



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

08 February 2022  
EMA/CHMP/782804/2021  
Human Medicines Division

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

Minutes for the meeting on 13-16 December 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

### Disclaimers

Some of the information contained in this set of 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, these minutes are 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. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), 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 current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions. See December 2021 CHMP minutes for the list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session held 13-16 December 2021.

Participants in this meeting 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.

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 and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 17 or more members were present remotely). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified. The views of the EEA member states will not be reflected separately, unless divergent to the CHMP opinion.

## 1.2. Adoption of agenda

CHMP agenda for 13-16 December 2021

The CHMP adopted the agenda.

## 1.3. Adoption of the minutes

CHMP minutes for 08-11 November 2021.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 06 December 2021.

The CHMP adopted the minutes of the November Plenary meeting as well as the minutes from the December PROM meeting.



## 2. Oral Explanations

### 2.1. Pre-authorisation procedure oral explanations

#### 2.1.1. sodium thiosulfate - PUMA - EMEA/H/C/005130

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

Scope: Oral explanation

**Action:** Oral explanation to be held on 14 December 2021 at 16:00

List of Outstanding Issues adopted on 24.06.2021. List of Questions adopted on 25.06.2020.

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

See 3.2

#### 2.1.2. Saphnelo - anifrolumab - EMEA/H/C/004975

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AstraZeneca AB; indicated as an add-on therapy for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), despite standard therapy

Scope: Possible oral explanation

**Action:** Possible oral explanation to be held on 15 December 2021 at 16:00

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

List of Outstanding Issues adopted on 14.10.2021, 22.07.2021. List of Questions adopted on 25.02.2021.

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

See 3.1

#### 2.1.3. gefapixant - EMEA/H/C/005476

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treatment of refractory or unexplained chronic cough

Scope: Possible oral explanation

**Action:** Possible oral explanation to be held on 14 December 2021 at 14:00

List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 24.06.2021.

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

See 3.2

#### 2.1.4. gefapixant - EMEA/H/C/005884

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treatment of refractory or unexplained chronic cough

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Scope: Possible oral explanation

**Action:** Possible oral explanation to be held on 14 December 2021 at 14:00

List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 24.06.2021.

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

See 3.2

## 2.2. Re-examination procedure oral explanations

No items

## 2.3. Post-authorisation procedure oral explanations

### 2.3.1. Tookad - padeliporfin - EMEA/H/C/004182/II/0013

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STEBA Biotech S.A

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maia Uusküla

Scope: "Modification of the wording of the existing indication. The new wording will be the treatment of adult patients with previously untreated, unilateral, low-risk, adenocarcinoma of the prostate with a life expectancy  $\geq 10$  years and clinical stage T1c or T2a, ISUP Grade Group  $\leq 2$ , based on high-resolution biopsy strategies, PSA  $\leq 10$  ng/mL, Low core positivity for Tookad; as a consequence, section 4.1 of the SmPC is updated. Version 6.0 of the RMP has also been submitted."

Oral explanation

**Action:** Oral explanation to be held on 14 December 2021 at 11:00

Request for Supplementary Information adopted on 16.09.2021, 20.05.2021.

An oral explanation was held on Tuesday 14 December 2021. The presentation by the applicant focused on the clinical data in support of the application.

See 5.4

### 2.3.2. Brilique - ticagrelor - EMEA/H/C/001241/II/0049

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AstraZeneca AB

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES), a phase III, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic stroke or transient ischaemic attack; 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 13 of the RMP has also been submitted.”

Oral explanation

**Action:** Oral explanation to be held on 15 December 2021 at 13:30

Request for Supplementary Information adopted on 24.06.2021, 28.01.2021, 17.09.2020.

An oral explanation was held on Wednesday 15 December 2021. The presentation by the applicant focused on the clinical data in support of the application.

See 5.4

### 2.3.3. Veklury - remdesivir - EMEA/H/C/005622/II/0016

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Gilead Sciences Ireland UC

Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová

Scope: “Extension of indication to include treatment of adults with pneumonia not requiring supplemental oxygen (moderate COVID-19), based on Part A of study GS-US-540-5774, a Phase 3, randomized, open-label, multicenter study comparing 2 RDV regimens (5 days and 10 days) versus standard of care in 584 participants with moderate COVID 19, and study CO US 540 5776 [Adaptive COVID-19 Treatment Trial (ACTT) 1, a National Institute of Allergy and Infectious Diseases (NIAID)-sponsored Phase 3, randomized, double blind, placebo controlled, multicenter study]. As a consequence, sections 4.1 and 5.1 of the SmPC are being updated and the Package Leaflet is updated in accordance. A revised version 1.2 of the RMP has also been submitted.”

Oral explanation

**Action:** Oral explanation to be held on 15 December 2021 at 09:00

Request for Supplementary Information adopted on 16.09.2021, 20.05.2021.

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

See 5.1

## 2.4. Referral procedure oral explanations

No items

# 3. Initial applications

## 3.1. Initial applications; Opinions

### 3.1.1. Aduhelm - aducanumab - EMEA/H/C/005558

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Biogen Netherlands B.V.; Alzheimer’s disease

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 22.07.2021. List of Questions adopted on 25.02.2021.

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

The refusal question and answers document was circulated for information.

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

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Pfizer Europe MA EEIG; prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 11.11.2021. List of Questions adopted on 22.07.2021.

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 Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed), contains five new serotypes, 8, 10A, 11A, 12F and 15B conjugated to CRM197 carrier protein which can be qualified as new active substances.

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

The summary of opinion was circulated for information.

### 3.1.3. [Dorianex- risperidone- EMEA/H/C/005406](#)

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Laboratorios Farmacéuticos Rovi, S.A.; treatment of schizophrenia

Scope: Opinion

**Action:** For adoption

Hybrid application (Article 10(3) of Directive No 2001/83/EC)

List of outstanding issues adopted on 15.10.2020. List of questions adopted on 28.05.2020.

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

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

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

The summary of opinion was circulated for information.

#### 3.1.4. Kerendia - finerenone - EMEA/H/C/005200

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Bayer AG; delay progression of kidney disease, reduce the risk of cardiovascular mortality and morbidity

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 11.11.2021, 16.09.2021. List of Questions adopted on 25.03.2021.

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 finerenone 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.

#### 3.1.5. Metformin Sitagliptin Mylan - metformin hydrochloride / sitagliptin hydrochloride monohydrate - EMEA/H/C/005678

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Mylan Ireland Limited; treatment of type 2 diabetes mellitus

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 25.03.2021.

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

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

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

The summary of opinion was circulated for information.

### 3.1.6. Ngenla - somatrogon - Orphan - EMEA/H/C/005633

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Pfizer Europe MA EEIG; indicated for the long-term treatment of paediatric patients with growth disturbance due to insufficient secretion of growth hormone.

Scope: Opinion

**Action:** For adoption

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

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

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

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

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

The CHMP noted the letter of recommendations dated 14 December 2021.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

### 3.1.7. Nuvaxovid – COVID-19 vaccine (recombinant, adjuvanted) – EMEA/H/C/005808

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Novavax CZ, a.s.; prevention of coronavirus disease-2019 (COVID-19)

Scope: Opinion

**Action:** For adoption

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

CHMP discussed the status of this application.

The CHMP noted that an extraordinary CHMP meeting was scheduled for 20 December 2021.

At the extraordinary CHMP meeting on 20 December 2021, the CHMP further discussed the marketing authorisation application for Nuvaxovid. The member Ilko Getov gave a PROXY to Bruno Sepodes and the member Outi Mäki-Ikola gave a PROXY to Jan Mueller-Berghaus.

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 SARS-CoV-2 recombinant spike protein 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.

### 3.1.8. [Ontilyv - opicapone - EMEA/H/C/005782](#)

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Bial Portela & Companhia S.A.; treatment of Parkinson's disease and motor fluctuations

Scope: Opinion

**Action:** For adoption

Informed consent application (Article 10c of Directive No 2001/83/EC), Informed Consent of Ongentys

List of Questions adopted on 22.07.2021.

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

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

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

The summary of opinion was circulated for information.

### 3.1.9. [Oxbryta - voxelotor – PRIME – Orphan - EMEA/H/C/004869](#)

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Global Blood Therapeutics Netherlands; Indicated for the treatment of haemolytic anaemia in adults and paediatric patients 12 years of age and older with sickle cell disease (SCD).

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 20.05.2021.

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 voxelotor 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 adopted the similarity assessment report.

### 3.1.10. [Padcev - enfortumab vedotin - EMEA/H/C/005392](#)

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Astellas Pharma Europe B.V.; treatment of locally advanced (LA) or metastatic urothelial cancer (mUC)

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 14.09.2021. List of Questions adopted on 22.06.2021.

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 enfortumab vedotin 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.

### 3.1.11. Saphnelo - anifrolumab - EMEA/H/C/004975

AstraZeneca AB; indicated as an add-on therapy for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), despite standard therapy

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 14.10.2021, 22.07.2021. List of Questions adopted on 25.02.2021.

See 2.1

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

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

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

Furthermore, the CHMP considered that anifrolumab 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 December 2021.

The summary of opinion was circulated for information.

### 3.1.12. Sapropterin Dipharma - sapropterin - EMEA/H/C/005646

Dipharma B.V.; treatment of hyperphenylalaninemia (HPA)

Scope: Opinion



**Action:** For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Kuvan  
List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 20.05.2021.

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

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

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

The CHMP noted the letter of recommendation dated 15 December 2021.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

### 3.1.13. Tepmetko - tepotinib - EMEA/H/C/005524

Merck Europe B.V.; treatment of advanced non-small cell lung cancer

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 16.09.2021. List of Questions adopted on 25.03.2021.

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 majority (20 out of 32 votes) together with the CHMP Assessment Report and translation timetable.

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

The Icelandic member was in agreement with the CHMP recommendation and the Norwegian member was not in agreement.

The divergent position (Silvijus Abramavicius, Christophe Focke, Christian Gartner, Armando Genazzani, Ilko Getov, Agnes Gyurasics, Andrea Laslop, Outi Mäki-Ikola, Jan Müller-Berghaus, Sinan Bardakci Sarac, Simona Badoi, Martina Weise, Ingrid Wang) was appended to the opinion.

The summary of opinion was circulated for information.

### 3.1.14. Xevudy - sotrovimab - EMEA/H/0005676

GlaxoSmithKline; Treatment of coronavirus disease 2019 (COVID-19)

Scope: Opinion

**Action:** For adoption

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

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 sotrovimab is a new active substance, as claimed by the applicant.

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

The CHMP noted the letter of recommendations dated 14 December 2021.

The summary of opinion was circulated for information.

### 3.1.15. [Yselty - linzagolix choline - EMEA/H/C/005442](#)

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ObsEva Ireland Ltd; for the management of heavy menstrual bleeding (HMB) associated with uterine fibroids

Scope: Opinion

**Action:** For adoption

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

List of Outstanding Issues adopted on 11.11.2021, 16.09.2021. List of Questions adopted on 22.04.2021.

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 linzagolix choline is a new active substance, as claimed by the applicant.

The CHMP noted the letter of recommendations dated 14 December 2021.

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

The summary of opinion was circulated for information.

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

### 3.2.1. [betaine anhydrous - EMEA/H/C/005637](#)

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treatment of homocystinuria

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 22.04.2021.

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. ciltacabtagene autoleucel – PRIME – Orphan - ATMP - EMEA/H/C/005095

Janssen-Cilag International NV; treatment of multiple myeloma

Scope: List of outstanding issues

**Action:** For information

List of Questions adopted on 10.09.2021.

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

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

### 3.2.3. gefapixant - EMEA/H/C/005884

treatment of refractory or unexplained chronic cough

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 24.06.2021.

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. difelikefalin - EMEA/H/C/005612

treatment of pruritus

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 22.07.2021.

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

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

### 3.2.5. teriparatide - EMEA/H/C/004932

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

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 28.01.2021.

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

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

### 3.2.6. lonafarnib - Orphan - EMEA/H/C/005271

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EigerBio Europe Limited; treatment of Hutchinson-Gilford Progeria Syndrome and Progeroid Laminopathies

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 16.09.2021, 25.02.2021. List of Questions adopted on 23.07.2020.

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.

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

### 3.2.7. gefapixant - EMEA/H/C/005476

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treatment of refractory or unexplained chronic cough

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 14.10.2021. List of Questions adopted on 24.06.2021.

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.

### 3.2.8. arimoclomol - Orphan - EMEA/H/C/005203

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Orphazyme A/S; treatment of Niemann-Pick disease type C (NPC)

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 16.09.2021. List of Questions adopted on 25.03.2021.

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.

The CHMP agreed to consult an ad-hoc expert group and adopted a list of questions to the experts.

### 3.2.9. relugolix - EMEA/H/C/005353

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treatment of adult patients with advanced prostate cancer

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 22.07.2021.

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

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

### 3.2.10. sodium thiosulfate - PUMA - EMEA/H/C/005130

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

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 24.06.2021. List of Questions adopted on 25.06.2020.

See 2.1

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

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

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

### 3.2.11. daridorexant - EMEA/H/C/005634

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treatment of insomnia

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 22.07.2021.

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

issues.

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

### 3.2.12. lasmiditan - EMEA/H/C/005332

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acute treatment of migraine with or without aura in adults

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 16.09.2021, 22.07.2021. List of Questions adopted on 25.03.2021.

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.

### 3.2.13. sitagliptin - EMEA/H/C/005598

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treatment of type 2 diabetes mellitus

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 16.09.2021, 20.05.2021. List of Questions adopted on 17.09.2020.

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.

### 3.2.14. teriparatide - EMEA/H/C/005827

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treatment of osteoporosis

Scope: List of outstanding issues

**Action:** For adoption

List of Questions adopted on 22.07.2021.

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.

### 3.2.15. vildagliptin / metformin hydrochloride - EMEA/H/C/005738

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treatment of type 2 diabetes mellitus

Scope: List of outstanding issues

**Action:** For adoption

List of Outstanding Issues adopted on 16.09.2021. List of Questions adopted on 22.04.2021.

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.

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

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

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indicated for in vitro labelling of kits for radiopharmaceutical preparation

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

#### **3.3.2. lutetium (177Lu) chloride - EMEA/H/C/005859**

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

Scope: 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. molnupiravir – EMEA/H/C/005789**

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Treatment of coronavirus disease 2019 (COVID-19)

Scope: List of questions

**Action:** For adoption

See also 10.2 for the Article 5(3) of Regulation (EC) No 726/2004.

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 EMA press release was circulated for information.

### 3.3.4. [lenacapavir - EMEA/H/C/005638](#)

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treatment of human immunodeficiency virus type 1 (HIV-1) infection

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

### 3.3.5. [octreotide - Orphan - EMEA/H/C/005826](#)

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FGK Representative Service GmbH; treatment of acromegaly

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

### 3.3.6. [pemetrexed - EMEA/H/C/005848](#)

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treatment of malignant pleural mesothelioma and non-small cell lung 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.

### 3.3.7. [efgartigimod alfa - Orphan - EMEA/H/C/005849](#)

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Argenx; treatment of generalised Myasthenia Gravis (gMG)

Scope: List of questions

**Action:** For adoption

The Committee discussed the issues identified in this application.

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

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

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

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prevention of dengue disease



Scope: Letter from the applicant dated 01 December 2021 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in November 2021.

**Action:** For adoption

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

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in November 2021.

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

prevention of dengue disease

Scope: Letter from the applicant dated 01 December 2021 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in November 2021.

**Action:** For adoption

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

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in November 2021.

### 3.4.3. rimegepant - EMEA/H/C/005725

management of migraine

Scope: Letter from the applicant dated 06 December 2021 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in November 2021.

**Action:** For adoption

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

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in November 2021.

### 3.4.4. betulae cortex dry extract (5-10: 1); extraction solvent: n-heptane 95% (w/w) - Orphan - EMEA/H/C/005035

Amryt Pharmaceuticals DAC; Treatment to achieve accelerated healing of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients from birth onwards.

Scope: Letter from third party

**Action:** For information

List of Outstanding Issues adopted on 11.11.2021. List of Questions adopted on 22.07.2021.

The CHMP noted the letter from the third party.

### 3.4.5. maribavir - Orphan - EMEA/H/C/005787

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Shire Pharmaceuticals Ireland Limited; treatment of cytomegalovirus (CMV) infection

Scope: Request for an extension to the clock stop to respond to the list of questions adopted in October 2021.

**Action:** For adoption

List of Questions adopted on 14.10.2021.

The CHMP agreed to the request for an extension to the clock stop to respond to the list of questions adopted in October 2021.

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

### 3.5.1. Ipique - bevacizumab - EMEA/H/C/005433

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Rotterdam Biologics B.V.; indicated in adults for the treatment of neovascular macular degeneration associated with aging and diabetes.

Scope: Call for re-examination rapporteurs

**Action:** For information

Well-established use application (Article 10a of Directive No 2001/83/EC)

Opinion adopted on 11.11.2021. List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 17.09.2020.

The CHMP noted the call for re-examination rapporteurs.

The CHMP noted the draft procedure timetable.

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

No items

## 3.7. Withdrawals of initial marketing authorisation application

### 3.7.1. Zektayos-Hepjuvo - obeticholic acid - EMEA/H/C/005249

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Intercept Pharma International Limited; improvement of liver fibrosis and resolution of steatohepatitis in adult patients with significant liver fibrosis due to non-alcoholic steatohepatitis (NASH)

Scope: Withdrawal of marketing authorisation application

**Action:** For information

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

List of Outstanding Issues adopted on 25.03.2021. List of Questions adopted on 28.05.2020.

The CHMP noted the withdrawal of initial 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. Comirnaty - tozinameran - EMEA/H/C/005735/X/0077

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BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst

Scope: "Extension application to add a new strength (0.1 mg/ml). The new presentations are indicated for children from 5 to 11 years of age."

**Action:** For adoption

At an extraordinary CHMP meeting on 25 November 2021, the CHMP discussed this extension application.

On 25 November 2021, the Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The CHMP press release was circulated for information.

#### 4.1.2. Mayzent - siponimod - EMEA/H/C/004712/X/0007

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Novartis Europharm Limited

Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to add a new strength of 1 mg film-coated tablet. The RMP (version 3.0) is updated in accordance."

**Action:** For adoption

List of Questions adopted on 16.09.2021.

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

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

#### 4.1.3. Yuflyma - adalimumab - EMEA/H/C/005188/X/0005

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Celltrion Healthcare Hungary Kft.

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new strengths of 80 mg solution for injection. Version 1.1 of the RMP has also been submitted."

**Action:** For adoption

List of Questions adopted on 16.09.2021.

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

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

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

### **4.2.1. Nucala - mepolizumab - EMEA/H/C/003860/X/0042**

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GlaxoSmithKline Trading Services Limited

Rapporteur: Peter Kiely, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension application to introduce a new strength of 40 mg for Nucala solution for injection in a pre-filled syringe for subcutaneous use to be used in children aged 6 to 11 years."

**Action:** For adoption

List of Questions adopted on 16.09.2021.

The Committee discussed the issues identified in this application, mainly concerning quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

### **4.2.2. Zejula - niraparib - Orphan - EMEA/H/C/004249/X/0029**

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GlaxoSmithKline (Ireland) Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension application to introduce a new pharmaceutical form (100 mg film-coated tablet). The RMP (version 5.1) is updated in accordance."

**Action:** For adoption

List of Questions adopted on 14.10.2021.

The Committee discussed the issues identified in this application, mainly concerning quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and 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**

No items

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

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

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Gilead Sciences Ireland UC

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ilaria Baldelli

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

Change of the timetable to respond to the list of questions adopted in November 2021.

**Action:** For adoption

List of questions adopted on 11.11.2021.

The CHMP agreed to the request by the applicant for a change of timeline to respond to the list of questions adopted in November 2021.

#### **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. Adjuvanrix - pandemic influenza vaccine (h5n1) (split virion, inactivated, adjuvanted) - EMEA/H/C/001206/II/0074**

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GlaxoSmithkline Biologicals SA

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of indication to include use in children from 6 months to <18 years for Adjuvanrix based on the results of the studies: study H5N1-013, a phase II, non-randomized, open-label study to evaluate the safety and immunogenicity in children aged 6 to 35 months and study H5N1-032, a phase III, randomized, open, active-controlled study to evaluate the safety and immunogenicity in children aged 3 to 17 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 6.6 of the SmPC are updated and the Package Leaflet is updated in accordance. Further, the MAH proposed to update section 4.4 with information on sodium and potassium content in line with the excipient guideline, as well as to add wording on traceability. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.2, the MAH performed minor editorial changes and removed information related to the withdrawal of the Prepandrix marketing authorisation. Version 13 of the RMP has also been submitted."

Letter from the applicant requesting an extension to the clock stop to respond to the request for supplementary information expected to be adopted at the December meeting.

**Action:** For adoption

Request for Supplementary Information adopted on 22.07.2021.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

The CHMP agreed to the request by the applicant for an extension to the clock stop with a specific timetable.

### 5.1.2. [Crysvita - burosumab - Orphan - EMEA/H/C/004275/II/0023](#)

Kyowa Kirin Holdings B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of FGF23-related hypophosphataemia in tumour-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised in patients aged 1 year and over, based on data from two ongoing open-label clinical studies, UX023T-CL201 and KRN23-002, in adults with TIO (144-week data and 88-week data are available, respectively). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated and the Package Leaflet is updated accordingly. An updated RMP version 4.0 has also been submitted. The MAH also applied for one additional year of market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

Request for Supplementary Information adopted on 22.04.2021.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

### 5.1.3. Entyvio - vedolizumab - EMEA/H/C/002782/II/0061

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Takeda Pharma A/S

Rapporteur: Armando Genazzani, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy for Entyvio; as a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC for Entyvio 300 mg are updated. The Package Leaflet is updated accordingly. The RMP is updated to version 7.

The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP)." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004).

**Action:** For adoption

Request for Supplementary Information adopted on 14.10.2021.

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

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

The summary of opinion was circulated for information.

### 5.1.4. Exparel liposomal - bupivacaine - EMEA/H/C/004586/II/0005

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Pacira Ireland Limited

Rapporteur: Elita Poplavska, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension of indication to include children over 6 years old."

**Action:** For adoption

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

### 5.1.5. Jakavi - ruxolitinib - EMEA/H/C/002464/II/0053

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Novartis Europharm Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Annika Folin

Scope: "Extension of indication to include treatment of patients with GvHD aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies for Jakavi; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity

to update the list of local representatives for The Netherlands in the Package Leaflet.”

**Action:** For adoption

Request for Supplementary Information adopted on 24.06.2021.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 5.1.6. Jardiance - empagliflozin - EMEA/H/C/002677/II/0060

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Eva A. Segovia

Scope: “Extension of indication to add the treatment of patients with Heart Failure with preserved ejection fraction based on the results from the clinical study 1245.110 EMPEROR-preserved. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC and sections 1 and 4 of the PIL are updated accordingly. Further, the MAH applied for an additional year of market protection. The updated RMP v 16.0 has also been submitted.

In addition, the statement 'sodium free' was re-located from section 2 of the SmPC to section 4.4. to comply with EMA'S QRD guidance and minor linguistic changes to the national translations are included in this submission”, 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, mainly concerning clinical aspects.

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

#### 5.1.7. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0108

Merck Sharp & Dohme B.V.

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

Scope: “Extension of indication to include the adjuvant treatment in monotherapy of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 35.1 of the RMP has also been submitted.”

**Action:** For adoption

Request for Supplementary Information adopted on 14.10.2021.

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. [Kineret - anakinra - EMEA/H/C/000363/II/0086](#)

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Swedish Orphan Biovitrum AB (publ)

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Anette Kirstine Stark

Scope: "C.I.6 - Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in adult patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure determined by plasma concentration of soluble urokinase plasminogen activator receptor (suPAR)  $\geq$  6 ng/ml for Kineret; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP is updated to version 5.9. 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 14.10.2021.

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. [Kymriah - tisagenlecleucel – PRIME – Orphan - ATMP - EMEA/H/C/004090/II/0044](#)

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Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of adult patients with follicular lymphoma (FL) after two or more lines of therapy who are refractory or relapsed during or within 6 months after completion of anti-CD20 antibody maintenance or relapsed after autologous haematopoietic stem cell transplantation (HSCT) for Kymriah. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and corresponding sections in the Package Leaflet are updated accordingly. The RMP has been updated to version 4.0 to align with the indication extension. Lastly, the minor editorial corrections are made throughout the SmPC and package leaflet to align with the current QRD template version 10.2.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

The CHMP was updated on discussions at the CAT. The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 5.1.10. [Lorviqua - lorlatinib - EMEA/H/C/004646/II/0015](#)

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Pfizer Europe MA EEIG

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication to include the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor based on results from the phase III randomised CROWN (1006) study listed as a specific obligation (SOB) in the Annex II; 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 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to include minor editorial changes in the PI."

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021, 20.05.2021.

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 Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

#### 5.1.11. Nexpovio - selinexor - EMEA/H/C/005127/II/0001/G

Karyopharm Europe GmbH

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

Scope: "Group of variations including an extension of indication for Nexpovio in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy and a quality variation for the addition of a new pack size to align with the dose modification guidance for the new indication. Sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 6.5 of the SmPC are updated to reflect the new indication and the new pack size. Annex II is updated to reflect the completion of the Specific Obligation. The Labelling and Package Leaflet are amended accordingly. The RMP (v 1.1) is amended consequently."

**Action:** For adoption

Request for Supplementary Information adopted on 22.07.2021.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 5.1.12. Olumiant - baricitinib - EMEA/H/C/004085/II/0029/G

Eli Lilly Nederland B.V.

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski

Scope: "Grouping of the following variations:

C.I.6 - Extension of indication to include treatment of severe alopecia areata in adult patients for Olumiant; 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 12.1 of the RMP has also been submitted.

C.I.11.z - Update of RMP (version 12.1) to change the category 3 study PASS I4V-MC-B011 end of data collection for the Atopic Dermatitis cohort and the subsequent final study report milestone.", 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, mainly concerning clinical aspects.

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

#### 5.1.13. RoActemra - tocilizumab - EMEA/H/C/000955/II/0101

Roche Registration GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "C.I.6 - Extension of indication to include the treatment of coronavirus disease 2019 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation for RoActemra; as a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC for RoActemra 20 mg/mL concentrate for solution for infusion are updated. The Package Leaflet has been updated in accordance. The RMP is updated to Version 27.1 and the Annex II has been updated accordingly. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev. 1. In addition, the list of local representatives in the PL has been revised to amend contact details for the representative of Hungary."

**Action:** For adoption

Request for Supplementary Information adopted on 14.10.2021.

At an extraordinary CHMP meeting on 06 December 2021, the CHMP discussed this extension application.

On 06 December 2021, the Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The CHMP noted the letter of recommendation dated 06 December 2021.

The CHMP press release was circulated for information.

#### 5.1.14. Senshio - ospemifene - EMEA/H/C/002780/II/0041

Shionogi B.V.

Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension of indication by deletion of information on specific subset of patients for Senshio. This is supported by the submission of the final study report of the imposed non-

interventional post-authorisation safety study. As mentioned in Annex IID, this is an observational retrospective cohort study of ospemifene to assess the incidence of venous thromboembolism and other safety concerns as agreed in the Risk Management Plan (RMP), in vulvar and vaginal atrophy (VVA) patients treated with ospemifene compared to 1) patients newly prescribed SERMs for oestrogen-deficiency conditions or breast cancer prevention, and 2) the incidence in untreated VVA patients. As a consequence, sections 4.1 and 4.4 of the SmPC are updated. The Package Leaflet and Annex IID are updated in accordance. Version 2 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to update the list of local representatives in the Package Leaflet.”

**Action:** For adoption

Request for Supplementary Information adopted on 14.10.2021.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 5.1.15. [Spikevax - COVID-19 mRNA vaccine \(nucleoside-modified\) - EMEA/H/C/005791/II/0041](#)

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Moderna Biotech Spain, S.L.

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

Scope: “Extension of indication to include use in children 6-11 years of age for Spikevax, based on data from study mRNA-1273-P204, an ongoing Phase 2/3, 2-part, open-label, dose-escalation, age de-escalation and subsequent randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity and effectiveness of mRNA-1273 in healthy children; 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.”

**Action:** For adoption

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 5.1.16. [Tecfidera - dimethyl fumarate - EMEA/H/C/002601/II/0073](#)

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Biogen Netherlands B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: “C.I.6 (Extension of indication) type II Art.29 Extension of indication to include treatment of relapsing remitting multiple sclerosis (RRMS) in paediatric patients from 10 years of age and over; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.3 are updated. The Package Leaflet is updated in accordance.

The MAH is requesting an extension of the market protection of one additional year in line with the guidance on elements required to support the significant clinical benefit in comparison with existing therapies of a new therapeutic indication in accordance with Article

14(11) of Regulation (EC) 726/2004.

Version 11.4 of the RMP has also been submitted to update the RMP (parts I-IV) based on study 109MS306 data supporting the request for a paediatric indication and the Applicant took the opportunity to update the RMP with the most updated data (Part II modules SIV, SV and SVII).”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 5.1.17. [Teysono - tegafur / gimeracil / oteracil - EMEA/H/C/001242/II/0045](#)

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Nordic Group B.V.

Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst

Scope: “Extension of indication to include as monotherapy or in combination with oxaliplatin or irinotecan, with or without bevacizumab, for the treatment of patients with metastatic colorectal cancer for whom it is not possible to continue treatment with another fluoropyrimidine due to hand-foot syndrome or cardiovascular toxicity that developed in the adjuvant or metastatic setting. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.2 of the RMP has also been submitted.”

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021, 28.01.2021.

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.

#### 5.1.18. [Veklury - remdesivir - EMEA/H/C/005622/II/0016](#)

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Gilead Sciences Ireland UC

Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová

Scope: “Extension of indication to include treatment of adults with pneumonia not requiring supplemental oxygen (moderate COVID-19), based on Part A of study GS-US-540-5774, a Phase 3, randomized, open-label, multicenter study comparing 2 RDV regimens (5 days and 10 days) versus standard of care in 584 participants with moderate COVID 19, and study CO US 540 5776 [Adaptive COVID-19 Treatment Trial (ACTT) 1, a National Institute of Allergy and Infectious Diseases (NIAID)-sponsored Phase 3, randomized, double blind, placebo controlled, multicenter study]. As a consequence, sections 4.1 and 5.1 of the SmPC

are being updated, and the Package Leaflet is updated in accordance. A revised version 1.2 of the RMP has also been submitted.”

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021, 20.05.2021.

See 2.3

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

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

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

#### **5.1.19. [Xeljanz - tofacitinib - EMEA/H/C/004214/II/0039](#)**

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Pfizer Europe MA EEIG

Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: “Extension of indication to include treatment of active ankylosing spondylitis for Xeljanz prolonged release; 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 18.1 of the RMP has also been submitted.”

**Action:** For adoption

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

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

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

#### **5.4. [Withdrawals of Type II variation; variation of therapeutic indication procedure according to Commission Regulation \(EC\) No 1234/2008](#)**

#### **5.4.1. [Brilique - ticagrelor - EMEA/H/C/001241/II/0049](#)**

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AstraZeneca AB

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC

Rapporteur: Menno van der Elst

Scope: "Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES), a phase III, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic stroke or transient ischaemic attack; 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 13 of the RMP has also been submitted."

**Action:** For adoption

Request for Supplementary Information adopted on 24.06.2021, 28.01.2021, 17.09.2020.

See 2.3

An oral explanation was held on Wednesday 15 December 2021. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the withdrawal of the extension of indication application.

#### 5.4.2. Tookad - padeliporfin - EMEA/H/C/004182/II/0013

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STEBA Biotech S.A

Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maia Uusküla

Scope: "Modification of the wording of the existing indication. The new wording will be the treatment of adult patients with previously untreated, unilateral, low-risk, adenocarcinoma of the prostate with a life expectancy  $\geq$  10 years and clinical stage T1c or T2a, ISUP Grade Group  $\leq$  2, based on high-resolution biopsy strategies, PSA  $\leq$  10 ng/mL, Low core positivity for Tookad; as a consequence, section 4.1 of the SmPC is updated. Version 6.0 of the RMP has also been submitted."

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021, 20.05.2021.

See 2.3

An oral explanation was held on Tuesday 14 December 2021. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the withdrawal of the extension of indication application.

## 6. Ancillary medicinal substances in medical devices

### 6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

No items

## 6.2. Update of Ancillary medicinal substances in medical devices

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. teclistamab - Orphan - H0005865

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Janssen-Cilag International N.V.; indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who previously received  $\geq 3$  prior lines of therapy, including a PI, an IMiD, and an anti-CD38 monoclonal antibody.

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

**Action:** For adoption

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

#### 8.1.2. nirsevimab - H0005304

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Prevention of lower respiratory tract infection caused by respiratory syncytial virus in all infants entering their first RSV season and children with Chronic Lung Disease or Congenital Heart Disease entering their first and second RSV season

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

**Action:** For adoption

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

### 8.2. Priority Medicines (PRIME)

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



### 8.2.1. List of applications received

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**Action:** For information

The CHMP noted the information.

### 8.2.2. Recommendation for PRIME eligibility

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**Action:** For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was accepted, 3 were denied and 1 was withdrawn.

The individual outcomes are listed in the PRIME Monthly Report on the EMA website.

## 9. Post-authorisation issues

### 9.1. Post-authorisation issues

#### 9.1.1. Caprelsa - vandetanib - EMEA/H/C/002315/II/0043

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Genzyme Europe BV

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "C.I.4 Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on interim results from study D4200C00104, listed as a specific obligation in the Annex II. This is an observational study (including a retrospective arm to evaluate the Benefit/Risk of vandetanib (Caprelsa) 300 mg in RET mutation negative and RET mutation positive patients with symptomatic, aggressive, sporadic, unresectable, locally advanced/metastatic thyroid cancer (MTC)), to confirm the efficacy and safety of Caprelsa in RET-negative patients with the aim to fulfil SOB001 and convert Caprelsa from conditional to normal Marketing Authorisation.

In addition, the MAH takes to opportunity to rectify the Dutch translation of the Caprelsa Product Information."

**Action:** For adoption

Request for Supplementary Information adopted on 24.06.2021, 28.05.2020.

The Committee discussed the issues identified in this application, mainly concerning clinical aspects.

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

#### 9.1.2. Cosentyx - secukinumab - EMEA/H/C/003729/II/0076

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Novartis Europharm Limited

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Eva A. Segovia

Scope: "C.I.4 - Update of sections 4.2 and 5.1 of the SmPC in order to introduce a new posology regimen for adult plaque psoriasis patients and psoriatic arthritis patients with concomitant moderate to severe plaque psoriasis based on the final results from study CAIN457A2324 and exposure-response modelling; this is a randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of sub-cutaneous secukinumab in subjects of body weight 90 kg or higher with moderate to severe chronic plaque-type psoriasis; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted."

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021, 24.06.2021.

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. Pemetrexed Lilly – pemetrexed – EMEA/H/C/004114

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Eli Lilly Nederland B.V.; treatment of malignant pleural mesothelioma and non-small cell lung cancer

Rapporteur: Alar Irs

Scope: Expiry of Marketing authorisation due to the application of the sunset clause

**Action:** For information

CHMP noted the expiry of marketing authorisation due to the application of the sunset clause.

### 9.1.4. Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0042

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Moderna Biotech Spain, S.L.,

Rapporteur: Jan Mueller-Berghaus

Scope: "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to include information on heterologous boosting using a 50 ug dose of Spikevax to boost subjects that have previously completed a primary vaccination series with any authorised COVID-19 vaccine, based on data from the DMID study 21-0012, a Phase 1/2 heterologous SARS-CoV-2 vaccine dosing (mRNA-1273 booster) study of the various vaccines authorised in the US under Emergency Use Authorisation in participants  $\geq$  18 years old (NCT04889209). In addition, the MAH took the opportunity to make minor editorial changes/corrections throughout the product information."

**Action:** For adoption

List of question

The Committee discussed the issues identified in this application, mainly relating to clinical

aspects.

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

#### 9.1.5. COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0033

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Janssen-Cilag International N.V.

Rapporteur: Christophe Focke

Scope: "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce an homologous booster dose (second dose) of COVID-19 vaccine Janssen based on interim efficacy, immunogenicity and safety results from different clinical studies including the two randomised, double blind, placebo-controlled Phase 3 studies COV3001 and COV3009. In addition, an update to introduce an heterologous booster dose of COVID-19 vaccine Janssen following completion of a primary vaccination with an approved mRNA COVID-19 vaccine is introduced based on immunogenicity and safety interim results from the phase 1/2 study DMID 21-0012. In addition, the MAH took the opportunity to update the efficacy data for the primary vaccination schedule based on final analysis from study COV3001. The Package Leaflet is updated accordingly."

**Action:** For adoption

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

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

#### 9.1.6. Ledaga - chlormethine – Orphan - EMEA/H/C/002826/II/0027

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Helsinn Birex Pharmaceuticals Limited

Rapporteur: Sinan B. Sarac

Scope: "Update of section 4.2 of the SmPC in order to allow flexibility in the starting frequency of the treatment based on current clinical practice; the Package Leaflet is updated accordingly."

**Action:** For adoption

Request for Supplementary Information adopted on 20.05.2021.

The CHMP noted the update.

#### 9.1.7. Bosulif - bosutinib - EMEA/H/C/002373/II/0050/G

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Pfizer Europe MA EEIG

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to reflect results from the studies B1871039 (SOB) and B1871040 (category 3); study B1871039 is A Phase 4 Safety and Efficacy Study of Bosutinib in Patients With Philadelphia Chromosome Positive

Chronic Myeloid Leukemia Previously Treated With One or More Tyrosine Kinase Inhibitors and study B1871040 is An Open-Label Bosutinib Treatment Extension Study for Subjects With Chronic Myeloid Leukemia (CML) who Have Previously Participated in Bosutinib Studies B1871006 or B1871008. The Package Leaflet is updated accordingly. The MAH requests deletion of the SOB from annex II of the PI and requests consideration for switch of the Conditional Marketing Authorisation to a full Marketing Authorisation. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives for Belgium, Luxemburg, Germany and Northern Island in the Package Leaflet. The MAH is also asking the deletion of the product from the additional monitoring list.”

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021.

The Committee discussed the issues identified in this application, relating to the wording of some SmPC sections.

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

#### 9.1.8. Ravicti - glycerol phenylbutyrate – Orphan – EMEA/H/C/003822/II/0038/G

Immedica Pharma AB

Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Ilaria Baldelli

Scope; “Group of variations consisting of:

- Submission of the final study report, HPN-100-014 non interventional registry study “Long-Term Registry of Patients with Urea Cycle Disorders (UCDs) conducted in the US”.
- An update to the RMP (version 7) submitted to remove the important potential risks of carcinogenicity and PAA toxicity. The update to the RMP is based on the review of new and available data including the study report for HPN-100-014 and a new toxicological expert examination of pre-clinical carcinogenicity findings as well as a cumulative review of literature and post-marketing data. In accordance with the proposed changes to the RMP, an update of Annex II is requested to waive the imposed condition related to the non-interventional post-authorisation safety study (PASS), “European Post-Authorization Registry for RAVICTI (glycerol phenylbutyrate) Oral Liquid in Partnership with the European Registry and Network for Intoxication Type Metabolic Diseases (E-IMD)”. The SmPC and Package Leaflet have been updated to delete the information on additional monitoring (including the black triangle).”

**Action:** For adoption

Request for Supplementary Information adopted on 22.07.2021.

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.

#### 9.1.9. Nuceiva – botulinum toxin type A – EMEA/H/C/004587/IB/0018

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Evolus Pharma Limited

Rapporteur: Peter Kiely

Scope: An extension to the introduction of an in vitro method as replacement for the potency assay of Nuceiva finished product.

**Action:** For adoption

The Committee discussed the IB variation.

The Committee confirmed that the variation is valid and therefore received a favourable opinion.

#### 9.1.10. Vaxzevria – COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0021/G

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AstraZeneca AB

Rapporteur: Sol Ruiz

Scope: Quality variation

**Action:** For adoption

Request for Supplementary Information adopted on 16.09.2021, 24.06.2021, 22.07.2021

The CHMP noted the withdrawal of the application.

#### 9.1.11. Staquis – crisaborole – EMEA/H/C/004863

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Pfizer Europe MA EEIG; treatment of mild to moderate atopic dermatitis

Rapporteur: Andrea Laslop, Co-Rapporteur: Jayne Crowe

Scope: Withdrawal of marketing authorisation

**Action:** For information

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

The CHMP noted the withdrawal of the marketing authorisation.

#### 9.1.12. Nulojix - belatacept - EMEA/H/C/002098

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Bristol-Myers Squibb Pharma EEIG

Rapporteur: Filip Josephson, Co-Rapporteur: Romaldas Mačiulaitis

DHPC

**Action:** For information

The CHMP noted the DHPC which will be circulated for adoption via written procedure after the plenary meeting.

## 10. Referral procedures

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

No items

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

#### 10.2.1. Paxlovid – PF-07321332/ritonavir – EMEA/H/A-5(3)/1513

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Pfizer Europe MA EEIG; Treatment for adult patients with symptomatic COVID-19

Rapporteur: Jean-Michel Race, Co-Rapporteur: Fatima Ventura

Scope: Appointment of rapporteurs, list of questions and timetable

**Action:** For adoption

Request for CHMP opinion under Article 5(3) of Regulation (EC) No 726/2004 on potential use of PF-07321332/ritonavir for the treatment of COVID-19 in adult patients

At an extraordinary CHMP meeting on 19 November 2021, the CHMP discussed this referral.

On 19 November 2021, the CHMP appointed Jean-Michel Race as referral Rapporteur and Fatima Ventura as referral Co-Rapporteur.

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

Notification: 19.11.2021

Start of the procedure (CHMP ): 19.11.2021

CHMP list of questions: 19.11.2021

Submission of responses: 23.11.2021

Re-start of the procedure: 24.11.021

Rapporteur and co-rapporteur assessment reports circulated to CHMP and PRAC: 07.12.2021

CHMP and PRAC members' comments: 08.12.2021

ETF discussion: 10.12.2021

Joint Rapporteur/co-rapporteur assessment report circulated to CHMP and PRAC: 10.12.2021

CHMP opinion: December 2021 CHMP

#### 10.2.2. Paxlovid – PF-07321332/ritonavir – EMEA/H/A-5(3)/1513

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Pfizer Europe MA EEIG; Treatment for adult patients with symptomatic COVID-19

Rapporteur: Jean-Michel Race, Co-Rapporteur: Fatima Ventura

Scope: Opinion

**Action:** For adoption

Request for CHMP opinion under Article 5(3) of Regulation (EC) No 726/2004 on potential use of PF-07321332 for the treatment of COVID-19 in adult patients.

The CHMP adopted a positive opinion by consensus, recommending that Paxlovid can be used for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19.

The CHMP press release was circulated for information.

### **10.2.3. Lagevrio – molnupiravir – EMEA/H/A-5(3)/1512**

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Merck Sharp & Dohme B.V.; Treatment of coronavirus disease 2019 (COVID-19)

Scope: Opinion

**Action:** For adoption

Request for CHMP opinion under Article 5(3) of Regulation (EC) No 726/2004 on potential use of molnupiravir for the treatment of COVID-19 in adult patients

At an extraordinary CHMP meeting on 19 November 2021, the CHMP discussed this referral.

On 19 November 2021, the Committee adopted a positive opinion by consensus, recommending that molnupiravir can be used for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

The CHMP press release was circulated for information.

See also 3.3 for the initial marketing authorisation application.

### **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**

### **10.7.1. Lidocain/ Prilocain IDETEC – lidocaine, prilocaine - EMEA/H/A-29(4)/1506**

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International Drug Development France

Re-examination Referral Rapporteur: Ewa Balkwicz Iskra, Re-examination Co-Rapporteur: Janet Koenig

Scope: Proposal to involve QWP; List of questions to QWP

**Action:** For adoption

The CHMP agreed to involve the QWP and adopted a list of questions to this expert group.

## **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**

December 2021 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

**Action:** For information



The CHMP noted the document.

## **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

No items

### 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 December 2021

**Action:** For adoption

The CHMP adopted the EURD list.

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

#### 14.3.1. Biologics Working Party (BWP)

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Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP December 2021 meeting to CHMP for adoption:

- 19 reports on products in scientific advice and protocol assistance
- 10 reports on products in pre-authorisation procedures
- 1 report on products in post-authorisation procedures
- 2 reports 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 09-10 November 2021.

**Action:** For adoption

The CHMP adopted the table of decisions.

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

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Chair: Anja Schiel

Report from the SAWP meeting held on 29 November - 02 December 2021. Table of

conclusions

**Action:** For information

The CHMP noted the report.

Scientific advice letters:

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

#### 14.3.4. Election of new Scientific Advice Working Party (SAWP) Chair

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Election of new SAWP chair. The mandate of Scientific Advice Working Party Chair Anja Schiel will expire on 28 February 2022.

**Action:** For election

Nomination(s) received

The CHMP elected Paolo Foggi as SAWP Chair. The mandate starting date is 01 March 2022.

#### 14.3.5. Election of new Safety Working Party (SWP) vice-chair

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Susanne Brendler-Schwaab (DE) left her position as SWP vice-chair to undertake the SWP chair position following election at the October 2021 CHMP meeting.

**Action:** For election

Nomination(s) received

The CHMP elected Günter Waxenecker (AT) as SWP vice-chair.

#### 14.3.6. Appointment of the chair and vice-chair of the Cardiovascular Scientific Advice Group

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Formal appointment of the chair and vice-chair of the SAG Cardiovascular following the elections.

**Action:** For endorsement

The CHMP endorsed the appointment of Franz Kleber as SAG-Cardiovascular chair and Jan Staessen as SAG-Cardiovascular vice-chair.

#### 14.3.7. ITF meeting

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Meeting date: 10 December 2021

**Action:** For adoption

CHMP endorsed the meeting.

#### 14.3.8. ITF meeting

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Meeting date: 15 December 2021

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**Action:** For adoption

CHMP endorsed the meeting.

#### **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**

##### **14.7.1. CHMP Work Plan 2022**

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Adoption of the CHMP Work Plan for 2022.

**Action:** For adoption

The CHMP adopted the CHMP Work Plan for 2022.

#### **14.8. Planning and reporting**

No items

#### **14.9. Others**

No items

### **15. Any other business**

#### **15.1. AOB topic**

##### **15.1.1. Update on COVID-19**

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**Action:** For information

The CHMP noted the information.

### 15.1.2. Pregnancy labelling for COVID-19 vaccines

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**Action:** For discussion

The CHMP discussed the pregnancy labelling for COVID-19 vaccines.

### 15.1.3. Revised procedural guidance for COVID-19 variation for variant

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**Action:** For adoption

The CHMP adopted the revised procedural guidance document.

## Lists of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 13-16 December 2021 CHMP meeting.

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	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Ilko Getov	Member	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	
Emilia Mavrokordatou	Alternate	Cyprus	No participation in final deliberations and voting on	COVID-19 vaccines
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Thalia Marie Estrup Blicher	Alternate	Denmark	No restrictions applicable to this meeting	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anastasia Mountaki	Alternate	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Peter Kiely	Alternate	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on	COVID-19 vaccines
Silvijus Abramavicius	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffer	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	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
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No interests declared	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No interests declared	
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	
Brigitte Mueller	Expert - via WebEx*	Austria	No interests declared	
Harald Bernsteiner	Expert - via WebEx*	Austria	No interests declared	
Elisabeth Wischnitzki	Expert - via WebEx*	Austria	No interests declared	
Vincent Gazin	Expert - via WebEx*	France	No interests declared	
Roxane Fornacciari	Expert - via WebEx*	France	No interests declared	
Melanie Leplay	Expert - via WebEx*	France	No interests declared	
Elisabeth Fuerst	Expert - via WebEx*	Austria	No interests declared	
Martin Walter	Expert - via WebEx*	Austria	No interests declared	
Mirjam Hinterleitner	Expert - via WebEx*	Austria	No interests declared	
Ieva Rutkovska	Expert - via WebEx*	Latvia	No interests declared	
Dace Peiseniece	Expert - via WebEx*	Latvia	No interests declared	
Ilze Kalve	Expert - via WebEx*	Latvia	No interests declared	
Vita Gulevska	Expert - via WebEx*	Latvia	No interests declared	
Iveta Eglite	Expert - via WebEx*	Latvia	No interests declared	
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	



Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Carolina Prieto Fernandez	Expert - via WebEx*	Spain	No interests declared	
Marcos Timón	Expert - via WebEx*	Spain	No interests declared	
C. Susana Rojo	Expert - via WebEx*	Spain	No interests declared	
Mair Powell	Expert - via WebEx*	Ireland	No interests declared	
Finbarr Leacy	Expert - via WebEx*	Ireland	No interests declared	
Eadaoin Griffin	Expert - via WebEx*	Ireland	No interests declared	
Orla Moriarty	Expert - via WebEx*	Ireland	No interests declared	
Caoimhin Concannon	Expert - via WebEx*	Ireland	No interests declared	
Eanna Forde	Expert - via WebEx*	Ireland	No interests declared	
Nicolas Lee	Expert - via WebEx*	Ireland	No restrictions applicable to this meeting	
Paolo Foggi	Expert - via WebEx*	Italy	No interests declared	
Adriana Ammassari	Expert - via WebEx*	Italy	No interests declared	
Sara Galluzzo	Expert - via WebEx*	Italy	No interests declared	
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Cristina Migali	Expert - via WebEx*	Italy	No interests declared	
Maria Grazia Evandri	Expert - via WebEx*	Italy	No interests declared	
Valentina Conti	Expert - via WebEx*	Italy	No interests declared	
Antonella Isgrò	Expert - via WebEx*	Italy	No interests declared	
Gabriella Passacquale	Expert - via WebEx*	Italy	No interests declared	
Edwige Haelterman Brenneisen	Expert - via WebEx*	Belgium	No interests declared	
Violette Dirix	Expert - via WebEx*	Belgium	No interests declared	
Inne Crèvecoeur	Expert - via WebEx*	Belgium	No participation in discussion, final deliberations and voting on:	gefapixant - EMEA/H/C/005476  gefapixant - EMEA/H/C/005884  molnupiravir – EMEA/H/C/005789 EMEA/H/A-5(3)/1512

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				Keytruda - pembrolizumab - EMEA/H/C/003820/I/0108
Toms Lams	Expert - via WebEx*	Belgium	No interests declared	
Ingrid Bourges	Expert - via WebEx*	Belgium	No interests declared	
Valerie Lescrainier	Expert - via WebEx*	Belgium	No interests declared	
Olga Kholmanskikh	Expert - via WebEx*	Belgium	No interests declared	
Trine Jensen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Lene Weber Vestermark	Expert - via WebEx*	Denmark	No interests declared	
Meera Varma	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Aaron Sosa Mejia	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Mette Linnert Jensen	Expert - via WebEx*	Denmark	No interests declared	
Doris Hovgaard	Expert - via WebEx*	Denmark	No interests declared	
Nanna Borup Johansen	Expert - via WebEx*	Denmark	No interests declared	
Bibi Fatima Syed Shah	Expert - via WebEx*	Denmark	No interests declared	
Ebru Karakoc Madsen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Deidre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Sine Buhl Naess-Schmidt	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Kristina Bech Jensen	Expert - via WebEx*	Denmark	No interests declared	
Theis Moeslund Jensen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Emilie Birch Kristensen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Mette Tranholm	Expert - via WebEx*	Denmark	No interests declared	
Susanne Høpner Rasmussen	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Paul Brown	Expert - via WebEx*	Denmark	No interests declared	
Anne-Marie Dalseg	Expert - via WebEx*	Denmark	No interests declared	
Rosemary Maher	Expert - via WebEx*	Ireland	No restrictions applicable to this meeting	
Andreja Kranjc	Expert - via WebEx*	Slovenia	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lucija Fasalek	Expert - via WebEx*	Slovenia	No interests declared	
Carlos Alves	Expert - via WebEx*	Portugal	No interests declared	
Nuno Rocha-Pereira	Expert - via WebEx*	Portugal	No restrictions applicable to this meeting	
Claudia Afonso	Expert - via WebEx*	Portugal	No restrictions applicable to this meeting	
Nuno Sousa	Expert - via WebEx*	Portugal	No part in discussions, final deliberations and voting	ciltacabtagene autoleucl - EMEA/H/C/005095  teclistamab - H0005865  COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - II/0033  Keytruda - pembrolizumab - II/0108  Padcev - enfortumab vedotin - EMEA/H/C/005392
Monika Posega	Expert - via WebEx*	Slovenia	No interests declared	
Maja Sommerfelt Grønvold	Expert - via WebEx*	Norway	No interests declared	
Claus Stage	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Antero Kallio	Expert - via WebEx*	Finland	No restrictions applicable to this meeting	
Elina Asikanius	Expert - via WebEx*	Finland	No restrictions applicable to this meeting	
Taina Methuen	Expert - via WebEx*	Finland	No interests declared	
Kairi Rooma	Expert - via WebEx*	Estonia	No interests declared	
Susanne Mueller-Egert	Expert - via WebEx*	Germany	No interests declared	
Hilke Zander	Expert - via WebEx*	Germany	No interests declared	
Bettina Kartmann	Expert - via WebEx*	Germany	No interests declared	
Annette Lommel	Expert - via WebEx*	Germany	No interests declared	
Mona Kassem-Youssef	Expert - via WebEx*	France	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sophie Teng	Expert - via WebEx*	France	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Irene Bachmann	Expert - via WebEx*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Ulla Wändel Liminga	Expert - via WebEx*	Sweden	No interests declared	
Elly Vereyken	Expert - via WebEx*	Netherlands	No restrictions applicable to this meeting	
Michel Kooijman	Expert - via WebEx*	Netherlands	No interests declared	
Steven Teerenstra	Expert - via WebEx*	Netherlands	No interests declared	
Johannes Petrus Theodorus Span	Expert - via WebEx*	Netherlands	No interests declared	
Nienke Rodenhuis	Expert - via WebEx*	Netherlands	No interests declared	
Tom Meyerson Goldschmidt	Expert - via WebEx*	Sweden	No restrictions applicable to this meeting	
Johanna Henriksnäs	Expert - via WebEx*	Sweden	No interests declared	
Camilla Svensson	Expert - via WebEx*	Sweden	No interests declared	
Hinke Hohanna Van der Woude	Expert - via WebEx*	Netherlands	No interests declared	
Adrianus Van Gompel	Expert - via WebEx*	Netherlands	No interests declared	
Joep Bergers	Expert - via WebEx*	Netherlands	No interests declared	
Marjolinj Schalk	Expert - via WebEx*	Netherlands	No interests declared	
Antonius Johannes van der Stappen	Expert - via WebEx*	Netherlands	No interests declared	
Jan Willem van der Laan	Expert - via WebEx*	Netherlands	No interests declared	
Eleonora Wijnans	Expert - via WebEx*	Netherlands	No interests declared	
Ingrid Schellens	Expert - via WebEx*	Netherlands	No interests declared	
Jacoba (Jacqueline) van Kuijk	Expert - via WebEx*	Netherlands	No interests declared	
Katrien Oude Rengerink	Expert - via WebEx*	Netherlands	No participation in discussion, final deliberations and voting on:	gefapixant - EMEA/H/C/005476 gefapixant - EMEA/H/C/005884 molnupiravir – EMEA/H/C/005789

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				EMA/H/A-5(3)/1512  Keytruda - pembrolizumab - II/0108  Tepmetko - tepotinib - EMA/H/C/005524
Angela de Kleynen	Expert - via WebEx*	Netherlands	No interests declared	
Marianne Kuijpers	Expert - via WebEx*	Netherlands	No interests declared	
Patrick Vrijlandt	Expert - via WebEx*	Netherlands	No interests declared	
Louise Claessen	Expert - via WebEx*	Netherlands	No interests declared	
Frank Holtkamp	Expert - via WebEx*	Netherlands	No interests declared	
Hester Peltenburg	Expert - via WebEx*	Netherlands	No interests declared	
Jana Klimasová	Expert - via WebEx*	Slovakia	No restrictions applicable to this meeting	
Peter Sisovsky	Expert - via WebEx*	Slovakia	No interests declared	
Eva Malikova	Expert - via WebEx*	Slovakia	No interests declared	
Anna Kubandová	Expert - via WebEx*	Slovakia	No interests declared	
Jana Schweigertova	Expert - via WebEx*	Slovakia	No interests declared	
Martina Schuessler-Lenz	Expert - via WebEx*	Germany	No interests declared	
Sarah Gilgunn	Expert - via WebEx*	Ireland	No interests declared	
Heidi Meyer	Expert - via WebEx*	Germany	No interests declared	
Andrea Röhmer	Expert - via WebEx*	Germany	No interests declared	
Michal Zwiewka	Expert - via WebEx*	Germany	No interests declared	
Benjamin Hofner	Expert - via WebEx*	Germany	No restrictions applicable to this meeting	
Koenraad Norga	Expert - via WebEx*	Belgium	No restrictions applicable to this meeting	
Stephanie Buchholz	Expert - via WebEx*	Germany	No interests declared	
Petra Vackova	Expert - via WebEx*	Czechia	No interests declared	
Larissa Higgins	Expert - via WebEx*	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Viktoria Starokozhko	Expert - via WebEx*	Netherlands	No restrictions applicable to this meeting	
Saskia Bergervoet	Expert - via WebEx*	Netherlands	No interests declared	
Elisabeth Penninga	Expert - via WebEx*	Denmark	No interests declared	
Anja Schiel	Expert - via WebEx*	Norway	No interests declared	
Zoltan Szekanecz	Expert - via Telephone*	Hungary	No restrictions applicable to this meeting	
Lothar Bergmann	Expert - via Telephone*	Germany	No restrictions applicable to this meeting	
Filip Kukulski	Expert - via WebEx*	Health Canada	No interests declared	
Evelyn Soo	Expert - via WebEx*	Health Canada	No interests declared	
Charlotte Geluk	Expert - via WebEx*	Swissmedic	No interests declared	
Mohit Khera	Expert - via WebEx*	TGA Australia	No interests declared	
Ting Lu	Expert - via WebEx*	TGA Australia	No interests declared	
Nitin Bagul	Expert - via WebEx*	TGA Australia	No interests declared	
Christine Haenggeli	Expert - via WebEx*	Swissmedic	No interests declared	
Deepak Rai	Expert - via WebEx*	TGA Australia	No interests declared	
Rolando Barbaro Dominguez Morales	Expert - via WebEx*	WHO	No interests declared	
Meeting run with the help of EMA staff				

\*Experts were evaluated against the product(s) they have been invited to talk about.

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the extraordinary CHMP meetings held 19, 25 November and 06, 20 December 2021.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Harald Enzmann	Chair	Germany	No interests declared		X	X	X	X
Andrea Laslop	Member	Austria	No interests declared		X	X	X	X
Daniela Philadelphly	Alternate	Austria	No interests declared		X	X	X	X
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting		X	X	X	X
Karin Janssen van Doorn	Alternate	Belgium	No interests declared				X	
Ilko Getov	Member	Bulgaria	No interests declared		X	X	X	
Margareta Bego	Member	Croatia	No interests declared		X	X	X	X
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared		X		X	
Helena Panayiotopoulou	Member	Cyprus	No interests declared		X	X	X	X
Emilia Mavrokordatou	Alternate	Cyprus	No participation in final deliberations and voting on	Covid-19 vaccines		X		
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting		X	X		X
Tomas Radimersky	Alternate	Czechia	No interests declared		X	X	X	X
Sinan B. Sarac	Member	Denmark	No interests declared		X		X	
Thalia Marie Estrup Blicher	Alternate	Denmark	No restrictions applicable to this meeting			X	X	X
Alar Irs	Member	Estonia	No restrictions applicable to this meeting		X		X	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting		X		X	X
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting		X	X	X	
Johanna Lähteenvuo	Alternate	Finland	No interests declared			X		
Alexandre Moreau	Member	France	No interests declared		X			
Jean-Michel Race	Alternate	France	No interests declared		X	X	X	X
Martina Weise	Member	Germany	No restrictions applicable to this meeting		X	X	X	
Janet Koenig	Alternate	Germany	No interests declared		X	X	X	X

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Anastasia Mountaki	Alternate	Greece	No interests declared		X	X	X	
Agnes Gyurasics	Alternate	Hungary	No interests declared		X	X	X	X
Hrefna Gudmundsdottir	Member	Iceland	No interests declared			X	X	
Jan Sjöberg	Alternate	Iceland	No interests declared		X	X	X	
Jayne Crowe	Member	Ireland	No interests declared		X	X	X	X
Peter Kiely	Alternate	Ireland	No interests declared		X			
Armando Genazzani	Member	Italy	No interests declared		X	X	X	
Elita Poplavska	Member	Latvia	No interests declared		X	X	X	X
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on	COVID-19 vaccines			X	
Martine Trauffler	Member	Luxembourg	No interests declared		X	X	X	X
John Joseph Borg	Member	Malta	No interests declared		X	X	X	X
Johann Lodewijk Hillege	Member	Netherlands	No interests declared		X	X	X	X
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared		X	X	X	
Ingrid Wang	Alternate	Norway	No interests declared		X	X	X	X
Eva Skovlund	Alternate	Norway	No interests declared					X
Ewa Balkowiec Iskra	Member	Poland	No interests declared		X	X	X	X
Grzegorz Cessak	Alternate	Poland	No restrictions applicable to this meeting		X	X	X	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared		X	X	X	X
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting		X	X	X	X
Simona Badoi	Member	Romania	No interests declared		X	X	X	
Dana Gabriela Marin	Alternate	Romania	No interests declared		X	X	X	X
Francisek Drafi	Member	Slovakia	No interests declared		X	X		X
Dorota Distlerova	Alternate	Slovakia	No interests declared		X		X	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared		X	X	X	X
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting				X	



Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared		X	X	X	X
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared		X	X	X	X
Kristina Dunder	Member	Sweden	No interests declared		X	X	X	X
Filip Josephson	Alternate	Sweden	No interests declared		X	X		
Christian Gartner	Co-opted member	Austria	No interests declared		X	X	X	X
Carla Torre	Co-opted member	Portugal	No interests declared		X	X	X	X
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared		X	X		X
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared		X	X	X	X
Sol Ruiz	Co-opted member	Spain	No interests declared		X	X		X
Brigitte Mueller	Expert - via WebEx*	Austria	No interests declared			X		
Andreas Kirisits	Expert - via WebEx*	Austria	No interests declared			X		
Harald Bernsteiner	Expert - via WebEx*	Austria	No interests declared			X		
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared			X	X	X
Katalina Mettke	Expert - via WebEx*	Germany	No interests declared				X	
Hilke Zander	Expert - via WebEx*	Germany	No interests declared				X	
Irene Bachmann	Expert - via WebEx*	Germany	No interests declared			X		X
Nicolas Lee	Expert - via WebEx*	Ireland	No restrictions applicable to this meeting		X			
Eanna Forde	Expert - via WebEx*	Ireland	No interests declared		X			
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared		X		X	X
Michal Zwiewka	Expert - via WebEx*	Germany	No interests declared				X	
Lukas Malte Aguirre Davila	Expert - via WebEx*	Germany	No interests declared				X	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Katharina Hees	Expert - via WebEx*	Germany	No interests declared				X	
Elena Wolff-Holz	Expert - via WebEx*	Germany	No interests declared				X	
Jacqueline Kerr	Expert - via WebEx*	Germany	No interests declared				X	
Steffen Gross	Expert - via WebEx*	Germany	No interests declared				X	
Martina Schuessler-Lenz	Expert - via WebEx*	Germany	No interests declared				X	
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting			X		X
Svein Rune Andersen	Expert - via WebEx*	Norway	No interests declared			X		X
Greger Abrahamsen	Expert - via WebEx*	Norway	No interests declared					X
Celine Chartier	Expert - via WebEx*	France	No interests declared			X		
Vincent Gazin	Expert - via WebEx*	France	No interests declared			X	X	
Nils Lilienthal	Expert - via WebEx*	Germany	No interests declared		X			
Luisa Valer	Expert - via WebEx*	Spain	No interests declared		X			
Lourdes Rodriguez Rojas	Expert - via WebEx*	Spain	No interests declared		X			
Cristina Lucia Rueda Pérez	Expert - via WebEx*	Spain	No restrictions applicable to this meeting		X			
Alicia Pérez González	Expert - via WebEx*	Spain	No interests declared			X		X
Ana Sagredo	Expert - via WebEx*	Spain	No interests declared			X		
Lorena Soledad Ver	Expert - via WebEx*	Spain	No interests declared			X		
Paula Contreras Alarcón	Expert - via WebEx*	Spain	No restrictions applicable to this meeting		X	X		X
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting		X	X		X

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Alfredo García-Arieta	Expert - via WebEx*	Spain	No interests declared				X	
Maria Jesus Fernández Cortizo	Expert - via WebEx*	Spain	No interests declared				X	
Matea Cartolano	Expert - via WebEx*	Germany	No interests declared			X		X
Ulrike Heissenberger	Expert - via WebEx*	Austria	No interests declared			X		
Jana Klimasová	Expert - via WebEx*	Slovakia	No restrictions applicable to this meeting			X		X
Eleonora Wijnans	Expert - via WebEx*	Netherlands	No interests declared			X		X
Ingrid Schellens	Expert - via WebEx*	Netherlands	No interests declared					X
Jacoba (Jacqueline) van Kuijk	Expert - via WebEx*	Netherlands	No interests declared					X
Katrien Oude Rengerink	Expert - via WebEx*	Netherlands	No restrictions applicable to this meeting					X
Marianne Kuijpers	Expert - via WebEx*	Netherlands	No interests declared					X
Marjilijn Schalk	Expert - via WebEx*	Netherlands	No interests declared					X
Angela de Kleynen	Expert - via WebEx*	Netherlands	No interests declared					X
Caoimhin Concannon	Expert - via WebEx*	Ireland	No interests declared		X			
Eadaoin Griffin	Expert - via WebEx*	Ireland	No interests declared		X			
Orla Moriarty	Expert - via WebEx*	Ireland	No interests declared		X			
Rosemary Maher	Expert - via WebEx*	Ireland	No restrictions applicable to this meeting		X			
Mair Powell	Expert - via WebEx*	Ireland	No interests declared		X			
Monica Beteta Robles	Expert - via WebEx*	Spain	No interests declared		X			
Monika Trojan	Expert - via WebEx*	Poland	No interests declared		X			

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Helve Vestman	Expert - via WebEx*	Estonia	No interests declared		X			
Adriana Ammassari	Expert - via WebEx*	Italy	No interests declared		X	X	X	X
Sarah Galluzzo	Expert - via WebEx*	Italy	No interests declared		X		X	X
Maria Grazia Evandri	Expert - via WebEx*	Italy	No interests declared			X	X	X
Paolo Foggi	Expert - via WebEx*	Italy	No interests declared				X	
Kim Sherwood	Expert - via WebEx*	Sweden	No interests declared			X		
Helena Back	Expert - via WebEx*	Sweden	No interests declared			X		
Helena Faust	Expert - via WebEx*	Sweden	No interests declared			X		
Charlotta Bergquist	Expert - via WebEx*	Sweden	No interests declared			X		X
Ulla Wändel Liminga	Expert - via WebEx*	Sweden	No interests declared					X
Carolien Versantvoort	Expert - via WebEx*	Netherlands	No interests declared				X	
Anja Schiel	Expert - via WebEx*	Norway	No interests declared				X	
Martin Oleksiewicz	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting					X
Susanne Havn Aamand	Expert - via WebEx*	Denmark	No interests declared					X
Nanna Aaby Kruse	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting					X
Jukka Sallinen	Expert - via WebEx*	Finland	No interests declared					X
Nitin Bagul	Expert - via WebEx*	TGA Australia	No interests declared			X		
Deepak Rai	Expert - via WebEx*	TGA Australia	No interests declared			X		X
Megan Hickie	Expert - via WebEx*	TGA Australia	No interests declared			X		

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Filip Kukulski	Expert - via WebEx*	Health Canada	No interests declared		X			
Violetta Skalski	Expert - via WebEx*	Health Canada	No interests declared		X			
Evelyn Soo	Expert - via WebEx*	Health Canada	No interests declared		X			
Dean Smith	Expert - via WebEx*	Health Canada	No interests declared					X
Christine Haenggeli	Expert - via WebEx*	Swissmedic	No interests declared		X			X
Charlotte Geluk	Expert - via WebEx*	Swissmedic	No interests declared		X		X	
Julia Djonova	Expert - via WebEx*	Swissmedic	No interests declared			X		
Mohit Khera	Expert - via WebEx*	TGA Australia	No interests declared		X			X
Sabine Straus	Expert - via WebEx*	Netherlands	No interests declared		X			
Jean-Michel Dogné	Expert - via WebEx*	Belgium	No interests declared		X			
Kirsti Villikka	Expert - via WebEx*	Finland	No interests declared		X			
Sophia Trantza	Expert - via WebEx*	Greece	No interests declared		X			
Ronan Grimes	Expert - via WebEx*	Ireland	No interests declared		X			
Amelia Cupelli	Expert - via WebEx*	Italy	No interests declared		X	X		
Anne-Cécile Vuillemin	Expert - via WebEx*	Luxembourg	No interests declared		X			
Menno van der Elst	Expert - via WebEx*	Netherlands	No interests declared		X			
David Olsen	Expert - via WebEx*	Norway	No restrictions applicable to this meeting		X			
Karen Pernille Harg	Expert - via WebEx*	Norway	No interests declared		X			
Adam Przybylkowski	Expert - via WebEx*	Poland	No interests declared		X			

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply	19.11.2021	25.11.2021	06.12.2021	20.12.2021
Alexandra - Maria Spurni	Expert - via WebEx*	Romania	No interests declared		X			
Maria del Pilar Rayon	Expert - via WebEx*	Spain	No interests declared		X			
Milou Daniel Drici	Expert - via WebEx*	Independent scientific expert	No restrictions applicable to this meeting		X			
Patricia McGettigan	Expert - via WebEx*	Independent scientific expert	No interests declared		X			
Roberto Frontini	Expert - via WebEx*	Healthcare Professionals Representative	No restrictions applicable to this meeting		X			
Meeting run with the help of EMA staff								

\*Experts were evaluated against the product(s) they have been invited to talk about.

## 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 February 2022  
EMA/CHMP/753516/2021

## Annex to 13-16 December 2021 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 December 2021: <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 December 2021: <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>Brineura - cerliponase alfa - EMEA/H/C/004065/S/0035, Orphan</b> BioMarin International Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Ulla Wändel Liminga	Positive Opinion adopted by consensus together with the CHMP assessment report.  The Marketing Authorisation remains under exceptional circumstances.
<b>Increlex - mecasecsermin - EMEA/H/C/000704/S/0070</b> Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka	Positive Opinion adopted by consensus together with the CHMP assessment report.  The Marketing Authorisation remains under exceptional circumstances.
<b>Lojuxta - lomitapide - EMEA/H/C/002578/S/0048</b> Amryt Pharmaceuticals DAC, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 16.12.2021.	Request for supplementary information adopted with a specific timetable.
<b>Strensiq - asfotase alfa - EMEA/H/C/003794/S/0056, Orphan</b> Alexion Europe SAS, Rapporteur: Armando Genazzani, PRAC Rapporteur: Rhea Fitzgerald	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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**Xeljanz - tofacitinib -****EMA/H/C/004214/R/0040**

Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan  
Request for Supplementary Information adopted on 14.10.2021.

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 an additional five-year renewal was required.

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

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**Axumin - fluciclovine (18f) -****EMA/H/C/004197/R/0027**

Blue Earth Diagnostics Ireland Limited, Rapporteur: Janet Koenig, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Rugile Pilviniene

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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**BESPONSA - inotuzumab ozogamicin -****EMA/H/C/004119/R/0023, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, Co-Rapporteur: Konstantina Alexopoulou, PRAC Rapporteur: Brigitte Keller-Stanislawski

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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**Deltyba - delamanid -****EMA/H/C/002552/R/0052, Orphan**

Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Laurence de Fays  
Request for Supplementary Information adopted on 16.12.2021.

Request for supplementary information adopted with a specific timetable.

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**Febuxostat Mylan - febuxostat -****EMA/H/C/004374/R/0011**

Mylan Pharmaceuticals Limited, Generic, Generic of Adenuric, Rapporteur: Elita Poplavska, 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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**Ivabradine Accord - ivabradine -****EMA/H/C/004241/R/0010**

Accord Healthcare S.L.U., Generic, Generic of Procoralan, Rapporteur: Konstantina

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

Based on the review of the available

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Alexopoulou, PRAC Rapporteur: Menno van der Elst	information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
<b>Kalydeco - ivacaftor - EMEA/H/C/002494/R/0106, Orphan</b> Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Maria del Pilar Rayon Request for Supplementary Information adopted on 16.12.2021.	Request for supplementary information adopted with a specific timetable.
<b>Kevzara - sarilumab - EMEA/H/C/004254/R/0029</b> sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Eva A. Segovia Request for Supplementary Information adopted on 16.12.2021.	Request for supplementary information adopted with a specific timetable.
<b>Refixia - nonacog beta pegol - EMEA/H/C/004178/R/0025</b> Novo Nordisk A/S, Rapporteur: Andrea Laslop, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 11.11.2021.	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.
<b>Rixathon - rituximab - EMEA/H/C/003903/R/0053</b> Sandoz GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Anette Kirstine Stark	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.
<b>Riximyo - rituximab - EMEA/H/C/004729/R/0054</b> Sandoz GmbH, Duplicate, Duplicate of Rixathon, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Anette Kirstine Stark	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.
<b>Skilarence - dimethyl fumarate - EMEA/H/C/002157/R/0030</b> Almirall S.A, Rapporteur: Janet Koenig, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 11.11.2021.	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.
<b>Spherox - spheroids of human autologous</b>	Request for supplementary information adopted

<p><b>matrix-associated chondrocytes - EMEA/H/C/002736/R/0024, ATMP</b> CO.DON AG, Rapporteur: Lisbeth Barkholt, Co-Rapporteur: Heli Suila, CHMP Coordinators: Kristina Dunder and Outi Mäki-Ikola, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 10.12.2021.</p>	<p>with a specific timetable.</p>
<p><b>Trimbow - beclometasone / formoterol / glycopyrronium bromide - EMEA/H/C/004257/R/0025</b> Chiesi Farmaceutici S.p.A., Rapporteur: Janet Koenig, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Veltassa - patiomer - EMEA/H/C/004180/R/0028</b> Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Jayne Crowe, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Kirsti Villikka Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Zykadia - ceritinib - EMEA/H/C/003819/R/0042</b> Novartis Europharm Limited, Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Annika Folin</p>	<p>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.</p>
<p><b>B.2.3. Renewals of Conditional Marketing Authorisations</b></p>	
<p><b>Bosulif - bosutinib - EMEA/H/C/002373/R/0051</b> Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/R/0023</b> Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can</p>

Wandel Liminga	<p>be granted.</p> <p>The Marketing Authorisation remains conditional.</p>
<p><b>JEMPERLI - dostarlimab - EMEA/H/C/005204/R/0004</b>  GlaxoSmithKline (Ireland) Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>
<p><b>Natpar - parathyroid hormone - EMEA/H/C/003861/R/0034, Orphan</b>  Takeda Pharmaceuticals International AG, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Rhea Fitzgerald  Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Pemazyre - pemigatinib - EMEA/H/C/005266/R/0003, Orphan</b>  Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Menno van der Elst</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>
<p><b>WAYLIVRA - volanesorsen - EMEA/H/C/004538/R/0016, Orphan</b>  Akcea Therapeutics Ireland Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber</p>	<p>Positive Opinion adopted by consensus together with the CHMP assessment report.</p> <p>The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted.</p> <p>The Marketing Authorisation remains conditional.</p>

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

#### Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 29 November – 02 December 2021 PRAC:



<p><b>Signal of Myocarditis and pericarditis</b></p> <p>Comirnaty - COVID-19 mRNA vaccine (nucleoside-modified)</p> <p>Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst</p> <p>PRAC recommendation on a variation adopted via written procedure on 03.12.2021.</p> <p><b>Action:</b> For information</p>	Noted
<p><b>Signal of Myocarditis and pericarditis</b></p> <p>Spikevax - COVID-19 mRNA vaccine (nucleoside-modified)</p> <p>Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Hans Christian Siersted</p> <p>PRAC recommendation on a variation adopted via written procedure on 03.12.2021.</p> <p><b>Action:</b> For information</p>	Noted
<p>PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its December 2021 meeting:</p>	
<p><b>Fexinidazole Winthrop - fexinidazole - EMEA/H/W/002320/PSUV/0008 (without RMP)</b></p> <p>sanofi-aventis groupe, Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Gross-Martirosyan, "16-Nov-2020 to 15-May-2021"</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, concerning the following change:</p> <p>Update of sections 4.4 and 4.8 of the SmPC to include 'suicidal ideation'. Sections 2 and 4 of the PL are updated accordingly.</p> <p>RMP version 2.1 was approved with this variation.</p>
<p><b>EMEA/H/C/PSUSA/0000226/202105</b> (apixaban)</p> <p>CAPS:</p> <p><b>Eliquis</b> (EMEA/H/C/002148) (apixaban), Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, "17/05/2020 To: 17/05/2021"</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):</p> <p>Update of section 4.8 the SmPC to add "cutaneous vasculitis" with a frequency "not known" for each indication. The Package leaflet is updated accordingly. In addition, the</p>

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marketing authorisation holder took the opportunity to implement minor editorial changes in sections 4.4, 5.1 and 5.2 of the SmPC.

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**EMA/H/C/PSUSA/0001267/202104**

(eslicarbazepine acetate)

CAPS:

**Zebinix** (EMA/H/C/000988) (eslicarbazepine acetate), Bial - Portela & C<sup>a</sup>, S.A., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "22/10/2018 To: 21/04/2021"

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, concerning the following change(s):

Update of section 4.8 of the SmPC to add SIADH-like syndrome. The Package leaflet is updated accordingly.

Update of section 4.8 of the SmPC to replace 'transaminases increased' by the broader term 'hepatic enzymes increased'. The Package leaflet is updated accordingly.

Update of section 4.6 of the SmPC to add warnings and recommendations on use during pregnancy and in women of childbearing potential. The Package leaflet is updated accordingly.

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**EMA/H/C/PSUSA/0002839/202103**

(tacrolimus (systemic formulations))

CAPS:

**Advagraf** (EMA/H/C/000712) (tacrolimus), Astellas Pharma Europe B.V., Rapporteur: Jayne Crowe

**Envarsus** (EMA/H/C/002655) (tacrolimus), Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg

**Modigraf** (EMA/H/C/000954) (tacrolimus), Astellas Pharma Europe B.V., Rapporteur: Kristina Dunder

NAPS:

**NAPs** - EU, PRAC Rapporteur: Ronan Grimes, "01/04/2018 To: 31/03/2021"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g (3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisations for the medicinal products containing the above referred active substance, concerning the following changes:

Update of section 4.4 to amend a warning on infections including opportunistic infections.

Update of section 4.4 to amend a warning on nephrotoxicity.

Update of section 4.5 of the SmPC to amend a warning on interactions.

Update of section 4.8 to amend a warning on infections and infestations.

The Package Leaflet is updated accordingly.

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**EMA/H/C/PSUSA/0003074/202105**

(ulipristal (female emergency contraceptive))

CAPS:

**ellaOne** (EMA/H/C/001027) (ulipristal acetate), Laboratoire HRA Pharma, Rapporteur: Paula Boudewina van Hennik

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the

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NAPS:

**NAPs** - LABORATOIRE HRA PHARMA, PRAC  
Rapporteur: Menno van der Elst, "15/05/2020  
To: 14/05/2021"

terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s):

Update of section 4.8 of the SmPC to add details on the hypersensitivity reactions associated to the medicinal product, with a frequency rare. The package leaflet is updated accordingly.

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**EMA/H/C/PSUSA/00010044/202104**

(meningococcal group a, c, w135, y conjugate vaccine (conjugated to tetanus toxoid carrier protein))

CAPS:

**MenQuadfi** (EMA/H/C/005084)

(meningococcal group a, c, w135 and y conjugate vaccine), Sanofi Pasteur, Rapporteur: Andrea Laslop

**Nimenrix** (EMA/H/C/002226) (meningococcal group a, c, w135 and y conjugate vaccine), Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang, PRAC Rapporteur: David Olsen, "20/04/2020 To: 19/04/2021"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):  
Update of section 4.8 of the SmPC to add the adverse reaction "Urticaria" with a frequency "uncommon" and "febrile convulsions" with a frequency "rare". The Package leaflet should be updated accordingly.

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**EMA/H/C/PSUSA/00010213/202104**

(delamanid)

CAPS:

**Deltyba** (EMA/H/C/002552) (delamanid), Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Laurence de Fays, "27/04/2020 To: 27/04/2021"

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 'hallucination' with a frequency 'common'. The package leaflet is updated accordingly. Update of section 5.1 of the SmPC to add information on in vitro studies and cross-resistance with pretomanid.

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**EMA/H/C/PSUSA/00010388/202104**

(empagliflozin, empagliflozin / metformin)

CAPS:

**Jardiance** (EMA/H/C/002677) (empagliflozin), Boehringer Ingelheim International GmbH, Rapporteur: Johann Lodewijk Hillege

**Synjardy** (EMA/H/C/003770) (empagliflozin / metformin), Boehringer Ingelheim International GmbH, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Eva A. Segovia, "17/04/2019 To: 17/04/2021"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):  
Update of section 4.8 of the SmPC to add the adverse reaction tubulointerstitial nephritis with a frequency very rare. The package leaflet is updated accordingly.  
Update of section 4.5 of the SmPC to add the

	drug-drug interaction empagliflozin and lithium. The package leaflet is updated accordingly.
<p><b>EMEA/H/C/PSUSA/00010550/202105</b> (mycophenolate mofetil, mycophenolic acid) CAPS: <b>CellCept</b> (EMEA/H/C/000082) (mycophenolate mofetil), Roche Registration GmbH, Rapporteur: Sinan B. Sarac <b>Myclausen</b> (EMEA/H/C/001218) (mycophenolate mofetil), Passauer Pharma GmbH, Rapporteur: Andrea Laslop <b>Mycophenolate mofetil Teva</b> (EMEA/H/C/000882) (mycophenolate mofetil), Teva B.V., Rapporteur: Ondřej Slanař <b>Myfenax</b> (EMEA/H/C/000884) (mycophenolate mofetil), Teva B.V., Rapporteur: Ondřej Slanař NAPS: <b>NAP</b> - EU PRAC Rapporteur: Anette Kirstine Stark, "03/05/2020 To: 02/05/2021"</p>	<p>The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g (3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus the variation to the terms of the marketing authorisations for the medicinal products containing the above referred active substance, concerning the following changes: Update of section 4.4 of the SmPC to add a warning on infections.</p>
<p><b>EMEA/H/C/PSUSA/00010644/202105</b> (atezolizumab) CAPS: <b>Tecentriq</b> (EMEA/H/C/004143) (atezolizumab), Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "17/05/2020 To: 17/05/2021"</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, concerning the following changes: Update of sections 4.2 and 4.4 of the SmPC to include a recommendation to permanently discontinue atezolizumab for <math>\geq</math> Grade 2 myocarditis and, given the potential for life-threatening or fatal evolution of myocarditis, to reinforce the need to suspend treatment with atezolizumab and initiate treatment with systemic corticosteroids as soon as myocarditis is suspected. Update of section 4.4 of the SmPC to include a recommendation that patients with possible myositis should be monitored for signs of myocarditis. Update of the PL (sections 2 and 4) to include specific signs of diabetic ketoacidosis.</p>
<p><b>EMEA/H/C/PSUSA/00010723/202104</b> (durvalumab) CAPS: <b>Imfinzi</b> (EMEA/H/C/004771) (durvalumab), AstraZeneca AB, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: David Olsen, "01/05/2020 To:</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 for the above</p>

30/04/2021"	mentioned medicinal product, concerning the following changes: Update of sections 4.4 and 4.8 of the SmPC to add the adverse reaction pancreatitis. The package leaflet is updated accordingly.
<b>EMA/H/C/PSUSA/00010917/202105</b> (selpercatinib) CAPS: <b>RETSEVMO</b> (EMA/H/C/005375) (selpercatinib), Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst, "08/11/2020 To: 08/05/2021"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Update of section 4.4 of the SmPC to add a warning in relation to the risk factors for tumour lysis syndrome and how to deal with TLS. The package leaflet is updated accordingly.

#### B.4. EPARs / WPARs

<b>Hukyndra – adalimumab –</b> <b>EMA/H/C/005548</b> STADA Arzneimittel AG, treatment of rheumatoid arthritis, psoriasis, hidradenitis suppurativa, Crohn’s disease, paediatric Crohn’s disease, ulcerative colitis, uveitis, paediatric uveitis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Libmyris - adalimumab -</b> <b>EMA/H/C/005947</b> STADA Arzneimittel AG; treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn’s disease, paediatric Crohn’s disease, ulcerative colitis, uveitis, paediatric uveitis , Similar biological application (Article 10(4) of Directive No 2001/83/EC), Duplicate of Hukyndra	For information only. Comments can be sent to the PL in case necessary.
<b>Lonapegsomatropin Ascendis Pharma -</b> <b>lonapegsomatropin - EMA/H/C/005367,</b> <b>Orphan</b> Ascendis Pharma Endocrinology Division A/S, Treatment of growth hormone deficiency, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Lumykras - sotorasib - EMA/H/C/005522</b>	For information only. Comments can be sent to

Amgen Europe B.V., treatment of locally advanced or metastatic non-small cell lung cancer, New active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
<b>Nexviadyme - avalglucosidase alfa - EMEA/H/C/005501, Orphan</b> Genzyme Europe BV, for long-term enzyme replacement therapy for the treatment of patients with Pompe disease., Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Nouryant - istradefylline - EMEA/H/C/005308</b> Kyowa Kirin Holdings B.V., indicated as an adjunctive treatment to levodopa-based regimens in patients with Parkinson's disease, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Regkirona - regdanvimab - EMEA/H/C/005854</b> Celltrion Healthcare Hungary Kft., treatment of COVID-19, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Riltrava Aerosphere - formoterol fumarate dihydrate / glycopyrronium / budesonide - EMEA/H/C/005311</b> AstraZeneca AB, maintenance treatment of chronic obstructive pulmonary disease (COPD), Informed Consent of Trixeo Aerosphere, Informed consent application (Article 10c of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Ronapreve - casirivimab / imdevimab - EMEA/H/C/005814</b> Roche Registration GmbH, prevention and treatment of COVID-19, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>TAVNEOS - avacopan - EMEA/H/C/005523, Orphan</b> Vifor Fresenius Medical Care Renal Pharma France, Treatment of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
<b>Tecovirimat SIGA - tecovirimat - EMEA/H/C/005248</b> SIGA Technologies Netherlands B.V., treatment of orthopoxvirus disease, New active substance	For information only. Comments can be sent to the PL in case necessary.

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

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**Uplizna - inebilizumab -  
EMA/H/C/005818, Orphan**

Viela Bio, indicated for the treatment of adults with neuromyelitis optica spectrum disorders, New active substance (Article 8(3) of Directive No 2001/83/EC)

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

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**Voraxaze - glucarpidase -  
EMA/H/C/005467, Orphan**

Serb, treatment of patients at risk of methotrexate toxicity, New active substance (Article 8(3) of Directive No 2001/83/EC)

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

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**Vyepti - eptinezumab - EMA/H/C/005287**

H. Lundbeck A/S, Indicated for the prophylaxis of migraine in adults, New active substance (Article 8(3) of Directive No 2001/83/EC)

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

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**Wegovy - semaglutide -  
EMA/H/C/005422**

Novo Nordisk A/S, treatment for weight loss and weight maintenance, Known active substance (Article 8(3) of Directive No 2001/83/EC)

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

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

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

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

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**ADYNOVI - ruriotocog alfa pegol -  
EMA/H/C/004195/II/0024**

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop  
Opinion adopted on 16.12.2021.

Positive Opinion adopted by consensus on 16.12.2021.

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**Ceprothin - human protein C -  
EMA/H/C/000334/II/0121/G**

Baxter AG, Rapporteur: Jan Mueller-Berghaus  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted on 09.09.2021.

Positive Opinion adopted by consensus on 16.12.2021.

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**Ceprothin - human protein C -  
EMA/H/C/000334/II/0122**

Baxter AG, Rapporteur: Jan Mueller-Berghaus  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted on 09.09.2021.

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Positive Opinion adopted by consensus on 16.12.2021.

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<p><b>Ceprotin - human protein C - EMA/H/C/000334/II/0124/G</b> Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.11.2021. Request for Supplementary Information adopted on 21.10.2021.</p>	<p>Positive Opinion adopted by consensus on 25.11.2021.</p>
<p><b>Cinacalcet Mylan - cinacalcet - EMA/H/C/004014/II/0016</b> Mylan Pharmaceuticals Limited, Generic, Generic of Mimpara, Rapporteur: Tomas Radimersky Request for Supplementary Information adopted on 16.12.2021, 23.09.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Cinryze - human c1-esterase inhibitor - EMA/H/C/001207/II/0089</b> Shire Services BVBA, Rapporteur: Jan Mueller- Berghaus Opinion adopted on 02.12.2021. Request for Supplementary Information adopted on 28.10.2021.</p>	<p>Positive Opinion adopted by consensus on 02.12.2021.</p>
<p><b>COMIRNATY - tozinameran - EMA/H/C/005735/II/0054/G</b> BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Grouped Variation: · Type II C.I.11.b, To update Annex II to implement changes and provision of data to fulfill specific obligations SO2f, SO4 and SO5. Opinion adopted on 16.12.2021. Request for Supplementary Information adopted on 14.10.2021.</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>
<p><b>COMIRNATY - tozinameran - EMA/H/C/005735/II/0056/G</b> BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, " C.I.11.b, (Type II)- To submit additional data to complete characterisation of the active substance and finished product, which are a condition to the Marketing Authorisation (Special Obligation SO1) C.I.11.b, (Type II)- To submit additional data to enhance the control strategy, including the active substance and finished product specifications, which are a condition to the Marketing Authorisation (Special Obligation SO2) Request for Supplementary Information adopted on 16.12.2021, 14.10.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>



<p><b>COMIRNATY - tozinameran - EMA/H/C/005735/II/0083/G</b></p> <p>BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson</p> <p>Opinion adopted on 17.11.2021.</p>	<p>Positive Opinion adopted by consensus on 17.11.2021.</p>
<p><b>COMIRNATY - tozinameran - EMA/H/C/005735/II/0086</b></p> <p>BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson</p> <p>Opinion adopted on 26.11.2021.</p>	<p>Positive Opinion adopted by consensus on 26.11.2021.</p>
<p><b>COMIRNATY - tozinameran - EMA/H/C/005735/II/0089</b></p> <p>BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson</p> <p>Request for Supplementary Information adopted on 09.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMA/H/C/005737/II/0026/G</b></p> <p>Janssen-Cilag International N.V., Rapporteur: Christophe Focke</p> <p>Opinion adopted on 16.12.2021.</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>
<p><b>Cyramza - ramucirumab - EMA/H/C/002829/II/0044</b></p> <p>Eli Lilly Nederland B.V., Rapporteur: Paula Boudewina van Hennik</p> <p>Opinion adopted on 16.12.2021.</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>
<p><b>Drovelis - drospirenone / estetrol - EMA/H/C/005336/II/0001/G</b></p> <p>Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder</p> <p>Opinion adopted on 09.12.2021.</p> <p>Request for Supplementary Information adopted on 16.09.2021.</p>	<p>Positive Opinion adopted by consensus on 09.12.2021.</p>
<p><b>Drovelis - drospirenone / estetrol - EMA/H/C/005336/II/0004/G</b></p> <p>Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder</p> <p>Opinion adopted on 16.12.2021.</p> <p>Request for Supplementary Information adopted on 23.09.2021.</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>
<p><b>Elonva - corifollitropin alfa - EMA/H/C/001106/II/0062</b></p> <p>Organon N.V., Rapporteur: Paula Boudewina van Hennik</p> <p>Request for Supplementary Information adopted</p>	<p>Request for supplementary information adopted with a specific timetable.</p>

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on 16.12.2021.

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**Emtricitabine/Tenofovir disoproxil Mylan - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050/II/0019** Positive Opinion adopted by consensus on 16.12.2021.  
Mylan Pharmaceuticals Limited, Generic,  
Generic of Truvada, Rapporteur: Romaldas Mačiulaitis  
Opinion adopted on 16.12.2021.

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**Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0010** Request for supplementary information adopted with a specific timetable.  
Daiichi Sankyo Europe GmbH, Rapporteur: Sinan B. Sarac  
Request for Supplementary Information adopted on 16.12.2021, 28.10.2021.

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**Entyvio - vedolizumab - EMEA/H/C/002782/II/0063/G** Positive Opinion adopted by consensus on 09.12.2021.  
Takeda Pharma A/S, Rapporteur: Armando Genazzani  
Opinion adopted on 09.12.2021.  
Request for Supplementary Information adopted on 28.10.2021.

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**Erelzi - etanercept - EMEA/H/C/004192/II/0038/G** Request for supplementary information adopted with a specific timetable.  
Sandoz GmbH, Rapporteur: Johann Lodewijk Hillege  
Request for Supplementary Information adopted on 02.12.2021.

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**Fasenra - benralizumab - EMEA/H/C/004433/II/0038/G** Request for supplementary information adopted with a specific timetable.  
AstraZeneca AB, Rapporteur: Fátima Ventura  
Request for Supplementary Information adopted on 16.12.2021.

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**Fasenra - benralizumab - EMEA/H/C/004433/II/0040** Positive Opinion adopted by consensus on 16.12.2021.  
AstraZeneca AB, Rapporteur: Fátima Ventura  
Opinion adopted on 16.12.2021.

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**Fendrix - hepatitis B (rDNA) vaccine (adjuvanted, adsorbed) - EMEA/H/C/000550/II/0076/G** Positive Opinion adopted by consensus on 09.12.2021.  
GlaxoSmithKline Biologicals, Rapporteur: Christophe Focke  
Opinion adopted on 09.12.2021.

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**Herceptin - trastuzumab - EMEA/H/C/000278/II/0174/G** Positive Opinion adopted by consensus on 16.12.2021.  
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus

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Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted  
on 07.10.2021.

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**Herzuma - trastuzumab -**  
**EMA/H/C/002575/II/0041/G**  
Celltrion Healthcare Hungary Kft., Rapporteur:  
Jan Mueller-Berghaus  
Opinion adopted on 09.12.2021.  
Request for Supplementary Information adopted  
on 21.10.2021.

Positive Opinion adopted by consensus on  
09.12.2021.

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**IKERVIS - ciclosporin -**  
**EMA/H/C/002066/II/0026/G**  
Santen Oy, Rapporteur: Peter Kiely  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted  
on 11.11.2021, 22.07.2021.

Positive Opinion adopted by consensus on  
16.12.2021.

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**Imfinzi - durvalumab -**  
**EMA/H/C/004771/II/0036**  
AstraZeneca AB, Rapporteur: Sinan B. Sarac  
Request for Supplementary Information adopted  
on 09.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Intrarosa - prasterone -**  
**EMA/H/C/004138/II/0015**  
Endoceutics S.A., Rapporteur: Jean-Michel Race  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted  
on 22.07.2021, 11.03.2021.

Positive Opinion adopted by consensus on  
16.12.2021.

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**Kadcyla - trastuzumab emtansine -**  
**EMA/H/C/002389/II/0061/G**  
Roche Registration GmbH, Rapporteur: Sinan B.  
Sarac  
Request for Supplementary Information adopted  
on 09.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Kirsty - insulin aspart -**  
**EMA/H/C/004965/II/0003/G**  
Mylan IRE Healthcare Limited, Rapporteur:  
Sinan B. Sarac  
Request for Supplementary Information adopted  
on 09.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Levetiracetam SUN - levetiracetam -**  
**EMA/H/C/002051/II/0026**  
Sun Pharmaceutical Industries Europe B.V.,  
Generic, Generic of Keppra, Rapporteur:  
Anastasia Mountaki  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted

Positive Opinion adopted by consensus on  
16.12.2021.

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on 21.10.2021.

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**Lydisilka - drospirenone / estetrol -  
EMA/H/C/005382/II/0001/G**

Estetra SRL, Duplicate, Duplicate of Drovelis,  
Rapporteur: Kristina Dunder  
Opinion adopted on 09.12.2021.  
Request for Supplementary Information adopted  
on 16.09.2021.

Positive Opinion adopted by consensus on  
09.12.2021.

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**Lydisilka - drospirenone / estetrol -  
EMA/H/C/005382/II/0004/G**

Estetra SRL, Duplicate, Duplicate of Drovelis,  
Rapporteur: Kristina Dunder  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted  
on 23.09.2021.

Positive Opinion adopted by consensus on  
16.12.2021.

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**Mepsevii - vestronidase alfa -  
EMA/H/C/004438/II/0024, Orphan**

Ultragenyx Germany GmbH, Rapporteur:  
Johann Lodewijk Hillege  
Opinion adopted on 02.12.2021.  
Request for Supplementary Information adopted  
on 02.09.2021.

Positive Opinion adopted by consensus on  
02.12.2021.

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**Mycamine - micafungin -  
EMA/H/C/000734/II/0044/G**

Astellas Pharma Europe B.V., Rapporteur: Janet  
Koenig  
Request for Supplementary Information adopted  
on 09.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Myocet liposomal - doxorubicin  
hydrochloride -  
EMA/H/C/000297/II/0066**

Teva B.V., Rapporteur: Filip Josephson  
Opinion adopted on 25.11.2021.

Positive Opinion adopted by consensus on  
25.11.2021.

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

Takeda Pharmaceuticals International AG,  
Rapporteur: Karin Janssen van Doorn  
Request for Supplementary Information adopted  
on 02.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Nepexto - etanercept -  
EMA/H/C/004711/II/0011**

Mylan IRE Healthcare Limited, Rapporteur:  
Martina Weise  
Opinion adopted on 02.12.2021.  
Request for Supplementary Information adopted  
on 02.09.2021.

Positive Opinion adopted by consensus on  
02.12.2021.

<p><b>Neulasta - pegfilgrastim - EMEA/H/C/000420/II/0117</b>  Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege  Opinion adopted on 18.11.2021.  Request for Supplementary Information adopted on 07.10.2021.</p>	<p>Positive Opinion adopted by consensus on 18.11.2021.</p>
<p><b>Nimenrix - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/002226/II/0112</b>  Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang  Opinion adopted on 18.11.2021.</p>	<p>Positive Opinion adopted by consensus on 18.11.2021.</p>
<p><b>Palynziq - pegvaliase - EMEA/H/C/004744/II/0024, Orphan</b>  BioMarin International Limited, Rapporteur: Johann Lodewijk Hillege  Opinion adopted on 25.11.2021.</p>	<p>Positive Opinion adopted by consensus on 25.11.2021.</p>
<p><b>ProQuad - measles, mumps, rubella and varicella vaccine (live) - EMEA/H/C/000622/II/0154</b>  MSD Vaccins, Rapporteur: Jan Mueller-Berghaus  Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Reagila - cariprazine - EMEA/H/C/002770/II/0020/G</b>  Gedeon Richter Plc., Rapporteur: Kristina Dunder  Opinion adopted on 16.12.2021.  Request for Supplementary Information adopted on 30.09.2021.</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>
<p><b>Reagila - cariprazine - EMEA/H/C/002770/II/0022</b>  Gedeon Richter Plc., Rapporteur: Kristina Dunder  Opinion adopted on 18.11.2021.  Request for Supplementary Information adopted on 30.09.2021.</p>	<p>Positive Opinion adopted by consensus on 18.11.2021.</p>
<p><b>Remsima - infliximab - EMEA/H/C/002576/II/0101/G</b>  Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola  Request for Supplementary Information adopted on 18.11.2021, 02.09.2021, 03.06.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>Revestive - teduglutide - EMEA/H/C/002345/II/0055, Orphan</b>  Shire Pharmaceuticals Ireland Limited,</p>	<p>Request for supplementary information adopted with a specific timetable.</p>

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Rapporteur: Sinan B. Sarac  
Request for Supplementary Information adopted  
on 16.12.2021.

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**RoActemra - tocilizumab -  
EMA/H/C/000955/II/0104/G** Positive Opinion adopted by consensus on  
16.12.2021.  
Roche Registration GmbH, Rapporteur: Jan  
Mueller-Berghaus  
Opinion adopted on 16.12.2021.

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**Spectrila - asparaginase -  
EMA/H/C/002661/II/0026** Request for supplementary information adopted  
with a specific timetable.  
medac Gesellschaft für klinische  
Spezialpräparate mbH, Rapporteur: Andrea  
Laslop  
Request for Supplementary Information adopted  
on 25.11.2021.

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**Spikevax - COVID-19 mRNA vaccine  
(nucleoside-modified) -  
EMA/H/C/005791/II/0024/G** Positive Opinion adopted by consensus on  
25.11.2021.  
Moderna Biotech Spain, S.L., Rapporteur: Jan  
Mueller-Berghaus  
Opinion adopted on 25.11.2021.  
Request for Supplementary Information adopted  
on 16.09.2021.

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**Spikevax - COVID-19 mRNA vaccine  
(nucleoside-modified) -  
EMA/H/C/005791/II/0043/G** Positive Opinion adopted by consensus on  
16.12.2021.  
Moderna Biotech Spain, S.L., Rapporteur: Jan  
Mueller-Berghaus  
Opinion adopted on 16.12.2021.

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**Supemtek - quadrivalent influenza vaccine  
(recombinant, prepared in cell culture) -  
EMA/H/C/005159/II/0005/G** Request for supplementary information adopted  
with a specific timetable.  
Sanofi Pasteur, Rapporteur: Jan Mueller-  
Berghaus  
Request for Supplementary Information adopted  
on 16.12.2021.

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**Synagis - palivizumab -  
EMA/H/C/000257/II/0127/G** Positive Opinion adopted by consensus on  
16.12.2021.  
AstraZeneca AB, Rapporteur: Sinan B. Sarac  
Opinion adopted on 16.12.2021.

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**Synflorix - pneumococcal polysaccharide  
conjugate vaccine (adsorbed) -  
EMA/H/C/000973/II/0166/G** Positive Opinion adopted by consensus on  
18.11.2021.  
GlaxoSmithkline Biologicals SA, Rapporteur:  
Kristina Dunder  
Opinion adopted on 18.11.2021.

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<p><b>Taltz - ixekizumab -</b>  <b>EMA/H/C/003943/II/0045/G</b>  Eli Lilly and Co (Ireland) Limited, Rapporteur:  Kristina Dunder  Opinion adopted on 16.12.2021.  Request for Supplementary Information adopted  on 14.10.2021.</p>	<p>Positive Opinion adopted by consensus on  16.12.2021.</p>
<p><b>Thyrogen - thyrotropin alfa -</b>  <b>EMA/H/C/000220/II/0109/G</b>  Genzyme Europe BV, Rapporteur: Peter Kiely  Request for Supplementary Information adopted  on 16.12.2021.</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>
<p><b>Trogarzo - ibalizumab -</b>  <b>EMA/H/C/004961/II/0016/G</b>  Theratechnologies Europe Limited, Rapporteur:  Johann Lodewijk Hillege  Request for Supplementary Information adopted  on 25.11.2021.</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>
<p><b>Vaxchora - cholera vaccine, oral, live -</b>  <b>EMA/H/C/003876/II/0009</b>  Emergent Netherlands B.V., Rapporteur: Ingrid  Wang  Opinion adopted on 16.12.2021.</p>	<p>Positive Opinion adopted by consensus on  16.12.2021.</p>
<p><b>Vaxzevria - COVID 19 Vaccine (ChAdOx1 S</b>  <b>[recombinant]) -</b>  <b>EMA/H/C/005675/II/0050</b>  AstraZeneca AB, Rapporteur: Sol Ruiz  Opinion adopted on 18.11.2021.</p>	<p>Positive Opinion adopted by consensus on  18.11.2021.</p>
<p><b>Vaxzevria - COVID 19 Vaccine (ChAdOx1 S</b>  <b>[recombinant]) -</b>  <b>EMA/H/C/005675/II/0051/G</b>  AstraZeneca AB, Rapporteur: Sol Ruiz  Opinion adopted on 18.11.2021.</p>	<p>Positive Opinion adopted by consensus on  18.11.2021.</p>
<p><b>VEYVONDI - vonicog alfa -</b>  <b>EMA/H/C/004454/II/0019/G</b>  Baxalta Innovations GmbH, Rapporteur: Jan  Mueller-Berghaus  Request for Supplementary Information adopted  on 16.12.2021, 02.09.2021.</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>
<p><b>VEYVONDI - vonicog alfa -</b>  <b>EMA/H/C/004454/II/0020</b>  Baxalta Innovations GmbH, Rapporteur: Jan  Mueller-Berghaus  Request for Supplementary Information adopted  on 16.12.2021.</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>
<p><b>Yuflyma - adalimumab -</b></p>	<p>Request for supplementary information adopted</p>

<p><b>EMA/H/C/005188/II/0009/G</b>  Celltrion Healthcare Hungary Kft., Rapporteur:  Outi Mäki-Ikola  Request for Supplementary Information adopted  on 16.12.2021.</p>	<p>with a specific timetable.</p>
<p><b>ZABDENO - ebola vaccine (rDNA,  replication-incompetent) -  EMA/H/C/005337/II/0006/G</b>  Janssen-Cilag International N.V., Rapporteur:  Johann Lodewijk Hillege  Opinion adopted on 16.12.2021.</p>	<p>Positive Opinion adopted by consensus on  16.12.2021.</p>
<p><b>Zavicefta - ceftazidime / avibactam -  EMA/H/C/004027/II/0027/G</b>  Pfizer Ireland Pharmaceuticals, Rapporteur:  Ingrid Wang  Request for Supplementary Information adopted  on 02.12.2021, 28.10.2021, 09.09.2021.</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>
<p><b>Zutectra - human hepatitis b  immunoglobulin -  EMA/H/C/001089/II/0050</b>  Biotest Pharma GmbH, Rapporteur: Jan Mueller-  Berghaus  Request for Supplementary Information adopted  on 02.12.2021.</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>
<p><b>WS2118/G</b>  <b>Blitzima-EMA/H/C/004723/WS2118/  0044/G</b>  <b>Truxima-EMA/H/C/004112/WS2118/  0048/G</b>  Celltrion Healthcare Hungary Kft., Lead  Rapporteur: Sol Ruiz  Opinion adopted on 02.12.2021.  Request for Supplementary Information adopted  on 16.09.2021.</p>	<p>Positive Opinion adopted by consensus on  02.12.2021.</p>
<p><b>WS2119/G</b>  <b>M-M-RVAXPRO-EMA/H/C/000604/  WS2119/0110/G</b>  <b>ProQuad-EMA/H/C/000622/WS2119/  0152/G</b>  MSD Vaccins, Lead Rapporteur: Jan Mueller-  Berghaus  Opinion adopted on 18.11.2021.</p>	<p>Positive Opinion adopted by consensus on  18.11.2021.</p>
<p><b>WS2120</b>  <b>Nuwiq-EMA/H/C/002813/WS2120/0045</b>  <b>Vihuma-  EMA/H/C/004459/WS2120/0027</b>  Octapharma AB, Lead Rapporteur: Jan Mueller-</p>	<p>Request for supplementary information adopted  with a specific timetable.</p>



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Berghaus  
Request for Supplementary Information adopted  
on 16.12.2021, 02.09.2021.

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**WS2132**  
**Infanrix hexa-EMEA/H/C/000296/**  
**WS2132/0305**  
GlaxoSmithkline Biologicals SA, Lead  
Rapporteur: Christophe Focke  
Opinion adopted on 02.12.2021.

Positive Opinion adopted by consensus on  
02.12.2021.

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**WS2138/G**  
**Hexacima-EMEA/H/C/002702/WS2138/**  
**0120/G**  
**Hexyon-EMEA/H/C/002796/WS2138/**  
**0124/G**  
Sanofi Pasteur Europe, Duplicate, Duplicate of  
Hexacima, Lead Rapporteur: Jan Mueller-  
Berghaus  
Request for Supplementary Information adopted  
on 02.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**WS2142**  
**M-M-RVAXPRO-**  
**EMEA/H/C/000604/WS2142/0111**  
**ProQuad-**  
**EMEA/H/C/000622/WS2142/0153**  
MSD Vaccins, Lead Rapporteur: Jan Mueller-  
Berghaus  
Opinion adopted on 09.12.2021.

Positive Opinion adopted by consensus on  
09.12.2021.

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**WS2165/G**  
**Blitzima-EMEA/H/C/004723/WS2165/**  
**0048/G**  
**Truxima-EMEA/H/C/004112/WS2165/**  
**0052/G**  
Celltrion Healthcare Hungary Kft., Duplicate,  
Duplicate of Truxima, Lead Rapporteur: Sol Ruiz  
Opinion adopted on 25.11.2021.

Positive Opinion adopted by consensus on  
25.11.2021.

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**WS2182/G**  
**Fluenz Tetra-**  
**EMEA/H/C/002617/WS2182/0110/G**  
**Pandemic influenza vaccine H5N1**  
**AstraZeneca-**  
**EMEA/H/C/003963/WS2182/0045/G**  
AstraZeneca AB, Lead Rapporteur: Christophe  
Focke  
Opinion adopted on 16.12.2021.

Positive Opinion adopted by consensus on  
16.12.2021.

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

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### **Adtralza - tralokinumab - EMA/H/C/005255/II/0001**

LEO Pharma A/S, Rapporteur: Jayne Crowe,  
"C.I.4

Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with cytochrome P450 and CYP substrates based on final results from study ECZTRA 4 (LP0162-1342). This is an open-label drug-drug interaction trial to investigate the effects of tralokinumab on the pharmacokinetics of selected CYP substrates in adult subjects with moderate-to-severe atopic dermatitis. In addition, the MAH took the opportunity to make editorial changes to sections 4.8, 6.5 and 9 of the SmPC."

Request for Supplementary Information adopted on 16.12.2021.

Request for supplementary information adopted with a specific timetable.

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### **Bimzelx - bimekizumab - EMA/H/C/005316/II/0002**

UCB Pharma S.A., Rapporteur: Peter Kiely,  
"C.I.4 - Update of section 5.1 of the SmPC in order to update efficacy information based on interim results from study PS0015; this is a multicenter, randomized, double-blind, active comparator controlled, parallel group study to evaluate the efficacy and safety of bimekizumab compared with secukinumab in adult study participants with moderate to severe plaque psoriasis. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2."

Request for Supplementary Information adopted on 16.12.2021.

Request for supplementary information adopted with a specific timetable.

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### **COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMA/H/C/005737/II/0033**

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a homologous booster dose (second dose) of COVID-19 vaccine Janssen based on interim efficacy, immunogenicity and safety results from different clinical studies including the two randomised, double blind, placebo-controlled Phase 3 studies COV3001 and COV3009. In addition, an update to introduce an heterologous booster dose of COVID-19 vaccine

Positive Opinion adopted by consensus on 14.12.2021.

See 9.1

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Janssen following completion of a primary vaccination with an approved mRNA COVID-19 vaccine is introduced based on immunogenicity and safety interim results from the phase 1/2 study DMID 21-0012. In addition, the MAH took the opportunity to update the efficacy data for the primary vaccination schedule based on final analysis from study COV3001. The Package Leaflet is updated accordingly.”  
Opinion adopted on 14.12.2021.

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**Cyramza - ramucirumab -  
EMA/H/C/002829/II/0043**

Eli Lilly Nederland B.V., Rapporteur: Paula Boudewina van Hennik, “Update of section 4.4 of the SmPC in order to add a new warning on heart failure following a detailed cumulative review of post-marketing data. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to update the package leaflet to include hypothyroidism as a common side effect.”  
Request for Supplementary Information adopted on 16.12.2021.

Request for supplementary information adopted with a specific timetable.

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**Dapivirine Vaginal Ring 25 mg - dapivirine  
- EMA/H/W/002168/II/0012/G**

International Partnership for Microbicides Belgium AISBL, Rapporteur: Paula Boudewina van Hennik, “Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with vaginal products (e.g. vaginal miconazole) that are metabolised by CYP and UGT enzymes and to update pharmacokinetic information based on the final study reports of 3 in vitro enzyme/transporter studies evaluating the interactions between dapivirine and transporters (study NPK/0025), dapivirine-miconazole interactions on CYP (study NPK/0026) and UGT enzymes (study NPK/0027).  
Submission of the final report from study evaluating the impact of dapivirine and miconazole on cellular tight junctions and assessing the impact of miconazole on dapivirine tissue permeability (study NPK/0028).  
These 4 in vitro studies were submitted to fulfil post-authorisation measures requested in the initial marketing authorisation application assessment report.”

Positive Opinion adopted by consensus on 09.12.2021.

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Opinion adopted on 09.12.2021.  
Request for Supplementary Information adopted  
on 28.10.2021.

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**Edarbi - azilsartan medoxomil -  
EMA/H/C/002293/II/0030/G**

Takeda Pharma A/S, Rapporteur: Johann  
Lodewijk Hillege, "Group of variations:  
· Type II C.I.4. - Update of SmPC sections 4.2,  
4.8 and 5.1 with paediatric clinical data from  
study AR14.001 (PIP study 8) following the  
outcome of procedure  
EMA/H/C/002293/P46/012.  
· Type II C.I.4. - Update of SmPC section 5.2  
with paediatric clinical data from study TAK-  
491\_109 (PIP study 7) following the outcome of  
procedure EMA/H/C/002293/P46/011.  
· Type II C.I.4. - Update of SmPC section 5.3  
with data from juvenile animal toxicity studies.  
· Type II C.I.4. - Update of SmPC section 4.5  
with drug-drug interaction information from  
clinical pharmacology studies TAK-491-013 and  
TAK-563-004.

Furthermore, the MAH is taking the opportunity  
to update the PI in line with the latest QRD  
template version 10.2, update the local  
representatives for Ireland, Slovenia and United  
Kingdom in the Package Leaflet (PL) and update  
minor editorial/typographical to product  
information."

Request for Supplementary Information adopted  
on 09.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Enhertu - trastuzumab deruxtecan -  
EMA/H/C/005124/II/0005/G**

Daiichi Sankyo Europe GmbH, Rapporteur:  
Sinan B. Sarac, "Submission of two final study  
reports recommended at the time of the initial  
MA:

I. study investigating in vitro pharmacological  
action of MAAA-11181d on receptors, channels,  
transporters and enzymes (Study No.: TW04-  
0008917);

II. pharmacodynamic study to investigate the  
in-vitro binding profile of MAAA-1181a in  
Human, Monkey, and Rat Liver Microsomes  
(Study No.: AE-8630-G).

Submission of the final report of the in vitro  
CYP3A4, CYP1A2 and CYP2B6 induction study in  
primary human hepatocytes (Study No.: TCRM-  
DMPK-2020-19)."

Positive Opinion adopted by consensus on  
18.11.2021.

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Opinion adopted on 18.11.2021.  
Request for Supplementary Information adopted  
on 16.09.2021.

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**Erleada - apalutamide -  
EMA/H/C/004452/II/0016**

Positive Opinion adopted by consensus on  
18.11.2021.

Janssen-Cilag International N.V., Rapporteur:  
Blanca Garcia-Ochoa, "Update of sections 4.4  
and 4.8 of the SmPC in order to add Stevens-  
Johnson Syndrome (SJS) to the list of adverse  
drug reactions (ADRs) with frequency not  
known. Cases of SJS were observed in post-  
marketing data. The Package Leaflet is updated  
accordingly.

SmPC new text Cases of Stevens-Johnson  
Syndrome (SJS) were observed in association  
with Erleada treatment in post-marketing data  
and has been added to the list of adverse drug  
reactions (ADRs) with frequency not known."

Opinion adopted on 18.11.2021.

Request for Supplementary Information adopted  
on 14.10.2021, 02.09.2021.

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**Evryssi - risdiplam -  
EMA/H/C/005145/II/0003, Orphan**

Positive Opinion adopted by consensus on  
18.11.2021.

Roche Registration GmbH, Rapporteur: Bruno  
Sepodes, "Update of section 4.8 of the SmPC to  
add undesirable effects based on post-  
marketing experience. The Package Leaflet (PL)  
is updated accordingly. In addition, the  
Marketing authorisation holder (MAH) took the  
opportunity to update the contact details of local  
representatives in the PL."

Opinion adopted on 18.11.2021.

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**Eylea - aflibercept -  
EMA/H/C/002392/II/0073**

Request for supplementary information adopted  
with a specific timetable.

Bayer AG, Rapporteur: Alexandre Moreau,  
"C.I.13 Other variations not specifically covered  
elsewhere in this Annex which involve the  
submission  
of studies to the competent authority. PFS  
design change."

Request for Supplementary Information adopted  
on 16.12.2021, 16.09.2021.

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**Fasenra - benralizumab -  
EMA/H/C/004433/II/0039**

Positive Opinion adopted by consensus on  
09.12.2021.

AstraZeneca AB, Rapporteur: Fátima Ventura,  
"C.I.4 - Update of section 5.1 in order to include  
information on the maintenance of long-term  
safety based on the results from study

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D3250C00037 (MELTEMI) listed as a category 3 study in the RMP. This is a multicenter, open-label safety extension study to evaluate the safety and tolerability of a fixed 30 mg dose of benralizumab in adults with severe asthma. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the Product information in line with the latest QRD template version 10.2.”

Opinion adopted on 09.12.2021.

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**Ganfort - bimatoprost / timolol -  
EMA/H/C/000668/II/0038**

Allergan Pharmaceuticals Ireland, Rapporteur:  
Sinan B. Sarac, “C.I.4  
Update of section 4.8 of the SmPC in order to add periorbital and lid changes associated with periorbital fat atrophy and skin tightness to the list of adverse drug reactions (ADRs) with frequency uncommon.”

Opinion adopted on 25.11.2021.

Positive Opinion adopted by consensus on 25.11.2021.

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**Keytruda - pembrolizumab -  
EMA/H/C/003820/II/0114**

Merck Sharp & Dohme B.V., Rapporteur:  
Armando Genazzani, “Update of sections 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-087 listed as an imposed PAES in the Annex II; this is a multicenter, single-arm, multi-cohort, non-randomized Phase 2 study of IV pembrolizumab in participants with relapsed or refractory classical Hodgkin lymphoma (cHL).”

Request for Supplementary Information adopted on 18.11.2021.

Request for supplementary information adopted with a specific timetable.

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**Keytruda - pembrolizumab -  
EMA/H/C/003820/II/0115**

Merck Sharp & Dohme B.V., Rapporteur:  
Armando Genazzani, “Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-426 listed as imposed PAES in the Annex II; this is a Phase III Randomized, Open-label Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in combination with Axitinib versus Sunitinib Monotherapy as a First-line Treatment for Locally Advanced or Metastatic Renal Cell Carcinoma (mRCC).”

Request for supplementary information adopted with a specific timetable.

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Request for Supplementary Information adopted on 02.12.2021.

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**Keytruda - pembrolizumab -  
EMA/H/C/003820/II/0116**

Merck Sharp & Dohme B.V., Rapporteur:  
Armando Genazzani, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-177 listed as PAES in Annex II of the Product Information; this is a 2-arm, multicenter, international, randomized, open-label, Phase 3 study evaluating the efficacy and safety of pembrolizumab monotherapy versus globally-accepted SOC therapies for Colorectal carcinoma (CRC) in participants with locally confirmed Deficient mismatch repair (dMMR) or Microsatellite instability-high (MSI-H) unresectable or metastatic CRC who have not received prior chemotherapy for their disease."  
Opinion adopted on 09.12.2021.

Positive Opinion adopted by consensus on 09.12.2021.

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**Kovaltry - octocog alfa -  
EMA/H/C/003825/II/0038**

Bayer AG, Rapporteur: Kristina Dunder, PRAC  
Rapporteur: Brigitte Keller-Stanislawski,  
"Update of the SmPC sections 4.8 and 5.1 to include data from the LEOPOLD Kids Part B (previously submitted as Art 46; an addendum on biomarker data is included in this submission) and Extension study results included as part of this submission. In addition, an editorial revision in section 4.2 and a clarification in section 6.5 of the SmPC are proposed. Section 4 of the Package is updated accordingly. A correction of a typo in the Greek product information is also included. The Risk Management Plan for Kovaltry is updated using Revision 2.0.1 of the template format."  
Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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**LEDAGA - chlormethine -  
EMA/H/C/002826/II/0027, Orphan**

Helsinn Birex Pharmaceuticals Limited,  
Rapporteur: Sinan B. Sarac, "Update of section 4.2 of the SmPC in order to allow flexibility in the starting frequency of the treatment based on current clinical practice; the Package Leaflet is updated accordingly."  
Request for Supplementary Information adopted

The CHMP noted the update on the procedure.

See 9.1

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on 20.05.2021.

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**Mavenclad - cladribine -  
EMA/H/C/004230/II/0016**

Merck Europe B.V., Rapporteur: Sinan B. Sarac,  
"Update of section 4.8 of the SmPC in order to  
add hypersensitivity to the list of adverse drug  
reactions (ADRs) with frequency "common"  
based on a review of cumulative clinical and  
post-marketing data. The Package Leaflet is  
updated accordingly."

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted  
on 02.09.2021, 20.05.2021, 14.01.2021.

Positive Opinion adopted by consensus on  
02.12.2021.

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**Methylthioninium chloride Proveblue -  
methylthioninium chloride -  
EMA/H/C/002108/II/0052/G**

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

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

Request for Supplementary Information adopted  
on 16.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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**Natpar - parathyroid hormone -  
EMA/H/C/003861/II/0030/G, Orphan**

Takeda Pharmaceuticals International AG,  
Rapporteur: Karin Janssen van Doorn,  
"Submission of the clinical study reports of the

Positive Opinion adopted by consensus on  
16.12.2021.



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following two studies:

- SHP634-402 - A Phase 4, Open-Label, Single-Center Clinical Study of Extended use of rhPTH(1-84) in Hypoparathyroidism
- SHP634-404 - An Open-label Study Investigating the Safety and Efficacy of rhPTH(1-84) in Subjects with Hypoparathyroidism.”

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted on 16.09.2021.

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**Noxafil - posaconazole -  
EMA/H/C/000610/II/0067**

Positive Opinion adopted by consensus on 25.11.2021.

Merck Sharp & Dohme B.V., Rapporteur: Alexandre Moreau, “Update of sections 4.3, 4.4 and 4.5 of the SmPC in order to add drug-drug interaction information between posaconazole and venetoclax. The Package leaflet is updated accordingly.”

Opinion adopted on 25.11.2021.

Request for Supplementary Information adopted on 30.09.2021.

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**Obizur - susoctocog alfa -  
EMA/H/C/002792/II/0042**

Request for supplementary information adopted with a specific timetable.

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, “Submission of the final report from OBIZUR study 241502. This is a Phase 3, multicentre, single-arm, open-label study of the efficacy and safety of B-Domain deleted recombinant porcine factor VIII (BAX 802) in subjects with congenital haemophilia A with factor VIII inhibitors undergoing surgical or other invasive procedures. No changes to the PI are proposed.”

Request for Supplementary Information adopted on 16.12.2021.

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**OCALIVA - obeticholic acid -  
EMA/H/C/004093/II/0030, Orphan**

Request for supplementary information adopted with a specific timetable.

Intercept Pharma International Limited, Rapporteur: Blanca Garcia-Ochoa, “Update of section 4.3 of the SmPC in order to include contraindication in patients with decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event based on the MAH's conclusion that it will not be feasible to establish the safety and efficacy of Ocaliva in these patients from either of the ongoing studies 747-302 and 747-401 listed as Specific Obligations in Annex II. Consequently, dosing instructions

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for patients with CP-B and CP-C cirrhosis are no longer applicable and section 4.2 has been updated accordingly.

In addition, section 4.4 of the SmPC to include a new warning on monitoring and management of patients for possible progression of PBC and other hepatic adverse reactions.

The MAH also took the opportunity to remove the outdated term "primary biliary cirrhosis" from section 4.1 and to make editorial changes to sections 4.8, 4.9, 5.1 and Annex IIE to improve clarity and correct typographical errors.

The Package Leaflet is updated accordingly.

Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2"

Request for Supplementary Information adopted on 16.12.2021, 16.09.2021.

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**Oncaspar - pegaspargase -  
EMA/H/C/003789/II/0038**

Les Laboratoires Servier, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on the risk of osteonecrosis and to include it as an adverse drug reaction associated with pegaspargase use with an unknown frequency, following review of all available non-clinical, epidemiological and clinical data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2."

Request for Supplementary Information adopted on 25.11.2021, 28.05.2021.

Request for supplementary information adopted with a specific timetable.

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**Oxlumo - lumasiran -  
EMA/H/C/005040/II/0007, Orphan**

Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Update of section 5.3 of the SmPC in order to update the non-clinical information based on the final results from the 26-week GLP carcinogenicity study of lumasiran by subcutaneous injection in TgRasH2 mice, as agreed as part of protocol assistance (EMA/H/SA/4014/2/2019/PA/PR/I). In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Opinion adopted on 09.12.2021.

Positive Opinion adopted by consensus on 09.12.2021.

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**Pradaxa - dabigatran etexilate -  
EMA/H/C/000829/II/0128**

Positive Opinion adopted by consensus on

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Boehringer Ingelheim International GmbH, 16.12.2021.  
Rapporteur: Sinan B. Sarac, "C.I.4,  
Update of section 4.2 of the SmPC in order to  
update the dosing information for Pradaxa  
coated granules and to introduce a new format  
of the dosing tables for all dosage forms of  
Pradaxa to avoid incorrect interpretation and  
possible mistakes.

In addition, a guidance related to the Schwartz  
formula is proposed to be included in section  
4.2 of the SmPC. The Package Leaflet was  
updated accordingly. Furthermore, the MAH  
took the opportunity to request introduction of  
the link to a training video by scanning the QR  
code in Annex IIIA and IIIB and to include  
additional updates to Annex IIIA and mock  
ups."

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted  
on 11.11.2021, 22.07.2021.

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**REKAMBYS - rilpivirine -  
EMA/H/C/005060/II/0006**

Positive Opinion adopted by consensus on  
16.12.2021.

Janssen-Cilag International N.V., Rapporteur:  
Johann Lodewijk Hillege, "Update of sections 4.2  
and 4.4 of the SmPC in order to amend an  
existing text on section post-injections  
reactions, based on the availability of new  
information from ongoing phase 3/3b clinical  
trials. Section 2 of the Package Leaflet is  
updated accordingly. In addition, the MAH took  
the opportunity to implement some minor  
editorial changes."

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted  
on 21.10.2021.

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**REKAMBYS - rilpivirine -  
EMA/H/C/005060/II/0008**

Request for supplementary information adopted  
with a specific timetable.

Janssen-Cilag International N.V., Rapporteur:  
Johann Lodewijk Hillege, "Update of sections 4.8  
and 5.1 of the SmPC in order to update efficacy  
and safety information based on week 96  
results from the clinical study 207966 (ATLAS-  
2M). This is a open-label, randomized, Phase  
IIIb trial to demonstrate non-inferior antiviral  
activity and safety of CAB + RPV Q8W compared  
with CAB + RPV Q4W. Supporting Cabotegravir  
(CAB) Long-acting Injectable (LA) + Rilpivirine  
(RPV) LA every 2 months (Q8W) dosing regimen  
for the treatment of HIV-1 infection."

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Request for Supplementary Information adopted on 16.12.2021.

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**Retsevmo - selpercatinib -  
EMA/H/C/005375/II/0010**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of sections 4.2 and 5.3 of the SmPC in order to reflect the need to monitor open growth plates in adolescent patients based on the results from a non-clinical juvenile toxicity study LOXO-292-TOX-028. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to correct figures in section 5.1 of the SmPC."

Request for Supplementary Information adopted on 16.12.2021.

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Request for supplementary information adopted with a specific timetable.

**Revatio - sildenafil -  
EMA/H/C/000638/II/0098**

Upjohn EESV, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.8 and 5.1 to include long-term safety data in adults for the approved dose, and evidence of safe and effective use in adults in higher than recommended doses, based on study A1481324; a multinational, multicentre randomized, double-blind, parallel-group study in 385 adults with Pulmonary Arterial Hypertension (PAH) undertaken to assess the effects of different dose levels of oral sildenafil on mortality. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Request for Supplementary Information adopted on 16.12.2021.

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Request for supplementary information adopted with a specific timetable.

**Rydapt - midostaurin -  
EMA/H/C/004095/II/0022, Orphan**

Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, "Update of section 5.1 of the SmPC in order to update efficacy information in elderly patients, based on final results from study ADE02T listed as a PAES in the Annex II; this is a phase II study to investigate the efficacy of midostaurin in combination with intensive induction, consolidation including allogenic SCT and single agent maintenance in patients aged 18-70 with FLT3 ITD mutated AML."

Opinion adopted on 16.12.2021.

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Positive Opinion adopted by consensus on 16.12.2021.

**Saxenda - liraglutide -**

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Positive Opinion adopted by consensus on

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<p><b>EMA/H/C/003780/II/0030</b>  Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, "Update in the SmPC section 5.1 based on results from phase 3a clinical trial NN8022-4179, listed as part of the PIP, to evaluate Efficacy/safety of liraglutide in obese children with Prader-Willi Syndrome from 6 up to 18 years."  Opinion adopted on 16.12.2021.  Request for Supplementary Information adopted on 16.09.2021.</p>	<p>16.12.2021.</p>
<p><b>Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMA/H/C/005791/II/0042</b>  Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to include information on heterologous boosting using a 50 ug dose of Spikevax to boost subjects that have previously completed a primary vaccination series with any authorised COVID-19 vaccine, based on data from the DMID Study 21-0012, a Phase 1/2 heterologous SARS-CoV-2 vaccine dosing (mRNA-1273 booster) study of the various vaccines authorized in the US under Emergency Use Authorisation in participants ≥ 18 years old (NCT04889209). In addition, the MAH took the opportunity to make minor editorial changes/corrections throughout the product information."  Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.   See 9.1</p>
<p><b>TAGRISO - osimertinib - EMA/H/C/004124/II/0045</b>  AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, "Update of section 5.3 of the SmPC in order to reflect the outcome of the 104 Week Oral (Gavage) Carcinogenicity Study (507363) in the Rat submitted as recommended by the CHMP."  Request for Supplementary Information adopted on 16.12.2021, 11.11.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>TAKHZYRO - lanadelumab - EMA/H/C/004806/II/0022, Orphan</b>  Takeda Pharmaceuticals International AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, "update to the SmPC sections 4.8 and 5.1 to reflect the result of study DX-2930-04 (HELP Study Extension<sup>TM</sup>: An Open-Label</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>

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Study to Evaluate the Long-Term Safety and Efficacy of DX-2930 for Prevention Against Acute Attacks of Hereditary Angioedema (HAE)). The Risk Management Plan is also updated following the completion of study DX-2930-04 and according to GVP Module V Rev 2 Integrated RMP template.

In addition, the MAH is taking the opportunity to include a refrigeration statement for the multi-pack pre-filled syringe in the SmPC and pre-filled syringe PIL in section 6.4.”

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted on 16.09.2021.

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**Tecentriq - atezolizumab -  
EMA/H/C/004143/II/0067**

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, “Update of section 4.8 of the SmPC in order to include the new ADR of rhinorrhoea for atezolizumab in combination therapy, as part of the grouped term of nasopharyngitis identified in the IMpassion031 study and reviewed in the context of a drug safety report. The package leaflet is proposed to be updated accordingly. Additional amendments are proposed to the footnotes of ADRs in the SmPC, the removal of the term ‘lung infection’, the inclusion of the term ‘orthostatic hypertension’ and the inclusion of a new footnote listing the preferred terms covered for the ADR of psoriasis. In addition, the MAH took the opportunity of this variation to further clarify the posology in section 4.2 of the SmPC.”

Opinion adopted on 02.12.2021.

Positive Opinion adopted by consensus on 02.12.2021.

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**Vaborem - meropenem / vaborbactam -  
EMA/H/C/004669/II/0010/G**

Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, “A grouped application including 8 type II variations (C.I.4) and 1 type II variation (C.I.13):

Update of section 4.5 of the SmPC based on the results of a series of non-clinical drug-drug interaction studies undertaken with vaborbactam or meropenem. The Package Leaflet has been updated accordingly. In addition, the MAH has submitted non-clinical data on the phototoxicity potential of meropenem from a 3T3 neutral red uptake phototoxicity test.”

Request for supplementary information adopted with a specific timetable.

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Request for Supplementary Information adopted on 25.11.2021, 11.03.2021.

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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/0090**

MCM Vaccine B.V., Rapporteur: Christophe Focke, "Update of section 4.8 of the Summary of Product Characteristics (SmPC) in order to add Convulsions with or without fever with frequency Not known to the list of post-marketing adverse events. The package leaflet (PL) is updated accordingly."

Opinion adopted on 02.12.2021.

Positive Opinion adopted by consensus on 02.12.2021.

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**Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0047**

AstraZeneca AB, Rapporteur: Sol Ruiz, "Submission of the final report from MS1222-0004 study "Binding of PF4 to AZD1222 and Purified ChAdOx1" and the Greinacher et al (Greinacher et al 2021) paper, titled "A prothrombotic thrombocytopenic disorder resembling heparin-induced thrombocytopenia following Coronavirus-19 vaccination" listed as a category 3 studies in the RMP."

Opinion adopted on 16.12.2021.

Positive Opinion adopted by consensus on 16.12.2021.

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**Veklury - remdesivir - EMEA/H/C/005622/II/0026/G**

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Grouped variation updating sections 5.2 and 5.3 of the SmPC in order to add additional pharmacokinetic (PK) data coming from non-clinical and clinical studies to fulfil two Post-Authorisation Measures for Veklury: Recommendation (REC) number 4 (non-clinical data to further characterise a previously unidentified metabolite, M27); and REC number 7 (to submit data from additional analysis of the circulating species of remdesivir from the human mass-balance study, GS-US-399-4231). Both were agreed during the initial conditional marketing application (EMEA/H/C/005622)."

Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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**Veklury - remdesivir - EMEA/H/C/005622/II/0028/G**

Positive Opinion adopted by consensus on 16.12.2021.

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Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "C.I.4. Grouping variation to update section 5.1 of the SmPC in order to add information related to in vitro testing reports of B.1.1.28 and B.1.617 variants with additional provision of the cell culture resistance report to further understand the antiviral activity of Remdesivir. They are listed as part of the specific obligation (SOB 012) in the Annex II of the renewal procedure EMEA/H/C/005622/R/0015 for Veklury.  
C.I.13. Grouping variation for the submission of the virology reports for GS-US-540-5773 and GS-US-540-5774 studies and the submission of the ACTT-1 final viral load analysis included as part of the specific obligation (SOB 012) in the Annex II of the renewal procedure EMEA/H/C/005622/R/0015 for Veklury."  
Opinion adopted on 16.12.2021.

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**VITRAKVI - Iarotrectinib -  
EMEA/H/C/004919/II/0021**

Bayer AG, Rapporteur: Filip Josephson, Co-Rapporteur: Alexandre Moreau, "Update of section 5.2 of the SmPC in order to reflect the outcome of an updated analysis of the population pharmacokinetic (PopPk) model based on additional PK sampling in patients aged 1 month to 6 years from study LOXO-TRK-15003 (SCOUT) imposed as a specific obligation (SOB). The MAH is also proposing to delete this SOB from Annex II. The MAH took the opportunity of this variation to introduce corrections to section 4.8 of the SmPC and to Annex II."  
Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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**Vocabria - cabotegravir -  
EMEA/H/C/004976/II/0008**

ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on week 96 results from the clinical study 207966 (ATLAS-2M). This is an open-label, randomized, Phase IIIb trial to demonstrate non-inferior antiviral activity and safety of CAB + RPV Q8W compared with CAB + RPV Q4W. Supporting Cabotegravir (CAB) Long-acting Injectable (LA) + Rilpivirine (RPV) LA every 2 months (Q8W) dosing regimen for the

Request for supplementary information adopted with a specific timetable.



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treatment of HIV-1 infection.”  
Request for Supplementary Information adopted  
on 16.12.2021.

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**Xagrid - anagrelide -  
EMA/H/C/000480/II/0091**

Shire Pharmaceuticals Ireland Limited,  
Rapporteur: Alexandre Moreau, “C.I.4  
Update of section 4.4 of the SmPC in order to  
add a new warning on the risks of fatal  
thrombotic complications associated with abrupt  
treatment discontinuation based on New  
Pharmacovigilance data. The Package Leaflet is  
updated accordingly. In addition, the MAH took  
the opportunity to perform a minor editorial  
change in section 4.2.”  
Request for Supplementary Information adopted  
on 09.12.2021, 02.09.2021.

Request for supplementary information adopted  
with a specific timetable.

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**WS2145  
DuoPlavin-EMA/H/C/001143/WS2145/  
0059**

**Iscover-EMA/H/C/000175/WS2145/  
0145  
Plavix-EMA/H/C/000174/WS2145/0143**  
sanofi-aventis groupe, Lead Rapporteur: Bruno  
Sepodes, “Update of section 4.5 of the SmPC to  
add the drug-drug interaction between  
clopidogrel and rosuvastatin based on a review  
of the available data including literature and the  
MAH safety database. The package leaflet is  
updated accordingly.”  
Opinion adopted on 25.11.2021.

Positive Opinion adopted by consensus on  
25.11.2021.

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**WS2154  
CONTROLOC Control-  
EMA/H/C/001097/WS2154/0038  
PANTOLOC Control-  
EMA/H/C/001100/WS2154/0043  
PANTOZOL Control-  
EMA/H/C/001013/WS2154/0040  
SOMAC Control-  
EMA/H/C/001098/WS2154/0039**

Takeda GmbH, Lead Rapporteur: Romaldas  
Mačiulaitis, “C.1.4 – Update of section 4.8 of the  
SmPC to update the existing term “Interstitial  
nephritis” to “Tubulointerstitial nephritis (TIN)”  
in line with the updated Company Core Data  
Sheet.  
In addition, section 4.4 of the SmPC for  
centralised authorised products is updated with  
the Excipient warning for Sodium as per EMA

Request for supplementary information adopted  
with a specific timetable.

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guideline EMA/CHMP/302620/2017/EN Rev. 1. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the PL and to bring the PI in line with the last QRD template (version 10.1). This procedure also includes NAPs as listed in Annex B.”  
Request for Supplementary Information adopted on 09.12.2021.

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**WS2163**

**Combivir-**

**EMA/H/C/000190/WS2163/0103**

**Kivexa-EMA/H/C/000581/WS2163/0093**

**Trizivir-EMA/H/C/000338/WS2163/0127**

ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, “Update of section 5.2 of the SmPC in order to add new information on the elimination half-life of lamivudine, based on final results from studies 204993 and 204994. Study 204993 was a phase I, relative oral bioavailability study of different fixed dose combinations of dolutegravir and lamivudine in healthy subjects. Study 204994 was an open-label, randomized, single dose, crossover, bioequivalence study of fixed-dose combination tablet(s) of dolutegravir and lamivudine versus dolutegravir and lamivudine single entities and food effect assessment in healthy volunteers. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2 and to introduce minor editorial changes.”

Opinion adopted on 16.12.2021.

Positive Opinion adopted by consensus on 16.12.2021.

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

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**Adenuric - febuxostat -**

**EMA/H/C/000777/II/0061**

Menarini International Operations Luxembourg S.A., Rapporteur: Andrea Laslop, PRAC Rapporteur: Jan Neuhauser, “C.I.4 - Update of sections 4.4, 4.8 and 5.1 of the SmPC based on the final results from study FAST (Febuxostat versus Allopurinol Streamlined Trial) listed as a category 3 study in the RMP; this is an interventional study investigating the cardiovascular safety of febuxostat in

Positive Opinion adopted by consensus on 16.12.2021.

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comparison with allopurinol in patients with chronic symptomatic hyperuricaemia. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the warning relevant to the content of sodium according to the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'."

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted on 14.10.2021, 24.06.2021.

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**Bosulif - bosutinib -  
EMA/H/C/002373/II/0050/G**

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to reflect results from the studies B1871039 (SOB) and B1871040 (category 3 ); study B1871039 is A Phase 4 Safety and Efficacy Study of Bosutinib in Patients With Philadelphia Chromosome Positive Chronic Myeloid Leukemia Previously Treated With One or More Tyrosine Kinase Inhibitors and study B1871040 is An Open-Label Bosutinib Treatment Extension Study for Subjects With Chronic Myeloid Leukemia (CML) who Have Previously Participated in Bosutinib Studies B1871006 or B1871008. The Package Leaflet is updated accordingly. The MAH request deletion of the SOB from annex II of the PI and request consideration for switch of the Conditional Marketing Authorisation to a full Marketing Authorisation. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives for Belgium, Luxemburg, Germany and Northern Island in the Package Leaflet. The MAH is also asking the deletion of the product from the additional monitoring list." Request for Supplementary Information adopted on 16.12.2021, 16.09.2021.

Request for supplementary information adopted with a specific timetable.

See 9.1

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**Bridion - sugammadex -  
EMA/H/C/000885/II/0042**

Merck Sharp & Dohme B.V., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka,

Positive Opinion adopted by consensus on 16.12.2021.

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“C.I.3 type II to update sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations and update safety, efficacy and pharmacokinetic information in children and adolescents (2-17 years) following EMEA/H/C/0885/P46/025 and based on final results from study P089MK8616. This is a Phase 4 Double-Blinded, Randomized, Active Comparator-Controlled Clinical Trial to Study the Efficacy, Safety and Pharmacokinetics of Sugammadex (MK-8616) for Reversal of Neuromuscular Blockade in Pediatric Participants. In addition, the MAH took the opportunity to implement some minor editorial changes throughout the Product Information (section 4.4 of Annex I and Annex II). The Package Leaflet is updated in accordance and the MAH took the opportunity to update the list of local representatives. Version 7.2 of the RMP has also been submitted to incorporate changes due to the completeness of PN089 and the MAH took the opportunity to update the RMP with information on completed clinical studies PN089, PN146 and PN145 and to implement the RMP GVP Module V Rev 2 template.”  
Opinion adopted on 16.12.2021.  
Request for Supplementary Information adopted on 16.09.2021.

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**Caprelsa - vandetanib -  
EMEA/H/C/002315/II/0043**

Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant,  
“C.I.4 Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on interim results from study D4200C00104, listed as a specific obligation in the Annex II. This is an observational study (including a retrospective arm to evaluate the Benefit/Risk of vandetanib (Caprelsa) 300 mg in RET mutation negative and RET mutation positive patients with symptomatic, aggressive, sporadic, unresectable, locally advanced/metastatic thyroid cancer (MTC)), to confirm the efficacy and safety of Caprelsa in RET-negative patients with the aim to fulfil SOB001 and convert Caprelsa from conditional to normal Marketing Authorisation.  
In addition, the MAH takes to opportunity to rectify the Dutch translation of the Caprelsa Product Information.”

Request for supplementary information adopted with a specific timetable.

See 9.1

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Request for Supplementary Information adopted on 16.12.2021, 24.06.2021, 28.05.2020.

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**Cosentyx - secukinumab - EMEA/H/C/003729/II/0076**

Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Eva A. Segovia, "C.I.4 - Update of sections 4.2 and 5.1 of the SmPC for Cosentyx 150 mg and 300 mg in order to introduce a new posology regimen for adult plaque psoriasis patients and psoriatic arthritis patients with concomitant moderate to severe plaque psoriasis with a body weight of 90 kg or higher based on the final results of study CAIN457A2324 and exposure-response modelling; this is a randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of sub-cutaneous secukinumab in subjects of body weight 90 kg or higher with moderate to severe chronic plaque-type psoriasis; the Package Leaflet is updated accordingly. The RMP version 9.3 has also been adopted."

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted on 16.09.2021, 24.06.2021.

Positive Opinion adopted by consensus on 16.12.2021.

See 9.1

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**COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0018**

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of an updated RMP version 2.5 in order to include the following:

- To include thrombocytopenia (including immune thrombocytopenia) as an important identified risk following the outcome of the signal of Embolic and Thrombotic events (SDA 018.1, EPITT number 19689) and the opinion of procedure EMEA/H/C/005737/II/0006/G
- To propose studies aimed at further characterisation of Thrombosis with Thrombocytopenia syndrome (TTS) and thrombocytopenia, following the outcome of the signal of Embolic and Thrombotic events (SDA 018.1, EPITT number 19689)
- To include Guillain-Barré syndrome as an important identified risk and update the RMP accordingly (EMEA/H/C/005737/II/0012).

Positive Opinion adopted by consensus on 02.12.2021.

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In addition, the MAH took the opportunity to update in the EU-RMP the submission milestone dates for VAC31518COV4001 and VAC31518COV4002 studies.”

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 30.09.2021.

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

**EMA/H/C/004171/II/0016/G**

Sanofi Pasteur, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, “Update of section 4.5 of the SmPC to include coadministration data on human papillomavirus (HPV) vaccines and tetanus, diphtheria, and pertussis (Tdap) vaccine from CYD67, CYD71 and CYD66 final study reports respectively (final reports from three MEA studies listed as category 3 studies in the RMP); these studies are focused on immunogenicity and safety of the concomitant administration. The Package Leaflet is updated accordingly.

In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 6.3 is approved with this variation”

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 10.06.2021, 11.02.2021.

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Positive Opinion adopted by consensus on 02.12.2021.

**Erleada - apalutamide -**

**EMA/H/C/004452/II/0017**

Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Tiphaine Vaillant, “Update of sections 5.3 of the SmPC in order to update non-clinical information based on final results from study TOX11338 listed as PAM (EMA/H/C/004452/MEA/006); this is a 2-year carcinogenicity study of JNJ-56021927-AAA by oral gavage in rats; The RMP version 4.1 has also been submitted. In addition, the MAH has taken this opportunity to include general information in the RMP regarding study TITAN (PCR3002).”

Request for Supplementary Information adopted on 02.12.2021.

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Request for supplementary information adopted with a specific timetable.

**Imbruvica - ibrutinib -**

**EMA/H/C/003791/II/0068**

Janssen-Cilag International NV, Rapporteur:

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Positive Opinion adopted by consensus on 02.12.2021.

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Filip Josephson, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of section 4.4 of the SmPC in order to add baseline monitoring in addition to the current warnings for periodic monitoring of cardiac failure and cardiac arrhythmias in patients receiving ibrutinib. The Package Leaflet is updated accordingly. The RMP version 18.2 has also been submitted."  
Opinion adopted on 02.12.2021.  
Request for Supplementary Information adopted on 30.09.2021.

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**Imraldi - adalimumab -  
EMA/H/C/004279/II/0048/G**

Samsung Bioepis NL B.V., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Ulla Wändel Liminga  
B.II.a.5 (Type II): To introduce an additional concentration of 40 mg/0.4 mL (same 40 mg strength) for the solution for subcutaneous injection in pre-filled syringe (PFS) and pre-filled pen (PFP).

B.II.a.3.b.3

B.II.e.5.a.1 (Type IA): To add 2 presentations

B.II.e.5.a.1 (Type IA): To add 2 presentations

B.II.e.5.a.1 (Type IA): To add 2 presentations

B.II.e.5.a.1 (Type IA): To add 2 presentations

An updated Risk Management Plan (version 7.0) is provided in relation to this application.

Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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**Lojuxta - lomitapide -  
EMA/H/C/002578/II/0046**

Amryt Pharmaceuticals DAC, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, "To propose an alternative study (LILITH) to the currently agreed protocol for the CAPTURE study. The new study proposes an evaluation of the effect of lomitapide treatment on major adverse cardiovascular events (MACE) in patients with homozygous familial hypercholesterolemia. Consequential submission of an updated RMP (version 6.4) and Annex IID of the Product Information. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2"

Request for Supplementary Information adopted on 16.12.2021, 22.07.2021, 09.04.2021.

Request for supplementary information adopted with a specific timetable.

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**LUTATHERA - lutetium (177Lu)  
oxodotreotide -**

Request for supplementary information adopted with a specific timetable.

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**EMA/H/C/004123/II/0030, Orphan**

Advanced Accelerator Applications, Rapporteur:

Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Update of the SmPC sections 4.4, 4.8 and 5.1 based on the pivotal Phase III study, NETTER-1. Additionally, updates are proposed in the PI to correct some information based on currently approved data. The PL is updated accordingly. The RMP v. 2.0 has been submitted. The MAH took also the opportunity to update the details of local representatives in the PL."

Request for Supplementary Information adopted on 16.12.2021.

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**Mekinist - trametinib -****EMA/H/C/002643/II/0051**

Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: David Olsen, "Update of sections 4.2 and 5.2 of the SmPC in order to change posology recommendations in hepatic impairment and update pharmacokinetic information based on final results from study MEC116354 listed as a category 3 study in the RMP; this is a Phase I Trial of Single Agent Trametinib (GSK1120212) in Advanced Cancer Patients with Hepatic Dysfunction. The RMP version 18 has also been submitted."

Request for Supplementary Information adopted on 16.12.2021.

Request for supplementary information adopted with a specific timetable.

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**NINLARO - ixazomib -****EMA/H/C/003844/II/0033, Orphan**

Takeda Pharma A/S, Rapporteur: Armando Genazzani, PRAC Rapporteur: Annika Folin, "C.I.11 Submission of the final report for the final analysis of OS for study C16010 fulfilling an obligation in the Annex II of the Product Information. This is a phase 3 study to evaluate efficacy and safety of ixazomib in combination with LenDex in adult patients with relapsed and/or refractory multiple myeloma. Section 4.4 is also updated to include a warning about occurrence of Stevens-Johnson syndrome. The Package Leaflet is updated accordingly. An updated RMP (version 7.0) has been submitted. The applicant also took the opportunity to update the list of local representatives."

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted

Positive Opinion adopted by consensus on 02.12.2021.



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on 28.10.2021, 02.09.2021.

**Ondexxya - andexanet alfa -  
EMA/H/C/004108/II/0022/G**

Alexion Europe SAS, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.4, 4.8 and 5.1 of the SmPC based the final study report from study 14-505 (ANNEXA-4). This is a Prospective, open-label study of andexanet alfa in patients receiving a factor Xa inhibitor who have acute major bleeding to confirm safety and efficacy in patients with acute major bleeds. The provision of this study report fulfils Specific Obligation 001, and as a consequence it has been deleted in the Annex II. The package leaflet was updated accordingly, and the applicant took the opportunity to implement editorial changes in the Annexes. The revised RMP version 2.4 has also been submitted.

Change to the summary of pharmacovigilance system due to change in QPPV."

Request for Supplementary Information adopted on 16.12.2021, 16.09.2021.

Request for supplementary information adopted with a specific timetable.

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**Onpattro - patisiran -  
EMA/H/C/004699/II/0022, Orphan**

Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "Type II variation C.I.4 in the Summary of Product Characteristics (SmPC), Labelling or Package Leaflet (PL) due to new quality, preclinical, clinical or pharmacovigilance data: update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC to confirm that the safety profile of patisiran in liver transplant recipients is comparable to data in patients without liver transplant, based on final results from study ALN-TTR02-008, a global phase 3b, open-label, extension study to evaluate safety, efficacy and pharmacokinetics of patisiran in patients with hereditary transthyretin-mediated amyloidosis (HATTR amyloidosis) with disease progression post-orthotopic liver transplant (OLT). The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to make some minor changes to the English PI in SmPC sections 5.1 and 6.3 (in line with EMA recommendation from procedure EMA/H/C/004699/IB/0014), PL section 2 (minor typographical error changes), 6 (update

Positive Opinion adopted by consensus on 16.12.2021.

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to contact numbers of local MAH representatives in Cyprus and Malta, and MAH local representative from 'United Kingdom' to 'United Kingdom [Northern Ireland] in line with the QRD template version 10.2) and implement minor linguistic changes and typographical error corrections in the Italian PI translation."  
Opinion adopted on 16.12.2021.

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**Praluent - alirocumab -  
EMA/H/C/003882/II/0065**

sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 5.1 of the SmPC in order to include information on the effect of alirocumab on the neurocognitive function based on final results from the study R727-CL-1532 listed as a category 3 study in the RMP; this is an interventional study to evaluate the neurocognitive function during the treatment, as well as the effect of the medicinal product in comparison with placebo on lipoproteins and to assess the safety and tolerability. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2 and to update the list of local representatives."  
Opinion adopted on 02.12.2021.  
Request for Supplementary Information adopted on 02.09.2021.

Positive Opinion adopted by consensus on 02.12.2021.

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**Pyramax - pyronaridine / artesunate -  
EMA/H/W/002319/II/0023/G**

Shin Poong Pharmaceutical Co., Ltd.,  
Rapporteur: Jean-Michel Race, PRAC  
Rapporteur: Nathalie Gault, "Grouping of variations providing the final clinical study reports (CSR) of two completed studies:  
- Study SP-C-021-15: A Phase IIIb/IV cohort event monitoring study conducted in Central Africa to evaluate the safety in patients after the local registration of Pyramax (CANTAM study). This study is a category 3 Required Additional Pharmacovigilance Activity described in the RMP (MEA 013).  
- SP-C-026-18: A Randomized Open-Label Exploratory Study to Determine The Efficacy of Different Treatment Regimens of Pyramax (Pyronaridine-Artesunate) In Asymptomatic Carriers Of Plasmodium Falciparum

Positive Opinion adopted by consensus on 02.12.2021.

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Monoinfections. This non-imposed study was conducted in The Gambia and Zambia and compared asymptomatic subjects with parasitaemia dosed according to the approved label of 3-day dosing with 2-day and 1-day dosing. There have been no new safety findings from the study but the RMP has been updated to reflect its details.

As a result of the additional clinical data, corresponding changes to the Product Information (SmPC and PL) are proposed with the Grouping.

RMP version 17 has also been submitted, updated to reflect the results of both above-mentioned CSRs, and converted to the new RMP integrated template format (Rev 2.0.1)."

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 02.09.2021, 06.05.2021, 14.01.2021.

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**RAVICTI - glycerol phenylbutyrate - EMEA/H/C/003822/II/0038/G, Orphan**

Immedica Pharma AB, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Ilaria Baldelli, "Group of variations consisting of:

- Submission of the final study report, HPN-100-014 non-interventional registry study "Long-Term Registry of Patients with Urea Cycle Disorders (UCDs) conducted in the US".

- An update to the RMP (version 7.3) submitted and agreed to remove the important potential risk of carcinogenicity. The update to the RMP is based on the review of new and available data including the study report for HPN-100-014 and a new toxicological expert examination of pre-clinical carcinogenicity findings as well as a cumulative review of literature and post-marketing data. In accordance with the proposed changes to the RMP, the requested waiving of the Annex II imposed condition related to the non-interventional post-authorisation safety study (PASS), "European Post-Authorization Registry for RAVICTI (glycerol phenylbutyrate) Oral Liquid in Partnership with the European Registry and Network for Intoxication Type Metabolic Diseases (E-IMD)" is agreed but this PASS agreed to be discontinued is retained in the RMP as a category 3 PASS until final PASS results submission. The SmPC and Package Leaflet have been updated to delete the information on

Positive Opinion adopted by consensus on 16.12.2021.

See 9.1

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additional monitoring (including the black triangle)."

Opinion adopted on 16.12.2021.

Request for Supplementary Information adopted on 22.07.2021.

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**Tecentriq - atezolizumab -  
EMA/H/C/004143/II/0066**

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "C.I.13: Submission of the final report from study WO29635 to fulfil a category 3 study activity (MEA/FSR 007). This is A Phase IB/II study of the safety and pharmacology of

Atezolizumab administered with or without Bacille Calmette-Guérin in patients with High Risk Non-Muscle-Invasive Bladder Cancer. The RMP version 22.0 has also been submitted. The RMP has additionally been amended to revise the due date for the submission of the final CSR for study MO39171 (TAIL)."

Opinion adopted on 02.12.2021.

Positive Opinion adopted by consensus on 02.12.2021.

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**Tresiba - insulin degludec -  
EMA/H/C/002498/II/0054**

Novo Nordisk A/S, Rapporteur: Kristina Dunder, Co-Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Annika Folin, "Update of sections 4.6 and 5.1 of the Summary of product characteristics in order to include new clinical data from the pregnancy trial EXPECT conducted for Tresiba.

The Package Leaflet is updated in accordance.

The RMP version 9.0 is also submitted."

Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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**Uptravi - selexipag -  
EMA/H/C/003774/II/0034**

Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Nathalie Gault, "Update of section 4.8 of the SmPC to add 'dyspepsia' as a new ADR with frequency 'common', and to include further information on the frequency of 'dyspepsia' and 'anaemia' specific to initial 2-step triple combination therapy, based on the studies AC-065A308 (TRITON) and AC-065A404 (TRACE). AC-065A308 (TRITON) study was a randomized, double-blind, placebo-controlled, parallel-group, Phase 3b, efficacy and safety study comparing

Request for supplementary information adopted with a specific timetable.

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triple oral combination therapy (selexipag, macitentan, tadalafil) with double oral combination therapy (placebo, macitentan, tadalafil) in newly diagnosed, treatment-naïve participants with PAH. The AC-065A404 (TRACE) study was a randomized, double-blind, placebo-controlled, parallel-group, exploratory Phase 4 study in participants with PAH to assess the effect of selexipag on daily life physical activity and participant's self-reported symptoms and their impacts. The package leaflet is updated accordingly. A revised RMP version 9.2 was provided as part of the application." Request for Supplementary Information adopted on 02.12.2021.

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**WS2098**  
**Komboglyze-EMA/H/C/002059/**  
**WS2098/0051**  
**Onglyza-EMA/H/C/001039/WS2098/**  
**0053**

Positive Opinion adopted by consensus on 02.12.2021.

AstraZeneca AB, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, "Submission of the final report from study D1680C00016 (MEASURE HF) (listed as a category 3 study in the RMP). This is a 24-week, multicentre, randomised, double-blind, parallel group, placebo-controlled study to investigate the effects of saxagliptin and sitagliptin on cardiac dimensions and function in patients with Type 2 Diabetes Mellitus and Heart Failure. The combined RMP for Komboglyze and Onglyza version 16 has also been submitted." Opinion adopted on 02.12.2021. Request for Supplementary Information adopted on 02.09.2021.

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**B.5.4. PRAC assessed procedures**

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PRAC Led  
**Adasuve - loxapine -**  
**EMA/H/C/002400/II/0033**

Request for supplementary information adopted with a specific timetable.

Ferrer Internacional s.a., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update safety information on Bronchospasm based on final results from study AMDC-204-401 EU PASS

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(assessed in procedure EMEA/H/C/0002400/II/0032): Post-authorisation Observational Study to Evaluate the Safety of ADASUVE (Staccato loxapine for inhalation) in Agitated Persons in Routine Clinical Care, a category 3 study in the RMP; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.” Request for Supplementary Information adopted on 02.12.2021.

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PRAC Led  
**AUBAGIO - teriflunomide - EMEA/H/C/002514/II/0038**  
sanofi-aventis groupe, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, “Submission of the final PASS OBS12753 study report listed as a category 3 study in the RMP. This is a prospective cohort study of long-term safety of teriflunomide in multiple sclerosis patients in Europe. The updated RMP v 7.1 is proposed.” Request for Supplementary Information adopted on 02.12.2021, 30.09.2021.

Request for supplementary information adopted with a specific timetable.

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PRAC Led  
**COMIRNATY - tozinameran - EMEA/H/C/005735/II/0080**  
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, “Update of section 4.4 of the SmPC in order to amend an existing warning on anxiety-related reactions to add “numbness” based on the outcome of the Post-Authorisation Measure PAM MEA-002.8 (EMEA/H/C/005735/MEA/002.8, dated 30. September 2021). In addition, the MAH took the opportunity to make minor editorial changes throughout the product information.” Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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PRAC Led  
**Duavive - estrogens conjugated / bazedoxifene - EMEA/H/C/002314/II/0030**  
Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, “Submission of the

Positive Opinion adopted by consensus on 02.12.2021.

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final report from study B2311060 listed as a category 3 study in the RMP. This is a non-interventional, post-authorisation safety study of conjugated estrogens/bazedoxifene (CE/BZA), with the aim to monitor the safety profile of Duavive (CE/BZA) in comparison to estrogen and progestin combination hormone therapy (E+P HT). As a consequence, the warnings on breast cancer and stroke are updated in section 4.4 of the SmPC and section 5.1 of the SmPC was updated to reflect the results of this study. The package leaflet is updated accordingly."

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 08.07.2021.

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PRAC Led

**Evenity - romosozumab -  
EMA/H/C/004465/II/0010**

UCB Pharma S.A., Rapporteur: Kristina Dunder, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of an updated RMP version 2.0 in order to remove the important identified risk of "immunogenicity", based on the Good Pharmacovigilance Practices (GVP) guidelines, EMA guidance on immunogenicity assessment, and the available non-clinical, clinical and post-marketing data. In addition, following the Pharmacovigilance Risk Assessment Committee (PRAC) recommendation (EMA/PRAC/265359/2021) dated 06 May 2021, the MAH is taking this opportunity to add "cardiac arrhythmia" as an important potential risk of romosozumab, update the protocol for the ongoing post-authorisation safety study (PASS) OP0004 to include cardiac arrhythmias as specific events to monitor, and include a targeted follow-up questionnaire related to cardiac arrhythmias in the RMP Part VII Annex 4.

The MAH is also taking this opportunity to introduce minor changes in the PASS protocols of three studies OP0004, OP0005 and OP0006." Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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PRAC Led

**Flucelvax Tetra - influenza vaccine surface  
antigen inactivated prepared in cell  
cultures - EMA/H/C/004814/II/0023**

Request for supplementary information adopted with a specific timetable.

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Seqirus Netherlands B.V., Rapporteur: Sol Ruiz,  
PRAC Rapporteur: Brigitte Keller-Stanislawski,  
PRAC-CHMP liaison: Jan Mueller-Berghaus,  
"Update of section 4.6 of the SmPC in order to  
update information on Pregnancy Registry  
130\_110B, listed as a category 3 study in the  
RMP. The PL is updated accordingly. The RMP  
version 3.1 has also been submitted in order to  
update information related to the pregnancy  
study, clinical and post-marketing exposure."  
Request for Supplementary Information adopted  
on 02.12.2021.

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PRAC Led

**Hemlibra - emicizumab -**

**EMA/H/C/004406/II/0025**

Roche Registration GmbH, Rapporteur:  
Alexandre Moreau, PRAC Rapporteur: Amelia  
Cupelli, PRAC-CHMP liaison: Armando  
Genazzani, "Update of sections 4.4, 4.8 and 5.1  
of the Product information concerning  
immunogenicity and loss of efficacy due to anti-  
emicizumab antibodies. The RMP (v. 3.0) is  
proposed to be updated accordingly."  
Request for Supplementary Information adopted  
on 02.12.2021, 02.09.2021.

Request for supplementary information adopted  
with a specific timetable.

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PRAC Led

**Hemlibra - emicizumab -**

**EMA/H/C/004406/II/0028**

Roche Registration GmbH, Rapporteur:  
Alexandre Moreau, PRAC Rapporteur: Amelia  
Cupelli, PRAC-CHMP liaison: Armando  
Genazzani, "Submission of the final study report  
for BO40853 (Hemlibra Survey to Prescribers  
and Patients/Carers to Evaluate Awareness,  
Knowledge, and Compliance to Additional Risk  
Minimization Measures, listed as a category 3  
study in the RMP). An updated RMP (version  
4.0) is presented in support of this application,"  
Request for Supplementary Information adopted  
on 02.12.2021.

Request for supplementary information adopted  
with a specific timetable.

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PRAC Led

**Latuda - lurasidone -**

**EMA/H/C/002713/II/0036**

Aziende Chimiche Riunite Angelini Francesco  
A.C.R.A.F. S.p.A., Rapporteur: Filip Josephson,  
PRAC Rapporteur: Ulla Wändel Liminga, PRAC-  
CHMP liaison: Filip Josephson, "Update of  
section 4.8 of the SmPC to amend the frequency  
of ADRs in adults and to add 'syncope'

Positive Opinion adopted by consensus on  
02.12.2021.



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(frequency uncommon) and 'cerebrovascular accident' (frequency rare) following the assessment of the procedure EMEA/H/C/PSUSA/00010114/202010. The Package Leaflet is updated accordingly. Minor adjustments of the PTs based on the MedDRA definitions were implemented and the ADR 'blood creatine phosphokinase increased' was moved to the SOC Investigations. In addition, the marketing authorisation holder has taken the opportunity to combine all the dosages in a single version of the SmPC, to update the list of local representatives in the PL and to bring the PI in line with the latest QRD template version 10.2 Rev. 1." Opinion adopted on 02.12.2021.

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PRAC Led

**Neulasta - pegfilgrastim -  
EMEA/H/C/000420/II/0116**

Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from study 20170701 listed as a category 3 study in the RMP (MEA-060.5). This is an observational study to assess the effectiveness of the Neulasta patient alert card and to measure medication errors related to the use of the On-Body Injector. Data provided justified additional activity to be included in the Patient Instruction for use in the package leaflet. The MAH took the occasion to amend local representative details for Malta, Germany and to align the PI to the recent QRD template version 10.2. The RMP version 8.0 has also been submitted."

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 02.09.2021.

Positive Opinion adopted by consensus on 02.12.2021.

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PRAC Led

**Prolia - denosumab -  
EMEA/H/C/001120/II/0091/G**

Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "- C.I.11.b: Submission of an updated RMP version 28.0 in order to remove osteonecrosis outside the jaw (OOJ) including external auditory canal (OEAC) as an important potential risk.

- C.I.11.b: Submission of an updated RMP

Positive Opinion adopted by consensus on 02.12.2021.

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version 28.0 in order to remove immunogenicity as missing information.

- C.I.11.b: Submission of an updated RMP version 28.0 in order to introduce changes to the category 3 PASS-retrospective cohort database study (study 20190038) for the potential increased risk of cardiovascular and cerebrovascular events among women with PMO and men with osteoporosis by adding the study objectives. In addition, the MAH took the opportunity to update the RMP in order to provide the date for the provision of the final study report for study 20190038 and to include the post-marketing exposure data from the last submitted PSUR/PBRER (#13).”  
Opinion adopted on 02.12.2021.

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PRAC Led

**Prolia - denosumab -  
EMA/H/C/001120/II/0092**

Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, “Submission of the final report from study 20190038 "Incidence of Cardiovascular and Cerebrovascular Events Among Postmenopausal Women and Men With Osteoporosis Who Initiated Treatment With Denosumab or Zoledronic Acid - a Retrospective Cohort Study". This is an observational PASS listed as category 3 study in the RMP.”  
Opinion adopted on 02.12.2021.

Positive Opinion adopted by consensus on 02.12.2021.

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PRAC Led

**Spikevax - COVID-19 mRNA vaccine  
(nucleoside-modified) -  
EMA/H/C/005791/II/0022**

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Sinan B. Sarac, “Submission of an updated RMP version 2.0 to include clinical safety data from study mRNA-1273 P203 (NCT04649151), a Phase 2/3, randomised, observer-blind, placebo-controlled study evaluating the safety, reactogenicity, and effectiveness of the mRNA-1273 vaccine in healthy adolescents aged  $\geq 12$  to  $< 18$  years.”  
Request for Supplementary Information adopted on 02.12.2021, 28.10.2021, 02.09.2021.

Request for supplementary information adopted with a specific timetable.

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PRAC Led

**Spikevax - COVID-19 mRNA vaccine**

Request for supplementary information adopted with a specific timetable.

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**(nucleoside-modified) -  
EMA/H/C/005791/II/0028**

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of an updated RMP version 2.1 to include myocarditis and pericarditis as an important identified risk, as requested by PRAC as an outcome of the myocarditis and pericarditis signal assessment procedure."  
Request for Supplementary Information adopted on 02.12.2021, 28.10.2021, 02.09.2021.

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PRAC Led

**TRISENOX - arsenic trioxide -  
EMA/H/C/000388/II/0076**

Teva B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.6 of the SmPC in order to update information on pregnancy and contraception in male patients following the decision and discussion made for EMA/H/C/PSUSA/00000235/202009. The Package Leaflet is updated accordingly."  
Request for Supplementary Information adopted on 02.12.2021.

Request for supplementary information adopted with a specific timetable.

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PRAC Led

**Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) -  
EMA/H/C/005675/II/0040**

AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Christophe Focke, "Update of the RMP to version 4.2 in order to:

- Add 'Thrombocytopenia, including immune thrombocytopenia' as an important identified risk, as per PRAC outcome of signal assessment procedure on immune thrombocytopenia (EPITT no: 19678);
- Add Guillain-Barré Syndrome (GBS) as important identified risk;
- Add acute macular neuroretinopathy / acute macular outer retinopathy, paracentral acute middle maculopathy, parasthesia and dysaesthesia in the list of AESIs, as per PRAC outcome of signal assessment procedure on acute macular outer retinopathy (EPITT no: 19703);
- Add thrombocytopenia, including immune thrombocytopenia in replacement of

Positive Opinion adopted by consensus on 02.12.2021.

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'Thrombocytopenia with associated bleeding' the list of AESIs, as per PRAC outcome of signal assessment procedure on immune thrombocytopenia (EPITT n°: 19678)

- Remove the Enhanced active surveillance (EAS) studies D8111R00003 [EU], D8110R00001 [US], D8111C00004 [UK]);
- Add the UK effectiveness study (D8111R00007), as per CHMP conclusion from MEA 010.1;
- Add a study D8111R00010 to assess the relationship between the exposure to COVID-19 vaccines and risk of thrombotic thrombocytopenia syndrome.
- Update the milestones for study D8111R00006 and correct milestone related to the SAP of Pregnancy registry as well as milestones date related to COV001, COV002, COV003 and COV005."

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 28.10.2021.

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PRAC Led

**VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0049, Orphan**

Takeda Pharmaceuticals International AG,  
Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of final physician data study results for PASS study "Evaluation of the Effectiveness of Risk Minimisation Measures: A Survey among Health Care Professionals and Patient/Caregivers to Assess their Knowledge and Attitudes on Prescribing and Home Administration Conditions of Velaglucerase Alpha (VPRIV) in 6 European Countries" (EUPASS 14255)"

Request for Supplementary Information adopted on 02.12.2021, 08.07.2021, 11.02.2021, 26.11.2020.

Request for supplementary information adopted with a specific timetable.

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PRAC Led

**Vyxeos liposomal - daunorubicin / cytarabine - EMEA/H/C/004282/II/0017, Orphan**

Jazz Pharmaceuticals Ireland Limited,  
Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, "Submission of a final CSR for post-

Positive Opinion adopted by consensus on 02.12.2021.

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marketing observational study of Vyxeos liposomal to assess the incidence of infusion-related reactions in adult patients. The primary objective of this study is to assess the nature, incidence, and severity of infusion-related reactions during and for up to one day following the last infusion of a five-day induction course in patients treated with the product. The secondary objective is to assess this information during and for up to one day following the last infusion of a five-day induction course in patients treated with Vyxeos.”

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 08.07.2021, 11.03.2021.

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PRAC Led

**Xeljanz - tofacitinib -**

**EMA/H/C/004214/II/0044**

Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, “C.I.3.b - Update of sections 4.4, 4.8 and 5.1 to add warnings and safety data on serious infections, viral reactivation, non-melanoma skin cancer and fractures. This is based on the final results from study A3921133 listed as a category 3 study in the RMP; this is a post-authorisation safety study conducted to evaluate the safety of tofacitinib 5 mg and 10 mg compared to TNFi in adults’ subjects aged ≥50 years with moderately or severely active RA and with at least 1 additional CV risk factor. The Package Leaflet is updated accordingly. The RMP version 21.1 has also been submitted. In addition, the MAH took the opportunity to update the Outer carton (section 4 for oral solution) to include a total volume of 240 mL as requested following the completion of the procedure EMA/H/C/004214/X/0024/G.”

Request for Supplementary Information adopted on 02.12.2021.

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Request for supplementary information adopted with a specific timetable.

PRAC Led

**WS2064**

**Nuwiq-EMA/H/C/002813/WS2064/0043**

**Vihuma-EMA/H/C/004459/WS2064/0024**

Octapharma AB, Lead PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, “To provide an updated RMP to remove

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Positive Opinion adopted by consensus on 02.12.2021.

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the completed studies GENA-05 and GENA-15. In addition, the RMP has been updated to GVP Module V Rev.2. No new safety concerns were added.”

Opinion adopted on 02.12.2021.

Request for Supplementary Information adopted on 02.09.2021, 10.06.2021.

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PRAC Led

**WS2158**

**Exviera-EMA/H/C/003837/WS2158/0051**

**Viekirax-EMA/H/C/003839/WS2158/0063**

AbbVie Deutschland GmbH & Co. KG, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, “To update the Annex IID study milestone due date , for the hepatocellular carcinoma (HCC) recurrence post-authorisation safety study (B20-146) following the EMA's recommendation on 6 July 2021.

In addition, the MAH is taking the opportunity to introduce few minor linguistic and typographical corrections in the Summary of Product Characteristics (SmPCs) for the Hungarian, Latvian and Romanian translations of the Exviera product information.”

Opinion adopted on 02.12.2021.

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Positive Opinion adopted by consensus on 02.12.2021.

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

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**Abecma - idecabtagene vicleucel - EMA/H/C/004662/II/0005/G, Orphan, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang  
Opinion adopted on 16.12.2021, 10.12.2021.

Positive Opinion adopted by consensus on 16.12.2021.

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**Libmeldy - atidarsagene autotemcel - EMA/H/C/005321/II/0004, Orphan, ATMP**

Orchard Therapeutics (Netherlands) BV, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege  
Opinion adopted on 16.12.2021, 10.12.2021.  
Request for Supplementary Information adopted on 08.10.2021.

Positive Opinion adopted by consensus on 16.12.2021.

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**Tecartus - autologous peripheral blood t**

Positive Opinion adopted by consensus on

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<p><b>cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured - EMEA/H/C/005102/II/0012, Orphan, ATMP</b></p> <p>Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus</p> <p>Opinion adopted on 16.12.2021, 10.12.2021.</p> <p>Request for Supplementary Information adopted on 08.10.2021.</p>	<p>16.12.2021.</p>
<p><b>Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0020/G, Orphan, ATMP</b></p> <p>Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege</p> <p>Request for Supplementary Information adopted on 10.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p><b>WS2181</b></p> <p><b>Tecartus-EMEA/H/C/005102/WS2181/0014</b></p> <p><b>Yescarta-EMEA/H/C/004480/WS2181/0044</b></p> <p>Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus</p> <p>Request for Supplementary Information adopted on 16.12.2021.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>

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

<p><b>Abecma - idecabtagene vicleucel - EMEA/H/C/004662/II/0009, Orphan, ATMP</b></p> <p>Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Annika Folin, "Update of sections 4.2 and 4.4 of the SmPC, Annex IID and PIL in order to add statements for the use of Abecma exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab."</p> <p>Opinion adopted on 16.12.2021, 10.12.2021.</p>	<p>Positive Opinion adopted by consensus on 16.12.2021.</p>
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<p><b>Kymriah - tisagenlecleucel -</b></p>	<p>Positive Opinion adopted by consensus on</p>
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**EMA/H/C/004090/II/0047, Orphan, ATMP** 16.12.2021.  
Novartis Europharm Limited, Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.2 and 4.4 of the SmPC, Annex IID and PIL (information intended for healthcare professionals) in order to add statements for the use of Kymriah exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab"."  
Opinion adopted on 16.12.2021, 10.12.2021.

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**WS2206** Positive Opinion adopted by consensus on 16.12.2021.  
**Tecartus-EMA/H/C/005102/WS2206/0015**  
**Yescarta-EMA/H/C/004480/WS2206/0045**  
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, Lead PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2 and 4.4 of the SmPC and Annex IID in order to add statements for the use of Tecartus and Yescarta exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab". The RMPs for both products are updated accordingly (version 1.2 for Tecartus and version 5.2 for Yescarta)."  
Opinion adopted on 16.12.2021, 10.12.2021.

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

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

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**WS2088/G** Positive Opinion adopted by consensus on 25.11.2021.  
**Brimica Genuair-EMA/H/C/003969/WS2088/0033/G**  
**Duaklir Genuair-EMA/H/C/003745/WS2088/0033/G**  
AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra  
Opinion adopted on 25.11.2021.  
Request for Supplementary Information adopted on 23.09.2021.

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**WS2089/G** Positive Opinion adopted by consensus on  
**Bretaris Genuair-EMA/H/C/002706/**

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<p><b>WS2089/0047/G</b>  <b>Eklira Genuair-EMA/H/C/002211/</b>  <b>WS2089/0047/G</b>  AstraZeneca AB, Lead Rapporteur: Ewa Balkowiec Iskra  Opinion adopted on 18.11.2021.  Request for Supplementary Information adopted on 16.09.2021.</p>	18.11.2021.
<p><b>WS2105/G</b>  <b>Corbilta-EMA/H/C/002785/WS2105/</b>  <b>0025/G</b>  <b>Levodopa/Carbidopa/Entacapone Orion-</b>  <b>EMA/H/C/002441/WS2105/0033/G</b>  <b>Stalevo-EMA/H/C/000511/WS2105/</b>  <b>0095/G</b>  Orion Corporation, Lead Rapporteur: Outi Mäki-Ikola  Opinion adopted on 25.11.2021.  Request for Supplementary Information adopted on 30.09.2021.</p>	Positive Opinion adopted by consensus on 25.11.2021.
<p><b>WS2128/G</b>  <b>Eucreas-</b>  <b>EMA/H/C/000807/WS2128/0090/G</b>  <b>Icandra-</b>  <b>EMA/H/C/001050/WS2128/0093/G</b>  <b>Zomarist-</b>  <b>EMA/H/C/001049/WS2128/0092/G</b>  Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder  Opinion adopted on 16.12.2021.  Request for Supplementary Information adopted on 11.11.2021.</p>	Positive Opinion adopted by consensus on 16.12.2021.
<p><b>WS2131</b>  <b>Herceptin-EMA/H/C/000278/WS2131/</b>  <b>0176</b>  <b>Kadcyla-EMA/H/C/002389/WS2131/</b>  <b>0060</b>  <b>Phesgo-EMA/H/C/005386/WS2131/0009</b>  Roche Registration GmbH, Lead Rapporteur: Jan Mueller-Berghaus  Opinion adopted on 25.11.2021.</p>	Positive Opinion adopted by consensus on 25.11.2021.
<p><b>WS2139</b>  <b>Hexacima-EMA/H/C/002702/WS2139/</b>  <b>0121</b>  <b>Hexyon-EMA/H/C/002796/WS2139/</b>  <b>0125</b>  Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-</p>	Positive Opinion adopted by consensus on 02.12.2021.

Berghaus Opinion adopted on 02.12.2021.	
<b>WS2147</b> <b>Infanrix hexa-EMEA/H/C/000296/</b> <b>WS2147/0306</b> GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 25.11.2021.	Positive Opinion adopted by consensus on 25.11.2021.
<b>WS2148/G</b> <b>Hexacima-</b> <b>EMEA/H/C/002702/WS2148/0122/G</b> <b>Hexyon-</b> <b>EMEA/H/C/002796/WS2148/0126/G</b> Sanofi Pasteur, Lead Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 09.12.2021.	Request for supplementary information adopted with a specific timetable.
<b>WS2152</b> <b>Aflunov-EMEA/H/C/002094/WS2152/</b> <b>0072</b> <b>Foclivia-EMEA/H/C/001208/WS2152/</b> <b>0069</b> Seqirus S.r.l, Lead Rapporteur: Armando Genazzani Opinion adopted on 18.11.2021. Request for Supplementary Information adopted on 14.10.2021.	Positive Opinion adopted by consensus on 18.11.2021.
<b>WS2161</b> <b>Mircera-EMEA/H/C/000739/WS2161/0085</b> <b>NeoRecormon-EMEA/H/C/000116/</b> <b>WS2161/0114</b> Roche Registration GmbH, Lead Rapporteur: Martina Weise Opinion adopted on 02.12.2021.	Positive Opinion adopted by consensus on 02.12.2021.
<b>WS2169</b> <b>Mirapexin-EMEA/H/C/000134/WS2169/</b> <b>0101</b> <b>Sifrol-EMEA/H/C/000133/WS2169/0092</b> Boehringer Ingelheim International GmbH, Lead Rapporteur: Sinan B. Sarac, "To update the annexes to bring them in line with QRD version 10.1. In addition, a thorough review of the annexes has been performed and inconsistencies have been corrected." Opinion adopted on 16.12.2021.	Positive Opinion adopted by consensus on 16.12.2021.
<b>WS2171</b> <b>Glyxambi-EMEA/H/C/003833/WS2171/</b>	Request for supplementary information adopted with a specific timetable.

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**0040**

**Synjardy-EMEA/H/C/003770/WS2171/**

**0058**

Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "To update section 4.8 of the SmPC and section 4 of the PL to include the side effect 'constipation' in order to align with the Jardiance PI following approval of EMEA/H/C/002677/II/0055." Request for Supplementary Information adopted on 02.12.2021.

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**WS2172**

**Aprovel-EMEA/H/C/000141/WS2172/0186**

**CoAprovel-EMEA/H/C/000222/WS2172/0205**

**Karvea-EMEA/H/C/000142/WS2172/0188**

**Karvezide-EMEA/H/C/000221/WS2172/0205**

sanofi-aventis groupe, Lead Rapporteur: Maria Concepcion Prieto Yerro, Opinion adopted on 25.11.2021.

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Positive Opinion adopted by consensus on 25.11.2021.

**WS2178/G**

**Aflunov-**

**EMEA/H/C/002094/WS2178/0074/G**

**Foclivia-**

**EMEA/H/C/001208/WS2178/0071/G**

Seqirus S.r.l, Lead Rapporteur: Armando Genazzani

Opinion adopted on 09.12.2021.

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Positive Opinion adopted by consensus on 09.12.2021.

**WS2179/G**

**Prezista-**

**EMEA/H/C/000707/WS2179/0114/G**

**Rezolsta-**

**EMEA/H/C/002819/WS2179/0045/G**

**Symtuza-**

**EMEA/H/C/004391/WS2179/0039/G**

Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege  
Opinion adopted on 09.12.2021.

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Positive Opinion adopted by consensus on 09.12.2021.

**WS2180**

**Aprovel-EMEA/H/C/000141/WS2180/0187**

**CoAprovel-EMEA/H/C/000222/WS2180/0206**

**Karvea-EMEA/H/C/000142/WS2180/0189**

**Karvezide-EMEA/H/C/000221/WS2180/0206**

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Positive Opinion adopted by consensus on 02.12.2021.

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sanofi-aventis groupe, Lead Rapporteur: Maria  
Concepcion Prieto Yerro  
Opinion adopted on 02.12.2021.

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

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<p>PRAC Led <b>Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0173</b> Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Removal of the additional risk minimisation measures (aRMMs) for the PrEP indication risks, from the Truvada EU RMP and Annex II of the Truvada PI. With this variation, version 17.2 of the RMP (dated 1st July 2021) is submitted." Request for Supplementary Information adopted on 30.09.2021.</p>	<p>The MAH withdrew the procedure on 22.11.2021.</p>
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<p><b>Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0021/G</b> AstraZeneca AB, Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 16.09.2021, 22.07.2021, 24.06.2021. Withdrawal request submitted on 14.12.2021.</p>	<p>See 9.1 The MAH withdrew the procedure on 14.12.2021.</p>
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### **B.5.10. Information on type II variation / WS procedure with revised timetable**

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<p><b>Enbrel - etanercept - EMEA/H/C/000262/II/0243/G</b> Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro Request for Supplementary Information adopted on 02.09.2021.</p>	<p>The CHMP agreed to the request for a clock stop extension to respond to the request for supplementary information adopted in September 2021.</p>
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## **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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**dimethyl fumarate - EMEA/H/C/006039**  
treatment of multiple sclerosis

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**dimethyl fumarate - EMEA/H/C/006042**

treatment of multiple sclerosis

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**tabelecleucel - EMEA/H/C/004577, Accelerated review  
Orphan, ATMP**

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

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**abaloparatide - EMEA/H/C/005928**

treatment of osteoporosis

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**spironolactone- EMEA/H/C/005535**

Management of refractory oedema

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**molnupiravir - EMEA/H/C/005789**

Treatment of coronavirus disease 2019 (COVID-19)

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**fosdenopterin - EMEA/H/C/005378, Accelerated review  
Orphan**

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

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**nvx-cov2373 - EMEA/H/C/005808**

prevention of coronavirus disease-2019 (COVID-19)

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**miglustat - EMEA/H/C/005695, Orphan**

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

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**pirfenidone - EMEA/H/C/005862**

treatment of Idiopathic Pulmonary Fibrosis (IPF)

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**cipaglucosidase alfa - EMEA/H/C/005703, Orphan**

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

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**sugammadex - EMEA/H/C/005935**

reversal of neuromuscular blockade induced by rocuronium or vecuronium

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**infigratinib - EMEA/H/C/005361, Orphan**

Helsinn Birex Pharmaceuticals Limited, treatment of cholangiocarcinoma

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**vadadustat - EMEA/H/C/005131**

Treatment of anaemia

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**olipudase alfa - EMEA/H/C/004850, Accelerated review  
Orphan**

Genzyme Europe BV, indicated as a disease-

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modifying enzyme replacement therapy for long-term treatment of non-Central Nervous System (CNS) manifestations of Acid Sphingomyelinase Deficiency (ASMD) in paediatric and adult patients

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**sotrovimab - EMEA/H/C/005676**

Treatment of coronavirus disease 2019 (COVID-19)

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

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

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**amifampridine - EMEA/H/C/005839**

treatment of Lambert-Eaton Myasthenic Syndrome

List of Questions adopted on 16.09.2021.

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**dimethyl fumarate - EMEA/H/C/005956**

treatment of multiple sclerosis

List of Questions adopted on 14.10.2021.

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**dimethyl fumarate - EMEA/H/C/005955**

treatment of multiple sclerosis

List of Questions adopted on 14.10.2021.

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**Sogroya - somapacitan - EMEA/H/C/005030/X/0001/G, Orphan**

Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin

Huber"Extension application to add a new strength of 5 mg/1.5 mL (3.3 mg/mL) grouped with a Type II Quality variation RMP was updated (version 2.0) accordingly.

Type II variation (B.II.b.1.c)

Type IA variation (B.II.d.1.a) "

List of Questions adopted on 14.10.2021.

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**capmatinib - EMEA/H/C/004845**

treatment of non-small cell lung cancer (NSCLC)

List of Questions adopted on 16.09.2021.

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**insulin aspart - EMEA/H/C/005635**

treatment of diabetes mellitus

List of Questions adopted on 16.09.2021.

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

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**Defitelio - defibrotide -**

**EMA/H/C/002393/S/0057, Orphan**

Gentium S.r.l., Rapporteur: Kristina Dunder,  
PRAC Rapporteur: Ulla Wändel Liminga

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**Obiltoxaximab SFL - obiltoxaximab -**

**EMA/H/C/005169/S/0004, Orphan**

SFL Pharmaceuticals Deutschland GmbH,  
Rapporteur: Jan Mueller-Berghaus, PRAC  
Rapporteur: Liana Gross-Martirosyan

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**Obizur - susoctocog alfa -**

**EMA/H/C/002792/S/0044**

Baxalta Innovations GmbH, Rapporteur: Andrea  
Laslop, PRAC Rapporteur: Brigitte Keller-  
Stanislawski

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**Vedrop - tocofersolan -**

**EMA/H/C/000920/S/0041**

Recordati Rare Diseases, Rapporteur: Agnes  
Gyurasics, PRAC Rapporteur: Melinda Palfi

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**Vyndaqel - tafamidis -**

**EMA/H/C/002294/S/0076, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel  
Race, 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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**Blitzima - rituximab -**

**EMA/H/C/004723/R/0049**

Celltrion Healthcare Hungary Kft., Duplicate,  
Duplicate of Truxima, Rapporteur: Sol Ruiz, Co-  
Rapporteur: Jan Mueller-Berghaus, PRAC  
Rapporteur: Anette Kirstine Stark

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**Fampyra - fampridine -**

**EMA/H/C/002097/R/0050**

Biogen Netherlands B.V., Rapporteur: Johann  
Lodewijk Hillege, Co-Rapporteur: Martina Weise,  
PRAC Rapporteur: Liana Gross-Martirosyan

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**Imraldi - adalimumab -**

**EMA/H/C/004279/R/0050**

Samsung Bioepis NL B.V., Rapporteur: Outi  
Mäki-Ikola, Co-Rapporteur: Daniela Philadelphly,  
PRAC Rapporteur: Ulla Wändel Liminga

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**Lorviqua - lorlatinib -**

**EMA/H/C/004646/R/0019**

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Pfizer Europe MA EEIG, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Nikica Mirošević Skvrce

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**Mavenclad - cladribine -  
EMA/H/C/004230/R/0022**

Merck Europe B.V., Rapporteur: Sinan B. Sarac, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

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**Ondexxya - andexanet alfa -  
EMA/H/C/004108/R/0025**

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

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**Pandemic influenza vaccine H5N1  
AstraZeneca - pandemic influenza vaccine  
(h5n1) (live attenuated, nasal) -  
EMA/H/C/003963/R/0047**

AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sonja Hrabcik

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**Rubraca - rucaparib -  
EMA/H/C/004272/R/0030**

Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin

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**Rydapt - midostaurin -  
EMA/H/C/004095/R/0023, Orphan**

Novartis Europharm Limited, Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

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**Tecentriq - atezolizumab -  
EMA/H/C/004143/R/0069**

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

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**Trumenba - meningococcal group b vaccine  
(recombinant, adsorbed) -  
EMA/H/C/004051/R/0036**

Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Jean-Michel Dogné

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**Vosevi - sofosbuvir / velpatasvir /  
voxilaprevir - EMA/H/C/004350/R/0053**

Gilead Sciences Ireland UC, Rapporteur: Filip Josephson, Co-Rapporteur: Alexandre Moreau,

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PRAC Rapporteur: Ana Sofia Diniz Martins

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**Xermelo - telotristat ethyl -  
EMA/H/C/003937/R/0032, Orphan**

Ipsen Pharma, Rapporteur: Martina Weise, Co-  
Rapporteur: Ondřej Slanař, PRAC Rapporteur:  
Adam Przybylkowski

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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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**Buvidal - buprenorphine -  
EMA/H/C/004651/II/0017**

Camurus AB, Rapporteur: Peter Kiely, PRAC  
Rapporteur: Tiphaine Vaillant, "To add the new  
therapeutic indication of treatment of moderate  
to severe chronic pain in patients with opioid  
dependence. As a consequence, sections 4.1,  
4.2, 4.5, 5.1 and 6.6 of the SmPC and sections  
1, 3 and Instruction for use of the PL are  
updated accordingly. The updated RMP version  
2.1 has also been submitted."

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**Eylea - aflibercept -  
EMA/H/C/002392/II/0077/G**

Bayer AG, Rapporteur: Alexandre Moreau, PRAC  
Rapporteur: Nathalie Gault "C.I.6 (Extension of  
indication) Extension of indication to include the  
paediatric indication retinopathy of prematurity  
(ROP) for Eylea; as a consequence, sections 2,  
4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3 and 6.6 of  
the SmPC are updated. The Package Leaflet is  
updated in accordance. Separate Package  
Leaflet is proposed for the guardians of preterm  
babies. Version 32.1 of the RMP has also been  
submitted. B.IV.1.a.3 "

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**LIBTAYO - cemiplimab -  
EMA/H/C/004844/II/0026**

Regeneron Ireland Designated Activity Company  
(DAC), Rapporteur: Sinan B. Sarac, PRAC  
Rapporteur: Menno van der Elst, "Extension of  
indication to include monotherapy treatment of  
adult patients with recurrent or metastatic  
cervical cancer with disease progression on or  
after chemotherapy for Libtayo; sections 4.1,  
4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are  
updated. The Package Leaflet is updated in

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accordance. Version 3 of the RMP has also been submitted.”

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**Polivy - polatuzumab vedotin -  
EMA/H/C/004870/II/0012, Orphan**

Roche Registration GmbH, Rapporteur:  
Alexandre Moreau, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Annika Folin,  
“Extension of the indication to include: Polivy in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone, is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) based on the efficacy and safety data from the Pivotal Phase III study GO39942 (POLARIX). This submission fulfils SOB003 thus supporting the switch from CMA to full MA. Annexes I, II, IIIB are revised. The RMP is also updated.”

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**RETSEVMO - selpercatinib -  
EMA/H/C/005375/II/0011**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst,  
“Extension of indication to include the first-line treatment of RET fusion-positive NSCLC for Retsevmo based on results from study LIBRETTO-001, an open-label, multicentre, global Phase 1/2 study of selpercatinib in patients with RET-altered advanced solid tumours; as a consequence, sections 4.1, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.”

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

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**Spikevax - COVID-19 mRNA vaccine  
(nucleoside-modified) -  
EMA/H/C/005791/II/0041**

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, “Extension of indication to include use in children 6-11 years of age for Spikevax, based on data from study mRNA-1273-P204, an ongoing Phase 2/3, 2-part, open-label, dose-escalation, age de-escalation and subsequent randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of

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mRNA-1273 in healthy children; 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.”

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**Yescarta - axicabtagene ciloleucel -  
EMA/H/C/004480/II/0046, Orphan,  
ATMP**

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, CHMP Coordinators: Jan Mueller-Berghaus and Karin Janssen van Doorn, PRAC Rapporteur: Anette Kirstine Stark, “Extension of indication to include treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) for Yescarta; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the product information with minor editorial changes.”

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

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

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**ADYNOVI - ruriococog alfa pegol -  
EMA/H/C/004195/II/0027**

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

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**Alymsys - bevacizumab -  
EMA/H/C/005286/II/0005**

Mabxience Research SL, Rapporteur: Christian Gartner

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**Apidra - insulin glulisine -  
EMA/H/C/000557/II/0088/G**

Sanofi-Aventis Deutschland GmbH, Rapporteur: Sinan B. Sarac

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**Aranesp - darbepoetin alfa -  
EMA/H/C/000332/II/0157/G**

Amgen Europe B.V., Rapporteur: Martina Weise

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**Aranesp - darbepoetin alfa -  
EMA/H/C/000332/II/0158**

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Amgen Europe B.V., Rapporteur: Martina Weise

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**Bexsero - meningococcal group b vaccine  
(recombinant, component, adsorbed) -  
EMA/H/C/002333/II/0106**

GSK Vaccines S.r.l, Rapporteur: Kristina Dunder

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**Bimzelx - bimekizumab -  
EMA/H/C/005316/II/0003/G**

UCB Pharma S.A., Rapporteur: Peter Kiely

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**Bimzelx - bimekizumab -  
EMA/H/C/005316/II/0004**

UCB Pharma S.A., Rapporteur: Peter Kiely

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**COMIRNATY - tozinameran -  
EMA/H/C/005735/II/0086**

See B.5.1

BioNTech Manufacturing GmbH, Rapporteur:  
Filip Josephson

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**COMIRNATY - tozinameran -  
EMA/H/C/005735/II/0089**

See B.5.1

BioNTech Manufacturing GmbH, Rapporteur:  
Filip Josephson

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**COVID-19 Vaccine Janssen - adenovirus  
type 26 encoding the SARS-CoV-2 spike  
glycoprotein - EMA/H/C/005737/II/0037**

Janssen-Cilag International N.V., Rapporteur:  
Christophe Focke

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**Darzalex - daratumumab -  
EMA/H/C/004077/II/0056/G, Orphan**

Janssen-Cilag International NV, Rapporteur:  
Sinan B. Sarac

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**Erbix - cetuximab -  
EMA/H/C/000558/II/0092**

Merck Europe B.V., Rapporteur: Filip Josephson

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**Febuxostat Mylan - febuxostat -  
EMA/H/C/004374/II/0012**

Mylan Pharmaceuticals Limited, Generic,  
Generic of Adenuric, Rapporteur: Elita Poplavska

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**Flud Tetra - influenza vaccine (surface  
antigen, inactivated, adjuvanted) -  
EMA/H/C/004993/II/0021**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

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**Hepcludex - bulevirtide -  
EMA/H/C/004854/II/0009/G, Orphan**

Gilead Sciences Ireland Unlimited Company,  
Rapporteur: Filip Josephson

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**Hepsera - adefovir dipivoxil -  
EMA/H/C/000485/II/0087**

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race

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**ILARIS - canakinumab -  
EMA/H/C/001109/II/0078**

Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus

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**Infanrix hexa - diphtheria, tetanus,  
pertussis (acellular, component), hepatitis  
B (rDNA), poliomyelitis (inact.) and  
haemophilus type B conjugate vaccine  
(adsorbed) -  
EMA/H/C/000296/II/0309/G**

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke

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**Insulin lispro Sanofi - insulin lispro -  
EMA/H/C/004303/II/0014/G**

sanofi-aventis groupe, Rapporteur: Outi Mäki-Ikola

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**Invokana - canagliflozin -  
EMA/H/C/002649/II/0058**

Janssen-Cilag International NV, Rapporteur: Martina Weise

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**Lamzede - velmanase alfa -  
EMA/H/C/003922/II/0023/G, Orphan**

Chiesi Farmaceutici S.p.A., Rapporteur: Johann Lodewijk Hillege

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**Leqvio - inclisiran -  
EMA/H/C/005333/II/0008**

Novartis Europharm Limited, Rapporteur: Martina Weise

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**Memantine Mylan - memantine /  
memantine hydrochloride -  
EMA/H/C/002660/II/0018**

Mylan Pharmaceuticals Limited, Generic, Generic of Ebixa, Rapporteur: Maria Concepcion Prieto Yerro

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**Menveo - meningococcal group a, c, w135  
and y conjugate vaccine -  
EMA/H/C/001095/II/0106/G**

GSK Vaccines S.r.l., Rapporteur: Johann Lodewijk Hillege

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**Mylotarg - gemtuzumab ozogamicin -  
EMA/H/C/004204/II/0023/G, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Sinan B.

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Sarac

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**Natpar - parathyroid hormone -**  
**EMA/H/C/003861/II/0035, Orphan**  
Takeda Pharmaceuticals International AG,  
Rapporteur: Karin Janssen van Doorn

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**Nordimet - methotrexate -**  
**EMA/H/C/003983/II/0021/G**  
Nordic Group B.V., Rapporteur: Bruno Sepodes

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**Nplate - romiplostim -**  
**EMA/H/C/000942/II/0081/G**  
Amgen Europe B.V., Rapporteur: Maria  
Concepcion Prieto Yerro

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**Onivyde pegylated liposomal - irinotecan  
hydrochloride trihydrate -**  
**EMA/H/C/004125/II/0029/G, Orphan**  
Les Laboratoires Servier, Rapporteur: Filip  
Josephson

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**Oyavas - bevacizumab -**  
**EMA/H/C/005556/II/0004**  
STADA Arzneimittel AG, Duplicate, Duplicate of  
Alymsys, Rapporteur: Christian Gartner

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**Polivy - polatuzumab vedotin -**  
**EMA/H/C/004870/II/0013/G, Orphan**  
Roche Registration GmbH, Rapporteur:  
Alexandre Moreau

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**Polivy - polatuzumab vedotin -**  
**EMA/H/C/004870/II/0013/G, Orphan**  
Roche Registration GmbH, Rapporteur:  
Alexandre Moreau

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**POTELIGEO - mogamulizumab -**  
**EMA/H/C/004232/II/0013/G, Orphan**  
Kyowa Kirin Holdings B.V., Rapporteur: Paula  
Boudewina van Hennik

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**Qarziba - dinutuximab beta -**  
**EMA/H/C/003918/II/0035/G, Orphan**  
EUSA Pharma (Netherlands) B.V., Rapporteur:  
Paula Boudewina van Hennik

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**Rekovelte - follitropin delta -**  
**EMA/H/C/003994/II/0030**  
Ferring Pharmaceuticals A/S, Rapporteur: Jean-  
Michel Race

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**Retacrit - epoetin zeta -**  
**EMA/H/C/000872/II/0108**  
Pfizer Europe MA EEIG, Rapporteur: Martina

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Weise

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**RoActemra - tocilizumab -**

**EMA/H/C/000955/II/0106/G**

Roche Registration GmbH, Rapporteur: Jan  
Mueller-Berghaus

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**Rybelsus - semaglutide -**

**EMA/H/C/004953/II/0020**

Novo Nordisk A/S, Rapporteur: Johann Lodewijk  
Hillege

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**SIBNAYAL - potassium citrate / potassium  
hydrogen carbonate -**

**EMA/H/C/005407/II/0002/G**

Advicenne, Rapporteur: Johann Lodewijk Hillege

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**Skyrizi - risankizumab -**

**EMA/H/C/004759/II/0019/G**

AbbVie Deutschland GmbH & Co. KG,  
Rapporteur: Peter Kiely

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**Soliris - eculizumab -**

**EMA/H/C/000791/II/0118/G, Orphan**

Alexion Europe SAS, Rapporteur: Blanca Garcia-  
Ochoa

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**Spikevax - COVID-19 mRNA vaccine  
(nucleoside-modified) -**

See B.5.1

**EMA/H/C/005791/II/0043/G**

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

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**Tigecycline Accord - tigecycline -**

**EMA/H/C/005114/II/0002/G**

Accord Healthcare S.L.U., Generic, Generic of  
Tygacil, Rapporteur: Daniela Philadelphia

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**Toviaz - fesoterodine -**

**EMA/H/C/000723/II/0065/G**

Pfizer Europe MA EEIG, Rapporteur: Maria  
Concepcion Prieto Yerro

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**Vaxelis - diphtheria, tetanus, pertussis  
(acellular, component), hepatitis b (rdna),  
poliomyelitis (inact.) and haemophilus type  
b conjugate vaccine (adsorbed) -**

**EMA/H/C/003982/II/0093/G**

MCM Vaccine B.V., Rapporteur: Christophe  
Focke

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**Xolair - omalizumab -**

**EMA/H/C/000606/II/0114**

Novartis Europharm Limited, Rapporteur:  
Kristina Dunder

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**Zercepac - trastuzumab -  
EMA/H/C/005209/II/0015/G**

Accord Healthcare S.L.U., Rapporteur: Sol Ruiz

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**Zercepac - trastuzumab -  
EMA/H/C/005209/II/0016**

Accord Healthcare S.L.U., Rapporteur: Sol Ruiz

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**Zutectra - human hepatitis b  
immunoglobulin -  
EMA/H/C/001089/II/0051**

Biotest Pharma GmbH, Rapporteur: Jan Mueller-Berghaus

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**WS2177/G  
Nilemdo-EMA/H/C/004958/WS2177/  
0018/G  
Nustendi-EMA/H/C/004959/WS2177/  
0020/G**

Daiichi Sankyo Europe GmbH, Lead Rapporteur:  
Johann Lodewijk Hillege

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**WS2188/G  
Hexacima-EMA/H/C/002702/WS2188/  
0124/G  
Hexyon-EMA/H/C/002796/WS2188/  
0128/G**

Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

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**WS2189  
Advate-EMA/H/C/000520/WS2189/0113  
ADYNOVI-EMA/H/C/004195/WS2189/  
0026**

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

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

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**ADYNOVI - ruriotocog alfa pegol -  
EMA/H/C/004195/II/0028**

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, "Update of section 4.8 of the SmPC in order to add "Urticaria" to the list of adverse drug reactions (ADRs) with frequency "common". The Package Leaflet is updated accordingly."

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**AYVAKYT - avapritinib -  
EMA/H/C/005208/II/0014, Orphan**

Blueprint Medicines (Netherlands) B.V.,  
Rapporteur: Blanca Garcia-Ochoa, "Submission"

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of the final report from study BLU-285-1101 listed as a Specific Obligation in the Annex II of the Product Information. This is an interventional Phase 1 study, designed to evaluate the safety, tolerability, PK, pharmacodynamics, and preliminary antineoplastic activity of avapritinib administered orally in patients with unresectable GIST or other relapsed or refractory solid tumours. The Annex II is updated accordingly.”

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**Blenrep - belantamab mafodotin - EMEA/H/C/004935/II/0006/G, Orphan**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Johanna Lähteenvuo, “C.I.4 Update of section 4.4 of the SmPC in order to add a new warning on pneumonitis based on reports from the GSK safety database and clinical trials.

C.I.4 Update of section 4.8 of the SmPC in order to add albuminuria to the list of adverse drug reactions (ADRs) with frequency common based on a safety review by the MAH.

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to perform minor editorial changes.”

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**Cometriq - cabozantinib - EMEA/H/C/002640/II/0049, Orphan**

Ipsen Pharma, Rapporteur: Paula Boudewina van Hennik, “Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on hypertension and add hypertensive crisis to the list of adverse drug reactions (ADRs) with frequency not known based on literature review and post-marketing and clinical data. The Package Leaflet is updated accordingly.”

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**COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0033**

See B.5.2 and 9.1

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, “Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce an homologous booster dose (second dose) of COVID-19 vaccine Janssen based on interim efficacy, immunogenicity and safety results from different clinical studies including the two randomised, double blind, placebo-controlled Phase 3 studies COV3001 and COV3009. In addition, an update to introduce a heterologous booster dose of COVID-19 vaccine Janssen following completion of a primary vaccination

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with an approved mRNA COVID-19 vaccine is introduced based on immunogenicity and safety interim results from the phase 1/2 study DMID 21-0012. In addition, the MAH took the opportunity to update the efficacy data for the primary vaccination schedule based on final analysis from study COV3001. The Package Leaflet is updated accordingly.”

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**Dapivirine Vaginal Ring 25 mg - dapivirine  
- EMEA/H/W/002168/II/0014/G**

International Partnership for Microbicides  
Belgium AISBL, Rapporteur: Paula Boudewina van Hennik, “C.I.13: Submission of the study report from study MTN-020 (Version 2.0). This is a multicenter, randomized, double-blind, placebo-controlled Phase III safety and effectiveness trial of a vaginal matrix ring containing dapivirine for the prevention of HIV-1 infection in women.

C.I.13: Submission of the Clinical Virology Report (Version 4.0). This report describes virologic characterisation of virus from HIV-1 seroconversion events during double-blind, placebo-controlled, randomized, multicenter Phase III clinical trials evaluating the safety and efficacy of Dapivirine Vaginal Ring.”

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**Dovprela - pretomanid -  
EMEA/H/C/005167/II/0008, Orphan**

Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, “Submission of the final report from study Nix-TB-(B-L-Pa) listed as a Specific Obligation the Annex II of the Product Information. This is a phase 3 open-label trial assessing the safety and efficacy of bedaquiline plus pretomanid plus linezolid in subjects with pulmonary infection of either extensively drug-resistant tuberculosis (XDR-TB) or treatment intolerant/non-responsive multi-drug resistant tuberculosis (MDR-TB). The Annex II is updated accordingly.”

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**Eylea - aflibercept -  
EMEA/H/C/002392/II/0076**

Bayer AG, Rapporteur: Alexandre Moreau, “Submission of the final report from study AZURE, a randomised PAES in patients with neovascular (wet) AMD with the primary objective of comparing the standard regime of injections every 8 weeks with a reactive regimen based on visual and anatomic

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outcomes, based on a CHMP approved protocol.”

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**Eylea - aflibercept -**

**EMA/H/C/002392/II/0078**

Bayer AG, Rapporteur: Alexandre Moreau,  
“C.I.4

Update of section 6.6 of the SmPC in order to add a cautionary statement for the Eylea pre-filled syringe; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2, for a text reduction, and to correct a typo.”

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**Fasenra - benralizumab -**

**EMA/H/C/004433/II/0041**

AstraZeneca AB, Rapporteur: Fátima Ventura,  
“Update of section 5.1 of the SmPC in order to update efficacy information based on the final results from study D3250C00065 (PONENTE); this is a multicenter, open-label, Phase IIIb efficacy and safety study of benralizumab 30 mg administered subcutaneously to reduce oral corticosteroid use in adult patients with severe eosinophilic asthma on high-dose inhaled corticosteroid plus long-acting  $\beta_2$  agonist and chronic oral corticosteroid therapy. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

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**IMCIVREE - setmelanotide -**

**EMA/H/C/005089/II/0003, Orphan**

Rhythm Pharmaceuticals Netherlands B.V.,  
Rapporteur: Karin Janssen van Doorn, “Update of sections 4.2 and 5.2 of the SmPC in order to change posology recommendations in patients with renal impairment, based on final results from study RM-493-029, a Phase I, open-label, single-dose study to evaluate the pharmacokinetics of setmelanotide in subjects with varying degrees of renal impairment; with secondary objectives to evaluate the safety and tolerability of a single dose of setmelanotide administered subcutaneously in subjects with varying degrees of renal impairment. The Package Leaflet is updated accordingly.”

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**JEMPERLI - dostarlimab -**

**EMA/H/C/005204/II/0007**

GlaxoSmithKline (Ireland) Limited, Rapporteur:  
Blanca Garcia-Ochoa, “Update of sections 4.2,

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

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**Myozyme - alglucosidase alfa -  
EMA/H/C/000636/II/0087**

Genzyme Europe BV, Rapporteur: Alexandre Moreau, “Update of section 4.8 of the SmPC in order to add palpitations, asthenia, malaise, feeling cold and blood pressure decreased to the list of adverse drug reactions (ADRs) with frequency “not-known” following the Final Assessment Report for the Post-Authorisation Measure MEAs 024.13 and 0.25.13 (the 2019 Pompe Disease Registry Annual Report) dated 15 October 2020; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 5.1 of the SmPC to update the internet website address of the Pompe Registry.”

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**Pradaxa - dabigatran etexilate -  
EMA/H/C/000829/II/0133**

Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, “- to remove rice cereal from the food compatibility list in the “Instructions for use”- “A) Administration of Pradaxa coated granules with soft foods” of the Package Leaflet for Pradaxa coated granules in sachets based on long-term stability results and in-use food compatibility study.”

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**REKAMBYS - rilpivirine -  
EMA/H/C/005060/II/0010**

Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, “Update of section 4.8 (Table 6) of the SmPC in order to update the adverse reactions section, adding information regarding the majority of pyrexia events having a close temporal association with injections (reported within one week of injections). Based on the data analysis from clinical trials study 201585 FLAIR, 201585 ATLAS and 207966

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ATLAS-2M. The Package Leaflet (section 4) is updated accordingly.”

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**RINVOQ - upadacitinib -  
EMA/H/C/004760/II/0014**

AbbVie Deutschland GmbH & Co. KG,  
Rapporteur: Kristina Dunder, “C.I.4 - Update of section 5.1 of the SmPC in order to update efficacy information based on interim results (week 156) from studies M14-465 and M13-545; these are randomized phase 3, double blind studies to evaluate the long-term safety, tolerability and efficacy of upadacitinib in subjects with Rheumatoid Arthritis. In addition, the MAH took the opportunity to introduce editorial changes in section 5.1 of the SmPC.”

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**Siklos - hydroxycarbamide -  
EMA/H/C/000689/II/0051**

Addmedica S.A.S., Rapporteur: Karin Janssen van Doorn, “C.I.3.b  
Update of section 5.1 of the SmPC with the available paediatric data from the studies NOHARM and Escort HU according to the PAM-Leg 34.”

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**Spikevax - COVID-19 mRNA vaccine  
(nucleoside-modified) -**

See B.5.2 and 9.1

**EMA/H/C/005791/II/0042**

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, “Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to include information on heterologous boosting using a 50 ug dose of Spikevax to boost subjects that have previously completed a primary vaccination series with any authorised COVID-19 vaccine, based on data from the DMID Study 21-0012, a Phase 1/2 heterologous SARS-CoV-2 vaccine dosing (mRNA-1273 booster) study of the various vaccines authorized in the US under Emergency Use Authorisation in participants ≥ 18 years old (NCT04889209). In addition, the MAH took the opportunity to make minor editorial changes/corrections throughout the product information.”

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**Tysabri - natalizumab -  
EMA/H/C/000603/II/0131**

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, “C.I.4 Type II Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic

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information based on final results from study 101MS329 (NOVA) part 1. This is a randomized, controlled phase 3b study of efficacy, safety and tolerability of 6-Week Extended Interval Dosing (EID) of Natalizumab in subjects with Relapsing-Remitting Multiple Sclerosis Switching From Treatment With 4-Week Natalizumab Standard Interval Dosing (SID) in Relation to Continued SID Treatment.”

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**Tyverb - lapatinib -**

**EMA/H/C/000795/II/0072/G**

Novartis Europharm Limited, Rapporteur: Filip Josephson, “Update of section 4.8 of the SmPC in order to add skin fissures to the list of adverse drug reactions (ADRs) with frequency common, following recently analysed safety data regarding skin fissures. The Package Leaflet is updated accordingly. The ATC code is also updated.”

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**Verzenio - abemaciclib -**

**EMA/H/C/004302/II/0021**

Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, “Update of section 5.1 of the SmPC in order to include second OS interim results from study MONARCH 3; this is a randomised, double blind, placebo-controlled phase 3 study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer with No Prior Systemic Therapy in this Disease Setting”

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**WS2170**

**OPDIVO-EMA/H/C/003985/WS2170/0114**

**Yervoy-EMA/H/C/002213/WS2170/0094**

Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Paula Boudewina van Hennik, “Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy information based on 5 years follow-up OS data from study CA209214; this is a phase 3, randomised, open-label study in previously untreated, intermediate/poor risk advanced RCC.”

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**WS2174**

**Hexacima-EMA/H/C/002702/WS2174/0123**

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**Hexyon-EMEA/H/C/002796/WS2174/  
0127**

Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information regarding the co-administration of Hexyon / Hexacima with varicella vaccines based on a re-analysis of the A3L15 clinical trial varicella serological data, submitted in the initial CTD dossier. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to correct some typo errors in the SmPC and PL."

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**WS2183**

**Infanrix hexa-EMEA/H/C/000296/  
WS2183/0310**

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke, "Update of sections 2 and 4.3 of the SmPC for Infanrix Hexa in order to remove the residue formaldehyde. The PL is updated accordingly. Moreover, these sections are also been updated for the removal of some residues currently mentioned in the Product Information (PI) of some of GSK's DTPa/dTpa combined vaccines (NAPs). In addition, the MAH took the opportunity to align the PI to the Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal product for human use" (sections 2, 4.4 and 6.1 of the SmPC). The MAH also took the opportunity to introduce some additional minor changes to the PI and to update the list of local representatives in the Package Leaflet."

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**B.6.10. CHMP-PRAC assessed procedures**

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**Alecensa - alectinib -  
EMEA/H/C/004164/II/0037/G**

Roche Registration GmbH, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add a new warning, dose modification advice and description of the known ADR haemolytic anaemia based on an updated Drug Safety Report; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial

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updates in the Maltese and Romanian product information. Moreover, the ATC code for alectinib is being updated from L01XE36 to L01ED03.”

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**Cablivi - caplacizumab -**

**EMA/H/C/004426/II/0035, Orphan**

Ablynx NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Jan Neuhauser, “Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on increased risk of bleeding and add blood and lymphatic system disorders to the list of adverse drug reactions (ADRs) with frequency not known based on a safety evaluation report; the Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted.”

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**Deltyba - delamanid -**

**EMA/H/C/002552/II/0053, Orphan**

Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Laurence de Fays, “Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs table) following the development of an improved methodology to identify relevant ADRs likely attributable to delamanid. The section 4 of the Package Leaflet is updated accordingly. The RMP version 3.6 has also been submitted.”

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**ELZONRIS - tagraxofusp -**

**EMA/H/C/005031/II/0009, Orphan**

Stemline Therapeutics B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst, “Submission of the final report from study 20255431 (CRL-263114) 'Characterization of fixed choroid plexus samples from primate study MPI-2231-007 by Immunohistochemistry with DT, CD123, IL-3 and IgG' (MEA002) listed as a category 3 study in the RMP. This is a non-interventional, post-authorisation study on blood brain barrier (BBB) models in order to determine a potential toxicity biomarker to further investigate the risk of choroid plexus lesions. The RMP version 2.0 has also been submitted.”

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**Enbrel - etanercept -**

**EMA/H/C/000262/II/0246**

Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva

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A. Segovia, "Update of section 5.1 of the SmPC in order to update clinical information based on final results obtained from the clinical paediatric study B1801023 (CLIPPER 2). The RMP version 7.5 has also been submitted."

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**Halaven - eribulin -  
EMA/H/C/002084/II/0060**

Eisai GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on results from clinical studies E7389-A001-113, E7389-G000-223 and E7389-G000-213 in the paediatric population (6 months to <18 years); the Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted."

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**IBRANCE - palbociclib -  
EMA/H/C/003853/II/0037**

Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Anette Kirstine Stark, "Submission of an updated RMP version 1.8 in order to remove the Important Potential Risk Hyperglycaemia based on the study results from A5481027, a PAM adopted at the initial MA; this is a multicentre, randomized, double-blind, phase 3 study of palbociclib plus letrozole versus placebo plus letrozole for the treatment of previously untreated Asian postmenopausal women with ER-positive, HER2-negative advanced breast cancer to evaluate the effect of palbociclib on hyperglycaemia - category 3 study."

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

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

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**Lemtrada - alemtuzumab -**

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**EMA/H/C/003718/II/0038**

Sanofi Belgium, Duplicate, Duplicate of Lemtrada (WD), Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Anette Kirstine Stark, "Update of sections 4.4 and 4.8 of the SmPC to add Adult Onset Still's Disease (AOSD) to the list of adverse drug reactions (ADRs) with frequency not known, based on a signal validated during a routine pharmacovigilance surveillance; the Package Leaflet is updated accordingly. The MAH took the opportunity to update the list of local representatives in the Package Leaflet. The RMP v.9.0 submitted to include AOSD; and to remove the PASS study OBS13436 (Pregnancy Registry)."

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**Mylotarg - gemtuzumab ozogamicin - EMA/H/C/004204/II/0024, Orphan**

Pfizer Europe MA EEIG, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of sections 4.8, 5.1 and 5.2 of the SmPC based on the final results from study B176103; this is a single-arm, open-label, phase 4 study evaluating the QT interval, pharmacokinetics, and safety of gemtuzumab ozogamicin as a single-agent regimen in patients with relapsed or refractory CD33-positive Acute Myeloid Leukemia. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce some editorial changes in the product information."

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**Nerlynx - neratinib -****EMA/H/C/004030/II/0027**

Pierre Fabre Medicament, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Menno van der Elst, "Update of section 5.1 of the SmPC in order to update the pharmacokinetic information with descriptive diarrhoea characteristics based on final results from study PUMA-NER-6201 (CONTROL), listed as a category 3 study in the RMP; this is an Open-Label Study to Characterize the Incidence and Severity of Diarrhea in Patients with Early Stage HER2+ Breast Cancer Treated with Neratinib and Loperamide. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial updates in section 4.2 of the SmPC."

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**Zejula - niraparib -**

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**EMA/H/C/004249/II/0033, Orphan**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning and add MDS/AML to the list of adverse drug reactions (ADRs) with frequency common, and update of section 5.1 based on final results from NOVA study (213356); this is a Phase 3 Randomized Double-Blind Trial of Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer. In addition, the MAH took this opportunity to update sections 4.4 and 4.6 to update information on contraception based on EMA and CTFG recommendations. The Package Leaflet is updated accordingly. The RMP version 6 has also been submitted."

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**WS2141****Ozempic-EMA/H/C/004174/WS2141/0024****Rybelsus-EMA/H/C/004953/WS2141/0018**

Novo Nordisk A/S, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Annika Folin, "Submission of the final report from study NN9535-4386 (SUSTAIN-11), listed as a category 3 study in the RMP. This is a 52-week, multi-centre, multinational, open-label, active controlled, two armed, parallel, randomised trial undertaken to investigate the effect on glycaemic control, body weight, safety and health-related quality of life of once-weekly semaglutide s.c. vs insulin aspart three times daily, both as add-on to metformin and optimised insulin glargine U100 treatment in subjects with inadequately controlled T2DM. 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

**Calquence - acalabrutinib -  
EMA/H/C/005299/II/0011**

AstraZeneca AB, Rapporteur: Filip Josephson, PRAC Rapporteur: Željana Margan Koletić, PRAC-CHMP liaison: Selma Arapovic Dzakula, "Submission of an updated RMP version 3 in order to add hepatotoxicity as an important potential risk to the safety concerns."

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PRAC Led

**Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0114**

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report from study EPI-HPV-048 listed as a category 3 study in the RMP. This surveillance study is part of two-phase national HPV surveillance programme that was initiated in the UK by the Health Protection Agency in order to evaluate the impact of HPV vaccination on HPV type replacement. The study aimed to assess the prevalence of type-specific HPV deoxyribonucleic acid (DNA) in young women in England since HPV immunisation using Cervarix was introduced. In addition, the MAH has included for information the protocol of study EPI-HPV-099 to address the safety concern "Impact and effectiveness against anal lesions and cancer. The RMP version 25 has also been submitted."

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PRAC Led

**COMIRNATY - tozinameran - EMEA/H/C/005735/II/0087**

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 2.6 to include data from the booster/third dose, including data in patients who have undergone a solid organ transplantation, following the outcomes of procedures EMEA/H/C/005735/II/0062 (third dose in immunocompromise as part of the primary vaccination) and EMEA/H/C/005735/II/0067 (booster dose).

The MAH takes the opportunity to update the RMP regarding the discontinuation of enrolment in study C4591015 (phase 2/3 study to evaluate the safety, tolerability, and immunogenicity in healthy pregnant women 18 years of age and older) and the CSR milestones."

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PRAC Led

**COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0029**

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Janssen-Cilag International N.V., Rapporteur:  
Christophe Focke, PRAC Rapporteur: Ulla  
Wändel Liminga, PRAC-CHMP liaison: Kristina  
Dunder, "Submission of an updated RMP version  
2.4 in order to upgrade the important potential  
risk of venous thromboembolism (VTE) to an  
important identified risk as an outcome of the  
procedure MEA-32, addition of the clinical trial  
VAC31518COV3003 and update of study  
VAC18193RSV2008 as additional  
pharmacovigilance activities to further  
characterise the important identified risks of  
Thrombosis with thrombocytopenia syndrome  
(TTS), Immune thrombocytopenia (ITP), and  
VTE, and the important potential risk  
Thrombocytopenia (excluding ITP and TTS) as  
an outcome of MEA 14.4. In addition, the MAH  
took the opportunity to include other minor  
updates in the RMP."

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PRAC Led

**COVID-19 Vaccine Janssen - adenovirus  
type 26 encoding the SARS-CoV-2 spike  
glycoprotein - EMEA/H/C/005737/II/0035**

Janssen-Cilag International N.V., Rapporteur:  
Christophe Focke, PRAC Rapporteur: Ulla  
Wändel Liminga, PRAC-CHMP liaison: Kristina  
Dunder, "  
Update of section 4.8 of the SmPC in order to  
add transverse myelitis to the list of adverse  
drug reactions (ADRs) with frequency not known  
based on the PRAC request from the post-  
authorisation measures MEA 14.5 and MEA 14.6  
(6th and 7th Monthly Summary Safety Report  
covering the months of August 2021 and  
September 2021, respectively) and update of  
section 4.4 of the SmPC in order to amend the  
wording on Thrombosis and thrombocytopenia  
syndrome (TTS) following the PRAC request  
from the post-authorisation measure MEA 14.5.  
The Package Leaflet is updated accordingly. In  
addition, the MAH took the opportunity to  
implement an editorial Quality review document  
(QRD) comment in the labelling following  
procedure EMEA/H/C/005737/II/014."

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PRAC Led

**Cystadrops - mercaptamine -  
EMEA/H/C/003769/II/0023, Orphan**

Recordati Rare Diseases, Rapporteur: Kristina  
Dunder, PRAC Rapporteur: Eva A. Segovia,

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PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "C.I.11 for RMP: Submission of an updated RMP version 1.4 in order to align with the new RMP format according to GVP Rev.2 and to remove a missing information from the list of safety concerns."

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PRAC Led

**Evoltra - clofarabine -**

**EMA/H/C/000613/II/0075**

Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.6 of the SmPC following a request during EMA/H/C/PSUSA/00000805/202012 to revise section 4.6 of the SmPC and corresponding sections in the PIL considering the recommendations of the Safety Working Party as reflected in the 'SWP recommendations on the duration of contraception following the end of treatment with a genotoxic drug' and available data. The proposed update of the product information should be based on a detailed scientific rationale from all available data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.2"

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PRAC Led

**Obizur - susoctocog alfa -**

**EMA/H/C/002792/II/0043**

Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from US PASS 241302 study, EUPAS register Number EUPAS36659, listed as a category 3 study in the RMP. This is a post-marketing non-interventional safety evaluation of Obizur in the treatment of bleeding episodes for patients with acquired hemophilia A (AHA). The primary objective is to determine the incidence of therapy-related serious adverse events (SAEs) in patients with AHA who are prescribed and treated with OBIZUR in routine clinical practice. The RMP version 5.0 has also been submitted."

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PRAC Led

**OFEV - nintedanib -**

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**EMA/H/C/003821/II/0046**

Boehringer Ingelheim International GmbH,  
Rapporteur: Peter Kiely, PRAC Rapporteur:  
Nikica Mirošević Skvrce, PRAC-CHMP liaison:  
Selma Arapovic Dzakula, "C.I.11 for RMP:  
Submission of an updated RMP version 11.0 in  
order to fulfil a request made in the renewal  
(EMA/H/C/003821/R/0025) to remove the  
following safety concerns (Modules SIV, SVII,  
SVIII; Parts III, V, VI; Appendices 4, 8) :

- 1-Important identified risks : Diarrhoea, Liver  
enzyme and bilirubin elevations including DIL,  
Bleeding, Myocardial infarction;
- 2-Important potential risks: Venous  
thromboembolism, Arterial thromboembolism  
excluding myocardial infarction, Perforation,  
Hepatic failure, Treatment of pregnant women  
and teratogenicity, Cardiac failure;
- 3- Missing information: Treatment of patients  
with moderate or severe hepatic impairment  
(Child Pugh B/C), Treatment of Black patients,  
Treatment of patients with healing wounds,  
Treatment of patients with severe renal  
impairment or end-stage renal disease,  
Treatment of patients receiving full-dose  
therapeutic anticoagulation, Treatment of  
breastfeeding women.

Moreover, it is updated ATC code (Part I) and  
post-marketing exposure (Module SV)."

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PRAC Led

**Olumiant - baricitinib -****EMA/H/C/004085/II/0031**

Eli Lilly Nederland B.V., Rapporteur: Johann  
Lodewijk Hillege, PRAC Rapporteur: Adam  
Przybylkowski, PRAC-CHMP liaison: Ewa  
Balkowiec Iskra, "C.I.4 - Update of section 4.4  
of the SmPC in order to add new warnings on  
Major Adverse Cardiac Events (MACE) and  
amend existing warning on Malignancy and  
Venous thromboembolism (VTE) following the  
request made in PSUSA  
(EMA/H/C/PSUSA/00010578/202102) and  
based on interim results from study I4V-MC-  
B023; this is a retrospective observational study  
to compare baricitinib relative to the standard of  
care. The Package Leaflet is updated  
accordingly. The RMP version 13.1 has also  
been submitted. In addition, the MAH has  
submitted a proposal for a DHPC and

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communication plan.”

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PRAC Led

**Remicade - infliximab -  
EMA/H/C/000240/II/0231**

Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, “Submission of the final report of the Remicade AntiRheumatic Therapy in Sweden (ARTIS) registry study. The ARTIS registry study was performed to fulfil a post-authorisation measure in the RMP for Remicade. The updated RMP v20.1. has also been submitted, including revisions agreed in previous procedures.”

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PRAC Led

**Tegsedi - inotersen -  
EMA/H/C/004782/II/0026, Orphan**

Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Peter Kiely, “Submission of an updated RMP version 3.0 to remove carcinogenicity in rats as missing information, add a targeted questionnaire as routine pharmacovigilance measure and a patient alert card as additional risk minimisation for liver transplant rejection. To add 'injection site reactions' and 'immunogenicity' as risks not considered important for inclusion in the summary of safety concerns, and to update the patient alert card with additional warnings on hepatic monitoring and ocular toxicity. Further sections of the RMP are updated.”

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PRAC Led

**Temodal - temozolomide -  
EMA/H/C/000229/II/0095**

Merck Sharp & Dohme B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, “Update of the RMP to version 6.1. to remove all the safety concerns (important identified risks, important potential risks and missing information). The deletion of the safety concerns is based on the guidance EU GVP Module V (Revision 2).”

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PRAC Led

**Vaxzevria - COVID 19 Vaccine (ChAdOx1 S  
[recombinant]) -  
EMA/H/C/005675/II/0055**

AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC

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Rapporteur: Jean-Michel Dogné, PRAC-CHMP  
liaison: Christophe Focke, "Update of section 4.4  
of the SmPC in order to update the warning on  
thrombosis with thrombocytopenia syndrome to  
indicate that the frequency after the second  
dose is lower than after the first dose based on  
the post-marketing data."

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PRAC Led

**Zessly - infliximab -**

**EMA/H/C/004647/II/0020**

Sandoz GmbH, Rapporteur: Ingrid Wang, PRAC  
Rapporteur: Ulla Wändel Liminga, PRAC-CHMP  
liaison: Kristina Dunder, "Submission of the  
updated RMP version 3.0 to remove the RABBIT  
registry as an additional pharmacovigilance  
activity in alignment with the updated version of  
the reference product Remicade RMP (v19) and  
to remove the BADBIR registry as an additional  
pharmacovigilance activity."

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PRAC Led

**WS2185**

**Entresto-EMA/H/C/004062/WS2185/  
0041**

**Neparvis-EMA/H/C/004343/WS2185/  
0039**

Novartis Europharm Limited, Lead PRAC  
Rapporteur: Anette Kirstine Stark, PRAC-CHMP  
liaison: Sinan B. Sarac, "To provide an updated  
RMP in response to the assessment report for  
procedure EMA/H/C/WS1830. In addition, the  
following changes have been introduced:  
- change to the agreed milestone for study  
CLCZ696B2320 (EU PASS category 3), to  
update the date for the submission of the final  
report ;  
- update of section 8.3.1 (Presentation of  
important identified risks and important  
potential risks);  
- updated exposure and post-marketing data  
have been provided for the data lock point of  
PSUR 9 (31-Jul-21)."

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PRAC Led

**WS2191**

**Incesync-**

**EMA/H/C/002178/WS2191/0040**

**Vipdomet- EMA/H/C/002654/WS2191/  
0036**

**Vipidia-EMA/H/C/002182/WS2191/0029**

Takeda Pharma A/S, Lead PRAC Rapporteur:

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Menno van der Elst, "Submission of a consolidated RMP version 11 for Vipidia, Vipdomet and Incresync in order to:

- Update the RMPs for Alogliptin, Alogliptin/Pioglitazone fixed dose combination (FDC) and Alogliptin/Metformin fixed dose combination (FDC) to consolidate within a single RMP as committed within the PSUR procedure (PSUSA/00010061/202104).
- Following review of cumulative safety data, removal of a number of safety concerns is done based on GVP Module V, Risk Management Systems (revision 2) guidelines.
- Remove the target follow-up Questionnaires of Severe Hypersensitivity and skin reactions, Pancreatitis, Hepatic events and follow up gastrointestinal events and infections from Alogliptin and Alo/Met RMPs.
- Reflect the removal of the inverted black triangle as agreed as part of the alogliptin renewal procedure (EMA/H/C/002178/R/0023) for Alogliptin and the FDC Alogliptin/Metformin. The black triangle was already removed from the FDC Alogliptin/Pioglitazone RMP as part of the Type II variation (EMA/H/C/002178/II/0029)."

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PRAC Led

**WS2192**

**Dovato-EMA/H/C/004909/WS2192/0026**

**Juluca-EMA/H/C/004427/WS2192/0040**

**Tivicay-EMA/H/C/002753/WS2192/0075**

**Triumeq-EMA/H/C/002754/WS2192/0099**

ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Update of section 4.8 of the SmPC to add "completed suicide" to the list of adverse drug reactions (ADRs) with frequency "rare" in the dolutegravir (Tivicay), dolutegravir/ abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato) following the finalisation of PSUSA procedure EMA/H/C/PSUSA/00010075/202101 (reporting period 17 Jan 2020 to 16 Jan 2021) based on reports of completed suicide from participants exposed to Dolutegravir containing regimen in ViiV Healthcare-sponsored clinical trials. As the changes impact all Dolutegravir containing products, the MAH did a worksharing procedure

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to include Juluca (Dolutegravir/Rilpivirine) product in accordance with Article 20 (worksharing procedure) of Commission Regulation (EC) 1234/2008. The Package Leaflet are updated accordingly.”

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PRAC Led

**WS2196**

**Glyxambi-EMEA/H/C/003833/WS2196/0042**

**Jardiance-EMEA/H/C/002677/WS2196/0063**

**Synjardy-EMEA/H/C/003770/WS2196/0060**

Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Eva A. Segovia, “Update of section 4.4 of the SmPC to delete the warning on ‘lower limb amputations’ as a consequence of the results from the final meta-analysis report of PASS 1245.171 ‘A meta-analysis of amputation risk in empagliflozin studies (1245.25, 1245.110, 1245.121)’ (included as a category 3 study in the RMP). The Package Leaflet has been updated accordingly. Updated RMP versions have also been submitted; version 17 for Jardiance, version 11 for Synjardy and version 6 for Glyxambi.”

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**B.6.12. CHMP-CAT assessed procedures**

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**Luxturna - voretigene neparvovec - EMEA/H/C/004451/II/0026/G, Orphan, ATMP**

Novartis Europharm Limited, Rapporteur: Sol Ruiz, CHMP Coordinator: Maria Concepcion Prieto Yerro

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**Tecartus - autologous peripheral blood t cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - EMEA/H/C/005102/II/0016, Orphan, ATMP**

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

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### **B.6.13. CHMP-PRAC-CAT assessed procedures**

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#### **Abecma - idecabtagene vicleucel - EMA/H/C/004662/II/0009, Orphan, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:  
Rune Kjekken, CHMP Coordinator: Ingrid Wang,  
PRAC Rapporteur: Annika Folin, "Update of  
sections 4.2 and 4.4 of the SmPC, Annex IID  
and PIL in order to add statements for the use  
of Abecma exceptionally during shortage of  
tocilizumab following the "CAT recommendation  
for the use of CAR-T cell-based therapies in EU  
during shortages of tocilizumab"

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#### **Abecma - idecabtagene vicleucel - EMA/H/C/004662/II/0010, Orphan, ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:  
Rune Kjekken, CHMP Coordinator: Ingrid Wang,  
PRAC Rapporteur: Annika Folin, "Update of  
section 5.1 of the SmPC in order to update  
efficacy information based on 24-month follow-  
up data from the pivotal study submitted during  
initial (BB2121-MM-001: A Phase 2, Multicenter  
Study to determine the Efficacy and Safety of  
bb2121 in Subjects with Relapsed and  
Refractory Multiple Myeloma) listed as a specific  
obligation in the Annex II and in the RMP; The  
annex II is updated with the proposed deletion  
of the relevant SOB. The RMP version 1.1 has  
also been submitted."

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#### **Kymriah - tisagenlecleucel - EMA/H/C/004090/II/0047, Orphan, ATMP**

Novartis Europharm Limited, Rapporteur: Rune  
Kjekken, CHMP Coordinator: Ingrid Wang, PRAC  
Rapporteur: Brigitte Keller-Stanislawski,  
"Update of sections 4.2 and 4.4 of the SmPC,  
Annex IID and PIL (information intended for  
healthcare professionals) in order to add  
statements for the use of Kymriah exceptionally  
during shortage of tocilizumab following the  
"CAT recommendation for the use of CAR-T cell-  
based therapies in EU during shortages of  
tocilizumab"."

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#### **WS2206**

**Tecartus-EMA/H/C/005102/WS2206/  
0015**

**Yescarta-EMA/H/C/004480/WS2206/**

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**0045**

Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, Lead PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2 and 4.4 of the SmPC and Annex IID in order to add statements for the use of Tecartus and Yescarta exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab". The RMPs for both products are updated accordingly (version 1.2 for Tecartus and version 5.2 for Yescarta)."

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**B.6.14. PRAC assessed ATMP procedures****B.6.15. Unclassified procedures and worksharing procedures of type I variations**

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**WS2111/G**

**Eucreas-EMEA/H/C/000807/WS2111/**

**0089/G**

**Icandra-EMEA/H/C/001050/WS2111/**

**0092/G**

**Zomarist-EMEA/H/C/001049/WS2111/**

**0091/G**

Novartis Europharm Limited, Lead Rapporteur:  
Kristina Dunder

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**WS2136**

**Esperoct-EMEA/H/C/004883/WS2136/**

**0009**

**NovoEight-EMEA/H/C/002719/WS2136/**

**0039**

Novo Nordisk A/S, Lead Rapporteur: Jan  
Mueller-Berghaus

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**WS2140**

**Infanrix hexa-EMEA/H/C/000296/**

**WS2140/0307**

GlaxoSmithkline Biologicals SA, Lead  
Rapporteur: Christophe Focke

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**WS2162**

**Prezista-EMEA/H/C/000707/WS2162/**

**0113**

**Rezolsta-EMEA/H/C/002819/WS2162/**

**0044**

**Symtuza-EMEA/H/C/004391/WS2162/**

**0038**

Janssen-Cilag International NV, Lead

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Rapporteur: Johann Lodewijk Hillege, "To update for the 3 Darunavir products (PREZISTA, REZOLSTA and Symtuza), section 4.3, section 4.4 (PREZISTA 100 mg/ml, 400 mg and 800 mg) and section 4.5 of each SmPC to emphasise that the lists of medications in the Contraindications and in the Interactions sections are not comprehensive and are to be considered as examples. The Package Leaflets are updated accordingly.

The MAH also has taken the opportunity to include several minor changes as follows:

- an update in section 4.5 of the SmPC and section 2 of the Patient leaflet of Symtuza to include information about elbasvir and grazoprevir, in order to align with the info provided in the PREZISTA and REZOLSTA labels (as approved in Feb 2017 in procedure WS1107/G);
- correcting the capitalization of 'wort' in St. John's Wort;
- adding the prefix for Belgian postcodes to the addresses in the respective Package Leaflets."

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**WS2173**

**HBVAXPRO-EMEA/H/C/000373/WS2173/0073**

**Vaxelis-EMEA/H/C/003982/WS2173/0091**

MCM Vaccine B.V., Lead Rapporteur: Christophe Focke

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**WS2175**

**Corbilta-EMEA/H/C/002785/WS2175/0026**

**Levodopa/Carbidopa/Entacapone Orion-EMEA/H/C/002441/WS2175/0034**

**Stalevo-EMEA/H/C/000511/WS2175/0096**

Orion Corporation, Lead Rapporteur: Outi Mäki-Ikola, "To add Sodium warning to sections 2, 4.4 of the SmPC; section 3 of Labelling and section 2 of package leaflet to Stalevo and its duplicates Corbilta and

Levodopa/Carbidopa/Entacapone Orion.

QRD template v10.2 update is implemented for Stalevo and Levodopa/Carbidopa/Entacapone Orion. Contact details of local representatives are updated as follows:

- Stalevo in France and United Kingdom (Northern Ireland);
  - Corbilta in France;
  - Levodopa/Carbidopa/Entacapone Orion in
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Lithuania, Estonia, Ireland, Latvia and United Kingdom (Northern Ireland).

Additionally, missing non-breaking spaces added, wherever applicable according to EMA guidance 'Compilation of QRD decisions on stylistic matters in product information'.

Minor linguistic and typographical corrections have been performed in several languages as follows:

Stalevo: CS, DE, EL, EN, ES, ET, FR, HR, HU, IS, LT, LV, MT, NL, NO, PL, PT, RO, SK and SL.

Corbilta: CS, DA, DE, EL, EN, ES, ET, FR, HR, HU, IS, LT, LV, MT, NL, NO, PL, PT, RO, SK, SL and SV.

Levodopa/Carbidopa/Entacapone Orion: CS, DA, DE, EL, EN, ES, ET, FR, HR, HU, IS, LT, LV, MT, NL, PL, PT, RO, SK and SL.”

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#### **WS2186**

**Blitzima-**

**EMA/H/C/004723/WS2186/0050**

**Truxima-**

**EMA/H/C/004112/WS2186/0053**

Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz,

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#### **WS2200**

**Glyxambi-**

**EMA/H/C/003833/WS2200/0041**

**Synjardy-**

**EMA/H/C/003770/WS2200/0059**

Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, “To update sections 4.2, 4.4 and 5.1 of the SmPC to propose a modification of the eGFR threshold in the EU PIs for the fixed dose combinations containing empagliflozin, for Synjardy (empagliflozin/metformin) and Glyxambi (empagliflozin/linagliptin) to allow for use of these empagliflozin containing products in patients with T2DM and high cardiovascular risk and an eGFR of  $\geq 30$  ml/min/1.73 m<sup>2</sup>. This is in line with the changed eGFR threshold for Jardiance (empagliflozin) which received a Positive Opinion on 16 Sep 2021 for the assessment of variation

EMA/H/C/002677/II/0057.

Additionally, some editorial changes are also proposed in the revised Synjardy and Glyxambi Product Information. Furthermore, only for Synjardy, Annex A is also suggested to be

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updated with minor editorial changes.  
Finally, the MAH took the opportunity to submit some Minor Linguistic Changes to Synjardy and Glyxambi Product Information for several countries, as detailed below:

- Glyxambi: SV, ES, FR, PL, HU and HR.
- Synjardy: FR, DE, SV, PL, MT, ET, IT, ES, NL, FI and HR.”

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**WS2203**

**Kinzalmono-**

**EMA/H/C/000211/WS2203/0117**

**Micardis-**

**EMA/H/C/000209/WS2203/0121**

**Pritor-EMA/H/C/000210/WS2203/0130**

Boehringer Ingelheim International GmbH, Lead Rapporteur: Armando Genazzani, “To introduce several minor linguistic and editorial changes in the PI in all the EEA languages in alignment with the English PI, following the EMA recommendation to perform a full linguistic review of the PI in all EEA languages.

In addition, the MAH has implemented the updated QRD template version 10.2 in all EEA languages including the English PI, for the products Pritor and Kinzalmono.”

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**WS2207**

**Copalia HCT-**

**EMA/H/C/001159/WS2207/0096**

**Dafiro HCT-**

**EMA/H/C/001160/WS2207/0098**

**Exforge HCT-**

**EMA/H/C/001068/WS2207/0095**

Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher, “To bring the annexes in line with the current QRD template v10.2. In addition the MAH has taken the opportunity to update the local contact details for the UK (Northern Ireland).”

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**WS2208**

**Blitzima-EMA/H/C/004723/WS2208/0051**

**Truxima-EMA/H/C/004112/WS2208/0054**

Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

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**WS2209**

**Blitzima-EMA/H/C/004723/WS2209/0052**

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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. Timetables – 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).

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## 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.1.1. List of procedures concluding at 13-16 December 2021 CHMP plenary:

<b><i>Gastroenterology-Hepatology</i></b>	
Treatment of alpha-1 antitrypsin deficiency (AATD)-associated liver disease	The CHMP denied eligibility to PRIME and adopted the critical summary report.
<b><i>Infectious Diseases</i></b>	
Prevention of recurrent Clostridioides difficile infection (rCDI) in patients at high risk of recurrence	The CHMP denied eligibility to PRIME and adopted the critical summary report.
<b><i>Oncology</i></b>	
<b>ARI-0001</b> Treatment of patients older than 25 years with relapsed/refractory acute lymphoblastic leukaemia ATMP	The CAT and the CHMP granted eligibility to PRIME and adopted the critical summary report.
Treatment of multiple myeloma	The PRIME eligibility request has been withdrawn.
Treatment of advanced cutaneous melanoma ATMP	The CAT and the CHMP denied eligibility to PRIME and adopted the critical summary report.

#### G.1.2. List of procedures starting in December 2021 for January 2022 CHMP adoption of outcomes

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