16 August 2021
EMA/CHMP/455051/2021
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for CHMP written procedure* 16-19 August 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

*** Written Procedure - comments on the draft documents should be forwarded to the Product Lead (PL) as identified in the CHMP agenda.**

Disclaimers

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

Note on access to documents

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

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

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Action: For information

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Action: For information

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Scope: Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in July 2021.

Action: For adoption

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Action: For adoption

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Action: For information

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Rapporteur: Alar Irs, PRAC Rapporteur: Ilaria Baldelli

Scope: "Extension application to add a new strength of 20 mg (hard capsule)."

Letter by the applicant dated 12 August 2021 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in February 2021

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Sanofi Pasteur

Rapporteur: Christophe Focke

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Letter by the applicant dated 10 August 2021 requesting an extension to the clock stop to respond to the Request for Supplementary Information adopted in May 2021.

Action: For adoption

Request for Supplementary Information adopted on 20.05.2021, 10.12.2020.

5.2.2. Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0012

Sanofi Pasteur

Rapporteur: Christophe Focke

Scope: "Extension of indication to include paediatric population from 6 years of age for Dengvaxia; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC and sections 1, 2 and 4 of the Package Leaflet are updated. Furthermore, the MAH takes the opportunity to add an instruction for the installation of the needle in the SmPC and the Package Leaflet of the single-dose presentation."

Letter by the applicant dated 10 August 2021 requesting an extension to the clock stop to respond to the Request for Supplementary Information adopted in May 2021.

Action: For adoption

Request for Supplementary Information adopted on 20.05.2021, 10.12.2020.

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7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

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Action: For adoption

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Rapporteur: Blanca Garcia-Ochoa

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

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

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

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

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Action: For information

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

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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 by the applicant for an extension to the clock stop to respond to the Request for Supplementary Information adopted in July 2021.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

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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), Hybrid application (Article 10(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

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0026/G Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 30.07.2021. Request for Supplementary Information adopted on 21.07.2021.	Positive Opinion adopted by consensus on 30.07.2021. 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/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 Opinion adopted on 27.07.2021.	Positive Opinion adopted by consensus on 27.07.2021. 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/0035/G AstraZeneca AB, Rapporteur: Sol Ruiz

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

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Lojuxta - lomitapide - 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	Amendment of the timetable to respond to the Request for Supplementary Information adopted in July 2021.

version 10.2” Request for Supplementary Information adopted on 22.07.2021, 09.04.2021.	
RAVICTI - glycerol phenylbutyrate - EMEA/H/C/003822/II/0038/G, Orphan lmmedica 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-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.	Amendment of the timetable to respond to the Request for Supplementary Information adopted in July 2021.
Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0013 Sanofi Pasteur, Rapporteur: Christophe Focke, “To update sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen from 3 doses to 2 doses for individuals from 9 years of age based on interim results from study CYD65 listed as a category 3 study in the RMP; this is a Phase II, observer-blind, placebo-controlled trial in order to assess Immunogenicity and Safety of Tetravalent Dengue Vaccine Given in 1-, 2-, or 3-Dose Schedules Followed by a Single Booster; section	Letter by the applicant dated 10 August 2021 requesting an extension to the clock stop to respond to the Request for Supplementary Information adopted in May 2021.

3 of the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 20.05.2021, 10.12.2020.	
Dengvaxia - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0016/G Sanofi Pasteur, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, "Update of section 4.5 of the SmPC to include co-administration data on Gardasil/Cervarix/Adacel from CYD67, CYD71 and CYD66 final study reports respectively (final reports from 3 PAM MEA studies listed as category 3 studies in the RMP); these studies are dedicated to immunogenicity and safety of the concomitant administration; the Package Leaflet is updated accordingly. The RMP version 6.1. has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 10.06.2021, 11.02.2021.	Letter by the applicant dated 10 August 2021 requesting an extension to the clock stop to respond to the Request for Supplementary Information adopted in May 2021.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

tebentafusp - EMEA/H/C/004929, Orphan Immunocore Ireland Limited, treatment of uveal melanoma	**Accelerated review**

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

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metformin hydrochloride / sitagliptin hydrochloride monohydrate - EMEA/H/C/005678 treatment of type 2 diabetes mellitus List of Questions adopted on 25.03.2021.
Ozempic - semaglutide - EMEA/H/C/004174/X/0021

Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Annika Folin, "Extension application to add a new strength of 2 mg solution for injection."
List of Questions adopted on 20.05.2021.

sapropterin - EMEA/H/C/005646
treatment of hyperphenylalaninemia (HPA)
List of Questions adopted on 20.05.2021.

sacituzumab govitecan - EMEA/H/C/005182
treatment of unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC)
List of Questions adopted on 22.06.2021.

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

Atriance - nelarabine - EMEA/H/C/000752/S/0055
Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Anette Kirstine Stark

IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/S/0069
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Mepsevii - vestronidase alfa - EMEA/H/C/004438/S/0025, Orphan
Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Eva A. Segovia

Naglazyme - galsulfase - EMEA/H/C/000640/S/0087
BioMarin International Limited, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins

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

Darzalex - daratumumab - EMEA/H/C/004077/R/0054, Orphan

Janssen-Cilag International NV, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

elmiron - pentosan polysulfate sodium - EMEA/H/C/004246/R/0024
bene-Arzneimittel GmbH, Rapporteur: Jean-Michel Race, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Ana Sofia Diniz Martins

Emtricitabine/tenofovir disoproxil Krka d.d. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004686/R/0017
KRKA, d.d., Novo mesto, Generic, Duplicate, Duplicate of Emtricitabine/Tenofovir disoproxil Krka, Rapporteur: John Joseph Borg, PRAC Rapporteur: Ana Sofia Diniz Martins

Erelzi - etanercept - EMEA/H/C/004192/R/0037
Sandoz GmbH, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Eva A. Segovia

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0039, Orphan, ATMP
Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Rhea Fitzgerald

Refixia - nonacog beta pegol - EMEA/H/C/004178/R/0025
Novo Nordisk A/S, Rapporteur: Andrea Laslop, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski

Skilarence - dimethyl fumarate - EMEA/H/C/002157/R/0030
Almirall S.A, Rapporteur: Janet Koenig, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Annika Folin

Spinraza - nusinersen - EMEA/H/C/004312/R/0025, Orphan
Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga

TAGRISSO - osimertinib - EMEA/H/C/004124/R/0044

AstraZeneca AB, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/R/0037 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné

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

Beovu - brolucizumab - EMEA/H/C/004913/II/0010 Novartis Europharm Limited, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to include treatment of visual impairment due to DME for Beovu; as a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."
Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0061 Organon N.V., Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Peter Kiely, PRAC Rapporteur: Menno van der Elst, "Extension of indication to include treatment of adolescent males (14 to less than 18 years) with hypogonadotropic hypogonadism, in combination with human Chorionic Gonadotropin (hCG) for Elonva, based on final results of the paediatric study P043. Study P043 was an open-label, non-comparative, multi-center safety and efficacy study of corifollitropin in association with hCG in male adolescents with hypogonadotropic hypogonadism, part of the paediatric investigation plan; as a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement some minor editorial

and formatting changes throughout the PI.”
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0110 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, “Extension of indication for Keytruda in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery of adults with locally advanced, inflammatory, or early-stage triple-negative breast cancer at high-risk of recurrence; as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 37.1 of the RMP has also been submitted.”
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0111 Merck Sharp & Dohme B.V., Rapporteur: Armando Genazzani, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, “Extension of indication to include the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB, Stage IIC or stage III melanoma and to include the treatment of adolescents aged 12 years and older with advanced melanoma for Keytruda; as a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 36.1 of the RMP has also been submitted.”
OPDIVO - nivolumab - EMEA/H/C/003985/II/0107 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Brigitte Keller-Stanislawski, “Extension of indication to include in combination with fluoropyrimidine- and platinum-based combination chemotherapy the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) for OPDIVO based on study CA209648; 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 25.0 of the RMP has also been submitted.”

RoActemra - tocilizumab - EMEA/H/C/000955/II/0101

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski, "C.I.6 - Extension of indication to include the treatment of coronavirus disease 2019 in hospitalised adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation for RoActemra; as a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8, 5.1 and 5.2 of the SmPC for RoActemra 20 mg/mL concentrate for solution for infusion are updated. The Package Leaflet is updated in accordance. Version 27 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev. 1."

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0042, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, CHMP Coordinators: Jan Mueller-Berghaus and Karin Janssen van Doorn, PRAC Rapporteur: Anette Kirstine Stark, "Extension of indication to include the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy. Consequently, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC, Annex II (Section D) and Package Leaflet are proposed to be updated. As a consequence, the RMP (version 5.1) has been updated to align with the indication extension. In addition, the applicant has taken the opportunity to make minor editorial corrections throughout the SmPC and package leaflet to align with the current Quality Review of Documents (QRD) template."
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

WS2065
Delstrigo-EMEA/H/C/004746/WS2065/0026
Pifeltro-EMEA/H/C/004747/WS2065/0019

Merck Sharp & Dohme B.V., Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, "Extension of indication to

include the new indication to the paediatric population weighing less than 35 kgs for PIFELTRO and DELSTRIGO. Sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP for each product have also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial corrections and to update the list of local representatives in the Package Leaflet."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Bavencio - avelumab - EMEA/H/C/004338/II/0028
Merck Europe B.V., Rapporteur: Filip Josephson

Buvidal - buprenorphine - EMEA/H/C/004651/II/0015/G
Camurus AB, Rapporteur: Peter Kiely

Cerezyme - imiglucerase - EMEA/H/C/000157/II/0123/G
Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege

Cinacalcet Mylan - cinacalcet - EMEA/H/C/004014/II/0016
Mylan S.A.S, Generic, Generic of Mimpara, Rapporteur: Tomas Radimersky

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0052/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0053/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0057
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) -

EMEA/H/C/005735/II/0060/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Drovelis - drospirenone / estetrol - EMEA/H/C/005336/II/0003
Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder

Drovelis - drospirenone / estetrol - EMEA/H/C/005336/II/0004/G
Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder

HEPLISAV B - hepatitis B surface antigen - EMEA/H/C/005063/II/0010
Dynavax GmbH, Rapporteur: Filip Josephson

Herceptin - trastuzumab - EMEA/H/C/000278/II/0174/G
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus

Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0019/G
Bayer AG, Rapporteur: Kirstine Moll Harboe

Kevzara - sarilumab - EMEA/H/C/004254/II/0028/G
sanofi-aventis groupe, Rapporteur: Jan Mueller-Berghaus

Lydisilka - drospirenone / estetrol - EMEA/H/C/005382/II/0003
Estetra SRL, Rapporteur: Kristina Dunder

Lydisilka - drospirenone / estetrol - EMEA/H/C/005382/II/0004/G
Estetra SRL, Rapporteur: Kristina Dunder

Neulasta - pegfilgrastim - EMEA/H/C/000420/II/0117
Amgen Europe B.V., Rapporteur: Johann Lodewijk Hillege

Nimenrix - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/002226/II/0111/G
Pfizer Europe MA EEIG, Rapporteur: Bjorg Bolstad

Onpattro - patisiran - EMEA/H/C/004699/II/0021/G, Orphan
Alnylam Netherlands B.V., Rapporteur: Kristina Dunder

Puregon - follitropin beta -
EMEA/H/C/000086/II/0122
Organon N.V., Rapporteur: Peter Kiely

Reagila - cariprazine -
EMEA/H/C/002770/II/0020/G
Gedeon Richter Plc., Rapporteur: Kristina Dunder

Reagila - cariprazine -
EMEA/H/C/002770/II/0022
Gedeon Richter Plc., Rapporteur: Kristina Dunder

Remicade - infliximab -
EMEA/H/C/000240/II/0229
Janssen Biologics B.V., Rapporteur: Kristina Dunder

Retacrit - epoetin zeta -
EMEA/H/C/000872/II/0105
Pfizer Europe MA EEIG, Rapporteur: Martina Weise

Rinvoq - upadacitinib -
EMEA/H/C/004760/II/0011
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder

Silapo - epoetin zeta -
EMEA/H/C/000760/II/0065
STADA Arzneimittel AG, Rapporteur: Martina Weise

Skyrizi - risankizumab -
EMEA/H/C/004759/II/0017/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Kiely

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) -
EMEA/H/C/005791/II/0029/G
Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus

Taltz - ixekizumab -
EMEA/H/C/003943/II/0045/G
Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder

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/0035/G
AstraZeneca AB, Rapporteur: Sol Ruiz

VITRAKVI - larotrectinib -
EMEA/H/C/004919/II/0017
Bayer AG, Rapporteur: Filip Josephson

WS2146
Nuwiq-EMEA/H/C/002813/WS2146/0046
Vihuma-EMEA/H/C/004459/WS2146/
0028
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

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

Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) -
EMEA/H/C/002333/II/0105
GSK Vaccines S.r.l, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add lymphadenopathy to the list of adverse drug reactions. The Package Leaflet section 4 is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2 rev1 (including addition of the "sodium-free" statement in the SmPC section 4.4) and update the list of local representatives."

Brilique - ticagrelor -
EMEA/H/C/001241/II/0054
AstraZeneca AB, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning and new adverse drug reactions on bradyarrhythmia and AV blocks based on a review of all currently available information, including clinical trial data, post- marketing reports, and plausible mechanism."

Calquence - acalabrutinib -
EMEA/H/C/005299/II/0006
AstraZeneca AB, Rapporteur: Filip Josephson, "Submission of updated report from study 1000-171974-6 ."

Calquence - acalabrutinib -
EMEA/H/C/005299/II/0007
AstraZeneca AB, Rapporteur: Filip Josephson,

"Submission of the final report from ACE-HV-114, an open-label, fixed sequence study in healthy subjects to assess the pharmacokinetics of acalabrutinib and its active metabolite, ACP-5862, when administered alone and in combination with moderate CYP3A4 inhibitors fluconazole or isavuconazole."

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0054/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0056/G
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Drovelis - drospirenone / estetrol - EMEA/H/C/005336/II/0002
Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder, "Update of section 5.3 of the SmPC following a revision of the Environmental Risk Assessment (ERA) in order to include the E4 PECsw based on a refined Fpen of 0.0044. In addition, the MAH has taken the opportunity to implement minor editorial changes in the SmPC and Package Leaflet."

Iclusig - ponatinib - EMEA/H/C/002695/II/0061, Orphan
Incyte Biosciences Distribution B.V., Rapporteur: Filip Josephson, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC based on results from the OPTIC study (AP24534-14-203) listed as a specific obligation in the Annex II. This is a randomised, open-label, Phase 2 trial of ponatinib in patients with chronic myeloid leukemia to characterise the efficacy and safety of ponatibib over a range of doses; the Package Leaflet is updated accordingly."

Ivemend - fosaprepitant - EMEA/H/C/000743/II/0045
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC with the final results from study P045; a non-randomised, single-group, multi-site, open-label study to evaluate the safety and tolerability of consecutive 3-day intravenous fosaprepitant in

paediatric participants scheduled to receive a moderately or highly emetogenic chemotherapy agent/regimen or a chemotherapy agent/regimen not previously tolerated due to vomiting. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Lydisilka - drospirenone / estetrol - EMEA/H/C/005382/II/0002

Estetra SRL, Rapporteur: Kristina Dunder, "Update of section 5.3 of the SmPC following a revision of the Environmental Risk Assessment (ERA) in order to include the E4 PECsw based on a refined Fpen of 0.0044. In addition, the MAH has taken the opportunity to implement minor editorial changes in the SmPC and Package Leaflet."

Mayzent - siponimod - EMEA/H/C/004712/II/0011/G

Novartis Europharm Limited, Rapporteur: Kirstine Moll Harboe, "- Update of sections 4.4 and 4.5 of the SmPC to add information in case of administration of non-live attenuated vaccines, based on the vaccination study A2130.
- Update of section 4.5 of the SmPC to clarify the CYP2C9/CYP3A4 inhibitors/inducers information.
- Update of section 5.2 to add information regarding CYP2C9 genotypes less frequent alleles."

Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0050

Orexigen Therapeutics Ireland Limited, Rapporteur: Kirstine Moll Harboe, "Submission of the final report of study 20077697; a Toxicity Study of Bupropion and Naltrexone by Twice Daily Oral (Gavage) in Juvenile Mice."

Noxafil - posaconazole - EMEA/H/C/000610/II/0067

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

Nuceiva - botulinum toxin type A - EMEA/H/C/004587/II/0017

Evolus Pharma Limited, Rapporteur: Peter Kiely, "Submission of the final reports of the non-interventional immunogenicity analysis (RMP cat 3 study)."	
Phesgo - pertuzumab / trastuzumab - EMEA/H/C/005386/II/0007 Roche Registration GmbH, Rapporteur: Sinan B. Sarac, "Update of the immunogenicity information in section 4.8 of the SmPC based on the analysis of the Federica study (Phase III clinical trial in patients with HER2 overexpressing early breast cancer)."	
ProQuad - measles, mumps, rubella and varicella vaccine (live) - EMEA/H/C/000622/II/0151/G MSD Vaccins, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC to remove adverse events with no biological plausible cause in response to an EMA comment received during procedure EMEA/H/C/000622/WS1392. In addition, the MAH proposed amendments to other aspects of SmPC section 4.8 to minimise redundancies and update outdated terms to the current version of the Medical Dictionary for Regulatory Activities (MedDRA). The Package Leaflet is updated accordingly. Update of section 4.9 of the SmPC to revise the information on overdose following review of MAH`s safety database search for ProQuad. In addition, the MAH took the opportunity to update the contact details for the local representatives in the Package Leaflet."	
Talzenna - talazoparib - EMEA/H/C/004674/II/0010/G Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC in order to update the frequency of myelodysplastic syndrome/acute myeloid syndrome (MDS/AML) based on a cumulative safety review; Update of section 5.1 of the SmPC with the revised ATC code. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and make minor corrections in the SmPC and PL."	
Tivicay - dolutegravir - EMEA/H/C/002753/II/0073/G	

ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 5.1 of the Tivicay SmPC in order to add new information on efficacy and safety based on data from studies 204861 (GEMINI-1) and 205543 (GEMINI-2). These are Phase III, identical, ongoing, randomized, double-blind, parallel group studies, to provide longer term efficacy and safety data on the use of dolutegravir (DTG) for the treatment of HIV-1 infection. The Package Leaflet is updated accordingly.
The grouping includes a Type IA variation to update the ATC code for both Film Coated and Dispersible Tablets."

Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0031

AstraZeneca AB, Rapporteur: Sol Ruiz, "Submission of the final study report for MS1222-0002 "In Vitro Assay to Determine Release of Spike Protein From Transduced Cells" to fulfil the imposed study as reflected in Annex II of the product information and the RMP. As a result, Annex II of the product information is being updated to remove this study.
The MAH is taking the opportunity to provide two additional studies linked to support the investigation on the platelet activation: the final study report for MS1222-0001 "Computational Prediction of Spike Protein Interaction with Platelet Factor 4 (PF4)" which is the first report requested within the required studies for "in vitro interaction of AZD1222 or spike protein with PF4 and/or platelets" as reflected in the RMP; and the study report for 520447 "Investigative Vaccine Study in the Mouse" to evaluate spike protein levels and haematology parameters."

Veklury - remdesivir - EMEA/H/C/005622/II/0025/G

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of sections 4.4, 4.5 and 5.1 of the SmPC with nonclinical results following final study reports addressing the activity of remdesivir in additional cell lines and chloroquine/hydroxychloroquine antagonism (fulfilment of 3 components of the Specific Obligation SOB 012 from EMEA/H/C/005622/R/0015). In addition, the

Marketing authorisation holder (MAH) took the opportunity to submit the interim results of the non-clinical studies related to the characterisation of clinical isolates and/or recombinant viruses with P323L, A97V and A547V substitutions."

Venclyxto - venetoclax - EMEA/H/C/004106/II/0035

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Submission of the final report from study M12-175 listed as a category 3 study in the RMP. This is a Phase 1 study evaluating the safety and pharmacokinetics of venetoclax in subjects with relapsed or refractory Chronic Lymphocytic Leukaemia and Non-Hodgkin's Lymphoma."

Venclyxto - venetoclax - EMEA/H/C/004106/II/0036

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Submission of the final report from study M13-982 listed as a category 3 study in the RMP. This is a phase 2 open-label study of the efficacy of ABT-199 in subjects with relapsed or refractory Chronic Lymphocytic Leukaemia Harboring the 17p Deletion."

Vocabria - cabotegravir - EMEA/H/C/004976/II/0007

ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to update the adverse reactions section, adding information regarding events of pyrexia have a close temporal association with injections. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to include minor typographical updates."

Votrient - pazopanib - EMEA/H/C/001141/II/0068

Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to add skin ulcer to the list of adverse drug reactions (ADRs) with frequency of "uncommon" and to update the frequency of the ADR aneurysm from "not known" to "rare". Further editorial changes and a simplification in the presentation of the frequencies of ADRs in

section 4.8 are being proposed. The Package Leaflet is updated accordingly."

Xyrem - sodium oxybate - EMEA/H/C/000593/II/0093
UCB Pharma S.A., Rapporteur: Bruno Sepodes, "Update of section 4.9 of the SmPC in order to add a new warning on acidosis and its management following the assessment of the signal 'metabolic acidosis' triggered by routine literature review; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement a minor editorial change in section 4.8 of the SmPC, 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."

Zeffix - lamivudine - EMEA/H/C/000242/II/0082
GlaxoSmithKline (Ireland) Limited, Duplicate, Duplicate of Epivir, Rapporteur: Jean-Michel Race, "Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on results from bioavailability studies (204993 and 204994) with lamivudine-containing products. 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."

Zeffix - lamivudine - EMEA/H/C/000242/II/0083
GlaxoSmithKline (Ireland) Limited, Duplicate, Duplicate of Epivir, Rapporteur: Jean-Michel Race, "Update of section 4.9 of the SmPC in order to update the Overdosage of the GDS for lamivudine-human immunodeficiency virus (HIV) information based on the safety database. The section 3 of the package Leaflet is updated accordingly."

B.6.10. CHMP-PRAC assessed procedures

Adcetris - brentuximab vedotin - EMEA/H/C/002455/II/0093, Orphan
Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2,

4.8, 5.1, 5.2 and 6.6 of the SmPC based on results from study C25004, an open-label study in order to assess the safety and tolerability, of brentuximab vedotin when combined with multiagent chemotherapy regimen for first-line treatment of advanced-stage Hodgkin lymphoma in paediatric patients. The RMP version 16 has also been submitted."

Alunbrig - brigatinib / brigatinib - EMEA/H/C/004248/II/0037

Takeda Pharma A/S, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study AP26113-13-301 listed as a PAES in the Annex II; this is a randomised, open-label, multicentre phase III study comparing brigatinib versus crizotinib in patients with advanced ALK-positive NSCLC who have not previously received ALK-directed therapy; The RMP version 5.4 has also been submitted."

Galafold - migalastat - EMEA/H/C/004059/II/0034, Orphan

Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Ulla Wändel Liminga, "To update sections 4.8, 5.1 and 5.2 of the SmPC based on final results from study AT1001-020 listed as category 3 in the RMP. Study AT1001-020-is a Phase 3b, 2-stage, open-label, uncontrolled, multicenter study to evaluate the safety, pharmacokinetic, pharmacodynamic and efficacy of migalastat treatment in paediatric subjects 12 to < 18 years of age and weighing ≥ 45 kg with Fabry disease and with amenable GLA variants. The updated RMP version 7.0 has also been submitted.

The final results of study AT1001-020, which is involving paediatric patients are submitted in fulfilment of Article 46 of Regulation 1901/2006, as amended.

In addition, the MAH took the opportunity to introduce some minor editorial changes to the SmPC and Package Leaflet and bring the PI in line with the latest QRD template v. 10.2."

Imbruvica - ibrutinib - EMEA/H/C/003791/II/0068, Orphan

Janssen-Cilag International NV, Rapporteur:

Filip Josephson, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of section 4.4 of the SmPC in order to add baseline monitoring in addition to the current warnings for periodic monitoring of cardiac failure and cardiac arrhythmias in patients receiving ibrutinib. The Package Leaflet is updated accordingly. The RMP version 18.1 has also been submitted."

TOOKAD - padeliporfin - EMEA/H/C/004182/II/0015

STEBA Biotech S.A, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maia Uusküla, "C.I.11.b - Submission of the Clinical Study Report for category 1 study: Post-authorisation efficacy study (PAES): CLIN1001 PCM301FU5, A European Randomised Phase 3 Study to Assess the Efficacy and Safety of TOOKAD Soluble for Localised Prostate Cancer compared to Active Surveillance. The Annex 2 has been updated to remove reference to this study."

Trogarzo - ibalizumab - EMEA/H/C/004961/II/0015

Theratechnologies Europe Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: David Olsen, "Submission of an updated RMP version 2.0 in order to reflect the new timelines of the PROMISE study and to align the information included in the RMP with the latest PSUR. As the PROMISE study is a condition of the Trogarzo marketing authorisation, the delayed start date results in a change to Annex II of the marketing authorisation. The date for providing the final study report is changing ."

WS2127 Effentora-EMEA/H/C/000833/WS2127/ 0058

Teva B.V., Lead Rapporteur: Janet Koenig, Lead PRAC Rapporteur: Martin Huber, "To bring the RMP in line with the GVP version 2 and to update the list of safety concerns in line with the recommendation from PSUSA/00001369/201704. In addition, the outcome of PSUSA/00001369/202004 is endorsed by the MAH and the list of key messages in educational materials to include greater emphasis on explaining off-label use and its potential to lead to serious risks such as misuse, abuse and dependence are implemented. Other elements were added to

promote the safe and effective use of fentanyl rapid-onset products."

B.6.11. PRAC assessed procedures

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

PRAC Led
COVID-19 Vaccine Janssen - adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein - EMEA/H/C/005737/II/0014
Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.8 of the SmPC in order to update safety information to include lymphadenopathy, paraesthesia, hypoesthesia, diarrhea, vomiting, and tinnitus as adverse drug reactions (ADRs). This is based on the outcome of the post authorization measure MEA 014.2 (3rd Monthly Summary Safety Report). In addition, the MAH took the opportunity to add editorial changes on sections 6.4 and 6.6 of the SmPC in line with the WHO recommendations. Finally, Annex IIIA has been updated to improve readability. The Package Leaflet and Labelling are updated accordingly."

PRAC Led
Fotivda - tivozanib - EMEA/H/C/004131/II/0018
EUSA Pharma (Netherlands) B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Rugile Pilviniene, PRAC-CHMP liaison: Romaldas Mačiulaitis, "Submission of an updated RMP version 4.0 in order to include data from the phase III Study TIVO-3, a randomised, controlled, multi-centre, open-label study to compare tivozanib with sorafenib in subjects with advanced Renal Cell Carcinoma. Additional

updates to the RMP include new information from clinical studies and post-marketing exposure."

PRAC Led

Inflectra - infliximab -

EMEA/H/C/002778/II/0100/G

Pfizer Europe MA EEIG, Duplicate, Duplicate of Remsima, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final CSRs for CT-P13 registry studies in IBD, AS and RA initiated with the objective of assessing long-term safety in these indications:

• Final report for CT-P13 4.3 (EU and Korean IBD Registry)

• Final report for CT-P13 4.4 (EU and Korean AS Registry)

• Final report for BSRBR-RA Registry

• Final report for RABBIT Registry"

PRAC Led

Nivestim - filgrastim -

EMEA/H/C/001142/II/0063

Pfizer Europe MA EEIG, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 10.0 in order to update the RMP in accordance with GVP Module V and the Guidance on the format of the RMP in the EU - in integrated format (Rev. 2.0.1) and to propose deletion of selected safety concerns listed as important identified risk, important potential risk and missing information."

PRAC Led

Otezla - apremilast -

EMEA/H/C/003746/II/0038

Amgen Europe B.V., Rapporteur: Peter Kiely, PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "C.I.13 - Submission of the final study report (CSR) from PsOBest Registry, listed as a category 3 study in the RMP. This is an observational study to assess the long-term safety and effectiveness of apremilast in routine clinical practice in Germany.

The RMP version 14.0 has also been submitted."

PRAC Led

Otezla - apremilast -

EMEA/H/C/003746/II/0039

Amgen Europe B.V., Rapporteur: Peter Kiely, PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "C.I.13-Submission of the final study report (CSR) from UK Clinical Practice Research Database (CPRD), listed as a category 3 study in the RMP. This is an observational study to assess the long-term data of apremilast in patients with psoriasis and psoriatic arthritis.
The RMP version 14.0 has also been submitted."

PRAC Led

Remsima - infliximab - EMEA/H/C/002576/II/0103/G

Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final CSRs for CT-P13 registry studies in IBD, AS and RA initiated with the objective of assessing long-term safety in these indications:
• Final report for CT-P13 4.3 (EU and Korean IBD Registry)
• Final report for CT-P13 4.4 (EU and Korean AS Registry)
• Final report for BSRBR-RA Registry
• Final report for RABBIT Registry"

PRAC Led

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0028

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 2.1 to include myocarditis and pericarditis as an important identified risk, as requested by PRAC as an outcome of the myocarditis and pericarditis signal assessment procedure."

PRAC Led

Suliqua - insulin glargine / lixisenatide - EMEA/H/C/004243/II/0024

sanofi-aventis groupe, Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final Clinical Study Report of the category 3 PASS INSLIC08571, a 'Survey to evaluate the knowledge and understanding of the key safety messages in the healthcare

professional guide and the patient guide'. The provision of the final survey results addresses post-authorisation measure (PAM) MEA 002. The updated RMP version 6.0 has also been submitted."

PRAC Led

Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0173

Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Removal of the additional risk minimisation measures (aRMMs) for the PrEP indication risks, from the Truvada EU RMP and Annex II of the Truvada PI.
With this variation, version 17.2 of the RMP (dated 1st July 2021) is submitted."

PRAC Led

WS2050/G
Corlentor-EMEA/H/C/000598/WS2050/0056/G
Procoralan-EMEA/H/C/000597/WS2050/0055/G

Les Laboratoires Servier, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "To update the RMP for Procoralan and Corlentor following the assessment for the same changes approved for Ivabradine Anpharm EMEA/H/C/4187/R/014. In addition, the PI also has been updated following EMA QRD review following the same assessment. The MAH has finally also introduced changes related to QRD 10.2 in section 6 of the PL."

B.6.12. CHMP-CAT assessed procedures

Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0046, ATMP

Amgen Europe B.V., Rapporteur: Heli Suila, CHMP Coordinator: Johanna Lähteenvuo, "Submission of the final report from study 20110265 listed as an obligation in the Annex II of the Product Information. This is a Phase 1b/3, multicenter, trial of talimogene laherparepvec in combination with pembrolizumab for treatment of unresectable

stage IIIB to IVM1c melanoma. The Annex II is updated accordingly.”
Kymriah - tisagenlecleucel - EMEA/H/C/004090/II/0040, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang
Tecartus - autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - EMEA/H/C/005102/II/0012, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Zolgensma - onasemnogene abeparvovec - EMEA/H/C/004750/II/0017/G, Orphan, ATMP Novartis Gene Therapies EU Limited, Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2091 **Efficib-EMEA/H/C/000896/WS2091/0102** **Janumet-EMEA/H/C/000861/WS2091/0102** **Januvia-EMEA/H/C/000722/WS2091/0076** **Ristaben-EMEA/H/C/001234/WS2091/0069** **Ristfor-EMEA/H/C/001235/WS2091/0090** **TESAVEL-EMEA/H/C/000910/WS2091/0076** **Velmetia-EMEA/H/C/000862/WS2091/0105** **Xelevia-EMEA/H/C/000762/WS2091/0081** Merck Sharp & Dohme B.V., Lead Rapporteur: Johann Lodewijk Hillege, “To combine the SmPC

as per QRD guidance, also the Package Leaflets were combined. The marketing authorisation holder also took the opportunity to align the PI to the latest QRD template (version 10.2). In addition the details of the local representatives for BE, DE and LU were also updated."	
WS2103 **Enurev Breezhaler-EMEA/H/C/002691/WS2103/0038** **Seebri Breezhaler-EMEA/H/C/002430/WS2103/0038** **Tovanor Breezhaler-EMEA/H/C/002690/WS2103/0042** **Ultibro Breezhaler-EMEA/H/C/002679/WS2103/0040** **Ulunar Breezhaler-EMEA/H/C/003875/WS2103/0041** **Xoterna Breezhaler-EMEA/H/C/003755/WS2103/0044** Novartis Europharm Limited, Lead Rapporteur: Kirstine Moll Harboe	
WS2105/G **Corbilta-EMEA/H/C/002785/WS2105/0025/G** **Levodopa/Carbidopa/Entacapone Orion-EMEA/H/C/002441/WS2105/0033/G** **Stalevo-EMEA/H/C/000511/WS2105/0095/G** Orion Corporation, Lead Rapporteur: Outi Mäki-Ikola	
WS2122 **Aprovel-EMEA/H/C/000141/WS2122/0185** **CoAprovel-EMEA/H/C/000222/WS2122/0204** **Karvea-EMEA/H/C/000142/WS2122/0187** **Karvezide-EMEA/H/C/000221/WS2122/0204** sanofi-aventis groupe, Lead Rapporteur: Maria Concepcion Prieto Yerro	
WS2144 **Abseamed-EMEA/H/C/000727/WS2144/0095** **Binocrit-EMEA/H/C/000725/WS2144/0094** **Epoetin alfa Hexal-EMEA/H/C/000726/WS2144/0094** Sandoz GmbH, Lead Rapporteur: Alexandre	

Moreau
WS2152 **Aflunov-EMEA/H/C/002094/WS2152/0072** **Foclivia-EMEA/H/C/001208/WS2152/0069** Seqirus S.r.l, Lead Rapporteur: Armando Genazzani

B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY

B.7.1. Yearly Line listing for Type I and II variations

B.7.2. Monthly Line listing for Type I variations

B.7.3. Opinion on Marketing Authorisation transfer (MMD only)

B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)

B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)

B.7.6. Notifications of Type I Variations (MMD only)

C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD (folder E).

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

G. ANNEX G

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