07 October 2021
EMA/CHMP/562166/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 19-22 July 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, the 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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Table of contents

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 July 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 19 -22 July 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.

1.2. Adoption of agenda

CHMP agenda for 19-22 July 2021

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 21-24 June 2021.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 12 July 2021.

The CHMP adopted the CHMP minutes for 21-24 June 2021.

The CHMP adopted the minutes from the PROM meeting held on 12 July 2021.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Nexviadyme - avalglucosidase alfa - Orphan - EMEA/H/C/005501

Genzyme Europe BV; for long-term enzyme replacement therapy for the treatment of patients with Pompe disease.

Scope: Oral explanation

Action: Oral explanation to be held on 20 July 2021 at time 14:00

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

List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 28.01.2021. The presentation by the applicant focused on quality aspects.

An oral explanation was held on Tuesday, 20 July 2021.

See 3.1

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0026

Eurocept International B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (350 mg/ml oral solution). The RMP (version 0.1) is updated in accordance."

Action: Oral explanation to be held on 19 July 2021 at 14:00

List of Outstanding Issues adopted on 22.04.2021. List of Questions adopted on 12.11.2020.

The CHMP noted the withdrawal of extension of marketing authorisation application.

See 4.4

2.3.2. Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0028

Eurocept International B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 0.1) is updated in accordance."

Action: Oral explanation to be held on 19 July 2021 at 16:00

List of Outstanding Issues adopted on 22.04.2021. List of Questions adopted on 12.11.2020.

The CHMP noted the withdrawal of extension of marketing authorisation application.

See 4.4

2.3.3. Vosevi - sofosbuvir / velpatasvir / voxilaprevir - EMEA/H/C/004350/X/0045/G

Gilead Sciences Ireland UC

Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new strength (200 mg /50 mg /50 mg film-coated tablets). The extension application is grouped with a type II variation (C.I.6.a) to include paediatric use in patients aged 12 years and older and weighing at least 30 kg. Sections 4.2, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated to support the extended indication. The RMP (version 5.0) is updated in accordance. Furthermore, the MAH took the opportunity to implement minor editorial updates throughout the Product Information, and to update the list of local representatives in the Package Leaflet."

Scope: Possible oral explanation

Action: Possible oral explanation to be held on 20 July 2021 at 16:00

List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 25.02.2021.

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

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Imatinib Koanaa - imatinib - EMEA/H/C/005595

KOANAA Healthcare GmbH; treatment of Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML), Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), myelodysplastic/myeloproliferative diseases (MDS/MPD), hypereosinophilic syndrome (HES), eosinophilic leukaemia (CEL), Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST), and unresectable dermatofibrosarcoma protuberans (DFSP)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 22.04.2021. List of Questions adopted on 12.11.2020.

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 Norwegian Member was in agreement with the CHMP recommendation.

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.

3.1.2. Nexviadyme - avalglucosidase alfa - Orphan - EMEA/H/C/005501

Genzyme Europe BV; for long-term enzyme replacement therapy for the treatment of patients with Pompe disease.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 28.01.2021.

See 2.1

An oral explanation was held on Tuesday, 20 July 2021.

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

At the extraordinary CHMP meeting on 23 July 2021, 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 avalglucosidase alfa is not a new active substance, as claimed by the applicant.

The Norwegian Member was in agreement with the CHMP recommendation.

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

The summary of opinion was circulated for information.

3.1.3. Nouryant - istradefylline - EMEA/H/C/005308

Kyowa Kirin Holdings B.V.; indicated as an adjunctive treatment to levodopa-based regimens in patients with Parkinson’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 25.02.2021. List of Questions adopted on 30.04.2020.

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

The Norwegian Member was in agreement with the CHMP recommendation.

The refusal question and answers document 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. arachis hypogaea extract - Article 28 - EMEA/H/C/004810

treatment of peanut allergy

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.02.2021.

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. aducanumab - EMEA/H/C/005558

Alzheimer’s disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.02.2021.

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.

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

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

B And O Pharm; Treatment of severe malaria

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.

3.2.4. adalimumab – EMEA/H/C/005548

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

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.

3.2.5. adalimumab - EMEA/H/C/005947

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

Scope: List of outstanding issues

Action: For adoption

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. lasmiditan - EMEA/H/C/005332

acute treatment of migraine with or without aura in adults

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.7. tanezumab - EMEA/H/C/005189

treatment of moderate to severe chronic pain associated with osteoarthritis (OA) in adult patients for whom treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and/or an opioid is ineffective, not tolerated or inappropriate

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 20.05.2021, 28.01.2021. 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 3rd list of outstanding issues with a specific timetable.

3.2.8. rivaroxaban - EMEA/H/C/005600

Treatment of deep vein thrombosis and pulmonary embolism, and prevention of recurrent DVT and PE in adults. Prevention of venous thromboembolism in adult patients undergoing elective hip or knee replacement surgery; Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors.

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.

3.2.9. anifrolumab - EMEA/H/C/004975

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.02.2021.

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. sitagliptin fumarate - EMEA/H/C/005741

treatment of type 2 diabetes mellitus

Scope: List of outstanding issues

Action: For adoption

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 list of outstanding issues with a specific timetable.

3.2.11. autologous glioma tumor cells, inactivated - Orphan - ATMP - EMEA/H/C/003693

Epitopoietic Research Corporation-Belgium (E.R.C.); treatment of glioma

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 22.01.2021.

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.

3.2.12. avacopan - Orphan - EMEA/H/C/005523

Vifor Fresenius Medical Care Renal Pharma France; Treatment of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.02.2021.

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.

3.2.13. tecovirimat - EMEA/H/C/005248

treatment of orthopoxvirus disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.02.2021.

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.

3.2.14. diroximel fumarate - EMEA/H/C/005437

treatment of relapsing remitting multiple sclerosis

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.

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

3.3.1. 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: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

3.3.2. ganirelix - EMEA/H/C/005641

Prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART).

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. difelikefalin - EMEA/H/C/005612

treatment of pruritus

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.4. opicapone - EMEA/H/C/005782

treatment of Parkinson’s disease and motor fluctuations

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

The CHMP agreed to the request by the applicant for an additional extension to the clockstop to respond to the List of questions.

3.3.5. oportuzumab monatox - EMEA/H/C/005730

Treatment and prevention of recurrence of carcinoma-in-situ (CIS) of the urinary bladder and prevention of recurrence of high grade Ta and/or T1 papillary tumours

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. relugolix - EMEA/H/C/005353

treatment of adult patients with advanced prostate 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. pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451

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: 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.

3.3.8. daridorexant - EMEA/H/C/005634

treatment of insomnia

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.

3.3.9. teriparatide - EMEA/H/C/005827

treatment of osteoporosis

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.

3.3.10. sugammadex - EMEA/H/C/005760

Reversal of neuromuscular blockade induced by rocuronium or vecuronium

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. zanubrutinib - Orphan - EMEA/H/C/004978

BeiGene Ireland Ltd; treatment of Waldenström’s macroglobulinaemia (WM)

Scope: Update of list of outstanding issues adopted in June 2021

Action: For adoption

List of Outstanding Issues adopted on 22.04.2021. List of Questions adopted on 15.10.2020.

The CHMP adopted an updated list of outstanding issues together with a specific timetable.

3.4.2. doxorubicin - EMEA/H/C/005320

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

Scope: Request from the applicant dated 12 July 2021 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in March 2020

Action: For adoption

List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

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 March 2020.

3.4.3. eptacog beta (activated) - EMEA/H/C/005655

treatment and for the prevention of bleeding

Scope: Letter from the applicant dated 06 July 2021 requesting an extension to the clock stop to respond to the list of questions adopted in June 2021.

Action: For adoption

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 questions adopted in June 2021.

3.4.4. obeticholic acid - EMEA/H/C/005249

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

Scope: Letter from the applicant dated 12 July 2021 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in March 2021.

Action: For adoption

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

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 March 2021.

3.4.5. retifanlimab - Orphan - EMEA/H/C/005632

Incyte Biosciences Distribution B.V.; Treatment of locally advanced or metastatic squamous carcinoma of the anal canal (SCAC) who have progressed on or who are intolerant of platinum-based chemotherapy

Scope: Letter from the applicant dated 09 July 2021 requesting an extension to the clock stop to respond to the list of questions adopted in June 2021.

Action: For adoption

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 questions adopted in June 2021.

3.4.6. leuprorelin - EMEA/H/C/005034

indicated for the treatment of hormone dependent advanced prostate cancer

Scope: Letter from the applicant dated 19 March 2021 requesting an extension to the clock stop to respond to the list of questions adopted in July 2020.

Action: For adoption

List of Questions adopted on 23.07.2020.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in July 2020.

3.4.7. teriparatide - EMEA/H/C/005793

treatment of osteoporosis

Scope: Letter from the applicant dated 22 July 2021 requesting an extension to the clock stop to respond to the list of questions adopted in May 2021.

Action: For adoption

List of Questions adopted on 20.05.2021.

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

3.4.8. teriparatide - EMEA/H/C/004932

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

Scope: Letter from the applicant dated 22 July 2021 requesting extension to the clock stop to respond to the List of Questions adopted in January 2021.

Action: For adoption

List of Questions adopted on 28.01.2021.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the List of Questions adopted in January 2021.

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

3.5.1. Flynpovi - eflornithine / sulindac - Orphan - EMEA/H/C/005043

Cancer Prevention Pharma (Ireland) Limited; treatment of adult patients with familial adenomatous polyposis (FAP)

Scope: Appointment of rapporteurs, draft timetable

Action: For adoption

Fixed combination application (Article 10b of Directive No 2001/83/EC)

The CHMP appointed a Re-examination Rapporteur and a Re-examination Co-Rapporteur.

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. Sildenafil FGK - sildenafil - EMEA/H/C/005439

FGK Representative Service GmbH; treatment of erectile dysfunction

Scope: Letter by the applicant dated 19 July 2021 informing about the withdrawal of the marketing authorisation application

Action: For information

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

List of Outstanding Issues adopted on 25.03.2021, 10.12.2020. List of Questions adopted on 25.06.2020.

The CHMP noted the withdrawal of marketing authorisation application.

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

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

4.1.1. Deltyba - delamanid - Orphan - EMEA/H/C/002552/X/0046/G

Otsuka Novel Products GmbH

Rapporteur: Christophe Focke, PRAC Rapporteur: Laurence de Fays

Scope: "Extension application to introduce a new pharmaceutical form (dispersible tablets) associated with a new strength (25 mg), grouped with a type II extension of indication variation (C.I.6.a) to include the treatment of multidrug-resistant tuberculosis (MDR-TB) children of at least 10 kg of body weight for the approved Deltyba 50 mg film-coated tablets; as a consequence, sections 3, 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated accordingly. Version 3.3 of the RMP has also been submitted and Annex II is updated to remove the specific obligation related to an in vitro study using the HFS-TB model."

Action: For adoption

List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 10.12.2020.

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 Norwegian Member was in agreement with the CHMP recommendation.

4.1.2. Volibris - ambrisentan - EMEA/H/C/000839/X/0061/G

GlaxoSmithKline (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension application to introduce a new strength (2.5 mg film-coated tablet), grouped with an extension of indication to include paediatric use (8 to less than 18 years). Version 9.0 of the RMP has been submitted.
Type IA category A.7"

Action: For adoption

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

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 Norwegian Member was in agreement with the CHMP recommendation.

4.1.3. Vosevi - sofosbuvir / velpatasvir / voxilaprevir - EMEA/H/C/004350/X/0045/G

Gilead Sciences Ireland UC

Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new strength (200 mg /50 mg /50 mg film-coated tablets). The extension application is grouped with a type II variation (C.I.6.a) to include paediatric use in patients aged 12 years and older and weighing at least 30 kg. Sections 4.2, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated to support the extended indication. The RMP (version 5.0) is updated in accordance. Furthermore, the MAH took the opportunity to implement minor editorial updates throughout the Product Information, and to update the list of local representatives in the Package Leaflet."

Action: For adoption

List of Outstanding Issues adopted on 20.05.2021. List of Questions adopted on 25.02.2021.

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 Norwegian Member was in agreement with the CHMP recommendation.

See 2.3

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. Lacosamide Accord - lacosamide - EMEA/H/C/004443/X/0007

Accord Healthcare S.L.U.

Rapporteur: John Joseph Borg, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form (solution for infusion), a new strength (10 mg/ml) and a new route of administration (intravenous use)."

Action: For adoption

List of Outstanding Issues adopted on 12.11.2020. List of Questions adopted on 26.03.2020.

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

The Committee adopted the CHMP recommendation and scientific discussion together with the 2nd list of outstanding issues and a specific timetable.

4.2.2. Noxafil - posaconazole - EMEA/H/C/000610/X/0063/G

Merck Sharp & Dohme B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form (gastro-resistant powder and solvent for oral suspension), grouped with a type II variation (C.I.6.a) to extend the approved indications for Noxafil to the paediatric population.
As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC, as well as the package leaflet, are updated. The RMP (version 17.1) is updated in accordance"

Action: For adoption

List of Questions adopted on 25.03.2021.

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

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

4.2.3. Paliperidone Janssen-Cilag International - paliperidone - EMEA/H/C/005486/X/0002/G

Janssen-Cilag International N.V.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce two new strengths of 700 mg and 1000 mg prolonged-release suspension for injection, grouped with the following variations:
A.2.a - To change the (invented) name of the medicinal product
A.7 -
6 x C.I.7.b. - To delete the 25 mg, 50 mg, 75 mg, 100 mg and 150 mg/100 mg strengths from the Paliperidone Janssen-Cilag marketing authorisation (EU/1/20/1453/001-006)."

Action: For adoption

List of Questions adopted on 22.04.2021.

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

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

4.3.1. Dupixent - dupilumab - EMEA/H/C/004390/X/0045/G

sanofi-aventis groupe

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola

Scope: "1- Extension of a marketing authorisation for Dupixent to add a new strength, 100 mg solution for injection.
The presentations proposed for dupilumab 100 mg strength are the following: 1 presentation (multipack).
2- Type II (C.I.6) - Extension of indication to include treatment of paediatric patients with severe asthma with type 2 inflammation aged 6 to 11 years old.
Version 6.0 of the RMP has also been submitted."

Action: For adoption

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

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

4.3.2. Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210/X/0056/G

Gilead Sciences Ireland UC

Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (coated granules in sachet) associated with strengths 200 mg/50 mg and 150 mg/37.5 mg. The new presentations are indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients 3 years of age and older. The extension application is grouped with a type II variation (C.I.6.a) to include paediatric use in patients 3 years of age and older to the existing presentations of the film-coated tablets. Sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC and the Package Leaflet are updated to support the extended indication.
The RMP (version 7.1) is updated in accordance.
In addition, the MAH took the opportunity to implement minor updates and corrections throughout the Product Information."

Action: For adoption

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

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

4.3.3. Kaftrio - ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA/H/C/005269/X/0008/G

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Martin Huber

Scope: "Extension application to introduce a new strength of 37.5 mg/25 mg/50 mg film-coated tablets. Grouped with a type II variation (C.I.6.a) to include paediatric use (6 to 11 years)."

Action: For adoption

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

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

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

4.4.1. Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0026

Eurocept International B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (350 mg/ml oral solution). The RMP (version 0.1) is updated in accordance."

Action: Oral explanation to be held on 19 July 2021 at 14:00

List of Outstanding Issues adopted on 22.04.2021. List of Questions adopted on 12.11.2020.

The CHMP noted the withdrawal of extension of marketing authorisation application.

See 2.3

4.4.2. Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/X/0028

Eurocept International B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 0.1) is updated in accordance."

Action: Oral explanation to be held on 19 July 2021 at 16:00

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

12.11.2020.

The CHMP noted the withdrawal of extension of marketing authorisation application.

See 2.3

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

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 Adjupanrix 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 withdrawn Prepandrix marketing authorisation. Version 13 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.2. Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0129

CSL Behring GmbH

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

Scope: "Extension of indication for Hizentra in order to align the wording for the already approved Secondary immunodeficiency (SID) indications in the Hizentra SmPC with the wording of the Guideline on core SmPC for human normal immunoglobulin for intravenous administration (EMA/CHMP/BPWP/94038/ 2007 Rev 5; CHMP, 2018). As a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.6 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

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

5.1.3. Kalydeco - ivacaftor - Orphan - EMEA/H/C/002494/II/0096

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication for Kalydeco tablets in combination regiment with Kaftrio to include the treatment of adults, adolescents and children aged 6 years and older with cystic fibrosis who are homozygous for the F508del mutation in the CFTR gene or heterozygous for F508del and have a minimal function (MF) mutation in the CFTR gene. This application is based on the results of study VX18-445-106, a phase 3, open-label, multicentre study in subjects 6 through 11 years of age, with F/MF and F/F genotypes. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Packaged Leaflet is updated in accordance. Version 12.0 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.4. 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

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

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

5.1.5. Noxafil - posaconazole - EMEA/H/C/000610/II/0062

Merck Sharp & Dohme B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension of indication to include primary treatment of invasive aspergillosis in adults and adolescents from 13 years of age for Noxafil gastroresistant tablet and concentrate for solution for infusion as result of conclusion of study P069 (a Phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus Voriconazole for the Treatment of Invasive Aspergillosis); 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 16.2 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.03.2021.

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

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

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

Eli Lilly Nederland B.V.

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

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

Action: For adoption

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

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

5.1.7. Opdivo - nivolumab - EMEA/H/C/003985/II/0096

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to use OPDIVO (nivolumab) in combination with fluoropyrimidine- and platinum-based combination chemotherapy, in first-line treatment of adult patients with advanced or metastatic gastric, gastro-oesophageal junction (GEJ) or

oesophageal adenocarcinoma (study CA209649); as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 21.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.03.2021.

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

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

5.1.8. Rapiscan - regadenoson - EMEA/H/C/001176/II/0038

GE Healthcare AS

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Jayne Crowe

Scope: "Modification of existing indication to allow use in line with new imaging technologies that have evolved since initial approval of Rapiscan; as a consequence, sections 4.1, 4.2 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, relating to non-clinical and clinical aspects.

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

5.1.9. Siklos - hydroxycarbamide - EMEA/H/C/000689/II/0047

Addmedica S.A.S.

Rapporteur: Karin Janssen van Doorn

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to include relevant information based on results from the non-interventional cohort study ESCORT-HU. The marketing authorisation holder (MAH) has also taken the occasion to include some editorial changes along the PI and to update the list of local representatives for Croatia in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.2."

Action: For adoption

Request for Supplementary Information adopted on 20.05.2021, 28.01.2021, 15.10.2020.

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 Norwegian Member was in agreement with the CHMP recommendation.

The summary of opinion was circulated for information.

5.1.10. Spikevax - COVID-19 mRNA Vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0021

Moderna Biotech Spain, S.L.

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

Scope: "Extension of indication to include use in adolescents 12 to 17 years of age for COVID-19 Vaccine Moderna; 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."

Scope: Opinion

Action: For adoption

At an extraordinary CHMP meeting on 23 July 2021, the CHMP discussed the extension of indication application.

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

On 23 July 2021, the Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Norwegian CHMP member was in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.11. Skyrizi - risankizumab - EMEA/H/C/004759/II/0014

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Peter Kiely, PRAC Rapporteur: Liana Gross-Martirosyan

Scope: "Extension of indication for the treatment of active psoriatic arthritis in adults. Consequently, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 to the SmPC have been updated. The package leaflet is updated accordingly. Additionally, Annex II is also updated."

Action: For adoption

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

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

5.1.12. Ultomiris - ravulizumab - EMEA/H/C/004954/II/0010

Alexion Europe SAS

Rapporteur: Blanca Garcia-Ochoa, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of paediatric patients with paroxysmal nocturnal haemoglobinuria (PNH) for Ultomiris; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, Annex II is updated to reflect the addition of a PNH Parent guide. Version 2.1 of the RMP has also been submitted, in order to include the new indication."

Action: For adoption

Request for Supplementary Information 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 by consensus together with the CHMP Assessment Report and translation timetable.

The Norwegian Member was in agreement with the CHMP recommendation.

The summary of opinion was circulated for information

5.1.13. Zeposia - ozanimod - EMEA/H/C/004835/II/0002/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Bruno Sepodes, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "C.I.6 (Extension of indication)
Extension of indication to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent for Zeposia; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 5.1 of the SmPC and Annex IID are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to implement editorial changes throughout the product information.
C.I.4
Update of sections 4.4 and 4.5 of the SmPC in order to update the current SmPC description about PK interaction with BCRP inhibitors based on the study report from a drug interaction study with cyclosporine l(RPC-1063-CP-001)."

Action: For adoption

Request for Supplementary Information adopted on 25.03.2021.

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

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

5.2.1. Lonquex - lipegfilgrastim - EMEA/H/C/002556/II/0058/G

Teva B.V.

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension of indication to include treatment of the paediatric population for Lonquex and introduction of an age appropriate presentation in vials; 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 12.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.1.",

Request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in November 2020.

Action: For adoption

Request for Supplementary Information adopted on 12.11.2020.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in November 2020.

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

No items

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. maralixibat chloride - Orphan - H0005857

FGK Representative Service GmbH, Treatment of cholestasis and pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

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

Action: For adoption

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

8.1.2. miglustat - H0005695

used in conjunction with cipaglucosidase alfa is indicated for long-term treatment in adult patients with Pompe disease (acid α-glucosidase [GAA] deficiency).

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

Action: For adoption

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

8.1.3. cipaglucosidase alfa - Orphan - H0005703

Amicus Therapeutics Europe Limited, used in conjunction with miglustat is indicated for long-term treatment in adult patients with Pompe disease (acid α-glucosidase [GAA] deficiency).

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

Action: For adoption

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

8.1.4. olipudase alfa - Orphan - H0004850

Genzyme Europe BV, Olipudase alfa is indicated as enzyme replacement therapy for the long-term treatment of non-central nervous system manifestations of Acid Sphingomyelinase Deficiency (ASMD).

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.

8.1.5. ganaxolone - Orphan - H0005825

Marinus Pharmaceuticals Emerald Limited, Treatment of Cyclin-dependent Kinase-like 5 Deficiency Disorder (CDD) in children aged 3 years and older, and young adults aged from 18 to 21 years.

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment will be adopted via written procedure in August 2021.

Action: For adoption

CHMP noted the status of this application with expected adoption via written procedure in August 2021.

8.1.6. Nicord NF/Nicord CF - H0005288

Treatment of patients with hematologic malignancies who need a hematopoietic stem cell transplant.

Scope: EMA/CAT report on a request for a combination pack

Action: For adoption

CHMP noted the adoption via written procedure of the agreement of combination pack.

8.2. Priority Medicines (PRIME)

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

8.2.1. List of applications received

Action: For information

The CHMP noted the information.

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was accepted and 4 were denied.

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. Cometriq - cabozantinib - EMEA/H/C/002640/II/0044, Orphan

Ipsen Pharma

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

Scope: Update of section 5.1 of the SmPC based on the final results from study XL184-401 (EXAMINER) (SOB 001), a randomised, double-blind study to evaluate the efficacy and safety of cabozantinib (XL184) at 60 mg/day compared to a 140 mg/day in progressive, metastatic medullary thyroid cancer patients and as a consequence update of annex II in order to delete SOB 001. With the fulfilment of SOB 001 the MAH is requesting for the Cometriq MA to no longer be subject to specific obligations. The package leaflet is updated accordingly. The updated RMP version 5.5 has also been submitted.
Furthermore, information on hepatotoxicity has been added to the section 4.4 and the cross reference between sections 4.1 and 4.4 has been removed for consistency.
Additionally, the MAH took the opportunity to bring the Product Information in line with the latest QRD template version 10.2 Rev 1, to add the sodium content in the Summary of product Characteristics and Package Information Leaflet in line with the guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' and update the details of local representatives.

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.

The Norwegian CHMP member was in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

9.1.2. COVID-19 Vaccine Janssen – COVID-19 vaccine (Ad26.COV2-S [recombinant]) – EMEA/H/C/005737/II/0012

Janssen Cilag International N.V.

Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Update of sections 4.4 and 4.8 of the SmPC in order to add a warning related to the possibility of developing a Guillain-Barré syndrome (GBS) following the administration of Ad26.COV2.S and to add GBS as an adverse drug reaction (ADR). This is based on the information accumulated on cases of GBS reported to the vaccine adverse event reporting system (VAERS) in recipients of the Janssen COVID-19 Vaccine and subsequently, on the analysis performed by the company on cases of GBS based on the available cumulative data from launch. In addition, the company took the opportunity to make some editorial changes. 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.

The Norwegian CHMP member was in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

9.1.3. Ninlaro - ixazomib – Orphan -EMEA/H/C/003844/R/0030

Takeda Pharma A/S

Rapporteur: Armando Genazzani, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin

Scope: Annual renewal

Action: For adoption

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

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

9.1.4. Lojuxta - lomitapide - EMEA/H/C/002578/II/0046

Amryt Pharmaceuticals DAC

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

Scope: "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"

Action: For adoption

Request for Supplementary Information adopted on 09.04.2021.

The Committee discussed the issues identified in this application, relating to the RMP.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

9.1.5. Ulipristal Acetate Richter Gedeon – ulipristal acetate – EMEA/H/C/005017

Gedeon Richter Plc.; treatment of uterine fibroids

Rapporteur: Kristina Dunder, Co-Rapporteur: Paula Boudewina van Hennik

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

Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.6. Presence of the nitrosamine N-nitroso-varenicline in Champix – EMEA/H/C/000699

Pfizer Europe MA EEIG

Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Johann Lodewijk Hillege

List of question and updated assessment report have been adopted via written procedure on Friday, 09 July 2021.

DHPC letter on lots to be recalled due to presence of impurity N-nitroso-varenicline above the Pfizer acceptable daily intake limit has been adopted via written procedure on 06 July 2021.

Action: For information

The CHMP noted the documents which were adopted via written procedure.

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

Immedica Pharma AB

Rapporteur: Kirstine Moll Harboe, 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

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

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

9.1.8. Xarelto - rivaroxaban - EMEA/H/C/000944/II/0081

Bayer AG

Rapporteur: Kristina Dunder

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC following the final results

from the VOYAGER PAD study, a multicentre, randomised, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularisation procedures. The Package Leaflet is updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 22.04.2021, 12.11.2020.

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 Norwegian CHMP member was in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

9.1.9. RoActemra – tocilizumab – EMEA/H/C/000955

Roche Registration GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics

Action: For adoption

The CHMP agreed to the request for expediated review for an upcoming submission for a type II variation / extension of indication (treatment of COVID-19)

9.1.10. Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0017/G

AstraZeneca AB

Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné

C.I.4 (type II) - Update of sections 4.6 and 5.3 of the SmPC in order to add the high-level results from the development and reproductive toxicity (DART) study (study number 490843).
C.I.4 (type II) - Submission of the final report from the biodistribution study (514559) listed as an obligation in the Annex II of the Product Information. The Annex II is updated accordingly.
The MAH is taking the opportunity to update the wording of section 5.3 of the SmPC to add the results from the already assessed repeat-dose toxicity study. Moreover, the MAH is taking the opportunity to address the nonclinical recommendations adopted during the initial CMA application and update the due date for the specific obligation to submit the primary analysis of study D8110C00001 from 30th April 2021 to 4th June 2021.

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.

The Norwegian CHMP member was in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

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

AstraZeneca AB

Rapporteur: Sol Ruiz, Co-Rapporteur: Hans Hillege, PRAC Rapporteur: Jean-Michel Dogné

Scope: Quality variation

Action: For adoption

Request for Supplementary Information adopted on 24.06.2021.

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

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

9.1.12. Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0026

AstraZeneca AB

Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to include updated efficacy and safety information based on primary analysis from study D8110C00001 listed as a specific obligation in Annex II; this is a phase III randomised, double-blind, placebo-controlled, multicenter study in adults to determine the safety, efficacy and immunogenicity of Vaxzevria; the Package Leaflet and Annex II are updated accordingly. The updated RMP Version 3 Succession 2 has also been submitted."

Action: For adoption

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

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

9.1.13. Vaxzevria - COVID-19 vaccine (ChAdOx1-S [recombinant]) - EMEA/H/C/005675/MEA 027.3

AstraZeneca AB

Rapporteur: Sol Ruiz, Co-Rapporteur: Hans Hillege, PRAC Rapporteur: Jean-Michel Dogné

Scope: Updated PRAC Assessment Report has been adopted via written procedure on Friday, 09 July 2021.

Action: For information

The CHMP noted the updated PRAC assessment report, which was adopted via written procedure on 9 July 2021.

10. Referral procedures

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

10.1.1. Zynteglo – betibeglogene autotemcel - EMEA/H/A-20/1504

Bluebird bio (Netherlands) B.V.

Referral PRAC Rapporteur: Brigitte Keller-Stanislawski; PRAC Co-rapporteur: Menno van der Elst

Rapporteurs for Zynteglo (EMEA/H/C/003691): Rapporteur: Carla Herberts, Co-Rapporteur: Violaine Closson Carella, CHMP Coordinators: Paula Boudewina van Hennik, Alexandre Moreau

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004 based on pharmacovigilance data

Opinion

Action: For adoption

The CHMP was informed about the discussions at the PRAC which concluded that there is no evidence Zynteglo causes a blood cancer known as acute myeloid leukaemia (AML).

The CHMP, having considered the PRAC recommendation and the draft opinion formulated by the *CAT, adopted an opinion by consensus, recommending that the benefit-risk balance of Zynteglo is favourable and agreed to changes to the product information and key messages to educational material.

The Norwegian Member was in agreement with the CHMP recommendation.

The CHMP noted the public health communication.

*Note: PRAC worked closely with experts from the Committee for Advanced Therapies (CAT)

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

10.2.1. Vaxzevria – COVID-19 Vaccine (ChAdOx1-S [recombinant]) – EMEA/H/A-5(3)/1507

Astra Zeneca AB

Referral Rapporteur: Johann Lodewijk Hillege, Referral Co-Rapporteur: Sol Ruiz

Scope: Request for PRAC advice, list of questions to the MAH and timetable

Action: For adoption

CHMP interim opinion adopted on 23.04.2021

Following the conclusion of a possible link between Vaxzevria and very rare cases of

unusual blood clots with low blood platelets, the EC/Commission representative requested a further analysis and stratification of data under Article 5(3) of Regulation (EC) 726/2004, as well as, if possible providing a recommendation on the administration of the second dose of Vaxzevria on the basis of the available data for which an interim opinion was adopted by the CHMP on 23rd April 2021.

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

CHMP request for PRAC advice: July 2021 CHMP

Submission of responses from the MAH: 23.07.2021

Joint PRAC Rapporteur/co-rapporteur assessment report circulated to PRAC and CHMP: 20.08.2021

Comments from PRAC: 25.08.2021

Updated joint PRAC Rapporteur/co-rapporteur assessment report circulated to PRAC and CHMP: 27.08.2021

PRAC advice to CHMP: 02.09.2021

Joint CHMP Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 03.09.2021

Comments: 08.09.2021

Updated joint CHMP rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 10.09.2021

CHMP opinion: September 2021 CHMP

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

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

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

such inspections

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Update on procedure for chair and vice-chair elections

Action: For information

The CHMP noted update on procedure for chair and vice-chair elections.

14.1.2. Timetable for August 2021 Written Procedure

Action: For adoption

CHMP adopted the timetable for August 2021 Written Procedure.

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

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

Chair: Sol Ruiz/Nanna Aaby Kruse

Reports from BWP July 2021 meeting to CHMP for adoption:

- 24 reports on products in scientific advice and protocol assistance
- 12 reports on products in pre-authorisation procedures
- 2 reports on products in post-authorisation procedures
- 3 reports on products in plasma master file

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Infectious Diseases Working Party (IDWP)

IDWP Chair election

The mandate of the IDWP chair Maria Jesús Fernández Cortizo expired in November 2020.

Nomination(s) received

Action: For election

The CHMP re-elected Maria Jesús Fernández Cortizo as IDWP Chair.

14.3.3. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 29-30 June 2021.

Action: For adoption

The CHMP adopted the table of decisions.

14.3.4. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

Report from the SAWP meeting held on 05-08 July 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.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Update on COVID-19

Action: For information

The CHMP noted the information.

15.1.2. Refined Approach to Rolling Review

Action: For adoption

The CHMP adopted the refined approach to rolling review.

15.1.3. bamlanivimab - EMEA/H/C/005836

treatment of COVID-19 alone or in combination with etesevimab

Scope: Rolling review interim opinion

Action: For adoption

The CHMP adopted the rolling review interim opinion.

15.1.4. etesevimab - EMEA/H/C/005837

treatment of COVID-19 in combination with bamlanivimab

Scope: Rolling review interim opinion

Action: For adoption

The CHMP adopted the rolling review interim opinion.

15.1.5. Scientific Advice Group (SAG) re-nominations

Re-nominations for IC SAG oncology, SAG Cardiovascular and SAG Neurology

Action: For adoption

CHMP was presented with the Draft List of candidates for the SAG (SAG Oncology, SAG Cardiovascular, SAG Neurology, SAG Vaccines and SAG Infectious diseases) membership nominations. CHMP adopted the SAG Oncology and SAG Neurology proposals and noted the draft proposal for the other areas.

15.1.6. Sotrovimab - EMEA/H/0005676

Treatment of coronavirus disease 2019 (COVID-19)

Scope: 2nd RR interim opinion

Action: For adoption

At an extraordinary CHMP meeting on 23 July 2021, the CHMP discussed the rolling review interim opinion.

On 23 July 2021, the Committee adopted a positive interim opinion on the 2nd rolling review by consensus.

The Norwegian CHMP member was in agreement with the CHMP recommendations.

Lists of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 19-22 July 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	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Kirstine Moll Harboe	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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
Martine Trauffler	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	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
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 restrictions applicable to this meeting	
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	
Filip Josephson	Alternate	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
Peter Mol	Expert - via Webex*	Netherlands	No interests declared	
Jan Sjöberg	Expert - via Webex*	Iceland	No interests declared	
Katalina Mettke	Expert - via Webex*	Germany	No interests declared	
Eva Malikova	Expert - via Webex*	Slovakia	No interests declared	
Anna Kubandová	Expert - via Webex*	Slovakia	No interests declared	
Melanie Leplay	Expert - via Webex*	France	No interests declared	
Cheryl Aquilina	Expert - via Webex*	Malta	No interests declared	
Michal Pirozynski	Expert - via Webex*	Malta	No interests declared	
Antero Kallio	Expert - via Webex*	Finland	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Expert - via Webex*	Finland	No interests declared	
Elina Asikanius	Expert - via Webex*	Finland	No participation in discussion, final deliberations and voting on	RoActemra – tocilizumab – EMEA/H/C/000955
Peter Sisovsky	Expert - via Webex*	Slovakia	No interests declared	
Clemens Mittmann	Expert - via Webex*	Germany	No interests declared	
Adriana Andrić	Expert - via Webex*	Croatia	No interests declared	
Larissa Higgins	Expert - via Webex*	Ireland	No interests declared	
Kristian Wennmalm	Expert - via Webex*	Sweden	No interests declared	
Catherine Byrne	Expert - via Webex*	Ireland	No interests declared	
Brian Aylward	Expert - via Webex*	Ireland	No interests declared	
Geraldine O'Dea	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
David Walsh	Expert - via Webex*	Ireland	No interests declared	
Wolfgang Herzog	Expert - via Webex*	Austria	No interests declared	
Elisabeth Fuerst	Expert - via Webex*	Austria	No interests declared	
Tanja Zahlner	Expert - via Webex*	Austria	No interests declared	
Elisabeth Wischnitzki	Expert - via Webex*	Austria	No interests declared	
Bojana Divkovic	Expert - via Webex*	Austria	No restrictions applicable to this meeting	
Franz Rieder-Rommer	Expert - via Webex*	Austria	No interests declared	
Bernhard Majer	Expert - via Webex*	Austria	No interests declared	
Philipp Janesch	Expert - via Webex*	Austria	No interests declared	
Angelina Doriguzzi	Expert - via Webex*	Austria	No restrictions applicable to this meeting	
Sanna Gevers	Expert - via Webex*	Netherlands	No interests declared	
Jaap Fransen	Expert - via Webex*	Netherlands	No interests declared	
Esther Brandon	Expert - via Webex*	Netherlands	No interests declared	
Sujuta Sengupta	Expert - via Webex*	Netherlands	No interests declared	
Stavros Nikolakopoulos	Expert - via Webex*	Netherlands	No interests declared	
Angela de Kleynen	Expert - via Webex*	Netherlands	No interests declared	
Elly Vereyken	Expert - via Webex*	Netherlands	No restrictions applicable to this meeting	
Hinke Johanna Van der Woude	Expert - via Webex*	Netherlands	No interests declared	
Elisabeth Johanne Rook	Expert - via Webex*	Netherlands	No interests declared	
Hanneke Mulder	Expert - via Webex*	Netherlands	No interests declared	
Susanne Breedijk-van den Ende	Expert - via Webex*	Netherlands	No interests declared	
Susanne Mueller-Egert	Expert - via Webex*	Germany	No interests declared	
Hilke Zander	Expert - via Webex*	Germany	No interests declared	
Birgit Ahrens	Expert - via Webex*	Germany	No interests declared	
Susanne Kaul	Expert - via Webex*	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Valerie Lescrainier	Expert - via Webex*	Belgium	No interests declared	
Stefan Bonné	Expert - via Webex*	Belgium	No interests declared	
Anne Rousseau	Expert - via Webex*	Belgium	No interests declared	
Inne Crèvecoeur	Expert - via Webex*	Belgium	No restrictions applicable to this meeting	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	
Lucia Lopez-Anglada Fernandez	Expert - via Webex*	Spain	No interests declared	
Macarena Gajardo	Expert - via Webex*	Spain	No interests declared	
Agustin Portela Moreira	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	
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	
George Aislaitner	Expert - via Webex*	Germany	No interests declared	
Christine Greiner	Expert - via Webex*	Germany	No interests declared	
Elmer Schabel	Expert - via Webex*	Germany	No interests declared	
Andreas Bonertz	Expert - via Webex*	Germany	No interests declared	
Francesca Galeotti	Expert - via Webex*	Italy	No restrictions applicable to this meeting	
Sara Galluzzo	Expert - via Webex*	Italy	No interests declared	
Antonella Isgrò	Expert - via Webex*	Italy	No interests declared	
Luca Santi	Expert - via Webex*	Italy	No interests declared	
Serena Zamponi	Expert - via Webex*	Italy	No participation in discussion, final deliberations and voting on	Ninlaro - ixazomib – EMEA/H/C/003844/R/30
Paolo Foggi	Expert - via Webex*	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Adriana Ammassari	Expert - via Webex*	Italy	No interests declared	
Kristina Bech Jensen	Expert - via Webex*	Denmark	No interests declared	
Mette Linnert Jensen	Expert - via Webex*	Denmark	No interests declared	
Ebru Karakoc Madsen	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Susanne Høpner Rasmussen	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Trine Jensen	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Aaron Emmanuel Sosa Mejia	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Deidre Mannion	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Nanna Borup Johansen	Expert - via Webex*	Denmark	No interests declared	
Mogens Westergaard	Expert - via Webex*	Denmark	No interests declared	
Mette Tranholm	Expert - via Webex*	Denmark	No interests declared	
Jeanette McCallion	Expert - via Webex*	Ireland	No interests declared	
Jutta Dedorath	Expert - via Webex*	Germany	No interests declared	
Alfredo García-Arieta	Expert - via Webex*	Spain	No interests declared	
Christian B. (Kit) Roes	Expert - via Webex*	Netherlands	No interests declared	
Andre Elferink	Expert - via Webex*	Netherlands	No interests declared	
Leon Bongers	Expert - via Webex*	Netherlands	No interests declared	
Ulla Wändel Liminga	Expert - via Webex*	Sweden	No interests declared	
Carla Herberts	Expert - via Webex*	Netherlands	No interests declared	
Kirsi Maija Kaukonen	Expert - via Webex*	Finland	No interests declared	
Vincent Gazin	Expert - via Webex*	France	No interests declared	
Solene Maitenaz	Expert - via Webex*	France	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
Cecile Dop	Expert - via Webex*	France	No restrictions applicable to this meeting	
Dina Sanctussy	Expert - via Webex*	France	No interests declared	
Christina Bokorou	Expert - via Webex*	Greece	No interests declared	
Johannes Petrus Theodorus Span	Expert - via Webex*	Netherlands	No interests declared	
Louise Claessen	Expert - via Webex*	Netherlands	No interests declared	
Anja Schiel	Expert - via Webex*	Norway	No interests declared	
Filip Kukulski	Expert - via Webex*	Health Canada	No interests declared	
Evelyn Soo	Expert - via Webex*	Health Canada	No interests declared	
Ian Chisholm	Expert - via Webex*	Health Canada	No interests declared	
Megan Hickie	Expert - via Webex*	Therapeutic Goods Administration (TGA)	No interests declared	
Alan Fauconnier	Expert - via Webex*	WHO	No interests declared	
Ming Cao	Expert - via Webex*	Health Canada	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

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

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the extraordinary CHMP meeting held on 23 July 2021.

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	
Tomas Radimersky	Alternate	Czechia	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Kirstine Moll Harboe	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Carola de Beaufort	Alternate	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	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
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 restrictions applicable to this meeting	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Filip Josephson	Alternate	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	
Anette Kirstine Stark	Expert - via Webex*	Denmark	No interests declared	
Meera Varma	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Bibi Fatima Syed Shah	Expert - via Webex*	Denmark	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anna Kubandová	Expert - via Webex*	Slovakia	No interests declared	
Jana Schweigertova	Expert - via Webex*	Slovakia	No interests declared	
Svein Rune Andersen	Expert - via Webex*	Norway	No interests declared	
Harald Bernsteiner	Expert - via Webex*	Austria	No interests declared	
Deirdre Mannion	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
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	
Maria Victoria Tudanca Pacios	Expert - via Webex*	Spain	No restrictions applicable to this meeting	
Lorena Soledad Ver	Expert - via Webex*	Spain	No interests declared	
Catherine Byrne	Expert - via Webex*	Ireland	No interests declared	
Maeve Lally	Expert - via Webex*	Ireland	No restrictions applicable to this meeting	
Finbarr Leacy	Expert - via Webex*	Ireland	No interests declared	
Elisabeth Fuerst	Expert - via Webex*	Austria	No interests declared	
Tanja Zahlner	Expert - via Webex*	Austria	No interests declared	
Wolfgang Herzog	Expert - via Webex*	Austria	No interests declared	
Adriana Ammassari	Expert - via Webex*	Italy	No interests declared	
Heidi Meyer	Expert - via Webex*	Germany	No interests declared	
Matea Cartolano	Expert - via Webex*	Germany	No interests declared	
Julia Djonova	Expert - via Webex*	Swissmedic	No interests declared	
Christine Gee	Expert - via Webex*	TGA	No interests declared	
Mohit Khera	Expert - via Webex*	TGA	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

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

Explanatory notes

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

Oral explanations *(section 2)*

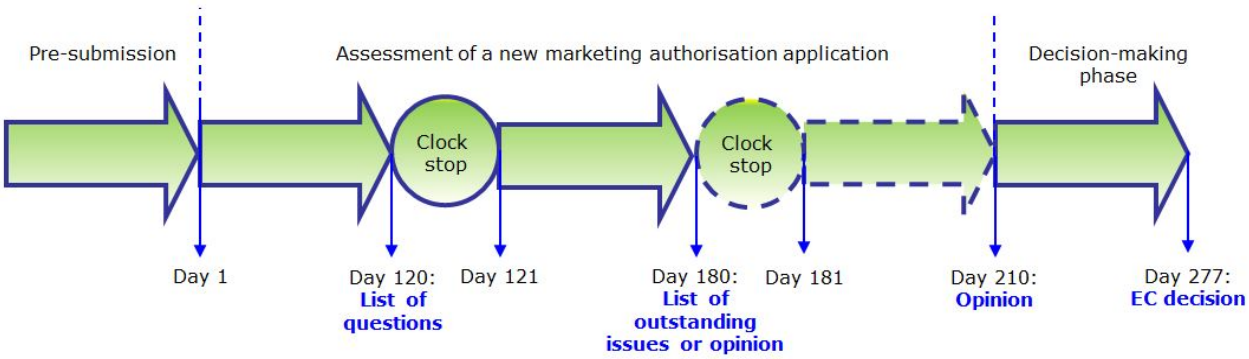
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

Extensions of marketing authorisations are applications for the change or addition of new strengths,

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a

particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 October 2021
EMA/CHMP/365990/2021

Annex to 19-22 July 2021 CHMP Minutes

Pre-submission and post-authorisation issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for July 2021: **For adoption**	Adopted

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

Final Outcome of Rapporteurship allocation for July 2021: **For adoption**	Adopted

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Chenodeoxycholic acid Leadiant - chenodeoxycholic acid - EMEA/H/C/004061/S/0017, Orphan Leadiant GmbH, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Adam Przybylkowski Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Elaprase - idursulfase - EMEA/H/C/000700/S/0092 Shire Human Genetic Therapies AB, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Firdapse - amifampridine - EMEA/H/C/001032/S/0071 SERB SA, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances. The Norwegian CHMP Member was in agreement with the CHMP opinion.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Cystadrops - mercaptamine - EMEA/H/C/003769/R/0022, Orphan Recordati Rare Diseases, Rapporteur: Kristina Dunder, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Darunavir Mylan - darunavir - EMEA/H/C/004068/R/0014 Mylan S.A.S, Generic, Generic of Prezista, Rapporteur: John Joseph Borg, PRAC Rapporteur: Liana Gross-Martirosyan Request for Supplementary Information adopted on 24.06.2021.	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Emtricitabine/Tenofovir disoproxil Krka - emtricitabine / tenofovir disoproxil - EMEA/H/C/004215/R/0018 KRKA, d.d., Novo mesto, Generic, Generic of Truvada, Rapporteur: John Joseph Borg, PRAC Rapporteur: Ana Sofia Diniz Martins Request for Supplementary Information adopted on 24.06.2021.	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Emtricitabine/Tenofovir disoproxil Mylan - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050/R/0016 Mylan S.A.S, Generic, Generic of Truvada, Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Ana Sofia Diniz Martins Request for Supplementary Information adopted on 24.06.2021.	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Ivabradine Zentiva - ivabradine - EMEA/H/C/004117/R/0008	Positive Opinion adopted by consensus together with the CHMP assessment report and

Zentiva k.s., Generic, Generic of Procoralan, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 20.05.2021.	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Movymia - teriparatide - EMEA/H/C/004368/R/0024 STADA Arzneimittel AG, Duplicate, Duplicate of Terrosa, Rapporteur: Daniela Philadelphy, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ronan Grimes Request for Supplementary Information adopted on 24.06.2021.	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Parsabiv - etelcalcetide - EMEA/H/C/003995/R/0017 Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Andrea Laslop (AT) (MNAT with AT for Clinical Efficacy, AT for Non-Clinical, AT for Coordination, AT for Clinical Pharmacology, AT for Clinical Safety, DE-BfArM for Quality), PRAC Rapporteur: Ilaria Baldelli Request for Supplementary Information adopted on 24.06.2021.	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Suliqua - insulin glargine / lixisenatide - EMEA/H/C/004243/R/0022 sanofi-aventis groupe, Rapporteur: Kristina Dunder, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Talmanco - tadalafil - EMEA/H/C/004297/R/0011 Mylan S.A.S, Generic, Generic of Adcirca, Cialis, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Maria del Pilar Rayon Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Terrosa - teriparatide - EMEA/H/C/003916/R/0020 Gedeon Richter Plc., Rapporteur: Daniela Philadelphy, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ronan Grimes Request for Supplementary Information adopted	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

on 24.06.2021.	the renewal of the marketing authorisation can be granted with unlimited validity. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/R/0035 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Ilaria Baldelli Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Vihuma - simoctocog alfa - EMEA/H/C/004459/R/0026 Octapharma AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Zinplava - bezlotoxumab - EMEA/H/C/004136/R/0029 Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Adam Przybylkowski	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. The Norwegian CHMP Member was in agreement with the CHMP opinion.

B.2.3. Renewals of Conditional Marketing Authorisations

Adakveo - crizanlizumab - EMEA/H/C/004874/R/0003, Orphan Novartis Europharm Limited, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Laurence de Fays Request for Supplementary Information adopted on 24.06.2021.	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional. The Norwegian CHMP Member was in agreement with the CHMP opinion.
Adcetris - brentuximab vedotin - EMEA/H/C/002455/R/0090, Orphan	Positive Opinion adopted by consensus together

Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst	with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional. The Norwegian CHMP Member was in agreement with the CHMP opinion.
NINLARO - ixazomib - EMEA/H/C/003844/R/0030, Orphan Takeda Pharma A/S, Rapporteur: Armando Genazzani, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable. See 9.1
Zynteglo - betibeglogene autotemcel - EMEA/H/C/003691/R/0018, Orphan, ATMP bluebird bio (Netherlands) B.V, Rapporteur: Carla Herberts, CHMP Coordinator: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski Request for Supplementary Information adopted on 22.01.2021.	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional. The Norwegian CHMP Member was in agreement with the CHMP opinion.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 05-08 July 2021 PRAC:	
Signal of myocarditis, pericarditis Comirnaty – COVID-19 mRNA vaccine (nucleoside-modified) Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst PRAC recommendation on a variation, DHPC, Communication plan; adopted via written procedure on Friday 09 July 2021 **Action:** For information	Noted

Signal of myocarditis, pericarditis Spikevax – COVID-19 mRNA vaccine (nucleoside-modified) Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Hans Christian Siersted PRAC recommendation on a variation, DHPC, Communication plan; adopted via written procedure on Friday 09 July 2021 **Action:** For information	Noted
Signal of immune-mediated cystitis Tecentriq, Bavencio, Libtayo, Imfinzi, Yervoy, Keytruda, Opdivo – Immune checkpoint inhibitors Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Menno van der Elst PRAC recommendation on a variation **Action:** For adoption	Adopted
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its July 2021 meeting:	
EMEA/H/C/PSUSA/00001838/202012 (lenalidomide) CAPS: **Lenalidomide Accord** (EMEA/H/C/004857) (lenalidomide), Accord Healthcare S.L.U., Rapporteur: Ewa Balkowiec Iskra **Lenalidomide Mylan** (EMEA/H/C/005306) (lenalidomide), Mylan Ireland Limited, Rapporteur: Eleftheria Nikolaidi **Revlimid** (EMEA/H/C/000717) (lenalidomide), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Alexandre Moreau NAPS: **NAPs** - EU PRAC Rapporteur: Tiphaine Vaillant, "17/07/2020 To 26/12/2020"	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 authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.4 of the SmPC to update a warning on tumour lysis syndrome in view of available data from spontaneous reports in myelodysplastic syndrome indication. The MAH of Lenalidomide Accord has taken the opportunity to implement pending corrections relevant to Annex II in line with the latest RMP v1.7 (EMEA/H/C/004857/IB/0015, 30 March 2021). The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00001838/202012 (lenalidomide) CAPS: **Lenalidomide Accord** (EMEA/H/C/004857)	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

(lenalidomide), Accord Healthcare S.L.U., Rapporteur: Ewa Balkowiec Iskra **Lenalidomide Mylan** (EMEA/H/C/005306) (lenalidomide), Mylan Ireland Limited, Rapporteur: Eleftheria Nikolaidi **Revlimid** (EMEA/H/C/000717) (lenalidomide), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Alexandre Moreau NAPS: **NAPs** - EU PRAC Rapporteur: Tiphaine Vaillant, "17/07/2020 To 26/12/2020"	and the PRAC assessment report as appended recommends by consensus, the variation to the 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 4.4 of the SmPC to update a warning on tumour lysis syndrome in view of available data from spontaneous reports in myelodysplastic syndrome indication. The MAH of Lenalidomide Accord has taken the opportunity to implement pending corrections relevant to Annex II in line with the latest RMP v1.7 (EMEA/H/C/004857/IB/0015, 30 March 2021). The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010694/202012 (rucaparib) CAPS: **Rubraca** (EMEA/H/C/004272) (rucaparib), Clovis Oncology Ireland Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Annika Folin, "20/06/2020 To: 19/12/2020"	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 changes: Update of section 4.8 of the SmPC to add the adverse reaction hypersensitivity with a frequency "Common". The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

B.4. EPARs / WPARs

Abecma - idecabtagene vicleucel - EMEA/H/C/004662, Orphan, ATMP Celgene Europe BV, treatment of multiple myeloma, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Abiraterone Mylan - abiraterone acetate - EMEA/H/C/005368 Mylan IRE Healthcare Limited, treatment of metastatic castration resistant prostate cancer, Generic, Generic of Zytiga, Generic application (Article 10(1) of Directive No 2001/83/EC); Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

Bimzelx - bimekizumab - EMEA/H/C/005316 UCB Pharma S.A., treatment of plaque psoriasis, 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.
Byooviz - ranibizumab - EMEA/H/C/005545 Samsung Bioepis NL B.V., treatment of neovascular age-related macular degeneration (AMD), 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.
Evrenzo - roxadustat - EMEA/H/C/004871 Astellas Pharma Europe B.V., treatment of anaemia, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Fingolimod Mylan - fingolimod - EMEA/H/C/005661 Mylan Ireland Limited, treatment of multiple sclerosis, Generic, Generic of Gilenya, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Flynpovi - eflornithine / sulindac - EMEA/H/C/005043, Orphan Cancer Prevention Pharma (Ireland) Limited, treatment of adult patients with familial adenomatous polyposis (FAP), Fixed combination application (Article 10b of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
MINJUVI - tafasitamab - EMEA/H/C/005436, Orphan Incyte Biosciences Distribution B.V., is indicated in combination with lenalidomide followed by Tafasimab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from low grade lymphoma, who are not eligible for, or refuse, autologous stem cell transplant (ASCT)., 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.
Voxzogo - vosoritide - EMEA/H/C/005475, Orphan BioMarin International Limited, Indicated for the treatment of achondroplasia., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Aimovig - erenumab - EMEA/H/C/004447/II/0016 Novartis Europharm Limited, Rapporteur: Kristina Dunder Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Alprolix - eftrenonacog alfa - EMEA/H/C/004142/II/0036/G, Orphan Swedish Orphan Biovitrum AB (publ), Rapporteur: Andrea Laslop Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Biopoin - epoetin theta - EMEA/H/C/001036/II/0048 TEVA GmbH, Rapporteur: Alexandre Moreau Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0040/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Request for Supplementary Information adopted on 15.07.2021.	Request for supplementary information adopted with a specific timetable.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0041/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 15.07.2021.	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0043 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 07.07.2021. Request for Supplementary Information adopted on 25.06.2021.	Positive Opinion adopted by consensus on 07.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0045/G	Positive Opinion adopted by consensus on 09.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 09.07.2021. Request for Supplementary Information adopted on 05.07.2021.	recommendation. Request for supplementary information adopted with a specific timetable.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0049/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 20.07.2021.	Positive Opinion adopted by consensus on 20.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Darzalex - daratumumab - EMEA/H/C/004077/II/0049/G, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004240/II/0015/G Mylan S.A.S, Generic, Generic of Atripla, Rapporteur: Bruno Sepodes Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Eporatio - epoetin theta - EMEA/H/C/001033/II/0047 ratiopharm GmbH, Rapporteur: Alexandre Moreau Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Eylea - aflibercept - EMEA/H/C/002392/II/0071/G Bayer AG, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 15.07.2021.	Request for supplementary information adopted with a specific timetable.
Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0017 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0021 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 08.07.2021.	
Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0109 AstraZeneca AB, Rapporteur: Christophe Focke Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Hemlibra - emicizumab - EMEA/H/C/004406/II/0023/G Roche Registration GmbH, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0068/G Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
IKERVIS - ciclosporin - EMEA/H/C/002066/II/0026/G Santen Oy, Rapporteur: Peter Kiely Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0064 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 01.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Increlex - mecasermin - EMEA/H/C/000704/II/0068/G Ipsen Pharma, Rapporteur: Outi Mäki-Ikola Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 17.06.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Intrarosa - prasterone - EMEA/H/C/004138/II/0015 Endoceutics S.A., Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 22.07.2021, 11.03.2021.	Request for supplementary information adopted with a specific timetable.
Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0011/G, Orphan	Request for supplementary information adopted with a specific timetable.

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 08.07.2021.	
Kineret - anakinra - EMEA/H/C/000363/II/0083 Swedish Orphan Biovitrum AB (publ), Rapporteur: Kirstine Moll Harboe Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lonquex - lipegfilgrastim - EMEA/H/C/002556/II/0064/G Teva B.V., Rapporteur: Outi Mäki-Ikola Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
MabThera - rituximab - EMEA/H/C/000165/II/0185/G Roche Registration GmbH, Rapporteur: Sinan B. Sarac Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Menveo - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0101 GSK Vaccines S.r.l, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nepexto - etanercept - EMEA/H/C/004711/II/0010/G Mylan IRE Healthcare Limited, Rapporteur: Martina Weise Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Nucala - mepolizumab - EMEA/H/C/003860/II/0043 GlaxoSmithKline Trading Services Limited, Rapporteur: Peter Kiely Opinion adopted on 15.07.2021.	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ondexxya - andexanet alfa - EMEA/H/C/004108/II/0020/G Alexion Europe SAS, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
OPDIVO - nivolumab - EMEA/H/C/003985/II/0103 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa Opinion adopted on 15.07.2021.	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

ReFacto AF - moroctocog alfa - EMEA/H/C/000232/II/0158/G Pfizer Europe MA EEIG, Rapporteur: Kirstine Moll Harboe Opinion adopted on 15.07.2021. Request for Supplementary Information adopted on 10.06.2021, 11.03.2021.	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Respreeza - human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0053/G CSL Behring GmbH, Rapporteur: Kristina Dunder Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 17.06.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
SARCLISA - isatuximab - EMEA/H/C/004977/II/0009/G, Orphan sanofi-aventis groupe, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Skyrizi - risankizumab - EMEA/H/C/004759/II/0015/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Kiely Opinion adopted on 15.07.2021.	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Spectrila - asparaginase - EMEA/H/C/002661/II/0025 medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Andrea Laslop Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0026/G Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 21.07.2021.	Request for supplementary information adopted with a specific timetable.
Tremfya - guselkumab - EMEA/H/C/004271/II/0029/G Janssen-Cilag International N.V., Rapporteur: Agnes Gyurasics Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 24.06.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) -	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/005675/II/0021/G AstraZeneca AB, Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 22.07.2021, 24.06.2021.	See 9.1
VEYVONDI - vonicog alfa - EMEA/H/C/004454/II/0017 Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
YUFLYMA - adalimumab - EMEA/H/C/005188/II/0002 Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola Opinion adopted on 01.07.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ziextenzo - pegfilgrastim - EMEA/H/C/004802/II/0014 Sandoz GmbH, Rapporteur: Andrea Laslop Request for Supplementary Information adopted on 15.07.2021.	Request for supplementary information adopted with a specific timetable.
Zubsolv - buprenorphine / naloxone - EMEA/H/C/004407/II/0015 Accord Healthcare S.L.U., Rapporteur: Peter Kiely Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
WS1908/G **Hefiya-EMEA/H/C/004865/WS1908/0030/G** **Hyrimoz-EMEA/H/C/004320/WS1908/0030/G** Sandoz GmbH, Lead Rapporteur: Daniela Philadelphy Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 17.06.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
WS1964 **HyQvia-EMEA/H/C/002491/WS1964/0072** **Kiovig-EMEA/H/C/000628/WS1964/0110** Baxalta Innovations GmbH, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS2026 **AMGEVITA-EMEA/H/C/004212/WS2026/0026** **Aranesp-EMEA/H/C/000332/WS2026/0155**	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

MVASI-EMEA/H/C/004728/WS2026/0021 **Prolia-EMEA/H/C/001120/WS2026/0089** **Repatha-EMEA/H/C/003766/WS2026/0052** **XGEVA-EMEA/H/C/002173/WS2026/0077** Amgen Europe B.V., Lead Rapporteur: Martina Weise Opinion adopted on 08.07.2021.	
WS2080/G **Hexacima-EMEA/H/C/002702/WS2080/0117/G** **Hexyon-EMEA/H/C/002796/WS2080/0121/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
WS2095/G **Blitzima-EMEA/H/C/004723/WS2095/0043/G** **Truxima-EMEA/H/C/004112/WS2095/0046/G** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.

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

Alecensa - alectinib - EMEA/H/C/004164/II/0034 Roche Registration GmbH, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to add haemolytic anaemia to the list of adverse drug reactions (ADRs) with frequency common, based on a report of cumulative safety data (DSR1104210); 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. Moreover, the MAH took the opportunity to introduce editorial changes in the Greek, Swedish, Dutch, Danish, Latvian, Croatian, Portuguese and Czech PI." Request for Supplementary Information adopted on 08.07.2021, 20.05.2021.	Request for supplementary information adopted with a specific timetable.
Alunbrig - brigatinib / brigatinib - EMEA/H/C/004248/II/0033/G Takeda Pharma A/S, Rapporteur: Sinan B. Sarac, "Update of section 4.5 of the SmPC in	Request for supplementary information adopted with a specific timetable.

order to add drug-drug interaction information about the effect of brigatinib on the pharmacokinetics of a sensitive cytochrome P450 3A substrate (midazolam) in patients with ALK-positive or ROS1-positive solid tumours based on a clinical study report (study 1001). Update of section 4.2 of the SmPC in order to clarify the existing renal impairment dosage adjustment recommendation based on results of previously submitted studies (clinical study AP26113-15-108, study 108). Update of section 4.2 of the SmPC in order to clarify the existing hepatic impairment dosage adjustment recommendation based on results of previously submitted studies (clinical study AP26113-15-107, study 107). Update of sections 4.4 and 4.5 of the SmPC in order to update drug-drug interaction information regarding concomitant treatment with moderate CYP3A inhibitors or inducers based on results of previously submitted studies (physiologically-based pharmacokinetic (PBPK) report and PBPK report addendum). Update of section 5.1 of the SmPC in order to amend the ATC code; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement a statement regarding the sodium content of Alunbrig in section 4.4 of the SmPC and Package Leaflet. The MAH also took the opportunity to bring the Product Information in line with the latest QRD template (version 10.2 rev.1) and to update the list of local representatives in the Package Leaflet. Moreover, the MAH took the opportunity to introduce minor editorial changes in the PI in different languages." Request for Supplementary Information adopted on 22.07.2021.	
Alunbrig - brigatinib / brigatinib - EMEA/H/C/004248/II/0034 Takeda Pharma A/S, Rapporteur: Sinan B. Sarac, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on photosensitivity based on a report of cumulative evidence for an association between exposure to brigatinib and subsequent development of photosensitivity reaction; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make a minor editorial change in section 4.8 of the SmPC."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 22.07.2021.	
Bosulif - bosutinib - EMEA/H/C/002373/II/0048 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, "C.I.4 Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update safety and efficacy information based on final results from study B18711053 (a recommendation of EMEA/H/C002373/II/25/G). This is an interventional safety and efficacy study covering submission of the long-term experience results secondary endpoints (duration of MMR and CCyR, EFS and OS). The Safety Data pool is also updated with results of interventional studies, B18711048 (final CSR submitted in variation II/41) and ongoing studies B18711039 and B18711040 (listed as category 3 studies in the RMP); the Package Leaflet is updated accordingly. PSUR Annex IV associated to procedure EMEA/H/C/PSUSA/00010073/202003 (commission decision dated 14 December 2020) has been proposed for removal." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 11.03.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0038/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, "To update section 4.4 of the SmPC to add a new warning on "vaccine stress-related responses" following signal detection and evaluation activity in the post-authorisation setting, as a result of internal review of post-authorisation cases; the Package Leaflet is updated accordingly. To update section 4.8 of the SmPC to add "extensive swelling of the vaccinated limb" to the list of adverse drug reactions (ADRs) with frequency "Not known" agreed by the PRAC following the outcome of the of the Post-Authorisation Measure PAM MEA-002.3 (EMEA/H/C/005735/MEA/002.3, dated 04. May 2021); the Package Leaflet is updated accordingly. To update section 4.8 of the SmPC to add	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.

("facial swelling") to the list of adverse drug reactions (ADRs) with frequency "Not known" agreed by the PRAC following the outcome of the Signal Assessment on localised swelling in patients with history of dermal filer injections with tozinameran (Comirnaty (COVID-19 mRNA vaccine), (EMEA/H/C/005735/SDA/023 (EPITT ref. 19674); the Package Leaflet is updated accordingly." Opinion adopted on 22.07.2021.	
Cosentyx - secukinumab - EMEA/H/C/003729/II/0073 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, "C.I.4 - Update of section 5.1 of the SmPC in order to include the 52 weeks results from study A2311; a multicenter, randomized, open-label study in paediatric patients aged 6 years to less than 18 years with moderate to severe chronic plaque psoriasis." Opinion adopted on 01.07.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Dovprela - pretomanid - EMEA/H/C/005167/II/0004/G, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, "Grouped application including three type II variations under category C.I.4. Update of sections 4.5 and 5.3 of the SmPC based on data from three non-clinical studies: - Assessment of pretomanid as an inhibitor of human OCT2-, OATP1B3-, BCRP-, and P-gp mediated transport; - In vitro evaluation of induction/inhibition of CYP 2C8, 2C9, and 2C19 in human hepatocytes; - A 24-Month Oral (Gavage) Carcinogenicity Study in Rats." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 10.06.2021, 09.04.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Dupixent - dupilumab - EMEA/H/C/004390/II/0046 sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 4.8 of the SmPC to introduce a new ADR (facial rash) with uncommon frequency. The package leaflet will be updated accordingly." Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
Erleada - apalutamide -	Request for supplementary information adopted

EMEA/H/C/004452/II/0015 Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, "Update of section 5.1 of the SmPC in order to update the efficacy and safety information based on final results from study 56021927PCR3002 (TITAN) listed as Letter of Recommendations (11 December 2019, EMEA/H/C/004452/II/0001); this is a double-blind, placebo-controlled, multinational, multicenter Phase 3 study in metastatic castration-sensitive prostate cancer (mCSPC) patients." Request for Supplementary Information adopted on 08.07.2021.	with a specific timetable.
Fasenra - benralizumab - EMEA/H/C/004433/II/0031 AstraZeneca AB, Rapporteur: Fátima Ventura, "Update of section 4.8 of the SmPC in order to add information on long-term safety based on the submission of the final report from study D3250C00037 (MELTEMI), listed as a category 3 study in the RMP. This is an open-label safety extension study to evaluate the safety and tolerability of a fixed 30 mg dose of benralizumab s.c. in severe asthma patients." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 06.05.2021, 11.02.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Fasenra - benralizumab - EMEA/H/C/004433/II/0036** AstraZeneca AB, Rapporteur: Fátima Ventura, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Update of RMP to remove long-term use of benralizumab, serious hypersensibility, loss of/reduction of long-term efficacy as safety concern and to change categorisation of helminth infection from important identified risk to important potential risk. RMP version 4.0 is submitted" Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
Feraccru - ferric maltol - EMEA/H/C/002733/II/0033 Norgine B.V., Rapporteur: Maria Concepcion Prieto Yerro, "to remove haemoglobin threshold from section 4.4 'Special warnings and precautions for use' of summary of product characteristics for Feraccru Capsules 30 mg,	Request for supplementary information adopted with a specific timetable.

deleting the reference made that states "Feraccru is not recommended for use in patients with haemoglobin (Hb) <9.5 g/dl."" Request for Supplementary Information adopted on 22.07.2021.	
Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/II/0077 Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, "Update of sections 4.8 and 5.1 of the SmPC based on study GS-US-292-0106. This was a phase 2/3, open-label study of pharmacokinetics, safety and antiviral activity in HIV-1 infected antiretroviral treatment-naïve adolescents and virologically suppressed children." Opinion adopted on 15.07.2021.	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Hemlibra - emicizumab - EMEA/H/C/004406/II/0021** Roche Registration GmbH, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ilaria Baldelli, PRAC-CHMP liaison: Armando Genazzani, "Submission of an updated RMP version 2.6 in order to add thromboembolic events without concomitant aPCC as an important potential risk in the safety specifications and to update the milestones for BO40853/SURVEY study following approval of the protocol v3 (via MEA PRO 002.2)." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 11.03.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
INREBIC - fedratinib - EMEA/H/C/005026/II/0003/G, Orphan Celgene Europe BV, Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.4 and 4.5 of the SmPC in order to update drug-drug interaction information regarding medicinal products renally excreted via organic cation transporter (OCT)2 and multidrug and toxin extrusion (MATE)1/2-K (e.g. metformin) based on data from study FEDR-CP-003 (drug transporter DDI study) listed as recommendation during initial assessment. The Package Leaflet is updated accordingly. In addition, the MAH is updating the recently revised ATC code in section 5.1 of the SmPC."	Positive Opinion adopted by consensus on 15.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 15.07.2021.	
Kyprolis - carfilzomib - EMEA/H/C/003790/II/0051/G, Orphan Amgen Europe B.V., Rapporteur: Blanca Garcia-Ochoa, "A.6 The ATC code of the product is updated C.I.4, Update of section 4.2 of the SmPC in order to modify administration instructions of daratumumab when Kyprolis is dosed in combination with daratumumab and dexamethasone, based on results from efficacy and safety studies MMY2040 (ongoing phase 2), MMY1001 (completed phase 1b) and CANDOR (ongoing phase 3)." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Phesgo - pertuzumab / trastuzumab - EMEA/H/C/005386/II/0004 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update in section 4.8, Undesirable Effects, to present the pooled data from Perjeta and Phesgo studies. In addition to this, the MAH has taken the opportunity to introduce minor updates in the SmPC and the Package leaflet: • Update in section 9 of the SmPC to reflect the date of first authorisation • Editorial update in section 4 of the Package Leaflet to add a space • Update in section 6 of the Package Leaflet to adapt to the revised QRD Template v10.2" Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0128 Boehringer Ingelheim International GmbH, Rapporteur: Kirstine Moll Harboe, "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	Request for supplementary information adopted with a specific timetable.

code in Annex IIIA and IIIB and to include additional updates to Annex IIIA and mock-ups." Request for Supplementary Information adopted on 22.07.2021.	
SIRTURO - bedaquiline - EMEA/H/C/002614/II/0043, Orphan Janssen-Cilag International NV, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC to include reference on the use of bedaquiline as specified in the product information of other medicines used for the treatment of pulmonary tuberculosis (TB) caused by multidrug-resistant Mycobacterium tuberculosis (MDR-TB), based on recent information regarding EU approval of pretomanid, as part of a combination regimen with bedaquiline and linezolid. In addition, the MAH took the opportunity to include an editorial correction in section 5.1 of the SmPC and to update the contact details for the local representative for UK in the package leaflet, in line with QRD version 10.2." Request for Supplementary Information adopted on 22.07.2021, 24.06.2021.	Request for supplementary information adopted with a specific timetable.
Sunosi - solriamfetol - EMEA/H/C/004893/II/0009 Jazz Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig, "Update of section 4.8 of the SmPC in order to add hypersensitivity reactions to the list of adverse drug reactions (ADRs) following confirmation of a post-marketing safety signal for hypersensitivity. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes and to bring the PI in line with the latest QRD template version 10.2." Opinion adopted on 01.07.2021. Request for Supplementary Information adopted on 29.04.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Synflorix - pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/000973/II/0160 GlaxoSmithkline Biologicals SA, Rapporteur: Kristina Dunder, "Update of section 5.1 Pharmacodynamic properties of the SmPC following submission of procedure EMEA/H/C/000973/P46/070 to include results of	Request for supplementary information adopted with a specific timetable.

the study 10PN-PD-DIT-082, a phase III, controlled, partially-blind study evaluating the interchangeability of Synflorix and 13-valent pneumococcal conjugate vaccine. Section 4.2 Posology and method of administration is updated to cross reference to section 5.1. In addition, the MAH took the opportunity to add in section 4.4 Special warnings and precautions of the SmPC a statement regarding the sodium content, in line with the guideline on "Excipients in the labelling and package leaflet of medicinal product for human use" and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 22.07.2021.	
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0060 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "C.I.4 Update of section 4.2 of the SmPC in order to harmonise the atezolizumab posology regimen of 840 mg every 2 weeks, 1200 mg every 3 weeks and 1680 mg every 4 weeks administered as an IV infusion across the currently authorised indications of NSCLC, ES-SCLC, TNBC and HCC, based on PK modelling and simulation data. As a consequence of the harmonised dose schedules, the MAH is applying for a combined SmPC and PL. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to include minor editorial changes to the PI." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Tecentriq - atezolizumab - EMEA/H/C/004143/II/0061 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Submission of an updated RMP version 20.0 in order to add severe cutaneous adverse reactions (SCARs) as an important identified risk and its associated risk minimisation measures, a DHPC, following the addition of SCARS to the Tecentriq PI with procedure EMEA/H/C/004143/II/0054. In addition, the MAH has also taken the	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

opportunity to update the due dates of final CSR of two Post-authorisation efficacy studies." Opinion adopted on 08.07.2021.	
Tysabri - natalizumab - EMEA/H/C/000603/II/0123 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "C.I.4. Update of section 4.2 of the SmPC of Tysabri 300 mg IV in order to modify administration instructions based on a review of clinical study database and global safety database reports. The Package Leaflet (section 2) is updated accordingly." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 25.03.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Tysabri - natalizumab - EMEA/H/C/000603/II/0127 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy following a safety signal assessment of cases of neonatal thrombocytopenia that may be associated with natalizumab treatment." Opinion adopted on 01.07.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0017/G AstraZeneca AB, Rapporteur: Sol Ruiz, "C.I.4 (type II) - Update of sections 4.6 and 5.3 of the SmPC in order to add the high-level results from the development and reproductive toxicity (DART) study (study number 490843). C.I.4 (type II) - Submission of the final report from the biodistribution study (514559) listed as an obligation in the Annex II of the Product Information. The Annex II is updated accordingly. The MAH is taking the opportunity to update the wording of section 5.3 of the SmPC to add the results from the already assessed repeat-dose toxicity study. Moreover, the MAH is taking the opportunity to address the nonclinical recommendations adopted during the initial CMA application and update the due date for the specific obligation to submit the primary analysis of study D8110C00001 ." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation. See 9.1

on 20.05.2021.	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0019 AstraZeneca AB, Rapporteur: Sol Ruiz, "Submission of the interim and primary clinical study reports from study D8111C00002, listed as a category 3 study in the RMP. This study is a Phase I/II randomised, double-blind, placebo-controlled, multicentre study in participants aged 18 years or older to determine the safety and immunogenicity of Vaxzevria."	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vazkepa - icosapent ethyl - EMEA/H/C/005398/II/0001 Amarin Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, "C.I.13: Submission of the final report from study assessing the in vitro effects of Eicosapentaenoic acid (EPA) on Cloned hERG Potassium Channels Expressed in Human Embryonic Kidney Cells." Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vectibix - panitumumab - EMEA/H/C/000741/II/0097 Amgen Europe B.V., Rapporteur: Bjorg Bolstad, "Update of sections 4.4 and 4.8 of the SmPC in order to add the risk of corneal perforation to the risks of keratitis and ulcerative keratitis and to add corneal perforation (including keratorhexis, which also includes lowest level term corneal rupture) to the list of the adverse reactions, respectively following a safety evaluation. The package leaflet has been updated accordingly. In addition, the applicant took the opportunity to remove frequency information due to variations in case frequency in section 4.8 of the SmPC and section 4 of the PL. Furthermore, the PI is being brought in line with the latest QRD template (version 10.2) and minor editorial changes was made in the PL." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Vfend - voriconazole - EMEA/H/C/000387/II/0142/G Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.3, 4.4 and 4.5 of the SmPC in order to add new contraindications to naloxegol and tolvaptan and	Request for supplementary information adopted with a specific timetable.

add a Drug-Drug Interaction with lurasidone, include clarification text regarding adrenal insufficiency and Cushing's syndrome to the warnings and precautions for use, and re-order some of the drug-drug interaction information, respectively. 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 correct an oversight from a previous procedure in the labelling (addition of the excipient sodium benzoate in section 3 of the outer and inner label for the powder for oral suspension in line with SmPC section 2 and PL sections 2 and 6)." Request for Supplementary Information adopted on 22.07.2021, 20.05.2021.	
Vfend - voriconazole - EMEA/H/C/000387/II/0143 Pfizer Europe MA EEIG, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on co-administration with glasdegib and add drug-drug interaction information with eszopiclone, glasdegib, tretinoin and tyrosine kinase inhibitors metabolised by CYP3A4; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
Viramune - nevirapine - EMEA/H/C/000183/II/0147 Boehringer Ingelheim International GmbH, Rapporteur: Bruno Sepodes, Co-Rapporteur: Christophe Focke, "Update of sections 4.4 and 5.2 of the SmPC in order to remove wording on precautionary measures related to reassuring that tablet remnants in faeces have no impact on the therapeutic response of Viramune, based on additional clinical and pharmacovigilance data that have become available; 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." Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Viread - tenofovir disoproxil - EMEA/H/C/000419/II/0204	Request for supplementary information adopted with a specific timetable.

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Tiphaine Vaillant, "Submission of final study report for study GS-US-174-0144, listed as category 3 study in the RMP for Viread. This is a randomized, double-blind evaluation of the antiviral efficacy, safety and tolerability of Tenofovir disporoxil fumarate. This application fulfils the Article 46 commitment to provide the final Week 192 study results for clinical measure 'Study 5' (Study GS_US_174-0144) listed in the PIP. Section 5.1 of the SmPC is being amended accordingly. Additionally, the risk minimisation measures for paediatrics are being removed from the RMP and Annex II of the PI. The Package Leaflet has been updated accordingly. The MAH took the opportunity to implement minor linguistic amendments throughout the PI. In addition, the expression of lactose content in Annex I for the tablets was changed, to refer to lactose base (not as monohydrate), in line with current practice. The RMP version 25.1 has been submitted." Request for Supplementary Information adopted on 08.07.2021.	
Xarelto - rivaroxaban - EMEA/H/C/000944/II/0081 Bayer AG, Rapporteur: Kristina Dunder, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC following the final results from the VOYAGER PAD study, a multicentre, randomised, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularisation procedures. The Package Leaflet is updated accordingly." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 22.04.2021, 12.11.2020.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation. See 9.1
Xerava - eravacycline - EMEA/H/C/004237/II/0012 Paion Deutschland GmbH, Rapporteur: Filip Josephson, "Update of sections 5.3 and 6.6 of the SmPC in order to update the results of the Environmental Risk Assessment studies	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

following their completion." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 28.05.2021, 11.03.2021.	
Yondelis - trabectedin - EMEA/H/C/000773/II/0063 Pharma Mar, S.A., Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to revise the frequency of ADRs based on a pooled safety analysis; 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 Rev. 1" Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 24.06.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
Zavesca - miglustat - EMEA/H/C/000435/II/0072/G Janssen-Cilag International N.V., Rapporteur: Kristina Dunder, "Update of sections 4.4, 4.6 and 5.3 of the SmPC in order to improve clarity and to implement linguistic changes following an update of the non-clinical information in the MAH's Company Core Data Sheet. In addition, the MAH took the opportunity to make editorial changes in the Annexes, and to update the list of local representatives in the Package Leaflet. The application also includes a type IA variation . Annex II is updated accordingly." Opinion adopted on 01.07.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1990 **Combivir-EMEA/H/C/000190/WS1990/0099** **Dovato-EMEA/H/C/004909/WS1990/0018** **Epivir-EMEA/H/C/000107/WS1990/0115** **Kivexa-EMEA/H/C/000581/WS1990/0088** **Triumeq-EMEA/H/C/002754/WS1990/0087** **Trizivir-EMEA/H/C/000338/WS1990/0120** ViiV Healthcare B.V., Lead Rapporteur: Jean-Michel Race, "Update of sections 4.2, 4.4 and 5.2 of the SmPC of the fixed-dose combination products Combivir, Dovato, Kivexa, Triumeq and Trizivir to include new information about use of the products in patients with renal impairment. Furthermore, minor editorial changes have been implemented throughout the Product	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.

Information and the lists of local representatives have been updated for all products." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 20.05.2021, 25.03.2021.	
WS2035 **Prezista-EMEA/H/C/000707/WS2035/0110** **Rezolsta-EMEA/H/C/002819/WS2035/0041** **Symtuza-EMEA/H/C/004391/WS2035/0032** Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, "To update section 4.5 of the SmPC to provide guidance on drug-drug interaction between cutaneously-administered corticosteroids and boosted darunavir, darunavir/cobicistat and darunavir/cobicistat/emtricitabine/tenofovir alafenamide, based on recent scientific literature publication. In addition, the MAH took the opportunity to include minor editorial updates in the Product Information consisting of formatting, spelling and typo corrections." Request for Supplementary Information adopted on 01.07.2021, 09.04.2021.	Request for supplementary information adopted with a specific timetable.
WS2054 **Enerzair Breezhaler-EMEA/H/C/005061/WS2054/0003** **Zimbus Breezhaler-EMEA/H/C/005518/WS2054/0003** Novartis Europharm Limited, Lead Rapporteur: Peter Kiely, "Update of section 5.1.Pharmacodynamic properties, based on the final results from the ARGON study, a Phase 3b, multicenter, partially-blinded, randomized, 24-week, parallel-group, non-inferiority, open-label active controlled study comparing the efficacy and safety of QVM149 with a free triple combination of salmeterol/fluticasone + tiotropium in patients with uncontrolled asthma. In addition, the MAH took the opportunity to make editorial changes by including an introduction, i.e. "Comparison of Enerzair Breezhaler to fixed combinations of LABA/ICS" to the pivotal study IRIDIUM in section 5.1. Pharmacodynamic properties-Clinical efficacy and safety of the SmPC and an update of the Local representative address in	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.

Northern Ireland in the leaflet." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 28.05.2021.	
WS2070 **Mekinist-EMEA/H/C/002643/WS2070/0047** **Tafinlar-EMEA/H/C/002604/WS2070/0052** Novartis Europharm Limited, Lead Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to modify administration instructions (pyrexia dose modification guidance in the Tafinlar and Mekinist SmPC); the Package Leaflet are updated accordingly. In addition, the WSA took the opportunity to update the list of local representatives for The Netherlands in the Package Leaflet and to include minor editorial changes" Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
WS2083/G **Nilemdo-EMEA/H/C/004958/WS2083/0013/G** **Nustendi-EMEA/H/C/004959/WS2083/0014/G** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Johann Lodewijk Hillege, "C.I.13: Submission of the final reports of non-clinical (in vitro) studies evaluating drug interactions of bempedoic acid with substrates of OAT2 (MEA 004.2, MEA 005.1 and MEA 006.2) ." Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.3. CHMP-PRAC assessed procedures

Cometriq - cabozantinib - EMEA/H/C/002640/II/0044, Orphan Ipsen Pharma, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst, "Update of section 5.1 of the SmPC based on the final results from study XL184-401 (EXAMINER) (SOB 001), a randomised, double-blind study to evaluate the efficacy and safety of cabozantinib (XL184) at 60 mg/day compared to a 140 mg/day in progressive, metastatic medullary thyroid cancer patients and as a consequence update of annex II in order to	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation. See 9.1

delete SOB 001. With the fulfilment of SOB 001 the MAH is requesting for the Cometriq MA to no longer be subject to specific obligations. The package leaflet is updated accordingly. The updated RMP version 5.5 has also been submitted. Furthermore, information on hepatotoxicity has been added to the section 4.4 and the cross reference between sections 4.1 and 4.4 has been removed for consistency. Additionally, the MAH took the opportunity to bring the Product Information in line with the latest QRD template version 10.2 Rev 1, to add the sodium content in the Summary of Product Characteristics and Package Information Leaflet in line with the guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' and update the details of local representatives." Opinion adopted on 22.07.2021. Request for Supplementary Information adopted on 24.06.2021.	
COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0036 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.8 and 5.1 of the SmPC to include new information based on updated interim results from study C4591001. This was a phase 1/2/3, placebo-controlled, observer-blind, interventional, dose-finding study to evaluate the safety, tolerability, immunogenicity and efficacy of SARS-CoV-2 RNA vaccine candidates against COVID-19 in healthy individuals. The Package Leaflet is updated accordingly. The updated RMP (version 2.1) has also been submitted." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Defitelio - defibrotide - EMEA/H/C/002393/II/0056, Orphan Gentium S.r.l., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final report from study 15-007 listed as a specific obligation in the Annex II of the Product Information. This is a phase 3, randomised, adaptive study (15-007) of Defibrotide vs. best supportive care in the	Request for supplementary information adopted with a specific timetable.

prevention of hepatic veno-occlusive disease in adult and paediatric patients undergoing hematopoietic stem cell transplant (HSCT). The RMP version 9 has also been submitted. The MAH has also taken the opportunity to align the PI to the latest QRD template 10.2 which replaces the United Kingdom with United Kingdom (Northern Ireland) in the PIL. In addition, the MAH is correcting the following errata during the linguistic review of the PI: correction of the paragraph number for Regulation (EC) No 726.2004 which was cited incorrectly in Annex II of the French PI and formatting updates to Norwegian and Swedish language PIs." Request for Supplementary Information adopted on 08.07.2021.	
Increlex - mecasermin - EMEA/H/C/000704/II/0067 Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Update of the conditions of the non-interventional PASS which is listed as a specific obligation in Annex II, by using different criteria of patient exposure and long-term follow-up to assess the relevant safety data, with consequential amendment of the study completion date. The RMP version 13 has also been submitted, also including an amended Global registry protocol (amendment 8). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, in line with the latest QRD template version 10.2 rev.1." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Isentress - raltegravir - EMEA/H/C/000860/II/0093 Merck Sharp & Dohme B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Update of section 4.6 of the SmPC in order to update safety information following pregnancy outcome data for raltegravir 400 mg film-coated tablet from prospective reports of pregnancy data with known outcome and time of raltegravir exposure. The updated RMP version 16.0 has also been submitted. In addition, the MAH took the opportunity to correct an inconsistency in the text describing	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

the possibility to divide the scored 100 mg chewable tablet by harmonising the text of the footer of Tables 1 and 2 of the chewable tablets' SmPC. Finally, the contact details of the German local representative have been updated in the Package Leaflet and the PI is being brought in line with the latest QRD template (version 10.1)." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 09.04.2021, 14.01.2021.	
Kisplyx - lenvatinib - EMEA/H/C/004224/II/0048 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: David Olsen, "Submission of the final report from study E7080-G000-211 listed as a category 3 study in the RMP. This is a Multicenter, Randomized, Double-Blind Phase 2 Trial of Lenvatinib (E7080) in subjects with 131 I-Refractory Differentiated Thyroid Cancer to evaluate whether an oral starting dose of 18 mg daily will provide comparable efficacy to a 24 mg starting dose but have a better safety profile. The RMP version 12.3 has also been submitted." Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lenvima - lenvatinib - EMEA/H/C/003727/II/0045 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Annika Folin, "Update of the SmPC section 5.1 with additional efficacy and safety data from the Phase 2 multicentre, randomized, double-blind, non-inferiority trial in Subjects with 131I-Refractory Differentiated Thyroid Cancer to evaluate whether an oral starting dose of 18 mg daily will provide comparable efficacy to a 24 mg starting dose with an improved safety profile (study E7080-G000-211). The RMP version 12.3 is updated accordingly to remove the commitment, MEA 005.5. In addition, the MAH took the opportunity to update the details of local representatives of Bulgaria, Croatia, Estonia, Hungary, Lithuania, Latvia, Malta, Poland, Romania and Slovenia." Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
Lojuxta - lomitapide -	Request for supplementary information adopted

EMEA/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 22.07.2021, 09.04.2021.	with a specific timetable. See 9.1
Qarziba - dinutuximab beta - EMEA/H/C/003918/II/0027/G, Orphan EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski, " -A.6 - Type IA - ATC code change to L01XC16 according to the WHO -C.I.4: Type II- Update of section 4.8 of the SmPC in order to include changes to the overall incidence of reported adverse reactions based on post-marketing data. In addition, minor changes are introduced in the Summary of Product Characteristics, Package Leaflet and Labelling in order to harmonise the Product Information with other regulatory regions. -C.I.11.b: Type II-Submission of RMP version 10.00 in order to include an alignment to post marketing data (PSUR6) and to introduce updates on the important identified risks and important potential risks. In addition, some linguistic corrections are included on Swedish, Finnish, Italian, Spanish and Portuguese EMA annexes." Request for Supplementary Information adopted on 22.07.2021	Request for supplementary information adopted with a specific timetable.
RAVICTI - glycerol phenylbutyrate - EMEA/H/C/003822/II/0038/G, Orphan Immedica Pharma AB, Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Ilaria Baldelli, "Group of variations consisting of: - Submission of the final study report, HPN-100-014 non interventional registry study "Long-	Request for supplementary information adopted with a specific timetable. See 9.1

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)." Request for Supplementary Information adopted on 22.07.2021.	
REKAMBYS - rilpivirine - EMEA/H/C/005060/II/0004 Janssen-Cilag International N.V., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Liana Gross-Martirosyan, "Update of section 4.2 (to change posology recommendations) and sections 4.8, 5.1 and 5.2 of the SmPC (to update safety and efficacy information) based on week 124 results from the FLAIR study. This is a Phase III, randomized, open-label study to evaluate the efficacy, safety and tolerability of the combined treatment Cabotegravir and Rilpivirine. The Package Leaflet has been updated accordingly. Editorial changes and corrections have been carried out throughout the PI. The RMP version 3.1 has also been submitted." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0069/G Biogen Netherlands B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "C.I.4 type II variation: Update of section 4.8 of the	Request for supplementary information adopted with a specific timetable.

SmPC in order to add rhinorrhoea to the list of adverse drug reactions (ADRs) with frequency unknown based on a systematic review of information from clinical and non-clinical studies, post-marketing data and scientific literature. The Package Leaflet has been updated accordingly. C.I.4 type II variation: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study 109MS303 (ENDORSE) listed as a category 3 study in the RMP. This is a dose-blind, multicenter, extension study to determine the long-term safety and efficacy of two doses of BG00012 monotherapy in subjects with Relapsing-Remitting Multiple Sclerosis. The RMP version 11.1 has also been submitted." Request for Supplementary Information adopted on 08.07.2021, 06.05.2021, 14.01.2021.	
Ultomiris - ravulizumab - EMEA/H/C/004954/II/0016 Alexion Europe SAS, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Kimmo Jaakkola, "to update section 4.4 Special warnings and precautions for use and section 4.8 Undesirable effects of the SmPC, with consequential updates to sections 2 and 4 of the Patient Information Leaflet regarding anaphylactic reaction, hypersensitivity and infusion-related reactions." Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0026 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to include updated efficacy and safety information based on primary analysis from study D8110C00001 listed as a specific obligation in Annex II; this is a phase III randomised, double-blind, placebo-controlled, multicenter study in adults to determine the safety, efficacy and immunogenicity of Vaxzevria; the Package Leaflet and Annex II are updated accordingly. The updated RMP Version 3 Succession 2 has also been submitted." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable. See 9.1

Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0030 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, PRAC Rapporteur: Ilaria Baldelli, "Update of sections 4.8 and 5.1 to include new information on safety and pharmacodynamic properties based on the final report from study GS-US-320-4018, listed as a category 3 study in the RMP. This was a phase 3, randomized, double blind study to evaluate the efficacy and safety of switching from tenofovir disoproxil fumarate 300 mg once daily to tenofovir alafenamide 25 mg once daily in subjects with chronic hepatitis B who are virologically suppressed. The RMP (v 8.0) has also been submitted." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 09.04.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vocabria - cabotegravir - EMEA/H/C/004976/II/0004 ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber, "Update of section 4.2 (to change posology recommendations) and sections 4.4, 4.8, 5.1 and 5.2 of the SmPC (to update safety and efficacy information) based on week 124 results from the FLAIR study. This is a Phase III, randomized, open-label study to evaluate the efficacy, safety and tolerability of the combined treatment Cabotegravir and Rilpivirine. The Package Leaflet has been updated accordingly. Editorial changes and corrections have been carried out throughout the PI. The RMP version 2 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet to bring the PI in line with the latest QRD template version 10.2." Request for Supplementary Information adopted on 22.07.2021.	Request for supplementary information adopted with a specific timetable.
Xeljanz - tofacitinib - EMEA/H/C/004214/II/0028 Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan, "Update of section 4.4 of the SmPC and annex II of the product information based on the submission of the final report on Biospecimen testing study, listed as a category	Request for supplementary information adopted with a specific timetable.

3 study in the RMP. This is an exploratory study to assess biomarkers related to VTE events in study A3921133. The RMP is updated to version 14.2." Request for Supplementary Information adopted on 08.07.2021, 14.01.2021.	

B.5.4. PRAC assessed procedures

PRAC Led **Abilify Maintena - aripiprazole - EMEA/H/C/002755/II/0040** Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study 15893N listed as a category 3 study in the RMP, requested by PRAC (EMA/PRAC/209497/2014, dated from 10 April 2014, EMEA/H/C/MEA/002). This is a non-interventional post-authorisation safety study (PASS) related to extrapyramidal symptoms: cohort study with a 2-year follow-up using European longitudinal electronic medical records or claims databases." Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Azarga - brinzolamide / timolol - EMEA/H/C/000960/II/0045** Novartis Europharm Limited, Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Kirstine Moll Harboe, "Update to the current Risk management plan (Version 3.0) to remove important identified risks (Respiratory disorders, Cardiovascular disorders, Corneal decompensation and Metabolic acidosis), Important potential risk (Long-term use of preserved eye drops) and Missing information (Use in paediatric patients)" Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Conbriza - bazedoxifene - EMEA/H/C/000913/II/0052** 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 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

final clinical study report (CSR) for the Conbriza Non-Interventional EU Post Authorisation Safety Study (EU PASS) B1781044 - Cohort Study of Venous Thromboembolism and Other Clinical Endpoints among Osteoporotic women prescribed bazedoxifene, bisphosphonates or raloxifene in Europe. This final CSR relates to the Post Approval Measure EMEA/H/C/000913/MEA/012.13." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 11.03.2021, 03.09.2020.	
PRAC Led **COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0006/G** Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, " C.I.4-To update section 4.4 of the SmPC to add a warning for individuals who have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or heparin-induced thrombocytopenia (HIT) to outweigh the potential risks before the administration of COVID-19 Vaccine Janssen; the Package Leaflet is updated accordingly. The updated RMP version 2.1 has also been submitted. C.I.11.b- To update the EU-RMP for COVID-19 Vaccine Janssen to include thrombosis with thrombocytopenia syndrome (TTS) in the list of the safety concerns as an important identified risk following the PRAC recommendation, dated 6 May 2021 in the outcome of the related signal of Embolic and Thrombotic events (procedure number SDA 018.1) with COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant]). In addition, the MAH sought agreement on a DHPC to alert health care professionals to the signs and symptoms of thromboembolism and/or thrombocytopenia in follow up to the adopted signal procedure at PRAC for TTS (Thrombosis with Thrombopenia Syndrome)." Opinion adopted on 07.07.2021.	Positive Opinion adopted by consensus on 07.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike**	Positive Opinion adopted by consensus on 07.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

glycoprotein - EMEA/H/C/005737/II/0010 Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of sections 4.3, 4.4 and 4.8 of the SmPC in order to add a contraindication related to the administration of Ad26.COV2.S to individuals with a history of Capillary Leak Syndrome (CLS) based on the cases reported following administration of this vaccine in the Global Medical Safety (GMS) up to the data lock point (DLP) of 21 June 2021. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add some minor editorial changes throughout the product information." Opinion adopted on 07.07.2021.	recommendation.
PRAC Led **COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0012** Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a warning related to the possibility of developing a Guillain-Barré syndrome (GBS) following the administration of Ad26.COV2.S and to add GBS as an adverse drug reaction (ADR). This is based on the information accumulated on cases of GBS reported to the vaccine adverse event reporting system (VAERS) in recipients of the Janssen COVID-19 Vaccine and subsequently, on the analysis performed by the company on cases of GBS based on the available cumulative data from launch. In addition, the company took the opportunity to make some editorial changes. The Package Leaflet is updated accordingly." Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation. See 9.1
PRAC Led **Cresemba - isavuconazole - EMEA/H/C/002734/II/0035/G, Orphan** Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Grouping of variations to - submit the final report from study (WSA-REG-	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

001) listed as a category 3 study in the RMP. This is a retrospective case-collection study, in which cases of invasive mucormycosis treated with isavuconazole were compared to cases treated with other systemic antifungals. The RMP version 8.2 has also been submitted. - remove Japanese study AK1820-301 as a category 3 study from the Cresemba RMP." Opinion adopted on 08.07.2021.	
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 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) in the US, with the aim to monitor the safety profile of Duavee (CE/BZA) in comparison to estrogen and progestin combination hormone therapy (E+P HT)." Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Fampyra - fampridine - EMEA/H/C/002097/II/0049** Biogen Netherlands B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Following a PSUR 10 assessment, update to the section 4.8 of SmPC to include new symptoms of trigeminal neuralgia. The package leaflet to be updated accordingly. The Marketing Authorisation Holder (MAH) introduced further editorial updates including bringing SmPC template to version 10.2 and updating contact details of the local representatives." Request for Supplementary Information adopted on 08.07.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Gilenya - fingolimod - EMEA/H/C/002202/II/0070/G** Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau,	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

"Submission of the non-interventional final study report D2403 (long-term, prospective, multinational, parallel-cohort study monitoring safety in patients with multiple sclerosis newly started on fingolimod once daily or treated with another approved disease-modifying therapy). Submission of the non-interventional final study report D2406/D2409 (long-term, prospective, non-interventional, multinational, parallel-cohort study monitoring safety in patients with MS newly initiated on fingolimod once daily or treated with another approved disease-modifying therapy (including cardiac sub-study D2409)). Consequently, the Annex IID is updated to remove the obligation to perform the PASS D2409. The RMP v 19.1 has been agreed. In addition, the MAH took the opportunity to implement some minor editorial changes and to update the UK (Northern Ireland) local representative details in the PL." Opinion adopted on 08.07.2021.	
PRAC Led **Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0079** Genzyme Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adrien Inoubli, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from study ALGMYC07390, Prevalence of immunology testing in patients treated with alglucosidase alfa with significant hypersensitivity/anaphylactic reactions (MEA 053 resulting from variation EMEA/H/C/000636/II/0052) to test the effectiveness of the approved Safety Information Packet (SIP)." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 11.03.2021, 26.11.2020, 09.07.2020, 12.03.2020.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0015/G** Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Kirstine Moll Harboe, "Grouped variation to address	Request for supplementary information adopted with a specific timetable.

PRAC requests raised in the 2nd and 3rd Moderna Monthly Safety Summary Report (MSSR) procedures (EMEA/H/C/005791/MEA/011.1 and EMEA/H/C/005791/MEA/011.2 respectively: - C.I.3.b (Type II): Update of section 4.4 of the SmPC to provide additional safety information regarding hypersensitivity and anaphylaxis, as requested by the PRAC in the 2nd Monthly Safety Summary Report. The Package Leaflet is updated accordingly. - C.I.3.b (Type II): Update of section 4.8 of the SmPC to include 'Delayed injection site reaction' as an adverse reaction, with the frequency 'Common', as requested by the PRAC in the 3rd Monthly Safety Summary. The Package Leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) submitted a justification for not adding diarrhoea to the PI as an adverse reaction, as requested by the PRAC in the 3rd Monthly Safety Summary Report, and took the opportunity to make minor editorial changes." Request for Supplementary Information adopted on 08.07.2021.	
PRAC Led **Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0015** AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Christophe Focke, "Submission of an updated RMP version 3 succession 3 in order to update the safety concerns to add 'Thrombosis in combination with thrombocytopenia' as an important identified risk and 'Thrombosis' as an important potential risk, with consequential changes in the RMP and to update the pharmacovigilance plan following the request by PRAC in the outcome of signal assessment procedure on embolic and thrombotic events with Vaxzevria EPITT no: 196833. The MAH has taken the opportunity to further update the RMP to reclassify "anaphylaxis" as an important identified risk, already reflected in the product information as an adverse reaction." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 20.05.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

PRAC Led **VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0049, Orphan** Shire Pharmaceuticals Ireland Limited, 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 08.07.2021, 11.02.2021, 26.11.2020.	Request for supplementary information adopted with a specific timetable.
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-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." Request for Supplementary Information adopted on 08.07.2021, 11.03.2021.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2013 Abseamed-EMEA/H/C/000727/WS2013/0092 Binocrit-EMEA/H/C/000725/WS2013/0091 Epoetin alfa Hexal-EMEA/H/C/000726/WS2013/0091** Sandoz GmbH, Lead Rapporteur: Alexandre	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Moreau, Lead PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of the RMP v.18.1 for Abseamed, Binocrit, Epoetin Alfa Hexal in line with the RMP of the originator product Eprex. The following changes have been introduced: · Wording of two potential risks was harmonised in line with the originator's RMP: The term "tumor growth potential" was replaced with "disease progression", and "premature death" was replaced with "survival impact". · The clinical study data on these two topics were shortened, in line with the originator's RMP. · Removal of TRIGONS study proposal (MEA18; HX575-502) as additional pharmacovigilance activity; in alignment with originator RMP, risks of disease progression and survival impact will be monitored by routine pharmacovigilance and continue to be reviewed in PSURs." Opinion adopted on 08.07.2021. Request for Supplementary Information adopted on 06.05.2021.	
PRAC Led **WS2086** **Epclusa-EMEA/H/C/004210/WS2086/0059** **Harvoni-EMEA/H/C/003850/WS2086/0097** **Sovaldi-EMEA/H/C/002798/WS2086/0071** Gilead Sciences Ireland UC, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "To provide an updated Annex II to revise the study milestone , for the hepatocellular carcinoma (HCC) recurrence post-authorisation safety study (PASS) following PRAC recommendation received on 11 June 2020 (EMA procedure no.: EMEA/H/C/PSA/J/0055) for the approval of protocol amendment 1 (version 4.2). In addition, the marketing authorisation holder has taken the opportunity to update the list of local representatives and align the PI to the latest QRD template (v. 10.2)." Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.5. CHMP-CAT assessed procedures

Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0015, Orphan, ATMP Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege, "Updates to sections 4.4, 4.8 and 5.1 of the SmPC to reflect the final study results from study AVXS-101-CL-302; a post-authorisation efficacy study intended to confirm the efficacy and safety and tolerability of a single dose of Zolgensma in patients younger than 6 months of age with SMA Type 1 with One or Two SMN2 Copies. The package leaflet has been updated accordingly and annex II has been updated to reflect completion of this Specific Obligation." Request for Supplementary Information adopted on 16.07.2021.	Request for supplementary information adopted with a specific timetable.
WS2071 **Tecartus-EMEA/H/C/005102/WS2071/0007** **Yescarta-EMEA/H/C/004480/WS2071/0039** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted on 16.07.2021.	Request for supplementary information adopted with a specific timetable.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

PRAC Led **Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0044, ATMP** Amgen Europe B.V., Rapporteur: Heli Suila, CHMP Coordinator: Johanna Lähteenvuo, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from study 20180099 listed as a category 3 study in the RMP. This is a cross-sectional survey to evaluate physician knowledge of safety messages included in the physician education booklet (PEB) for Imlygic."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 16.07.2021, 12.05.2021.

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

WS1985 **Aflunov-EMEA/H/C/002094/WS1985/0067** **Foclivia-EMEA/H/C/001208/WS1985/0063** Seqirus S.r.l, Lead Rapporteur: Armando Genazzani Opinion adopted on 01.07.2021. Request for Supplementary Information adopted on 25.02.2021, 14.01.2021.	Positive Opinion adopted by consensus on 01.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS2075 **Riarify-EMEA/H/C/004836/WS2075/0014** **Trimbow-EMEA/H/C/004257/WS2075/0019** **Trydonis-EMEA/H/C/004702/WS2075/0014** Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig Opinion adopted on 08.07.2021.	Positive Opinion adopted by consensus on 08.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS2076 **Ambirix-EMEA/H/C/000426/WS2076/0116** **Twinrix Adult-EMEA/H/C/000112/WS2076/0151** **Twinrix Paediatric-EMEA/H/C/000129/WS2076/0152** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke, Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
WS2087 **Infanrix hexa-EMEA/H/C/000296/WS2087/0301** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke, Opinion adopted on 22.07.2021.	Positive Opinion adopted by consensus on 22.07.2021. The Norwegian CHMP Member was in agreement with the CHMP recommendation.
WS2100/G **Prezista-EMEA/H/C/000707/WS2100/0112/G** **Rezolsta-EMEA/H/C/002819/WS2100/0043/G** **Symtuza-EMEA/H/C/004391/WS2100/0036/G**	Positive Opinion adopted by consensus on 22.07.2021. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege Opinion adopted on 22.07.2021.	

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

Yellox - bromfenac - EMEA/H/C/001198/II/0025 Bausch Health Ireland Limited, Rapporteur: Kirstine Moll Harboe Request for Supplementary Information adopted on 11.03.2021, 03.09.2020. Withdrawal request submitted on 12.07.2021.	The MAH withdrew the procedure on 12.07.2021.

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

PRAC Led **Beovu - brolucizumab - EMEA/H/C/004913/II/0008** Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC in order to include the description of intraocular inflammation, based on final results from a non-interventional retrospective real-world evidence study conducted in patients with neovascular (wet) age-related macular degeneration (nAMD) to better understand the incidence of adverse events/safety signal after initiating treatment with brolucizumab for up to 6 months." Request for Supplementary Information adopted on 10.06.2021.	Request by the applicant dated 06 July 2021 for an extension to the clock stop to respond to the request for supplementary information adopted in June 2021. The CHMP agreed to the request by the applicant.
Adenuric - febuxostat - EMEA/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 comparison with allopurinol in patients with	Request by the applicant dated 07 July 2021 for an extension to the clock stop to respond to the request for supplementary information adopted in June 2021. The CHMP agreed to the request by the applicant.

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'.” Request for Supplementary Information adopted on 24.06.2021.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

insulin human - EMEA/H/W/005779, Article 58 treatment of diabetes mellitus
asciminib - EMEA/H/C/005605, Orphan Novartis Europharm Limited, treatment of Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP)
mobocertinib - EMEA/H/C/005621 Treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).
eptacog alfa (activated) - EMEA/H/C/005547 treatment of bleeding episodes and for the prevention of bleeding
insulin human - EMEA/H/W/005780, Article 58 treatment of diabetes mellitus
voclosporin - EMEA/H/C/005256 indicated in combination with background immunosuppressive therapies for the treatment of adult patients with class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN).
mitapivat - EMEA/H/C/005540, Orphan

Agios Netherlands B.V., treatment of pyruvate kinase deficiency	
ranibizumab - EMEA/H/C/005019 The treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation (CNV)	
valoctocogene roxaparvovec - EMEA/H/C/005830, Orphan, ATMP BioMarin International Limited, treatment of severe haemophilia A	**Accelerated review**
surufatinib - EMEA/H/C/005728 treatment of progressive neuroendocrine tumours	
sorafenib - EMEA/H/C/005921 treatment of hepatocellular carcinoma and renal cell carcinoma	

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

Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/X/0079/G Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ilaria Baldelli, "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."	
Ilumetri - tildrakizumab - EMEA/H/C/004514/X/0023	

Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski, "Extension application to introduce a new strength (200 mg solution for injection)."

Procysbi - mercaptamine - EMEA/H/C/002465/X/0035, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Extension application to introduce a new pharmaceutical form associated with two new strengths (75 and 300 mg gastro-resistant granules). The RMP (version 7.2) is updated in accordance."

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

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/X/0018
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop, PRAC Rapporteur: Menno van der Elst, "Extension application to add a new strength of 3000 IU for RURIOCTOCOG ALFA PEGOL powder and solvent for solution for injection, for intravenous use.
Furthermore, the MAH took the opportunity to include editorial changes to update the naming convention from BAX855 to rurioctocog alfa pegol throughout the section and removed the reference to Baxalta as well as update table numbering throughout the documents in module 3. Furthermore, change omitted from the dossier following approval of variations EMEA/H/C/004195/IB/0004/G and EMEA/H/C/004195/IB/0015/G were also included."
List of Questions adopted on 22.04.2021.

hepatitis B surface antigen - EMEA/H/C/005466
indicated for the prevention of infection caused by all known subtypes of the hepatitis B virus in adults.
List of Questions adopted on 22.04.2021.

finerenone - EMEA/H/C/005200
delay progression of kidney disease, reduce the risk of cardiovascular mortality and morbidity
List of Questions adopted on 25.03.2021.

sotorasib - EMEA/H/C/005522
treatment of locally advanced or metastatic non-small cell lung cancer
List of Questions adopted on 20.05.2021.

arimoclomol - EMEA/H/C/005203, Orphan
Orphazyme A/S, treatment of Niemann-Pick disease type C (NPC)
List of Questions adopted on 25.03.2021.

Nuwiq - simoctocog alfa - EMEA/H/C/002813/X/0042
Octapharma AB, Rapporteur: Jan Mueller-Berghaus, "Extension application to add a new strength of 1500 IU for simoctocog alfa powder and solvent for solution for injection, for Intravenous use.
The marketing authorisation holder took the opportunity to align the PI to the latest QRD template (version 10.2)."
List of Questions adopted on 24.06.2021.

amivantamab - EMEA/H/C/005454
for treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy.
List of Questions adopted on 20.05.2021.

tepotinib - EMEA/H/C/005524
Treatment of advanced non-small cell lung cancer.
Treatment of adult patients with advanced non-small cell lung cancer
List of Questions adopted on 25.03.2021.

inebilizumab - EMEA/H/C/005818, Orphan
Viela Bio, indicated for the treatment of adults with neuromyelitis optica spectrum disorders
List of Questions adopted on 22.04.2021.

pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/005477
immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae.
List of Questions adopted on 22.04.2021.

vildagliptin / metformin hydrochloride - EMEA/H/C/005738
treatment of type 2 diabetes mellitus

List of Questions adopted on 22.04.2021.

eptinezumab - EMEA/H/C/005287
Indicated for the prophylaxis of migraine in adults
List of Questions adopted on 22.04.2021.

Xeljanz - tofacitinib - EMEA/H/C/004214/X/0030/G
Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, PRAC Rapporteur: Liana Gross-Martirosyan, "Extension application to add a new strength (22 mg prolonged-release tablet) grouped with a type II variation C.I.4: Update of sections 4.1, 4.2, 4.4 , 4.8, 5.1 and 5.2 of Xeljanz 11 mg prolonged-release tablets SmPC in order to include the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent; as an alternative to the immediate release film-coated tablets; section 4.2 of Xeljanz film-coated tablets is also updated to include switching with the prolonged-release tablet in the treatment of UC. The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted."
List of Questions adopted on 25.02.2021.

linzagolix choline - EMEA/H/C/005442
for the management of heavy menstrual bleeding (HMB) associated with uterine fibroids
List of Questions adopted on 22.04.2021.

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

MVABEA - ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/S/0006
Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné,

Qarziba - dinutuximab beta - EMEA/H/C/003918/S/0028, Orphan
EUSA Pharma (Netherlands) B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

ZABDENO - ebola vaccine (rDNA,

replication-incompetent) -
EMEA/H/C/005337/S/0005
Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Jean-Michel Dogné

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

AMGEVITA - adalimumab -
EMEA/H/C/004212/R/0029
Amgen Europe B.V., Rapporteur: Kristina Dunder, Co-Rapporteur: Armando Genazzani, PRAC Rapporteur: Ulla Wändel Liminga

Chenodeoxycholic acid Leadiant - chenodeoxycholic acid -
EMEA/H/C/004061/R/0018, Orphan
Leadiant GmbH, Rapporteur: Konstantinos Markopoulos, PRAC Rapporteur: Adam Przybylkowski

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) -
EMEA/H/C/005735/R/0046
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst

Enhertu - trastuzumab deruxtecan -
EMEA/H/C/005124/R/0006
Daiichi Sankyo Europe GmbH, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

OCALIVA - obeticholic acid -
EMEA/H/C/004093/R/0027, Orphan
Intercept Pharma International Limited, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Liana Gross-Martirosyan

Polivy - polatuzumab vedotin -
EMEA/H/C/004870/R/0008, Orphan
Roche Registration GmbH, Rapporteur: Alexandre Moreau, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Annika Folin

Roteas - edoxaban -
EMEA/H/C/004339/R/0021
Berlin Chemie AG, Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur:

Martina Weise, PRAC Rapporteur: Tiphaine Vaillant
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/R/0025 Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Hans Christian Siersted
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/R/0010, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Rune Kjeken, CHMP Coordinators: Jan Mueller-Berghaus and Ingrid Wang, PRAC Rapporteur: Menno van der Elst
Xeljanz - tofacitinib - EMEA/H/C/004214/R/0040 Pfizer Europe MA EEIG, Rapporteur: Armando Genazzani, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Liana Gross-Martirosyan

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

Cosentyx - secukinumab - EMEA/H/C/003729/II/0079 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Eva A. Segovia, "C.I.6 (Extension of indication) Extension of indication to include treatment of Juvenile Idiopathic Arthritis (Enthesitis-Related Arthritis and Juvenile Psoriatic Arthritis) in patients 2 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy for Cosentyx; 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 10.0 of the RMP has also been submitted."

Entyvio - vedolizumab - EMEA/H/C/002782/II/0061

Takeda Pharma A/S, Rapporteur: Armando Genazzani, PRAC Rapporteur: Adam Przybylkowski, "To add a new therapeutic indication "treatment of adult patients with pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with, lost response to, or were intolerant to antibiotic therapy" for Entyvio 300 mg (powder for concentrate for solution for infusion), based on final results from study Vedolizumab-4004 (ERNEST). This was an interventional, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Entyvio (intravenous) in the treatment of chronic pouchitis.
As a consequence, sections 4.1, 4.2, 4.5, 5.1 and 5.2 of the SmPC for Entyvio 300 mg are updated. The Package Leaflet are updated in accordance. Version 7.0 of the RMP is also submitted."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0108

Merck Sharp & Dohme B.V., Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "C.I.6.a
Update of sections 4.1, 4.2 and 5.1 of the SmPC in order to extend the existing therapeutic indications for Keytruda to include the adjuvant treatment in monotherapy of adults with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. The Package Leaflet are updated accordingly. The RMP version 35.1 has also been submitted"

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0109

Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Extension of indication for Keytruda as monotherapy in the treatment of unresectable or metastatic MSI-H or dMMR colorectal,

endometrial, gastric, small intestine, biliary, or pancreatic cancer in adults who have received prior therapy. The proposed indication is based on the results from the KEYNOTE-164 (KN164) and KEYNOTE-158 (KN158) trials.
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. An updated version of the RMP (Version 34.1) has been submitted."

Kineret - anakinra - EMEA/H/C/000363/II/0086

Swedish Orphan Biovitrum AB (publ), Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Anette Kirstine Stark, "C.I.6 - Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in adult patients with pneumonia who are at risk of developing severe respiratory failure 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. Version 5.6 of the RMP has also been submitted."

Senshio - ospemifene - EMEA/H/C/002780/II/0041

Shionogi B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Kirsti Villikka, "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."

Tecentriq - atezolizumab - EMEA/H/C/004143/II/0064

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "C.I.6 (Extension of indication)
Extension of indication to include adjuvant treatment of non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy for adult patients whose tumours have PD-L1 expression on ≥ 1% of tumour cells (TC) for Tecentriq as monotherapy based on the results from the pivotal phase III study GO29527 (IMpower010); as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of both the Tecentriq 840 mg concentrate for solution for infusion SmPC and the Tecentriq 1,200 mg concentrate for solution for infusion SmPC are updated. Minor editorial changes have been made throughout the SmPC. The Package Leaflets are updated in accordance. Version 21.0 of the RMP has also been submitted."

Zerbaxa - ceftolozane / tazobactam - EMEA/H/C/003772/II/0036

Merck Sharp & Dohme B.V., Rapporteur: Bjorg Bolstad, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Adam Przybylkowski, "Extension of indication to include treatment of paediatric patients aged birth to less than 18 years for Zerbaxa, based on final results from studies MK-7625A-034 (A Phase 2, Randomized, Active Comparator-Controlled, Double-Blind Clinical Trial to Study the Safety and Efficacy of Ceftolozane/ Tazobactam Versus Meropenem in Paediatric Subjects with Complicated Urinary Tract Infection, Including Pyelonephritis) and MK-7625A-035 (A Phase 2, Randomized, Active Comparator-Controlled, Double-Blind Clinical Trial to Study the Safety and Efficacy of Ceftolozane/Tazobactam Plus Metronidazole Versus Meropenem in Paediatric Subjects with Complicated Intra-Abdominal Infection).
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted.

In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

ADYNOVI - rurioctocog alfa pegol - EMEA/H/C/004195/II/0022/G
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

Aimovig - erenumab - EMEA/H/C/004447/II/0017
Novartis Europharm Limited, Rapporteur: Kristina Dunder

AJOVY - fremanezumab - EMEA/H/C/004833/II/0022
TEVA GmbH, Rapporteur: Jan Mueller-Berghaus

Aybintio - bevacizumab - EMEA/H/C/005106/II/0009
Samsung Bioepis NL B.V., Rapporteur: Andrea Laslop

Benlysta - belimumab - EMEA/H/C/002015/II/0098
GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder

Ceprotin - human protein c - EMEA/H/C/000334/II/0121/G
Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus

Ceprotin - human protein c - EMEA/H/C/000334/II/0122
Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus

Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0112/G
GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0047/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0049/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson	See B.5.1
Drovelis - drospirenone / estetrol - EMEA/H/C/005336/II/0001/G Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder	
Enbrel - etanercept - EMEA/H/C/000262/II/0243/G Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro	
Epidyolex - cannabidiol - EMEA/H/C/004675/II/0014/G, Orphan GW Pharma (International) B.V., Rapporteur: Kirstine Moll Harboe	
Eylea - aflibercept - EMEA/H/C/002392/II/0074 Bayer AG, Rapporteur: Alexandre Moreau	
Flebogamma DIF - human normal immunoglobulin - EMEA/H/C/000781/II/0067 Instituto Grifols, S.A., Rapporteur: Jan Mueller-Berghaus	
Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0046 MSD Vaccins, Rapporteur: Kristina Dunder	
Herceptin - trastuzumab - EMEA/H/C/000278/II/0173 Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus	
Iclusig - ponatinib - EMEA/H/C/002695/II/0060/G, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Filip Josephson	
Imfinzi - durvalumab - EMEA/H/C/004771/II/0032 AstraZeneca AB, Rapporteur: Sinan B. Sarac	
LIBTAYO - cemiplimab - EMEA/H/C/004844/II/0020/G Regeneron Ireland Designated Activity Company (DAC), Rapporteur: Sinan B. Sarac	

Lydisilka - drospirenone / estetrol - EMEA/H/C/005382/II/0001/G
Estetra SRL, Rapporteur: Kristina Dunder

Lysodren - mitotane - EMEA/H/C/000521/II/0024
HRA Pharma Rare Diseases, Rapporteur: Blanca Garcia-Ochoa

MabThera - rituximab - EMEA/H/C/000165/II/0186
Roche Registration GmbH, Rapporteur: Sinan B. Sarac

Menveo - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0103
GSK Vaccines S.r.l, Rapporteur: Johann Lodewijk Hillege

Mepsevii - vestronidase alfa - EMEA/H/C/004438/II/0024, Orphan
Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege

Metalyse - tenecteplase - EMEA/H/C/000306/II/0064/G
Boehringer Ingelheim International GmbH, Rapporteur: Martina Weise

Miglustat Gen.Orph - miglustat - EMEA/H/C/004366/II/0018
Gen.Orph, Generic, Generic of Zavesca, Rapporteur: Daniela Philadelphy

Nepexto - etanercept - EMEA/H/C/004711/II/0011
Mylan IRE Healthcare Limited, Rapporteur: Martina Weise

Ogivri - trastuzumab - EMEA/H/C/004916/II/0033
Mylan S.A.S, Rapporteur: Karin Janssen van Doorn

Olanzapine Apotex - olanzapine - EMEA/H/C/001178/II/0045
Apotex Europe BV, Generic, Generic of Zyprexa, Rapporteur: John Joseph Borg

Olanzapine Apotex - olanzapine - EMEA/H/C/001178/II/0046/G
Apotex Europe BV, Generic, Generic of Zyprexa, Rapporteur: John Joseph Borg

OPDIVO - nivolumab -

EMEA/H/C/003985/II/0106/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa	
Palforzia - defatted powder of arachis hypogaea l., semen (peanuts) - EMEA/H/C/004917/II/0004/G Aimmune Therapeutics Ireland Limited, Rapporteur: Jan Mueller-Berghaus	
Perjeta - pertuzumab - EMEA/H/C/002547/II/0060/G Roche Registration GmbH, Rapporteur: Sinan B. Sarac	
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0024/G Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus	
Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0026/G Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus	See B.5.1
Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and Haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0085/G MCM Vaccine B.V., Rapporteur: Christophe Focke	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0030/G AstraZeneca AB, Rapporteur: Sol Ruiz	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0032/G AstraZeneca AB, Rapporteur: Sol Ruiz	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0033/G AstraZeneca AB, Rapporteur: Sol Ruiz	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0035/G AstraZeneca AB, Rapporteur: Sol Ruiz	

Vazkepa - icosapent ethyl - EMEA/H/C/005398/II/0003
Amarin Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise

VEYVONDI - vonicog alfa - EMEA/H/C/004454/II/0019/G
Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus

Zavicefta - ceftazidime / avibactam - EMEA/H/C/004027/II/0027/G
Pfizer Ireland Pharmaceuticals, Rapporteur: Bjorg Bolstad

WS2118/G
Blitzima-EMEA/H/C/004723/WS2118/0044/G
Truxima-EMEA/H/C/004112/WS2118/0048/G
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

WS2120
Nuwiq-EMEA/H/C/002813/WS2120/0045
Vihuma-EMEA/H/C/004459/WS2120/0027
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

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

Adempas - riociguat - EMEA/H/C/002737/II/0032/G, Orphan
Bayer AG, Rapporteur: Johann Lodewijk Hillege, "Group of variations:
Type II C.I.4. update to SmPC section 4.3 and section 4.5 to contraindicate coadministration of riociguat (adempas) with other sGC stimulators.
Type II C.I.4. update to SmPC section 4.5 to rectify the Cmax value related to concomitant use with HAART treatment.
The package leaflet is updated accordingly.
In addition, the MAH takes to opportunity to implement editorial changes and updates to QRD Template version 10.2."

Afinitor - everolimus - EMEA/H/C/001038/II/0073
Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of the SmPC section 5.1 based

on the results of the analysis of final overall survival (OS) for study CRAD001T2302."

CellCept - mycophenolate mofetil - EMEA/H/C/000082/II/0165/G

Roche Registration GmbH, Rapporteur: Kirstine Moll Harboe, "C.I.4 (Type II) - Update of section 5.1 of the SmPC with recent findings from a clinical Pharmacology position paper on Mycophenolate mechanism of Action.
- C.I.4 (Type II) - Update of section 5.2 of the SmPC to add new information to the distribution and elimination subsections based on a Clinical Pharmacology Position Paper.
- C.I.4 (Type II) - Update of section 5.2 of the SmPC to amend the existing information on patients taking oral contraceptives based on study Roche Report N-181041/ BP 15543. Section 4.5 of the SmPC has been updated accordingly.
- C.I.Z (Type IB) - Update of section 2 and section 6 of the Package Leaflet to implement recommendations from NCA (Ireland) and EMA. The Package Leaflet is updated accordingly. In addition, the Marketing Authorisation Holder (MAH) has taken the opportunity to implement minor editorial changes to the SmPC and Package Leaflet. Furthermore, the PI is being brought in line with the latest QRD template version 10.2."

Darzalex - daratumumab - EMEA/H/C/004077/II/0050, Orphan

Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "C.I.4
Update of section 4.8 of the SmPC in order to add hypogammaglobulinemia to the list of adverse drug reactions (ADRs) with frequency common, based on new information and previously reviewed pooled safety data from Part 2 of Phase 3 Clinical Study 54767414MMY3006 comparing daratumumab versus observation as maintenance in patients with newly diagnosed Multiple Myeloma who are post-ASCT transplant. The Package Leaflet is updated accordingly."

Darzalex - daratumumab - EMEA/H/C/004077/II/0051/G, Orphan

Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, "C.I.4
Update of section 5.1 of the SmPC in order to

update PFS and OS data based on interim results from study MMY3006 (CCO 27/8/2020); this is a Phase 3, randomized, open-label, parallel-group, active-control, multicenter study of daratumumab combined with VTd for NDMM patients eligible for ASCT. This fulfils a post-approval commitment of procedure EMEA/H/C/004077//II/0030 to provide updated Part 1 PFS and OS data, with censoring the patients randomized to daratumumab in Part 2 of this study. C.I.4 Update of section 5.1 of the SmPC of DARZALEX SC formulation to provide the mature OS data based on final results from study MMY3012 (CCO 04/11/2020); this is a Phase 3, multicenter, randomized, open-label, active-controlled study to demonstrate that the efficacy and PK for daratumumab SC are not inferior to those for daratumumab IV in subjects with RRMM submitted for the approval of the SC formulation in procedure EMEA/H/C/004077//II/0032”	
Darzalex - daratumumab - EMEA/H/C/004077/II/0053, Orphan Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, “C.I.4 Update of section 5.1 of the SmPC in order to update PFS and OS (CCO 19/2/2021) data based on interim results from study MMY3008; This is a Phase 3, randomized, open-label, active controlled, parallel-group, multicenter study in adults with newly diagnosed MM not eligible for ASCT comparing DRd vs Rd. The Marketing authorisation holder (MAH) took the opportunity to make minor formatting and linguistic changes in the PI.”	
Erleada - apalutamide - EMEA/H/C/004452/II/0016 Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, “Update of section 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.”	
Eylea - aflibercept - EMEA/H/C/002392/II/0073	

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."

Fintepla - fenfluramine - EMEA/H/C/003933/II/0002, Orphan

Zogenix ROI Limited, Rapporteur: Kirstine Moll Harboe, "Update of section 4.2 of the SmPC to reduce the potential for confusion of the posology instructions by removing the dosing tables. This change is based on the inconsistencies found between the hand calculations and the values in the dosing tables following unsolicited comments from doctors and a recommendation from Zogenix Advisory Board."

Giotrif - afatinib - EMEA/H/C/002280/II/0039/G

Boehringer Ingelheim International GmbH, Rapporteur: Filip Josephson, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update the description of paediatric information based on results of paediatric study 1200.120. This is in compliance with a completed paediatric investigation plan which do not support a paediatric indication. The Package Leaflet is updated accordingly. The ATC code is also updated. In addition, the MAH took the opportunity to make some minor administrative changes to the labelling and package leaflet."

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

Gilead Sciences Ireland UC, Rapporteur: Kristina Dunder, "C.I.4 - Update of section 4.8 of the SmPC in order to add Lymphopenia to the list of adverse drug reactions (ADRs) with frequency common and update the information on serum phosphate and the experience from the long-term extension studies based on interim results from study GS-US-417-0304 (FINCH 4); this is a Multicenter, Double-Blind, Long Term Extension Study to Assess the Safety and Efficacy of Filgotinib in Subjects with Rheumatoid Arthritis; the Package Leaflet is updated accordingly."

Kanuma - sebelipase alfa - EMEA/H/C/004004/II/0032, Orphan

Alexion Europe SAS, Rapporteur: Karin Janssen van Doorn, "Update of section 4.2 of the SmPC in order to introduce a new posology regimen (higher starting dose of 3 mg/kg once weekly) based on cumulative data from clinical studies and real-world clinical practice for patients with Rapidly Progressive LAL deficiency presenting within the first six months of life. Consequently, the dosing information for patients with Rapidly Progressive LAL deficiency and paediatric and adult patients with LAL deficiency is modified. In addition, editorial update is made in sections 4.8, 5.1, 5.2 and 6.6 following the new posology regimen. The Package Leaflet is updated accordingly."	
Lynparza - olaparib - EMEA/H/C/003726/II/0048 AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ilaria Baldelli, "Update of section 5.1 of the olaparib tablet SmPC based on results from study D0816C00020 (OPINION) listed as a PAES in the Annex II; this is a Phase IIIb single arm, multicentre study, investigating olaparib as a maintenance treatment in patients with platinum-sensitive relapsed ovarian, fallopian tube or primary peritoneal cancer following 2 or more lines of platinum based chemotherapy and who did not have a known deleterious or suspected deleterious gBRCA mutation; the Annex II is updated accordingly. The RMP version 22.1 has also been submitted."	
MenQuadfi - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/005084/II/0006 Sanofi Pasteur, Rapporteur: Andrea Laslop, "Update of section 5.1 of the SmPC based on final results from study MET62, listed in the Annex II (category 1 in the RMP); this is a study to investigate immunogenicity and safety of an investigational quadrivalent meningococcal conjugate vaccine administered as a booster dose in children vaccinated 3 years earlier as toddlers (ANX 001)."	
Myalepta - metreleptin - EMEA/H/C/004218/II/0020/G, Orphan Amryt Pharmaceuticals DAC, Rapporteur: Karin Janssen van Doorn, "2 x C.I.13: Submission of 2 final non-clinical study reports assessing the binding of metreleptin to proteins in serum and	

characterising the tissue distribution of metreleptin. These are two agreed PAM-REC studies: a comparative in-vitro study of the binding of 125I-labelled leptin and 125I-labelled metreleptin in human serum at the therapeutic concentration range, and an in-vivo study comparing the tissue distribution of 125I-labelled metreleptin and 125I-labelled leptin in mice."	
Natpar - parathyroid hormone - EMEA/H/C/003861/II/0030/G, Orphan Shire Pharmaceuticals Ireland Limited, Rapporteur: Karin Janssen van Doorn, "Submission of the clinical study reports of the 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."	
OCALIVA - obeticholic acid - EMEA/H/C/004093/II/0029, Orphan Intercept Pharma International Limited, Rapporteur: Blanca Garcia-Ochoa, "Update of sections 4.2, 4.5 and 5.2 of the SmPC in order to clarify information on posology recommendations in renally impaired patients and add information on pharmacokinetic properties following the results from study 474-120 (a Phase I, Open-Label Study to Investigate the Effect of Renal Impairment on the Single-Dose Pharmacokinetics of Obeticholic Acid). Editorial changes have also been made to section 4.5."	
OCALIVA - obeticholic acid - EMEA/H/C/004093/II/0030, Orphan 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	

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"	
Omnitrope - somatropin - EMEA/H/C/000607/II/0071 Sandoz GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.8 of the SmPC in order to add 'headache' and 'hypothyroidism' to the list of adverse drug reactions (ADRs) with frequency not known based on final results from study EP00-501 (PATRO children), which were assessed in accordance with Article 46 of Regulation (EC) No1901/2006; this is an international, non-interventional, non-controlled, longitudinal, open and multicenter study, designed to record the safety and effectiveness data of paediatric patients treated with Omnitrope in various indications within routine clinical practice; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to align the summary of the safety profile and the tabulated list of ADRs, to introduce statements in the PI as per the Excipients guideline and to bring the PI in line with the latest QRD template version 10.2."	
Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0075 Merck Europe B.V., Rapporteur: Kirstine Moll Harboe, "Update of sections 4.1, 4.2, 4.4, 5.1, 5.2 and 6.6 of the SmPC in order to revise the definition of severe LH and FSH deficiency and to clarify the treatment target and the pharmacokinetic and pharmacodynamic properties of the two gonatropins included in the medicinal product, as well as disposal precautions, based on current medical	

guidelines, clinical practice and literature; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1 and to align with the guideline on the Excipients in the labelling and package leaflet of the medicinal products for human use."	
Prialt - ziconotide - EMEA/H/C/000551/II/0068 Riemser Pharma GmbH, Rapporteur: Christophe Focke, "Update of section 4.2 of the SmPC to introduce a new posology regimen. The Package Leaflet to be updated accordingly. In addition, the MAH took the opportunity to update QRD template to v.10.2 Rev.1 and implement editorial changes in SmPC, PL and Labelling."	
Saxenda - liraglutide - EMEA/H/C/003780/II/0030 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 PIP, to evaluate efficacy/safety of liraglutide in obese children with Prader-Willi Syndrome from 6 up to 18 years."	
Spinraza - nusinersen - EMEA/H/C/004312/II/0023, Orphan Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC to include information on real-world use of nusinersen in adults."	
TAKHZYRO - lanadelumab - EMEA/H/C/004806/II/0022, Orphan Shire Pharmaceuticals Ireland Limited, 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 ExtensionTM: An Open-Label 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."

Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0172

Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, "Submission of the final report from study GS-US-276-0104, listed as a category 3 study in the RMP. This is a Pooled Observational Study of pre-exposure prophylaxis (PrEP) users who took Truvada for PrEP, designed to collect and analyse data to examine the association between levels of adherence to the once-daily dosing regimen and risk of seroconversion, resistance development, and renal and skeletal adverse events."

Veltassa - patiromer - EMEA/H/C/004180/II/0024

Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Jayne Crowe, "Update of section 4.2 of the SmPC in order to update the posology with information to add the option to use various liquids and soft foods instead of the currently approved options (water, apple, cranberry juice) for preparation of Veltassa oral suspension. This is based on results from a new compatibility study report of Veltassa with juices/liquids and soft foods (REP074062TC). The Package Leaflet is updated accordingly."

Xagrid - anagrelide - EMEA/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 Due to 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."

WS2067

Keppra-EMEA/H/C/000277/WS2067/0194

UCB Pharma S.A., Lead Rapporteur: Karin Janssen van Doorn, "Update section 4.8 of the SmPC to include predisposition of the Japanese population to neuroleptic malignant syndrome (NMS). The package leaflet to be updated

accordingly. In addition, the MAH takes the opportunity to introduce further editorial changes in the labelling and update the contact details of the MAH in the package leaflet. The PI is brought in line with the latest QRD template version 10.2."	
WS2130/G **Elebrato Ellipta-EMEA/H/C/004781/ WS2130/0023/G** **Temybric Ellipta-EMEA/H/C/005254/ WS2130/0011/G** **Trelegy Ellipta-EMEA/H/C/004363/ WS2130/0020/G** GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Peter Kiely, "Update of section 4.8 of the SmPC to add the ADR (dysgeusia') and change frequencies for already reported ADRs ('nasopharyngitis', 'viral respiratory tract infection', and 'dysphonia') based on an updated safety analysis. The PL is updated accordingly."	

B.6.10. CHMP-PRAC assessed procedures

Adenuric - febuxostat - EMEA/H/C/000777/II/0062 Menarini International Operations Luxembourg S.A., Rapporteur: Andrea Laslop, PRAC Rapporteur: Jan Neuhauser, "C.I.4 - Update of sections 4.4 and 4.5 of the SmPC in order to amend an existing warning on the drug-drug interaction information with mercaptopurine/azathioprine based on final results from study FAI-01 listed as a category 3 study in the RMP; this is a phase I, drug-drug interaction study investigating the PK profile of 6-mercaptopurine following coadministration of two doses febuxostat and azathioprine in healthy subjects. The RMP version 9.0 has also been submitted."	
Bosulif - bosutinib - EMEA/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."

Bridion - sugammadex - EMEA/H/C/000885/II/0042

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

Forxiga - dapagliflozin -

EMEA/H/C/002322/II/0071

AstraZeneca AB, Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin, "Removal of the indication for 'the treatment of patients with Type 1 Diabetes Mellitus (T1DM) as an adjunct to insulin in patients with BMI ≥ 27 kg/m2 when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy' and related additional Risk Minimisation Measures from Annex II for Forxiga 5 mg film-coated tablets.
As a consequence, affected sections of the SmPC of the 5 mg tablets are updated. The Package Leaflet is updated in accordance.
A combined SmPC/ Package Leaflet with the 10 mg tablets has been submitted.
The RMP version 26. 1 has also been submitted."

GIVLAARI - givosiran -
EMEA/H/C/004775/II/0006, Orphan

Alnylam Netherlands B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Martin Huber, "Type II C.I.4: Update of SmPC section 4.8 to add 'blood homocysteine increase' as a new ADR and update to SmPC section 4.4 to add a related warning. The package leaflet is being updated accordingly. RMP v1.1 is also being submitted: consequences of blood homocysteine increase is being added as a new important potential risk, the clinical and post-marketing exposure is being updated and the due dates for ALN-AS1-002 and ALN-AS1-003 final study reports are being postponed.
In addition, the MAH took the opportunity to make editorial changes to the Product Information in other EU languages and to update the contact number of the local representatives for Malta and Cyprus."

Jyseleca - filgotinib -
EMEA/H/C/005113/II/0006

Gilead Sciences Ireland UC, Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce, "C.I.4 - Update of sections 4.5 and 5.2 of the SmPC in order to update pharmacokinetic information on the effect of filgotinib on OATP/CYP3A, OATP/BCRP, and OATP substrates based on final results from study GS-US-417-5937; this is a Phase 1, randomized, two-way crossover, open-label, single and multiple dose,

single center study to evaluate the effect of filgotinib on a mixed OATP/CYP3A, OATP/BCRP, and OATP substrates using phenotypic probes; the Package Leaflet is updated accordingly. The RMP version 2.1 has also been submitted."	
Naglazyme - galsulfase - EMEA/H/C/000640/II/0086 BioMarin International Limited, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins, "C.I.11.b variation to update the RMP to version 6.4 to remove gastrointestinal haemorrhage, hepatic impairment and thrombocytopenia from the list of important potential risks. This proposed update is supported by the submission of the final report from the MPS VI Clinical Surveillance Program (CSP) listed as a Specific Obligation (SOB002) in the Annex II of the Product Information for this MAA under exceptional circumstances. This observational CSP was undertaken to characterise the natural progression of MPS VI; to evaluate the long-term safety and efficacy data from Naglazyme treatment; to collect information on the effect of Naglazyme treatment on lactation, growth and development of infants of Naglazyme treated mothers; and to evaluate the effects of Naglazyme treatment on children under 5 years of age."	
NINLARO - ixazomib - EMEA/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 listed as an obligation in the Annex II of the Product Information. This is a phase 3, randomized, double-blind study to evaluate ixazomib in combination with LenDex in adult patients with relapsed and/or refractory multiple myeloma. The Annex II and the RMP (submitted version 7.0) are updated accordingly."	
Ondexxya - andexanet alfa - EMEA/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.”	
Ontruzant - trastuzumab - EMEA/H/C/004323/II/0036 Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Submission of the final report from clinical study (SB3-G31-BC-E) listed as a category 3 study in the RMP. This is an observational cohort study assessing the long-term cardiac safety (for Cardiac Safety and Survival Cohort) and survival (Survival Only Cohort and Cardiac Safety and Survival Cohort) in patients who received treatment in study SB3-G31-BC. The RMP version 5.0 is also provided.”	
OPDIVO - nivolumab - EMEA/H/C/003985/II/0105 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Update of sections 4.4, 4.8 and 5.1 of the SmPC based on final results from study CA209205 listed as a PAES in the Annex II; this is a Phase 2, open-label, multi-cohort, single-arm study of nivolumab in patients with classical Hodgkin's Lymphoma; The RMP version 20.3 has also been submitted.”	
Perjeta - pertuzumab - EMEA/H/C/002547/II/0059 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Anette Kirstine Stark, “Submission of the final clinical study report for the following clinical trial WO29217 (BERENICE), a multicenter, multinational, Phase II study to evaluate Perjeta in combination with Herceptin and standard neoadjuvant anthracycline-based chemotherapy in patients with HER2 positive, locally advanced, inflammatory, or early-stage breast cancer. The version 14.0 of the EU RMP	

is updated."

Praluent - alirocumab - EMEA/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."

Symtuza - darunavir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004391/II/0037

Janssen-Cilag International N.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the final report from final clinical study results GS-US-292-0109 listed as a category 3 study in the RMP. This is a Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects final safety and efficacy. The RMP version 7.1 has also been submitted."

Zeposia - ozanimod - EMEA/H/C/004835/II/0005

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "C.I.4 Type II Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on Progressive Multifocal Leukoencephalopathy (PML) and to add PML to the list of adverse drug reactions (ADRs) with rare frequency based on a PML case observed with ozanimod treatment in the RPC01-3001 open-label extension (OLE) study in patients with Multiple Sclerosis. The Package Leaflet (sections 2 and 4) is updated accordingly. The RMP version 1.3 has also been submitted."

WS2098

Komboglyze-EMEA/H/C/002059/WS2098/0051
Onglyza-EMEA/H/C/001039/WS2098/0053
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."

B.6.11. PRAC assessed procedures

PRAC Led
COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0010
Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of sections 4.3, 4.4 and 4.8 of the SmPC in order to add a contraindication related to the administration of Ad26.COV2.S to individuals with a history of Capillary Leak Syndrome (CLS) based on the cases reported following administration of this vaccine in the Global Medical Safety (GMS) up to the data lock point (DLP) of 21 June 2021. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add some minor editorial changes throughout the product information."
Opinion adopted on 07.07.2021.

PRAC Led
COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0012
Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a warning related to the

possibility of developing a Guillain-Barré syndrome (GBS) following the administration of Ad26.COV2.S and to add GBS as an adverse drug reaction (ADR). This is based on the information accumulated on cases of GBS reported to the vaccine adverse event reporting system (VAERS) in recipients of the Janssen COVID-19 Vaccine and subsequently, on the analysis performed by the company on cases of GBS based on the available cumulative data from launch. In addition, the company took the opportunity to make some editorial changes. The Package Leaflet is updated accordingly." Opinion adopted on 22.07.2021.

PRAC Led

Dapivirine Vaginal Ring 25 mg - dapivirine - EMEA/H/W/002168/II/0011

International Partnership for Microbicides Belgium AISBL, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Andrea Laslop, "Submission of the final report from study/studies MTN-16 listed as a category 3 study in the RMP. This is an observational study in women who became pregnant in the Phase III trial MTN-020 (ASPIRE) and the open-label extension study MTN-025 (HOPE) and who subsequently enrolled in the MTN-016 (EMBRACE) study. This study assessed the pregnancy and delivery outcomes in these women and infant follow up for the first year of life. The RMP version 0.8 has also been submitted."

PRAC Led

Enbrel - etanercept - EMEA/H/C/000262/II/0244

Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "C.I.13: Submission of the final report from study B1801310 (BIKER), listed as a category 3 study in the RMP. This is an observational Post-Authorisation Safety Study (PASS) of Etanercept and Methotrexate in the treatment of Juvenile Idiopathic Arthritis (JIA) using data obtained from participants in the German Biologics JIA Registry (BIKER) to monitor long-term safety and effectiveness of etanercept in the treatment of JIA in regular clinical practice."

PRAC Led

Eylea - aflibercept - EMEA/H/C/002392/II/0075

Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of this type II variation as response to commitment undertaken in procedure II/68 covering the following elements:
1) validation of a follow-up questionnaire on Intraocular pressure (IOP) increase,
2) simplification of the educational material (prescriber guide and injection video) based on the data being collected and after the consultation with the panel of ophthalmologists,
3) RMP submission to include follow-up questionnaire on IOP increase and timing of IOP increase report submission"

PRAC Led

Hemlibra - emicizumab - EMEA/H/C/004406/II/0025

Roche Registration GmbH, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ilaria Baldelli, 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."

PRAC Led

Lyxumia - lixisenatide - EMEA/H/C/002445/II/0033

sanofi-aventis groupe, Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report of study EUPAS 19769, a Post-Authorisation Safety Study (PASS) included as a category 3 study in the RMP. The submission of this report addresses MEA 008.5.
This is a registry to monitor the occurrences of events of interest including acute pancreatitis, pancreatic cancer and thyroid cancer, especially medullary carcinoma of the thyroid, among adult type 2 diabetes patients treated with lixisenatide using the data from national registers and databases in Italy and Belgium. The updated RMP version 7.0 has also been submitted."

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. 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. The RMP version 8.0 has also been submitted."

PRAC Led

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0022

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Hans Christian Siersted, PRAC-CHMP liaison: Kirstine Moll Harboe, "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 ≥ 12 to < 18 years."

PRAC Led

Suliqua - insulin glargine / lixisenatide - EMEA/H/C/004243/II/0023

sanofi-aventis groupe, Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final study report from the "Patient registry of lixisenatide use in adult type 2 diabetes", which is included as a category 3 PASS in the RMP. This study's objective is to monitor the occurrences of events of interest including acute pancreatitis, pancreatic cancer and thyroid cancer, especially medullary carcinoma of the thyroid (MCT), among adult type 2 diabetes patients treated with Lixisenatide using the data from national registers and databases in Italy and Belgium. The provision of the study report addresses post-authorisation measure (PAM) MEA 005.3."

PRAC Led

WS2078

Lixiana-EMEA/H/C/002629/WS2078/0034

Roteas-EMEA/H/C/004339/WS2078/0020
Daiichi Sankyo Europe GmbH, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "C.I.13: Submission of the final report from study ETNA-VTE-EUROPE (DSE-EDO-05-14-EU), listed as a category 3 study in the RMP. This is a Non-Interventional Study on Edoxaban Treatment in Routine Clinical Practice in Patients with Venous Thromboembolism in Europe. The RMP version 12.0 has also been submitted."

PRAC Led
WS2082
Efficib-EMEA/H/C/000896/WS2082/0101
Janumet-EMEA/H/C/000861/WS2082/0101
Januvia-EMEA/H/C/000722/WS2082/0075
Ristaben-EMEA/H/C/001234/WS2082/0068
Ristfor-EMEA/H/C/001235/WS2082/0089
TESAVEL-EMEA/H/C/000910/WS2082/0075
Velmetia-EMEA/H/C/000862/WS2082/0104
Xelevia-EMEA/H/C/000762/WS2082/0080
Merck Sharp & Dohme B.V., Lead PRAC Rapporteur: Menno van der Elst, "To provide an updated RMP to reflect clinical trial exposure to sitagliptin in patients 10-17 years of age. In particular, to update the patient exposure data in the safety specifications Part II and implement the already assessed clinical data (variations for children 10-17 years) within finalised EMEA/H/C/WS1727 and EMEA/H/C/WS1898 procedures."

PRAC Led
WS2115
Humalog-EMEA/H/C/000088/WS2115/0191
Liprolog-EMEA/H/C/000393/WS2115/0151
Eli Lilly Nederland B.V., Informed Consent of Humalog, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Annika Folin, "To provide an updated RMP to reflect the completion of a routine pharmacovigilance activity . The final commitment report on that

activity was submitted to the Agency on 29th April 2021.
Additionally, the MAH took this opportunity to modify milestones for a post-approval safety surveillance programme for severe hypoglycaemia related to the use of a new presentation. The current version of the EU RMP submission has been changed from '31 March 2021' to 'Within 6 months of first commercialisation'. Therefore, the final due date for this study report was amended as follows: 'Within 3 years of first commercialisation'.
Finally, the status of a paediatric PK/PD study has been updated since it was completed.
Furthermore, the marketing authorisation status of Lyumjev has been added."

B.6.12. CHMP-CAT assessed procedures

Alofisel - darvadstrocel - EMEA/H/C/004258/II/0027, Orphan, ATMP
Takeda Pharma A/S, Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

PRAC Led
Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0040, Orphan, ATMP
Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of the final study report for the non-interventional study KT-EU-471-0116 (Quantitative Testing of Healthcare Provider Knowledge about Yescarta (axicabtagene ciloleucel) Risk Minimisation Measures) in fulfilment of an additional pharmacovigilance activity (category 3) listed in the EU Risk Management Plan for Yescarta."

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

WS2090/G
Copalia HCT-EMEA/H/C/001159/WS2090/0093/G
Dafiro HCT-EMEA/H/C/001160/WS2090/0095/G
Exforge HCT-EMEA/H/C/001068/WS2090/0092/G
Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe

WS2093
Perjeta-EMEA/H/C/002547/WS2093/0058
Phesgo-EMEA/H/C/005386/WS2093/0006
Roche Registration GmbH, Lead Rapporteur: Sinan B. Sarac

WS2094
Infanrix hexa-EMEA/H/C/000296/WS2094/0302
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke substance Hib conjugated bulk."

WS2099
HyQvia-EMEA/H/C/002491/WS2099/0073
Kiovig-EMEA/H/C/000628/WS2099/0111
Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus

WS2101
Hexacima-EMEA/H/C/002702/WS2101/0118
Hexyon-EMEA/H/C/002796/WS2101/0122
MenQuadfi-EMEA/H/C/005084/WS2101/0007
Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

WS2104
CABOMETYX-EMEA/H/C/004163/WS2104/0022
Cometriq-EMEA/H/C/002640/WS2104/0046
Ipsen Pharma, Lead Rapporteur: Bjorg Bolstad

WS2106
Actraphane-EMEA/H/C/000427/WS2106/0090
Insulatard-EMEA/H/C/000441/WS2106/0088

Mixtard-EMEA/H/C/000428/WS2106/0091
NovoMix-EMEA/H/C/000308/WS2106/0109
Protaphane-EMEA/H/C/000442/WS2106/0087
Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe

WS2108/G
Galvus-EMEA/H/C/000771/WS2108/0070/G
Jalra-EMEA/H/C/001048/WS2108/0072/G
Xiliarx-EMEA/H/C/001051/WS2108/0070/G
Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder

WS2109
Copalia-EMEA/H/C/000774/WS2109/0120
Copalia HCT-EMEA/H/C/001159/WS2109/0094
Dafiro-EMEA/H/C/000776/WS2109/0124
Dafiro HCT-EMEA/H/C/001160/WS2109/0096
Exforge-EMEA/H/C/000716/WS2109/0119
Exforge HCT-EMEA/H/C/001068/WS2109/0093
Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe

WS2110/G
Afinitor-EMEA/H/C/001038/WS2110/0074/G
Votubia-EMEA/H/C/002311/WS2110/0072/G
Novartis Europharm Limited, Lead Rapporteur: Janet Koenig

WS2112
Hexacima-EMEA/H/C/002702/WS2112/0119
Hexyon-EMEA/H/C/002796/WS2112/0123
Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus

WS2116/G
Kivexa-EMEA/H/C/000581/WS2116/0092/G
Triumeq-EMEA/H/C/002754/WS2116/

0096/G **Trizivir-EMEA/H/C/000338/WS2116/0126/G** **Ziagen-EMEA/H/C/000252/WS2116/0121/G** ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson	
WS2117 **Entresto-EMEA/H/C/004062/WS2117/0040** **Neparvis-EMEA/H/C/004343/WS2117/0038** Novartis Europharm Limited, Lead Rapporteur: Johann Lodewijk Hillege	
WS2123 **Blitzima-EMEA/H/C/004723/WS2123/0045** **Truxima-EMEA/H/C/004112/WS2123/0049** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, "To update section 6.6 of the SmPC to add new instructions for the injections in order to align the PI with its originator Mabthera during assessment and finalisation of procedure IB-181 adopted on February 2021. In addition, the MAH would like to include minor editorial changes in the Spanish and German language versions of the product information."	
WS2124/G **Corbilta-EMEA/H/C/002785/WS2124/0024/G** **Levodopa/Carbidopa/Entacapone Orion-EMEA/H/C/002441/WS2124/0032/G** **Stalevo-EMEA/H/C/000511/WS2124/0094/G** Orion Corporation, Lead Rapporteur: Outi Mäki-Ikola	

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 - EMEA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

G.2. PRIME

Some information related to PRIME cannot be released at the present time as these contain commercially confidential information.

G.2.1. List of procedures concluding at 19-22 July 2021 CHMP plenary:

Oncology	
Treatment of Merkel Cell Carcinoma (SME)	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Treatment of relapsed and refractory Multiple Myeloma (SME)	The CAT and the CHMP denied eligibility to PRIME and adopted the critical summary report.
Immunology-rheumatology-transplantation	
MB-107 Treatment of X-linked severe combined immunodeficiency (XSCID) in newly diagnosed infants (SME) ATMP	The CAT and the CHMP granted eligibility to PRIME and adopted the critical summary report.
Haematology – Hemostaseology	
Treatment of essential thrombocythaemia (SME)	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Neurology	
Treatment of dementia with Lewy Bodies (SME)	The CHMP denied eligibility to PRIME and adopted the critical summary report.

G.2.2. List of procedures starting in July 2021 for September 2021 CHMP adoption of outcomes

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