/0017/G, Orphan**

Recordati Rare Diseases, Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon, "Grouped application comprising two type II variations (C.I.4) as follows:

- 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 LINC4 (study CLCI699C2302 - A Phase III, multi-center, randomized, double-blind, 48 week study with

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an initial 12 week placebo-controlled period to evaluate the safety and efficacy of osilodrostat in patients with Cushing's disease).

- 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 LINC3 (study CLCI699C2301 - A Phase III, multi-center, double-blind, randomized withdrawal study of LCI699 following a 24 week, single-arm, open-label dose titration and treatment period to evaluate the safety and efficacy of LCI699 for the treatment of patients with Cushing's disease).

The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the PI."

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#### **Piqray - alpelisib -**

#### **EMA/H/C/004804/II/0022/G**

Novartis Europharm Limited, Rapporteur:  
Carolina Prieto Fernandez, PRAC Rapporteur:  
Menno van der Elst, "Grouped application comprising two type II variations (C.I.4) as follows:

- Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information on prophylactic use of metformin for hyperglycaemia based on the results from study CBYL719CES01T (METALLICA). METALLICA is a Phase II study aimed to evaluate the effect of prophylactic use of metformin for hyperglycaemia in HR-positive, HER2-negative, PIK3CA-mutated advanced breast cancer patients treated with alpelisib plus endocrine therapy.

- Update of section 4.8 of the SmPC in order to add "uveitis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on a cumulative review of the MAH safety database and literature.

The Package Leaflet and Annex II are updated accordingly. The RMP version 7.0 has also been submitted."

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#### **B.6.11. PRAC assessed procedures**

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PRAC Led

**Heplisav B - Hepatitis B surface antigen (rDNA) - EMA/H/C/005063/II/0031**

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Dynavax GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study DV2-HBV-28 - Post-marketing observational surveillance study to evaluate pregnancy outcomes among women who receive HEPLISAV-B or Engerix-B; HBV-28 was conducted using the same patient population as two observational post-marketing surveillance studies designed to evaluate the incidence of AMI (HBV-25) or new-onset immunemediated diseases, herpes zoster, and anaphylaxis (HBV-26) in recipients of HEPLISAV-B compared with recipients of Engerix-B. The primary objective of this study was to describe and compare pregnancy outcomes in recipients of HEPLISAV-B and recipients of Engerix-B. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3."

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PRAC Led

**Juluca - dolutegravir / rilpivirine -  
EMA/H/C/004427/II/0054**

ViiV Healthcare B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from non-interventional PASS study COMBINE-2 listed as a category 3 study in the RMP. This is a real-world evidence study to evaluate effectiveness of two drug regimen, antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor. The RMP version 6.0 has also been submitted in order to remove the important identified risk of "drug resistance"."

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PRAC Led

**MabThera - rituximab -  
EMA/H/C/000165/II/0199**

Roche Registration GmbH, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa Mejia, "Submission of the final report for study BE29950 (RIVAS), listed as a category 3 study in the RMP. This is a prospective, single center, secondary data use, long-term surveillance, non-interventional PASS with the objective to better characterise the risk profile of MabThera"

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by collecting long term safety data in patients with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have been treated with rituximab (MabThera) or other available non-rituximab therapies. The RMP version 24.0 has also been submitted.”

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PRAC Led

**Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0127**

Pfizer Europe MA EEIG, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, “Submission of an updated RMP version 9.0 in order to remove the important potential risks ‘Change in meningococcal epidemiology/serogroup replacement’ and ‘Lack of Efficacy’ from the list of the safety concerns, to remove ‘Long-term persistence of the vaccine response and need for a booster dose’ as missing information and to remove ‘Use during pregnancy’ from the list of safety concerns.”

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PRAC Led

**Nivestim - filgrastim - EMEA/H/C/001142/II/0074/G**

Pfizer Europe MA EEIG, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, “Grouped application consisting of: C.I.13: Submission of the final report from non-interventional PASS study ZOB-NIV-1513/C1121008 listed as a category 3 study in the RMP. This is a multinational, multi-centre, prospective, non-interventional, post-authorisation safety study in Healthy Donors (HDs) exposed to nivestim (biosimilar filgrastim) for Haematopoietic Stem Cell (HSC) Mobilisation (NEST). The RMP version 12 has also been submitted. C.I.11 for RMP: Submission of an updated RMP version 12.0 in order to align it with the reference product, Neupogen, RMP v. 6.3 dated June 2022. ”

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PRAC Led

**Revatio - sildenafil - EMEA/H/C/000638/II/0107**

Upjohn EESV, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Patrick Vrijlandt, “Submission of an updated RMP version 8.0 in order to remove “Long-term Mortality” as missing information based on the completion of

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Study A1481324 - A multinational, multicentre study to assess the effects of oral sildenafil on mortality in adults with pulmonary arterial hypertension (PAH). In addition, the MAH took the opportunity to reflect the completion of the studies A1481324 and A1481319.”

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PRAC Led

**Simponi - golimumab -**

**EMA/H/C/000992/II/0117/G**

Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “Grouped application consisting of:

C.I.13: Submission of the final report from study UC Nordic (MK-8259-013) listed as a category 3 study in the RMP. This is a Non-interventional Observational Longitudinal Post Authorization Safety Study (PASS) of SIMPONI in Treatment of Ulcerative Colitis using Nordic National Health Registries.

C.I.13: Submission of the final report from study ENEIDA (MK-8259-042) listed as a category 3 study in the RMP. This is a Post-Authorisation Safety Study (PASS) of Golimumab in UC Using the Spanish ENEIDA Registry.

The RMP version 27.1 has also been submitted.”

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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, “Submission of an updated RMP version 18.0 in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects.”

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PRAC Led

**Vedrop - tocopherol -**

**EMA/H/C/000920/II/0047**

Recordati Rare Diseases, PRAC Rapporteur: Melinda Palfi, PRAC-CHMP liaison: Beata Maria Jakline Ullrich, “Submission of an updated RMP version 10.1 in order to remove all important potential risks and missing information from the list of safety concerns, to align with the new RMP format according to Good

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Pharmacovigilance Practices Module V Revision 2 and to remove one closed post-authorisation safety study of category 2 (Recordati Rare Diseases's Vedrop registry) from the pharmacovigilance plan."

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PRAC Led

**Zaltrap - aflibercept -  
EMA/H/C/002532/II/0071**

Sanofi Winthrop Industrie, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 5.0 in order to update the Risk Minimisation Measures and List of Safety Concerns removing "Nephrotic syndrome", "Cardiac failure and ejection fraction decreased", "Posterior reversible encephalopathy syndrome", "Thrombotic microangiopathy" and "Osteonecrosis of jaw" of the important identified risks, "Reproductive and developmental toxicity" as an important potential risk and "Safety in patients with severe hepatic impairment" of the missing information, following the assessment of PSUSA/00010019/202108."

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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 1245-0201. 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."

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**B.6.12. CHMP-CAT assessed procedures**

**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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**WS2576**

**Elebrato Ellipta-**

**EMA/H/C/004781/WS2576/0037**

**Relvar Ellipta-**

**EMA/H/C/002673/WS2576/0064**

**Revinty Ellipta-**

**EMA/H/C/002745/WS2576/0061**

**Trelegy Ellipta-**

**EMA/H/C/004363/WS2576/0034**

GlaxoSmithKline (Ireland) Limited, Lead

Rapporteur: Maria Concepcion Prieto Yerro

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**WS2578**

**Fluenz Tetra-**

**EMA/H/C/002617/WS2578/0133**

**Pandemic influenza vaccine H5N1**

**AstraZeneca-**

**EMA/H/C/003963/WS2578/0067**

AstraZeneca AB, Lead Rapporteur: Jan Mueller-

Berghaus

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**WS2579/G**

**Fluenz Tetra-**

**EMA/H/C/002617/WS2579/0134/G**

**Pandemic influenza vaccine H5N1**

**AstraZeneca-**

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

AstraZeneca AB, Lead Rapporteur: Christophe

Focke

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**WS2582**

**HyQvia-EMA/H/C/002491/WS2582/0092**

**Kiovig-EMA/H/C/000628/WS2582/0124**

Takeda Manufacturing Austria AG, Lead

Rapporteur: Jan Mueller-Berghaus

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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**

## **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**

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

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