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Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 31 August - 03 September 2020

Chair: Sabine Straus – Vice-Chair: Martin Huber

31 August 2020, 10:30 – 19:30, via teleconference

01 September 2020, 08:30 – 19:30, via teleconference

02 September 2020, 08:30 – 19:30, via teleconference

03 September 2020, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

17 September 2020, 09:00 – 12:00, via teleconference

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

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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, Rev. 1](#)).



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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 31 August – 03 September 2020. See September 2020 PRAC minutes (to be published post October 2020 meeting).

1.2. Agenda of the meeting on 31 August-03 September 2020

Action: For adoption

1.3. Minutes of the previous meeting on 06-09 July 2020

Action: For adoption

2. EU referral procedures for safety reasons: urgent EU procedures

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

3. EU referral procedures for safety reasons: other EU referral procedures

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.3.1. Ulipristal acetate¹ – ESMYA (CAP); NAP - EMEA/H/A-31/1496

Applicant(s): Gedeon Richter Plc.; various

PRAC Rapporteur: Annika Folin; PRAC Co-rapporteur: Menno van der Elst

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Action: For adoption of a recommendation to CHMP

3.4. Re-examination procedures²

None

3.5. Others

None

4. Signals assessment and prioritisation³

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Anastrozole (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of depressed mood disorders

Action: For adoption of PRAC recommendation

EPITT 19592 – New signal

Lead Member State(s): LV

4.1.2. Filgrastim – ACCOFIL (CAP), FILGRASTIM HEXAL (CAP), GRASTOFIL (CAP), NIVESTIM (CAP), RATIOGRASTIM (CAP), TEVAGRASTIM (CAP), ZARZIO (CAP); NAP

Applicant(s): Accord Healthcare S.L.U. (Accofil, Grastofil), AbZ Pharma GmbH (Biograstim), Pfizer Europe MA EEIG (Nivestim), Ratiopharm GmbH (Ratiograstim), Sandoz GmbH (Zarzio), Teva GmbH (Tevagrastim)

PRAC Rapporteur: To be appointed

Scope: Signal of immune reconstitution inflammatory syndrome (IRIS)

Action: For adoption of PRAC recommendation

EPITT 19587 – New signal

Lead Member State(s): FI, NL

¹ 5 mg

² Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC

³ Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

4.1.3. 3-hydroxy 3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins): atorvastatin (NAP); fluvastatin (NAP); lovastatin (NAP); pitavastatin (NAP); pravastatin (NAP); rosuvastatin (NAP); simvastatin (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of bullous pemphigoid

Action: For adoption of PRAC recommendation

EPITT 19586 – New signal

Lead Member State(s): CZ, DE, ES, FI, FR, NL

4.1.4. Pembrolizumab – KEYTRUDA (CAP)

Applicant(s): Merck Sharp & Dohme B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Signal of vasculitis

Action: For adoption of PRAC recommendation

EPITT 19578 – New signal

Lead Member State(s): NL

4.1.5. Pembrolizumab – KEYTRUDA (CAP)

Applicant(s): Merck Sharp & Dohme B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Signal of systemic scleroderma

Action: For adoption of PRAC recommendation

EPITT 19591 – New signal

Lead Member State(s): NL

4.1.6. Tofacitinib – XELJANZ (CAP)

Applicant(s): Pfizer Europe MA EEIG (Xeljanz)

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Signal of psychiatric disorders

Action: For adoption of PRAC recommendation

EPITT 19585 – New signal

Lead Member State(s): NL

4.2. New signals detected from other sources

4.2.1. Ceftriaxone (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of hepatitis

Action: For adoption of PRAC recommendation

EPITT 19603 – New signal

Lead Member State(s): LV

4.2.2. Sacubitril, valsartan – ENTRESTO (CAP); NEPARVIS (CAP)

Applicant(s): Novartis Europharm Limited

PRAC Rapporteur: Anette Kirstine Stark

Scope: Signal of psychosis and psychotic disorders

Action: For adoption of PRAC recommendation

EPITT 19600 – New signal

Lead Member State(s): DK

4.3. Signals follow-up and prioritisation

4.3.1. Abiraterone – ZYTIGA (CAP) - EMEA/H/C/002321/SDA/023

Applicant(s): Janssen-Cilag International NV

PRAC Rapporteur: Eva Segovia

Scope: Signal of anaphylactic reaction

Action: For adoption of PRAC recommendation

EPITT 19535 – Follow-up to April 2020

4.3.2. Chloroquine (NAP); hydroxychloroquine (NAP)

Applicant(s): various

PRAC Rapporteur: Anette Kirstine Stark

Scope: Signal of psychiatric disorders

Action: For adoption of PRAC recommendation

EPITT 19572 – Follow-up to June 2020

4.3.3. Fluoroquinolones:
ciprofloxacin (NAP); delafloxacin – QUOFENIX (CAP) - EMEA/H/C/004860/SDA/003;
levofloxacin – QUINSAIR (CAP) - EMEA/H/C/002789/SDA/005, NAP; lomefloxacin
(NAP); moxifloxacin (NAP); norfloxacin (NAP); ofloxacin (NAP); pefloxacin (NAP);
prulifloxacin (NAP); rufloxacin (NAP)

Applicant(s): A. Menarini Industrie Farmaceutiche Riunite (Quofenix), Chiesi Farmaceutici
S.p.A. (Quinsair), various

PRAC Rapporteur: Martin Huber

Scope: Signal of heart valve regurgitation, cervical artery dissection, and aortic aneurysm and
dissection

Action: For adoption of PRAC recommendation

EPITT 19522 – Follow-up to May 2020

4.3.4. Interferon alfa-2a (NAP); interferon alfa-2b - INTRONA (CAP) -
EMEA/H/C/000281/SDA/054; peginterferon alfa-2a – PEGASYS (CAP) -
EMEA/H/C/000395/SDA/056; peginterferon alfa-2b - PEGINTRON (CAP) -
EMEA/H/C/000280/SDA/087, VIRAFERONPEG (CAP) - EMEA/H/C/000329/SDA/084

Applicant(s): Merck Sharp & Dohme B.V. (IntronA, PegIntron, ViraferonPeg); Roche
Registration GmbH (Pegasys), various

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Signal of neuromyelitis optica spectrum disorder

Action: For adoption of PRAC recommendation

EPITT 19532 – Follow-up to March 2020

4.3.5. Paclitaxel – ABRAXANE (CAP) - EMEA/H/C/000778/SDA/030, APEALEA (CAP) -
EMEA/H/C/004154/SDA/002, PAZENIR (CAP) - EMEA/H/C/004441/SDA/002; NAP

Applicant(s): Celgene Europe BV (Abraxane), Oasmia Pharmaceutical AB (Apealea),
ratiopharm GmbH (Pazenir), various

PRAC Rapporteur: Menno van der Elst

Scope: Signal of progressive multifocal leukoencephalopathy (PML)

Action: For adoption of PRAC recommendation

EPITT 19553 – Follow-up to April 2020

4.3.6. Pomalidomide – IMNOVID (CAP) - EMEA/H/C/002682/SDA/014

Applicant(s): Celgene Europe BV

PRAC Rapporteur: Eva Segovia

Scope: Signal of progressive multifocal leukoencephalopathy (PML)

Action: For adoption of PRAC recommendation

EPITT 19546 – Follow-up to April 2020

4.3.7. Vedolizumab – ENTYVIO (CAP) - EMEA/H/C/002782/SDA/005

Applicant(s): Takeda Pharma A/S

PRAC Rapporteur: Adam Przybylkowski

Scope: Signal of Evans' syndrome, autoimmune haemolytic anaemia, immune thrombocytopenic purpura

Action: For adoption of PRAC recommendation

EPITT 19547 – Follow-up to April 2020

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Baloxavir marboxil - EMEA/H/C/004974

Scope: Treatment of influenza in patients aged 12 and above, including patients at high risk of developing influenza-related complications and for post-exposure prophylaxis of influenza in individuals aged 12

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.2. Duvelisib - EMEA/H/C/005381, Orphan

Applicant: Verastem Europe GmbH

Scope: Treatment of adult patients with relapsed or refractory chronic lymphocytic leukaemia (CLL), small lymphocytic lymphoma (SLL) and relapsed or refractory follicular lymphoma (FL)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.3. Glucagon – EMEA/H/C/005391

Scope: Treatment of severe hypoglycaemia in adults, adolescents and children aged 2 years and over with diabetes mellitus

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.4. Icosapent ethyl - EMEA/H/C/005398

Scope: Reduction of cardiovascular risk as an adjunct to statin therapy

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.5. Idecabtagene vicleucel - EMEA/H/C/004662, Orphan

Applicant: Celgene Europe BV, ATMP⁴

Scope (accelerated assessment): Treatment of multiple myeloma

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CAP and

⁴ Advanced therapy medicinal product

CHMP

5.1.6. Inclisiran – EMEA/H/C/005333

Scope: Treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.7. Netarsudil, latanoprost - EMEA/H/C/005107

Scope: Reduction of elevated intraocular pressure

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.8. Pemigatinib - EMEA/H/C/005266, Orphan

Applicant: Incyte Biosciences Distribution B.V.

Scope: Treatment of locally advanced or metastatic cholangiocarcinoma

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.9. Trastuzumab deruxtecan - EMEA/H/C/005124

Scope (accelerated assessment): Treatment of unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.2. Medicines in the post-authorisation phase – PRAC-led procedures

5.2.1. Agomelatine - THYMANAX (CAP) - EMEA/H/C/000916/WS1849/0045; VALDOXAN (CAP) - EMEA/H/C/000915/WS1849/0047

Applicant(s): Les Laboratoires Servier (Valdoxan), Servier (Ireland) Industries Ltd. (thymanax)

PRAC Rapporteur: Pernille Harg

Scope: Submission of an updated RMP (version 23.1) in order to revise the list of safety concerns, important identified and potential risks in line with revision 2 of GVP module V on 'Risk management systems'. In addition, the completed studies have been deleted and, as agreed in the conclusions of LEG 031 adopted in January 2019, the frequency of the educational material distribution is updated to once yearly

Action: For adoption of PRAC Assessment Report

5.2.2. Clofarabine - EVOLTRA (CAP) - EMEA/H/C/000613/II/0069

Applicant: Genzyme Europe BV

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of an updated RMP (version 9.0) to reflect amended information regarding the Evoltra (clofarabine) European registry programme and to remove all safety concerns from the list of important identified and potential risks and missing information in line with revision

2 of GVP module V on 'Risk management systems'

Action: For adoption of PRAC Assessment Report

5.2.3. Estrogens conjugated, bazedoxifene - DUAVIVE (CAP) - EMEA/H/C/002314/II/0024

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated RMP (version 3.0) in order to include amended study milestones and to bring the RMP in line with revision 2 of GVP module V on 'Risk management systems' and revision 2.0.1 of the guidance on the format of RMP in the EU (template)

Action: For adoption of PRAC Assessment Report

5.2.4. Gefitinib - IRESSA (CAP) - EMEA/H/C/001016/II/0033

Applicant: AstraZeneca AB

PRAC Rapporteur: Annika Folin

Scope: Submission of an updated RMP (version 11.0) in order to amend the list of safety concerns in line with revision 2 of GVP module V on 'Risk management systems' and to implement changes agreed in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00001518/201807) adopted in February 2019

Action: For adoption of PRAC Assessment Report

5.2.5. Ioflupane (¹²³I) - DATSCAN (CAP) - EMEA/H/C/000266/II/0060

Applicant: GE Healthcare B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the first RMP (version 0.1) following the introduction of a signification change to the marketing authorisation(s)

Action: For adoption of PRAC Assessment Report

5.2.6. Naloxegol - MOVENTIG (CAP) - EMEA/H/C/002810/II/0029/G

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Grouped variations consisting of the submission of an updated RMP (version 6.0) in order to: 1) update the list of safety concerns in line with revision 2 of GVP module V on 'Risk management systems'; 2) reclassify the risk of gastrointestinal (GI) perforation as requested in the conclusions of the PSUR single assessment (PSUSA) (PSUSA/00010317/201809) concluded in April 2019

Action: For adoption of PRAC Assessment Report

5.2.7. Pramipexole - MIRAPEXIN (CAP) - EMEA/H/C/000134/WS1897/0096; SIFROL (CAP) - EMEA/H/C/000133/WS1897/0087

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Anette Kirstine Stark

Scope: Submission of an updated RMP (version 12.0) as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00002491/201904) adopted in December 2019 in order to remove cardiac failure from the list of important identified risks and to amend the information on dopamine agonist withdrawal syndrome (DAWS) as an important identified risk

Action: For adoption of PRAC Assessment Report

5.3. Medicines in the post-authorisation phase – CHMP-led procedures

5.3.1. Ambrisentan - VOLIBRIS (CAP) - EMEA/H/C/000839/X/0061/G

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Eva Segovia

Scope: Grouped applications consisting of: 1) extension application to introduce a new strength (2.5 mg film-coated tablet); 2) extension of indication to include paediatric use (8 to less than 18 years). The RMP (version 9.0) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.2. Atezolizumab - TECENTRIQ (CAP) - EMEA/H/C/004143/II/0039

Applicant: Roche Registration GmbH

PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: Extension of indication to include in combination with bevacizumab the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy, based on the results of pivotal study YO40245 (IMbrave150): a phase 3, open-label, randomised study of atezolizumab in combination with bevacizumab compared with sorafenib in patients with untreated locally advanced or metastatic hepatocellular carcinoma, as well as data from arms A and F of the supportive Phase Ib study GO30140: an open-label, multicentre phase 1b study of the safety and efficacy of atezolizumab administered in combination with bevacizumab and/or other treatments in patients with solid tumours. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the Tecentriq (atezolizumab) 1200 mg concentrate for solution for infusion SmPC are updated. The package leaflet and the RMP (version 13.0) are updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.3. Avatrombopag - DOPTLET (CAP) - EMEA/H/C/004722/II/0004/G

Applicant: Dova Pharmaceuticals Ireland Limited

PRAC Rapporteur: Eva Segovia

Scope: Grouped variations consisting of: 1) extension of indication to include the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. In addition, section 5.3 of the SmPC is updated with data from juvenile toxicity studies; 2) addition of a pack size of 30 tablets with subsequent updates of sections 6.5 and 8 of the SmPC. The package leaflet, labelling and the RMP (version 2.1) are updated in

accordance. Furthermore, the product information is brought in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.4. [Avelumab - BAVENCIO \(CAP\) - EMEA/H/C/004338/II/0018](#)

Applicant: Merck Europe B.V.

PRAC Rapporteur: Hans Christian Siersted

Scope: Extension of indication to include treatment as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 2.3) are updated in accordance. The MAH took the opportunity to include some editorial changes throughout the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.5. [Beclometasone dipropionate, formoterol fumarate dihydrate, glycopyrronium - TRIMBOW \(CAP\) - EMEA/H/C/004257/X/0008/G](#)

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Grouped application consisting of: 1) extension application to introduce a new strength (172 µg / 5 µg / 9 µg); 2) update of sections 4.1, 4.2, 4.4, 5.1 and 5.2 to extend the indication to the maintenance treatment in adult patients with asthma who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or who are already treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist plus a long-acting muscarinic antagonist. The RMP (version 6.1) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.6. [Bortezomib - BORTEZOMIB ACCORD \(CAP\) - EMEA/H/C/003984/X/0023](#)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (2.5 mg/mL, solution for injection). The RMP (version 11.0) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.7. [Bosutinib - BOSULIF \(CAP\) - EMEA/H/C/002373/II/0043](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Update of section 5.3 of the SmPC in order to update non-clinical information following the final results from the six-month transgenic rasH2 mouse carcinogenicity study (listed as a category 3 study). The RMP (version 5.0) is updated accordingly. The MAH took the opportunity to implement changes in the product information in line with the European

Commission (EC) guideline on 'excipients in the labelling and package leaflet of medicinal products for human use'

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.8. [Brolucizumab - BEOVU \(CAP\) - EMEA/H/C/004913/II/0002](#)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation. The package leaflet and RMP (version 3.0) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.9. [Cholera vaccine, oral, live - VAXCHORA \(CAP\) - EMEA/H/C/003876/II/0003/G](#)

Applicant: Emergent Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Grouped variations consisting of: 1) extension of indication for the active immunisation against disease caused by *Vibrio cholerae* serogroup O1, from the currently approved age range 'adults and children aged 6 years and older' to 'adults and children aged 2 years and older'. 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 and the RMP (version 2.0) are updated in accordance; 2) update section 5.1 of the SmPC to include long-term immunogenicity data supporting Vaxchora (cholera vaccine, oral, live) effectiveness at generating a protective immune response that persists for 2 years following vaccination; based on the final results from study PXVX-VC-200-006: a randomised, double-blind, placebo-controlled trial aimed to assess the safety and immunogenicity of Vaxchora in children 2 to <18 years of age. The MAH took the opportunity to include editorial changes in the SmPC and Annex II

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.10. [Clopidogrel - ISCOVER \(CAP\) - EMEA/H/C/000175/WS1769/0140; PLAVIX \(CAP\) - EMEA/H/C/000174/WS1769/0138](#)

Applicant: Sanofi-aventis groupe

PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: Extension of indication to include adult patients with high risk transient ischemic attack (TIA) (ABCD² score ≥ 4) or minor ischemic stroke (IS) (National Institutes of Health Stroke Scale (NIHSS) ≤ 3) within 24 hours of either the TIA or IS event. The new indication is based on the results of 1) study POINT: a double-blind, randomised, placebo-controlled phase 3 study on platelet-oriented inhibition in new TIA and minor IS; 2) study CHANCE: a double-blind, randomised, placebo-controlled phase 3 study comparing the effects of a 3-month clopidogrel regimen, combined with acetylsalicylic acid (ASA) during the first 21 days, versus ASA alone for the acute treatment of TIA or minor stroke. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 1.0) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.11. [Dapagliflozin - EDISTRIDE \(CAP\) - EMEA/H/C/004161/WS1737/0034; FORXIGA \(CAP\) - EMEA/H/C/002322/WS1737/0053](#)

Applicant: AstraZeneca AB

PRAC Rapporteur: Annika Folin

Scope: Extension of indication to add a new indication for the treatment of symptomatic heart failure with reduced ejection fraction in adults. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet and labelling are updated in accordance. The RMP (version 18) is updated accordingly. Furthermore, the product information is brought in line with the latest quality review of documents (QRD) template (version 10.1). Finally, the MAH took the opportunity to introduce an editorial change in the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.12. [Darolutamide - NUBEQA \(CAP\) - EMEA/H/C/004790/II/0002](#)

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Update of section 5.1 of the SmPC in order to update efficacy information based on final overall survival (OS) results from study 17772 (ARAMIS) (listed as a post-authorisation efficacy study (PAES) in Annex II): a multinational, randomised, double-blind, placebo-controlled, phase 3 efficacy and safety study of darolutamide in men with high-risk non-metastatic castration-resistant prostate cancer. Annex II-D on 'Conditions or restrictions with regard to the safe and effective use of the medicinal product' and the RMP (version 1.1) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.13. [Deferiprone - FERRIPROX \(CAP\) - EMEA/H/C/000236/X/0145](#)

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Extension application to introduce a new pharmaceutical form (gastro-resistant tablets). The RMP (version 14.0) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.14. [Defibrotide - DEFITELIO \(CAP\) - EMEA/H/C/002393/II/0048, Orphan](#)

Applicant: Gentium S.r.l.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of the SmPC section 5.1 based on the results of study DF VOD-2013-03-REG: a multicentre, multinational, prospective observational registry to collect safety and outcome data in patients diagnosed with severe hepatic veno-occlusive disease (VOD) following hematopoietic stem cell transplantation (HSCT) and treated with Defitelio (defibrotide) or supportive care (control group). The RMP (version 8.0) is updated accordingly. In addition, the MAH took the opportunity to introduce minor amendments throughout the product information and to bring it in line with the latest Annex to the European Commission (EC) guideline on

'excipients in the labelling and package leaflet of medicinal products for human use' on sodium content. Moreover, the RMP is updated in line with the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00010086/201910) adopted in May 2020 to update the list of safety concerns

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.15. Eftrenonacog alfa - ALPROLIX (CAP) - EMEA/H/C/004142/II/0029, Orphan

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of sections 4.2, 4.8 and 5.1 of the SmPC to add information on previously untreated patients (PUPs) following the completion of study 998HB303: an open-label, multicentre evaluation of the safety and efficacy of recombinant coagulation factor IX Fc fusion protein (rFIXFc; BIIB029) in the prevention and treatment of bleeding in PUPs with severe haemophilia B (already assessed in procedure P46 006). The package leaflet and the RMP (version 12.1) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.16. Enzalutamide - XTANDI (CAP) - EMEA/H/C/002639/II/0049

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Segovia

Scope: Update of sections 4.7, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to update efficacy and safety information based on final results from study MDV3100-14 (PROSPER) (listed as a post-authorisation efficacy study (PAES) in Annex II): a phase 3, randomized, double-blind, placebo-controlled, efficacy and safety study of enzalutamide in patients with non-metastatic castration-resistant prostate cancer. The package leaflet, Annex II-D on 'Conditions or restrictions with regard to the safe and effective use of the medicinal product' and the RMP (version 14.0) are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet, to introduce few editorial updates and to bring the product information in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.17. Eravacycline - XERAVA (CAP) - EMEA/H/C/004237/X/0009

Applicant: Tetrphase Pharmaceuticals Ireland Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to add a new strength of 100 mg for eravacycline powder for concentrate for solution for infusion. The RMP (version 3.0) is updated in accordance. Additionally, the MAH took the opportunity to bring the product information in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.18. [Glecaprevir, pibrentasvir - MAVIRET \(CAP\) - EMEA/H/C/004430/X/0033/G](#)

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Grouped application consisting of: 1) extension application to introduce a new pharmaceutical form (50/20 mg coated granules in sachet); 2) extension of indication to include the treatment of children from 3 to 12 years of age for the approved Maviret (glecaprevir/pibrentasvir) 100 mg/40 mg film-coated tablets. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The package leaflet, labelling and the RMP (version 5.0) are updated accordingly. Furthermore, the product information is brought in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.19. [Human papillomavirus vaccine \[types 16, 18\] \(recombinant, adjuvanted, adsorbed\) - CERVARIX \(CAP\) - EMEA/H/C/000721/II/0110](#)

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include the prevention of head and neck cancers causally related to certain oncogenic human papillomavirus types. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 23.0) are updated in accordance. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet. Furthermore, the product information is brought in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.20. [Ipilimumab - YERVOY \(CAP\) - EMEA/H/C/002213/WS1783/0077; nivolumab - OPDIVO \(CAP\) - EMEA/H/C/003985/WS1783/0081](#)

Applicant(s): Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Extension of indication to include first-line treatment of metastatic non-small cell lung cancer (NSCLC) in adults with no epidermal growth factor receptor (EGFR) or anaplastic large-cell lymphoma kinase (ALK) positive tumour mutations for combination of Opdivo (nivolumab) and Yervoy (ipilimumab). 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. The RMPs (version 17.0 for Opdivo (nivolumab), version 27.0 for Yervoy (ipilimumab)) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.21. [Iron - VELPHORO \(CAP\) - EMEA/H/C/002705/X/0020/G](#)

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Kimmo Jaakkola

Scope: Grouped application consisting of: 1) extension application to add a new pharmaceutical form with a new strength - powder for oral suspension 125 mg, 2) extension of indication to add the use of Velphoro (iron) for the control of serum phosphorus levels in

paediatric patients 2 years of age and older with chronic kidney disease (CKD) stages 4-5 (defined by a glomerular filtration rate (GFR) <30 mL/min/1.73 m²) or with CKD on dialysis, based on the results from study PA-CL-PED-01: an open-label, randomised, active-controlled, parallel group, multicentre, phase 3 study investigating the safety and efficacy of Velphoro (iron) and calcium acetate in paediatric and adolescent CKD patients with hyperphosphataemia. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The package leaflet, labelling and the RMP (version 7.0) are updated in accordance. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet. Furthermore, the product information is brought in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.22. Ivacaftor - KALYDECO (CAP) - EMEA/H/C/002494/II/0086, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to extend the indication of Kalydeco (ivacaftor) granules in the treatment of infants aged at least 4 months, toddlers and children weighing 5 kg to less than 25 kg with cystic fibrosis who have one of the following gating (class III) mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and the RMP (version 8.9) are updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.23. Ivacaftor - KALYDECO (CAP) - EMEA/H/C/002494/X/0083/G, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Grouped variations consisting of: 1) extension application to add a new strength of 75 mg film-coated tablets of ivacaftor to enable administration to patients aged 6 to less than 11 years; 2) update of sections 4.1, 4.2 and 6.5 the SmPC for the 150 mg film-coated tablet presentations to extend the indication for use in children aged 6 to less than 11 years old in combination with tezacaftor/ivacaftor and to bring it in line with the new dosage form. The package leaflet and the RMP (version 8.6) are updated in accordance. In addition, the MAH took the opportunity to implement minor updates throughout the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.24. Levetiracetam - KEPRA (CAP) - EMEA/H/C/000277/WS1664/0187

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Laurence de Fays

Scope: Update of section 4.2 of the SmPC to recommend the same dosing for monotherapy and adjunctive therapy based on data from modelling and simulation project. The package leaflet and the RMP (version 9.1) are updated accordingly. The MAH took the opportunity to move Braille to another box section and to review and adapt the German product information

in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.25. [Methotrexate - NORDIMET \(CAP\) - EMEA/H/C/003983/II/0016](#)

Applicant: Nordic Group B.V.

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include the treatment of mild to moderate Crohn's disease either alone or in combination with corticosteroids in patients refractory or intolerant to thiopurines. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 5.0) are updated in accordance. Furthermore, the MAH took the opportunity to update the RMP in line with revision 2.0.1 of the guidance on the format of RMP in the EU (template) and the outcome of the referral procedure for methotrexate-containing products under Article 31 of Directive 2001/83/EC (EMEA/H/A-31/1463) finalised in July 2019

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.26. [Midostaurin - RYDAPT \(CAP\) - EMEA/H/C/004095/II/0014, Orphan](#)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to change posology recommendations and add special warnings and precautions for use in the paediatric population following the occurrence of severe dose limiting toxicities (DLTs) based on findings in study CPKC412A2218 (currently on clinical hold): a phase 2, open-label, single arm study to evaluate the safety, efficacy, and pharmacokinetics of twice daily midostaurin (PKC412) combined with standard chemotherapy and as a single agent post-consolidation therapy in children with untreated FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukaemia (AML). The package leaflet and the RMP (version 5.0) are updated accordingly. The MAH took the opportunity to introduce minor editorial changes in the product information and to bring it in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.27. [Niraparib - ZEJULA \(CAP\) - EMEA/H/C/004249/II/0019, Orphan](#)

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include the maintenance treatment of adult patients with advanced high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. As a consequence, sections 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 4.0) are updated in accordance. The RMP is also brought in line with revision 2.0.1 of the guidance on the format of RMP in the EU (template) and includes updated due dates for category 3 studies. Finally, the MAH took the opportunity to introduce minor corrections throughout the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.28. Nitisinone - NITISINONE MDK (CAP) - EMEA/H/C/004281/X/0007

Applicant: MendeliKABS Europe Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to add a new strength of 20 mg (hard capsule). The RMP (version 2.0) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.29. Nitisinone - ORFADIN (CAP) - EMEA/H/C/000555/II/0071

Applicant: Swedish Orphan Biovitrum International AB

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of adult patients with alkaptonuria (AKU). As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1 and 10 of the SmPC are updated. The package leaflet and the RMP (version 5.2) are updated in accordance. The RMP is also brought in line with revision 2 of GVP module V on 'Risk management systems'

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.30. Oritavancin - ORBACTIV (CAP) - EMEA/H/C/003785/II/0030

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of the final report from study 14-TMC-01 (listed as a category 3 study in the RMP): a surveillance study investigation, part of the global SENTRY antimicrobial surveillance programme platform, to monitor the activity of oritavancin against Gram-positive clinical isolates collected from U.S. and European medical centres (in fulfilment of MEA 003.4). The RMP (version 3.0) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.31. Peginterferon beta-1a - PLEGRIDY (CAP) - EMEA/H/C/002827/X/0056

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Extension application to introduce a new route of administration (intramuscular use) for the 125 µg solution for injection. The RMP (version 5.1) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.32. Pegvaliase - PALYNZIQ (CAP) - EMEA/H/C/004744/II/0007/G, Orphan

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Grouped variations consisting of an update of sections 4.4, 4.8 and 5.1 of the SmPC based on final results from: 1) study 1655-003 (listed as a category 3 study in the RMP): a long-term extension of a phase 2, open-label, dose-finding study; 2) study 165-302 (listed as

a category 3 study in the RMP): a phase 3, randomised, double-blind, placebo-controlled, four-arm, discontinuation study to evaluate executive function in adults with phenylketonuria. The RMP (version 2.0) is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes in the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.33. Pembrolizumab - KEYTRUDA (CAP) - EMEA/H/C/003820/II/0090

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Extension of indication to include in the currently approved treatment in adults of relapsed or refractory classical Hodgkin lymphoma (rrcHL) paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) following at least one prior therapy when ASCT is not a treatment option, based on the results of study KEYNOTE-204: a randomized, open-label, phase 3 trial evaluating pembrolizumab monotherapy versus brentuximab vedotin for the treatment of patients with rrcHL and supportive data from updated analysis of KEYNOTE-087 (pivotal study supporting the initial rrcHL indication): a phase 2 clinical trial of pembrolizumab in subjects with relapsed or refractory (R/R) classical Hodgkin lymphoma (cHL). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 28.1) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.34. Perampanel - FYCOMPA (CAP) - EMEA/H/C/002434/II/0047

Applicant: Eisai GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: Extension of indication to include adjunctive treatment in paediatric patients from 2 to 11 years of age in partial-onset (focal) seizures with or without secondary generalisation and primary generalised tonic-clonic seizures with idiopathic generalised epilepsy. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and the RMP (version 4.3) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.35. Pitolisant - WAKIX (CAP) - EMEA/H/C/002616/II/0023/G, Orphan

Applicant: Bioprojet Pharma

PRAC Rapporteur: Kirsti Villikka

Scope: Grouped variations consisting of an update of sections 4.2, 4.4, 4.5, 5.1 and 5.2 of the SmPC based on new clinical data from: 1) study P09-10 (HARMONY III): an open-label naturalistic pragmatic study to assess the long-term safety of pitolisant in the treatment of excessive daytime sleepiness (EDS) (with or without cataplexy) in narcolepsy; 2) study P16-02: a randomised, double-blind, active- and placebo-controlled, single-dummy, 4-way crossover study to determine the abuse potential of pitolisant compared to phentermine and placebo, in healthy, non-dependent recreational stimulant users. The proposed update also includes results of a post approval network meta-analysis which compares efficacy and safety

of multiple treatments, multi-arm studies, and multi-criteria treatment decisions. The package leaflet and the RMP (version 6.0) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.36. [Rituximab - BLITZIMA \(CAP\) - EMEA/H/C/004723/WS1893/0034; RITEMVIA \(CAP\) - EMEA/H/C/004725/WS1893/0034; TRUXIMA \(CAP\) - EMEA/H/C/004112/WS1893/0037](#)

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Hans Christian Siersted

Scope: Submission of the final clinical study report (CSR) for study CT-P10 3.4: a phase 3, randomised, parallel-group, active-controlled, double-blind study to compare efficacy and safety between CT-P10 and Rituxan (rituximab) in patients with low tumour burden follicular lymphoma (LTBFL). The RMP (version 10.1) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.37. [Rituximab - MABTHERA \(CAP\) - EMEA/H/C/000165/II/0177](#)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Hans Christian Siersted

Scope: Submission of the final clinical study report (CSR) for study WA29330 (PEMPHIX): a randomised, double-blind, double-dummy, active-comparator, multicentre study to evaluate the efficacy and safety of rituximab versus mycophenolate mofetil (MMF) in patients with pemphigus vulgaris in order to fulfil the post authorisation measure (PAM) in Annex II-D on 'Conditions or restrictions with regard to the safe and effective use of the medicinal product' following 48 week safety follow up period of the study. The RMP (version 22.0) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.38. [Rivaroxaban - XARELTO \(CAP\) - EMEA/H/C/000944/X/0074/G](#)

Applicant: Bayer AG

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Grouped applications consisting of: 1) extension application to introduce a new pharmaceutical form, granules for oral suspension, 1 mg/mL; 2) extension of indication to include treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children and adolescents aged less than 18 years following initiation of standard anticoagulation treatment for Xarelto (rivaroxaban) 15 mg and 20 mg tablets. As a consequence, sections 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The package leaflet and the RMP (version 12.1) are updated accordingly. In addition, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated for all other dose strengths (2.5/10 mg and 15/20 mg initiation packs). Furthermore, the MAH took the opportunity to update the product information with regards to sodium content in line with the Annex to the European Commission (EC) guideline on 'excipients in the labelling and package leaflet of medicinal products for human use'

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.39. Romiplostim - NPLATE (CAP) - EMEA/H/C/000942/II/0077

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Eva Segovia

Scope: Extension of indication to add the use of romiplostim in adult patients who have had immune thrombocytopenia (ITP) for ≤ 12 months and who have had an insufficient response to corticosteroids or immunoglobulins. As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and the RMP (version 20.0) are updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC. Furthermore, the product information is brought in line with the latest quality review of documents (QRD) template (version 10.1)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.40. Rucaparib - RUBRACA (CAP) - EMEA/H/C/004272/II/0020

Applicant: Clovis Oncology Ireland Limited

PRAC Rapporteur: Annika Folin

Scope: Update of sections 4.2 and 5.2 of the SmPC in order to update the information on the use of rucaparib in patients with hepatic impairment based on final results from Part I of study CO-338-078 (listed as a category 3 study in the RMP): a phase 1, open-label, parallel group study to determine the pharmacokinetics, safety and tolerability of rucaparib in patients with an advanced solid tumour and either moderate hepatic impairment or normal hepatic function. The package leaflet and the RMP (version 4.0) are updated accordingly. The MAH took the opportunity to introduce minor corrections in the SmPC, to update the list of local representatives in the package leaflet, and to bring the product information in line with the latest quality review of documents (QRD) template (version 10.1).and in line with the European Commission (EC) guideline on 'excipients in the labelling and package leaflet of medicinal products for human use'

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.41. Secukinumab - COSENTYX (CAP) - EMEA/H/C/003729/X/0059

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Segovia

Scope: Extension application to add a new strength of 300 mg (in 2 mL) solution for injection in pre-filled syringe and pre-filled pen. The RMP (version 7.0) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.42. Sodium oxybate - XYREM (CAP) - EMEA/H/C/000593/II/0076

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include adolescents and children older than 7 years to the existing indication of treatment of narcolepsy with cataplexy in adults. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet and

the RMP (version 9.0) are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.43. Tedizolid phosphate - SIVEXTRO (CAP) - EMEA/H/C/002846/II/0037

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of section 5.1 of the SmPC in order to update the description of the potential risk of emergence of drug resistance with tedizolid phosphate based on final results from study 'surveillance of tedizolid activity and resistance (STAR)' (listed as a category 3 study in the RMP); a surveillance study established in January 2014 to monitor tedizolid susceptibility activity and emergence of resistance across the US, 11 European Union countries, Russia and Turkey. The RMP (version 6.2) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.44. Teriflunomide - AUBAGIO (CAP) - EMEA/H/C/002514/X/0031/G

Applicant: Sanofi-aventis groupe

PRAC Rapporteur: Martin Huber

Scope: Grouped application consisting of: 1) extension application to add a new strength of 7 mg film-coated tablet for use in paediatric patients from 10 years of age and older with relapsing remitting multiple sclerosis (MS); 2) extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting MS for Aubagio (teriflunomide) 14 mg tablet. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet, labelling and the RMP (version 6.0) are updated in accordance. The MAH also applied for an extension of the market protection of one additional year in line with the guidance on elements required to support significant clinical benefit in comparison with existing therapies of a new therapeutic indication

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.45. Tezacaftor, ivacaftor - SYMKEVI (CAP) - EMEA/H/C/004682/X/0015/G, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Grouped variations consisting of: 1) extension application to add a new strength of 50/75 mg film-coated tablets of tezacaftor/ivacaftor to enable administration to patients aged 6 to less than 11 years; 2) update of sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.1 of the SmPC for the 100/150 mg film-coated tablet presentations to extend the indication for use in children aged 6 to less than 11 years old in combination with ivacaftor and to bring it in line with the new dosage form. The package leaflet and the RMP (version 2.1) are updated in accordance. In addition, the MAH took the opportunity to implement minor updates in the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.46. Thiotepa - TEPADINA (CAP) - EMEA/H/C/001046/X/0036

Applicant: Adienne S.r.l.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (400 mg powder and solvent for solution for infusion). The RMP (version 14) is updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.47. Ticagrelor - BRILIQUE (CAP) - EMEA/H/C/001241/II/0049

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: Extension of indication to include, in co-administration with acetylsalicylic acid (ASA), the prevention of stroke in adult patients with acute ischaemic stroke or transient ischaemic attack (TIA), based on the final results of study D5134C00003 (THALES): a phase 3, international, multicentre, randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ticagrelor and ASA compared with ASA in the prevention of stroke and death in patients with acute ischaemic stroke or transient ischaemic attack. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The package leaflet and the RMP (version 13.0) are updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.48. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/II/0025

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Submission of the final report from study A3921092 (listed as a category 3 study in the RMP): a long term, open-label extension study of tofacitinib for the treatment of adult patients with psoriatic arthritis (PsA). The RMP (version 11.1) is updated accordingly. The MAH took the opportunity to update the milestones for study A3921347: a prospective, non-interventional active surveillance study examining tofacitinib safety in ulcerative colitis (UC)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.49. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/II/0004

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Extension of indication to include the treatment of active psoriatic arthritis in adult patients. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and the RMP (version 2.0) are updated in accordance. The MAH took the opportunity to introduce minor updates to Annex II

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.50. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/II/0005

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Extension of indication to include the treatment of active ankylosing spondylitis in adult patient. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and the RMP (version 3.0) are updated in accordance. The MAH took the opportunity to introduce minor editorial changes throughout the SmPC and Annex II

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

6. Periodic safety update reports (PSURs)

6.1. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) only

6.1.1. Abatacept - ORENCIA (CAP) - PSUSA/00000013/201912

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Adalimumab - AMGEVITA (CAP); HALIMATOZ (CAP); HEFIYA (CAP); HULIO (CAP); HUMIRA (CAP); HYRIMOZ (CAP); IDACIO (CAP); IMRALDI (CAP) - PSUSA/00010783/201912

Applicant(s): Amgen Europe B.V. (Amgevita), Mylan S.A.S (Hulio), AbbVie Deutschland GmbH & Co. KG (Humira), Sandoz GmbH (Halimatoz, Hefiya, Hyrimoz), Fresenius Kabi Deutschland GmbH (Idacio), Samsung Bioepis NL B.V. (Imraldi)

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Albutrepenonacog alfa - IDELVION (CAP) - PSUSA/00010497/202001

Applicant: CSL Behring GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Apalutamide - ERLEADA (CAP) - PSUSA/00010745/202001

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Asparaginase⁵ - SPECTRILA (CAP) - PSUSA/00010445/202001

Applicant: Medac Gesellschaft für klinische Spezialpräparate mbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Atazanavir, cobicistat - EVOTAZ (CAP) - PSUSA/00010404/202001

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Baricitinib - OLUMIANT (CAP) - PSUSA/00010578/202002

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Beclometasone, formoterol, glycopyrronium bromide - RIARIFY (CAP); TRIMBOW (CAP); TRYDONIS (CAP) - PSUSA/00010617/202001

Applicant(s): Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Bictegravir, emtricitabine, tenofovir alafenamide - BIKTARVY (CAP) - PSUSA/00010695/202002

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

⁵ Centrally authorised product(s) only

6.1.10. Birch bark extract⁶ - EPISALVAN (CAP) - PSUSA/00010446/202001

Applicant: Amryt GmbH

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Botulinum toxin type A - NUCEIVA (CAP) - PSUSA/00010796/202001

Applicant: Evolus Pharma Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Brexpiprazole - RXULTI (CAP) - PSUSA/00010698/202001

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Michal Radik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Brivaracetam - BRIVIACT (CAP) - PSUSA/00010447/202001

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Budesonide⁷ - JORVEZA (CAP) - PSUSA/00010664/202001

Applicant: Dr. Falk Pharma GmbH

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Carfilzomib - KYPROLIS (CAP) - PSUSA/00010448/202001

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Evaluation of a PSUSA procedure

⁶ Centrally authorised product(s) only

⁷ Centrally authorised product(s) only

Action: For adoption of recommendation to CHMP

6.1.16. Cenegermin - OXERVATE (CAP) - PSUSA/00010624/202001

Applicant: Dompe farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Colistimethate sodium⁸ - COLOBREATHE (CAP) - PSUSA/00009112/202002

Applicant: Teva B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Dapagliflozin, metformin - EBYMECT (CAP); XIGDUO (CAP) - PSUSA/00010294/202001

Applicant(s): AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Dasabuvir - EXVIERA (CAP); ombitasvir, paritaprevir, ritonavir - VIEKIRAX (CAP) - PSUSA/00010773/202001

Applicant(s): AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Daunorubicin, cytarabine - VYXEOS LIPOSOMAL (CAP) - PSUSA/00010701/202002

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Dolutegravir - TIVICAY (CAP); dolutegravir, lamivudine - DOVATO (CAP); dolutegravir, abacavir, lamivudine - TRIUMEQ (CAP) - PSUSA/00010075/202001

Applicant(s): ViiV Healthcare B.V.

⁸ Dry inhalation powder only

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Elbasvir, grazoprevir - ZEPATIER (CAP) - PSUSA/00010519/202001

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Elosulfase alfa - VIMIZIM (CAP) - PSUSA/00010218/202002

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Eptifibatide - INTEGRILIN (CAP) - PSUSA/00001246/202001

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Etanercept - BENEPALI (CAP); ENBREL (CAP); ERELZI (CAP) - PSUSA/00010795/202002

Applicant(s): Samsung Bioepis NL B.V. (Benepali), Pfizer Europe MA EEIG (Enbrel), Sandoz GmbH (Erelzi)

PRAC Rapporteur: Eva Segovia

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Fampridine - FAMPYRA (CAP) - PSUSA/00001352/202001

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. [Glucagon⁹ - BAQSIMI \(CAP\) - PSUSA/00010826/202001](#)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. [Glycerol phenylbutyrate - RAVICTI \(CAP\) - PSUSA/00010454/202001](#)

Applicant: Immedica Pharma AB

PRAC Rapporteur: Ilaria Baldelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. [Guselkumab - TREMFYA \(CAP\) - PSUSA/00010652/202001](#)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. [Hydrocortisone¹⁰ - ALKINDI \(CAP\) - PSUSA/00010674/202002](#)

Applicant: Diurnal Europe BV

PRAC Rapporteur: Annika Folin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. [Inotersen - TEGSEDI \(CAP\) - PSUSA/00010697/202001](#)

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. [Ivacaftor - KALYDECO \(CAP\) - PSUSA/00009204/202001 \(with RMP\)](#)

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

⁹ Centrally authorised product(s) only

¹⁰ Centrally authorised product(s) for adrenal insufficiency, paediatric use only

Action: For adoption of recommendation to CHMP

6.1.33. [L-lysine hydrochloride, L-arginine hydrochloride - LYSAKARE \(CAP\) - PSUSA/00010786/202001](#)

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. [Lenvatinib - KISPLYX \(CAP\); LENVIMA \(CAP\) - PSUSA/00010380/202002](#)

Applicant(s): Eisai GmbH

PRAC Rapporteur: Annika Folin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. [Lixisenatide - LYXUMIA \(CAP\) - PSUSA/00010017/202001](#)

Applicant: Sanofi-aventis groupe

PRAC Rapporteur: Annika Folin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. [Lonococog alfa - AFSTYLA \(CAP\) - PSUSA/00010559/202001](#)

Applicant: CSL Behring GmbH

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. [Macimorelin - MACIMORELIN AETERNA ZENTARIS \(CAP\) - PSUSA/00010746/202001](#)

Applicant: Aeterna Zentaris GmbH

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. [Mercaptamine¹¹ - CYSTADROPS \(CAP\) - PSUSA/00010574/202001](#)

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Eva Segovia

¹¹ Indicated for the treatment of corneal cystine crystal deposit

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Metreleptin - MYALEPTA (CAP) - PSUSA/00010700/202001

Applicant: Amryt Pharmaceuticals DAC

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Neratinib - NERLYNX (CAP) - PSUSA/00010712/202001

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Nilotinib - TASIGNA (CAP) - PSUSA/00002162/202001

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Hans Christian Siersted

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Omalizumab - XOLAIR (CAP) - PSUSA/00002214/201912

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Annika Folin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Patisiran - ONPATTRO (CAP) - PSUSA/00010715/202002

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Phenylephrine, ketorolac - OMIDRIA (CAP) - PSUSA/00010419/202001

Applicant: Omeros Ireland Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Plerixafor - MOZOBIL (CAP) - PSUSA/00002451/201912

Applicant: Genzyme Europe BV

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - PREVENAR 13 (CAP) - PSUSA/00009263/202001

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Romosozumab - EVENITY (CAP) - PSUSA/00010824/202001

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Rufinamide - INOVELON (CAP) - PSUSA/00002671/202001

Applicant: Eisai GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. Sarilumab - KEVZARA (CAP) - PSUSA/00010609/202001

Applicant: Sanofi-aventis groupe

PRAC Rapporteur: Eva Segovia

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. Silodosin - SILODYX (CAP); UROREC (CAP) - PSUSA/00002701/202001

Applicant(s): Recordati Ireland Ltd

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. [Smallpox vaccine \(live, modified vaccinia Ankara virus\) - IMVANEX \(CAP\) - PSUSA/00010119/202001](#)

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.52. [Sorafenib - NEXAVAR \(CAP\) - PSUSA/00002773/201912](#)

Applicant: Bayer AG

PRAC Rapporteur: Annika Folin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.53. [Spheroids of human autologous matrix-associated chondrocytes - SPHEROX \(CAP\) - PSUSA/00010630/202001](#)

Applicant: CO.DON AG, ATMP¹²

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.54. [Tasimelteon - HETLIOZ \(CAP\) - PSUSA/00010394/202001](#)

Applicant: Vanda Pharmaceuticals Germany GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.55. [Tezacaftor, ivacaftor - SYMKEVI \(CAP\) - PSUSA/00010730/202002](#)

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.56. [Tipranavir - APTIVUS \(CAP\) - PSUSA/00002973/201912](#)

Applicant: Boehringer Ingelheim International GmbH

¹² Advanced therapy medicinal product

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.57. Tisagenlecleucel - KYMRIA[®] (CAP) - PSUSA/00010702/202002

Applicant: Novartis Europharm Limited, ATMP¹³

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.58. Vismodegib - ERIVEDGE (CAP) - PSUSA/00010140/202001

Applicant: Roche Registration GmbH

PRAC Rapporteur: Annika Folin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.59. Voretigene neparvovec - LUXTURNA (CAP) - PSUSA/00010742/202001

Applicant: Novartis Europharm Limited, ATMP¹⁴

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.60. Zanamivir¹⁵ - DECTOVA (CAP) - PSUSA/00010763/202001

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs)

6.2.1. Abacavir - ZIAGEN (CAP); NAP - PSUSA/00000010/201912

Applicant(s): ViiV Healthcare B.V. (Ziagen), various

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

¹³ Advanced therapy medicinal product

¹⁴ Advanced therapy medicinal product

¹⁵ Centrally authorised product(s) only

Action: For adoption of recommendation to CHMP

6.2.2. Abacavir, lamivudine - KIVEXA (CAP); NAP - PSUSA/00000011/201912

Applicant(s): ViiV Healthcare B.V. (Kivexa), various

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Abacavir, lamivudine, zidovudine - TRIZIVIR (CAP); NAP - PSUSA/00003144/201912

Applicant(s): ViiV Healthcare B.V. (Trizivir), various

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Pregabalin - LYRICA (CAP); PREGABALIN PFIZER (CAP); NAP - PSUSA/00002511/202001

Applicant(s): Upjohn EESV (Lyrica, Pregabalin Pfizer), various

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.3. PSUR single assessment (PSUSA) procedures including nationally authorised products (NAPs) only

6.3.1. 5-fluorouracil¹⁶ (NAP) - PSUSA/00010000/202001

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Alitretinoin¹⁷ (NAP) - PSUSA/00010710/202001

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

¹⁶ For topical formulation(s) only

¹⁷ For oral use only

6.3.3. [Dactylis glomerata L., Phleum pratense L., Anthoxanthum odoratum L., Lolium perenne L., Poa pratensis L.^{18 19} \(NAP\) - PSUSA/00010465/201912](#)

Applicant(s): various

PRAC Lead: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. [Amisulpride \(NAP\) - PSUSA/00000167/202001](#)

Applicant(s): various

PRAC Lead: Ronan Grimes

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. [Bendamustine hydrochloride \(NAP\) - PSUSA/00003162/202001](#)

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. [Beta-alanine \(NAP\) - PSUSA/00010510/202001](#)

Applicant(s): various

PRAC Lead: Željana Margan Koletić

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. [Bismuth, lidocaine, zinc oxide \(NAP\); lidocaine, zinc oxide \(NAP\) - PSUSA/00010621/202001](#)

Applicant(s): various

PRAC Lead: Rugilė Pilvinienė

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. [Calcium chloride, glucose, magnesium chloride hexahydrate, sodium chloride, sodium hydrogen carbonate \(NAP\) - PSUSA/00010375/201912](#)

Applicant(s): various

PRAC Lead: Melinda Palfi

¹⁸ Allergen for therapy

¹⁹ Sublingual tablet(s) only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Celiprolol (NAP) - PSUSA/00000617/202001

Applicant(s): various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Codeine camphosulphonate, sodium benzoate (NAP); codeine camphosulphonate, sulfogaiacol, grindelia²⁰ (NAP) - PSUSA/00010542/201912

Applicant(s): various

PRAC Lead: Željana Margan Koletić

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Cyanocobalamin, diclofenac, pyridoxine, thiamine (NAP) - PSUSA/00001041/202001

Applicant(s): various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Human alpha₁-proteinase inhibitor²¹ (NAP) - PSUSA/00000108/201912

Applicant(s): various

PRAC Lead: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Iopamidol (NAP) - PSUSA/00001771/201912

Applicant(s): various

PRAC Lead: Ronan Grimes

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

²⁰ Soft extract

²¹ All except centrally authorised product(s)

6.3.14. Landiolol (NAP) - PSUSA/00010570/202002

Applicant(s): various

PRAC Lead: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Levonorgestrel, ethinylestradiol; ethinylestradiol²² (NAP) - PSUSA/00010442/202001

Applicant(s): various

PRAC Lead: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Lidocaine, phenazone (NAP) - PSUSA/00002359/202001

Applicant(s): various

PRAC Lead: Rugilè Pilviniené

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.17. Metamizole sodium, triacetonamine tosilate (NAP) - PSUSA/00001999/202001

Applicant(s): various

PRAC Lead: Maria Popova-Kiradjieva

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Omega-3-acid ethyl esters (NAP) - PSUSA/00010312/202001

Applicant(s): various

PRAC Lead: Ilaria Baldelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Phenylephrine²³ (NAP) - PSUSA/00010402/202001

Applicant(s): various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

²² Combination pack only

²³ Ophthalmic formulation(s) only

Action: For adoption of recommendation to CMDh

6.3.20. Sertindole (NAP) - PSUSA/00002695/202001

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Sodium benzoate, grindelia²⁴, polygala²⁵ (NAP) - PSUSA/00010543/201912

Applicant(s): various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Tizanidine (NAP) - PSUSA/00002977/201912

Applicant(s): various

PRAC Lead: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Varicella-zoster immunoglobulin (NAP) - PSUSA/00010266/201912

Applicant(s): various

PRAC Lead: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Baricitinib - OLUMIANT (CAP) - EMEA/H/C/004085/LEG 011

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Detailed review of cases with potential increase of immunosuppression-related serious infections, opportunistic infections and varicella-zoster infections when baricitinib is used in combination with other rheumatoid arthritis (RA) drugs as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00010578/201908) adopted in March 2020

Action: For adoption of advice to CHMP

²⁴ Tincture

²⁵ Syrup

6.4.2. Choriogonadotropin alfa - OVITRELLE (CAP) - EMEA/H/C/000320/LEG 055

Applicant: Merck Europe B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Detailed review of criteria for classification of events as 'non-reactions' and methodology for causality assessment as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00000736/201909) adopted in April 2020

Action: For adoption of advice to CHMP

6.4.3. Natalizumab - TYSABRI (CAP) - EMEA/H/C/000603/LEG 070.1

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: MAH's response to LEG 070 [analyses of cumulative data on pregnancy including foetal outcomes as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00002127/201908) adopted in February 2020] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Vismodegib - ERIVEDGE (CAP) - EMEA/H/C/002602/II/0046

Applicant: Roche Registration GmbH

PRAC Rapporteur: Annika Folin

Scope: Submission of an update of the educational materials as part of the pregnancy prevention programme in line with the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00010140/201901) finalised in September 2019. Annex II-D on 'Conditions or restrictions with regard to the safe and effective use of the medicinal product' and the RMP (version 14.0) are updated accordingly. Furthermore, section 4.4 of the SmPC is updated to remove the warning on cutaneous squamous cell carcinoma. Finally, the MAH took the opportunity to update the package leaflet to implement the statement on 'sodium' content in accordance with the European Commission (EC) guideline on 'excipients in the labelling and package leaflet of medicinal products for human use'

Action: For adoption of PRAC Assessment Report

6.6. Expedited summary safety reviews²⁶

6.6.1. Remdesivir - VEKLURY (CAP) - EMEA/H/C/005622/MEA 017

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Eva Jirsová

Scope: Third expedited monthly summary safety report for remdesivir for July 2020 including

²⁶ Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC

spontaneously reported data and data from compassionate use and expanded access programmes for the duration of the coronavirus disease (COVID-19) pandemic

Action: For adoption of PRAC Assessment Report

6.6.2. [Remdesivir - VEKLURY \(CAP\) - EMEA/H/C/005622/MEA 017.1](#)

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Eva Jirsová

Scope: Fourth expedited monthly summary safety report for remdesivir for August 2020 including spontaneously reported data and data from compassionate use and expanded access programmes for the duration of the coronavirus disease (COVID-19) pandemic

Action: For adoption of PRAC Assessment Report

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)²⁷

7.1.1. [Blinatumomab – BLINCYTO \(CAP\) - EMEA/H/C/PSA/S/0057](#)

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Amendment to a protocol previously agreed in February 2020 for study 20180130: an observational PASS to describe the long-term safety profile of first-relapse B-precursor acute lymphocytic leukaemia (ALL) paediatric patients who have been treated with blinatumomab or chemotherapy prior to undergoing haemopoietic stem cell transplant (HSCT)

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.2. [Hydroxyethyl starch \(HES\) \(NAP\) - EMEA/H/N/PSA/J/0056](#)

Applicant(s): Fresenius Kabi (Volulyte, Voluven), B. Braun Melsungen AG (Tetraspan, Venofundin)

PRAC Rapporteur: Adrien Inoubli

Scope: Amendment to a joint protocol previously agreed in June 2019 for a retrospective, multinational, drug utilisation study (DUS) to assess the non-adherence of physicians in hydroxyethyl starch (HES) accredited hospitals to the approved European product information regarding indication for use, contraindications and posology (dosage) for HES 130-containing medicinal products in clinical routine after implementation of a set of risk minimisation measures, as required in the outcome of the referral procedure under Article 107i of Directive 2001/83/EC for HES completed in 2018 (EMEA/H/A-107i/1457)

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.3. [Valproate \(NAP\) - EMEA/H/N/PSA/J/0059](#)

Applicant(s): Sanofi-Aventis Recherche & Développement (on behalf of a consortium)

²⁷ In accordance with Article 107n of Directive 2001/83/EC

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Amendment to a joint protocol previously agreed in February 2020 for a joint survey among healthcare professionals (HCP) to assess the knowledge of HCP and behaviour with regard to the pregnancy prevention programme (PPP), the receipt/use of direct healthcare professional communication (DHPC) and educational materials as well as for a survey among patients to assess the knowledge of patients with regards to PPP and receipt/use of educational materials, as required in the outcome of the referral procedure under Article 31 of Directive 2001/83/EC on valproate-containing products completed in February 2018 (EMA/H/A-31/1454)

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)²⁸

7.2.1. Botulinum toxin type A - NUCEIVA (CAP) - EMA/H/C/004587/MEA 002.1

Applicant: Evolus Pharma Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: MAH's response to MEA 002 [protocol for study EV-010: a non-interventional post-authorisation safety study of Nuceiva (botulinum toxin type A) for the treatment of moderate-to-severe glabellar lines] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.2. Cannabidiol - EPIDYOLEX (CAP) - EMA/H/C/004675/MEA 007

Applicant: GW Pharma (International) B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Protocol for study GWEP19022 (listed as a category 3 study in the RMP): a long-term safety study to assess the potential for chronic liver injury in patients treated with Epidyolex (cannabidiol oral solution)

Action: For adoption of advice to CHMP

7.2.3. Dibotermin alfa - INDUCTOS (CAP) - EMA/H/C/000408/LEG 074.3

Applicant: Medtronic BioPharma B.V.

PRAC Rapporteur: Menno van der Elst

Scope: MAH's response to LEG 074.2 [protocol for a cross-sectional study to evaluate the effectiveness of additional risk minimisation measures: a survey amongst physicians to assess their knowledge and understanding of selected risks of Inductos (dibotermin alfa) in Europe] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

²⁸ In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

7.2.4. Dimethyl fumarate - TECFIDERA (CAP) - EMEA/H/C/002601/MEA 008.4

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: MAH's response to MEA 008.3 [protocol for study 109MS402: Biogen multiple sclerosis (MS) pregnancy exposure registry to prospectively evaluate pregnancy outcomes in women with MS who were exposed to a registry-specified Biogen MS product during the eligibility window for that product] as per the request for supplementary information (RSI) adopted at the November 2019²⁹ PRAC meeting, together with the fourth annual progress report for study 109MS402

Action: For adoption of advice to CHMP

7.2.5. Hydroxycarbamide - XROMI (CAP) - EMEA/H/C/004837/MEA 002

Applicant: Nova Laboratories Ireland Limited

PRAC Rapporteur: Laurence de Fays

Scope: Protocol for a healthcare professional (HCP) survey to assess HCPs' understanding of the content of the educational materials distributed as an additional risk minimisation measure (RMM) [final study report expected 8-12 months after the protocol approval] (from initial marketing authorisation/opinion)

Action: For adoption of advice to CHMP

7.2.6. Idelalisib - ZYDELIG (CAP) - EMEA/H/C/003843/MEA 015.4

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Martin Huber

Scope: Amendment to protocol previously agreed in January 2018 together with interim results for study GS-EU-313-4172: a non-interventional study to assess the safety profile of idelalisib in patients with refractory follicular lymphoma (FL)

Action: For adoption of advice to CHMP

7.2.7. Infliximab - REMSIMA (CAP) - EMEA/H/C/002576/MEA 020.1

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: MAH's response to MEA 020 [protocol for study CT-P13 4.8: an observational, prospective cohort study to evaluate the safety of Remsima (infliximab) subcutaneous in patients with rheumatoid arthritis (RA)] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.8. Inotersen - TEGSEDI (CAP) - EMEA/H/C/004782/MEA 001.4

Applicant: Akcea Therapeutics Ireland Limited

²⁹ Held 29-31 October 2019

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 001.3 [protocol for a long-term observational study to evaluate and further characterize the events of thrombocytopenia, glomerulonephritis and retinal toxicity/eye disease related to vitamin A deficiency when Tegsedi (inotersen) is prescribed in normal clinical practice, consisting of a protocol for a cohort of inotersen-exposed patients (TEG4001) and a protocol for an external comparator cohort (TEG4003)] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

7.2.9. Inotersen - TEGSEDI (CAP) - EMEA/H/C/004782/MEA 002.4

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 002.3 [protocol for study TEG4002: a retrospective chart review for evaluating adherence to and effectiveness of the proposed platelet monitoring schedule, proposed cut-off points, dose adaptation, and initiation of corticosteroids on thrombocyte recovery] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

7.2.10. Ipilimumab - YERVOY (CAP) - EMEA/H/C/002213/MEA 036.3

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Menno van der Elst

Scope: MAH's response to MEA 036.2 [amendment to protocol previously agreed in November 2018 for study CA184-557: extension of the long-term follow-up of ipilimumab in the Dutch melanoma treatment registry (DMTR) to include paediatric subjects and collect safety data to obtain additional safety information in paediatric patients] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.11. Naldemedine - RIZMOIC (CAP) - EMEA/H/C/004256/MEA 001.2

Applicant: Shionogi B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 001.1 [protocol for an observational PASS of patients with chronic opioid use for non-cancer and cancer pain who have opioid-induced constipation (OIC) [final clinical study report (CSR) expected in January 2026]] as per the request for supplementary information (RSI) adopted in May 2020

Action: For adoption of advice to CHMP

7.2.12. Neratinib - NERLYNX (CAP) - EMEA/H/C/004030/MEA 002.2

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Menno van der Elst

Scope: MAH's response to MEA 002.1 [protocol for study PUMA-NER-6202: a randomised study to characterise the incidence and severity of diarrhoea in patients with early stage epidermal growth factor receptor 2 + (HER2+) breast cancer treated with neratinib and intensive loperamide prophylaxis versus neratinib and intensive loperamide prophylaxis plus a bile acid sequestrant in the first month of treatment [final study results expected in December 2021]] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.13. Netarsudil - RHOKIINSA (CAP) - EMEA/H/C/004583/MEA 001

Applicant: Aerie Pharmaceuticals Ireland Ltd

PRAC Rapporteur: Eva Segovia

Scope: Protocol for study AR-13324-OBS02: a non-interventional, observational cohort study to investigate the long-term safety of netarsudil beyond 12 months treatment [final clinical study report (CSR) expected in June 2026] (from opinion/initial marketing authorisation)

Action: For adoption of advice to CHMP

7.2.14. Osilodrostat - ISTURISA (CAP) - EMEA/H/C/004821/MEA 003

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Eva Segovia

Scope: Protocol for a registry: a multi-country, observational study to collect clinical information on patients with endogenous Cushing's syndrome treated with osilodrostat and to document the long-term safety [final study results expected in December 2027] (from initial marketing authorisation/opinion)

Action: For adoption of advice to CHMP

7.2.15. Patisiran - ONPATTRO (CAP) - EMEA/H/C/004699/MEA 003

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Protocol for non-interventional study ALN-TTR02-010: patisiran-lipid nanoparticle (LNP) observational pregnancy surveillance programme

Action: For adoption of advice to CHMP

7.2.16. Pegvaliase - PALYNZIQ (CAP) - EMEA/H/C/004744/MEA 003.1

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 003 [protocol for study 165-501: a multicentre, prospective global observational study to evaluate the long term safety of subcutaneous injections of pegvaliase in patients with phenylketonuria [final clinical study report (CSR) expected in Q2 2030]] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.17. Pegvaliase - PALYNZIQ (CAP) - EMEA/H/C/004744/MEA 005.1

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 005 [protocol for study 165-504: a prospective global multicentre observational safety surveillance study to assess maternal, foetal and infant outcomes of exposure to Palynziq (pegvaliase) during pregnancy and breastfeeding [final clinical study report (CSR) expected in Q2 2030]] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.18. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - MOSQUIRIX (Art 58³⁰) - EMEA/H/W/002300/MEA 003.2

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: Amended protocol previously agreed in May 2018 for study EPI-MAL-003 (listed as a category 3 study in the RMP): a phase 4 prospective observational study to evaluate the safety, effectiveness and impact of Mosquirix (plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)) in young children in sub-Saharan Africa in order to estimate the incidence of potential adverse events of special interest (AESI) and other adverse events leading to hospitalisation or death, in children vaccinated with the vaccine

Action: For adoption of advice to CHMP

7.2.19. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 001.2

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: MAH's response to MEA 001.1 [protocol for study P19-633: a post-marketing registry-based prospective cohort study of long-term safety of risankizumab in real world setting in Denmark and Sweden [final study report expected in December 2031]] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.2.20. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 002.2

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: MAH's response to MEA 002.1 [protocol for study P16-751 on pregnancy exposures and outcomes in psoriasis patients treated with risankizumab: a cohort study utilising large healthcare databases with mother-baby linkage in the United States [final study report expected in Q3 2026] (from initial opinion/marketing authorisation)] as per the request for supplementary information (RSI) adopted in March 2020

³⁰ Article 58 of Regulation (EC) No 726/2004 allows the Committee for Medicinal Products for Human Use (CHMP) to give opinions, in co-operation with the World Health Organisation (WHO) on medicinal products for human use that are intended exclusively for markets outside of the European Union (EU)

Action: For adoption of advice to CHMP

7.2.21. Romiplostim - NPLATE (CAP) - EMEA/H/C/000942/MEA 003.7

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Eva Segovia

Scope: Amendment to a protocol previously agreed in December 2012 for post-marketing surveillance study 20070797: a population based prospective study evaluating the short and long term safety of romiplostim treatment in real-life clinical practice in adult patients with chronic idiopathic (immune) thrombocytopenic purpura (ITP) based on national health registry systems in Denmark, Sweden, and Norway (Nordic Country Patient Registry for Romiplostim [NCPRR])

Action: For adoption of advice to CHMP

7.2.22. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 001.1

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Adrien Inoubli

Scope: MAH's response to MEA 001 [protocol for study OP0005: a European non-interventional PASS to study the adherence to the risk minimisation measures (RMMs) in the product information by estimating the compliance with contraindications and target indication(s) amongst incident romosozumab users, and analysing the utilisation pattern using the EU-adverse drug reactions (EU-ADR) Alliance [final study results expected in March 2026]] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

7.2.23. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 002.1

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Adrien Inoubli

Scope: MAH's response to MEA 002 [Protocol for study OP0004: a European non-interventional PASS to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions using the EU-adverse drug reactions (EU-ADR) Alliance [final study results expected in December 2026]] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

7.2.24. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 003.1

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Adrien Inoubli

Scope: MAH's response to MEA 003 [protocol for study OP0006: a European non-interventional PASS to evaluate potential differences in terms of serious infection between romosozumab and currently available therapies used in comparable patients in real-world

conditions using the EU-adverse drug reactions (EU-ADR) Alliance [final study results expected in December 2024]] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

7.2.25. Ropeginterferon alfa-2b - BESREMI (CAP) - EMEA/H/C/004128/MEA 001.3

Applicant: AOP Orphan Pharmaceuticals AG

PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva

Scope: MAH's response to MEA 001.2 [protocol for EUPAS29462 study: a prospective, multicentre, non-interventional observational PASS to further investigate the safety and tolerability of ropeginterferon alfa-2b in polycythaemia vera patients with a special focus on hepatotoxicity to evaluate the effectiveness of risk minimisation measures and to evaluate cardiovascular safety during titration phase [final study report expected in Q3 2023]] as per the request for supplementary information (RSI) adopted April 2020

Action: For adoption of advice to CHMP

7.2.26. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 047

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Rhea Fitzgerald

Scope: Protocol for study SWIBREG-UST UC: an observational PASS to describe the safety of ustekinumab and other ulcerative colitis treatments in a cohort of patients with ulcerative colitis using the Swedish Inflammatory Bowel Disease Register (SWIBREG) as requested in the conclusions of variation II/071 finalised in July 2019 [final clinical study report (CSR) expected in May 2027]

Action: For adoption of advice to CHMP

7.2.27. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 048

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Rhea Fitzgerald

Scope: Protocol for study SNDS-UST UC: an observational PASS to describe the safety of ustekinumab and other ulcerative colitis treatments in a cohort of patients with ulcerative colitis using the French administrative healthcare database (SNDS³¹) as requested in the conclusions of variation II/071 finalised in July 2019 [final clinical study report (CSR) expected in May 2027]

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)³²

None

³¹ Système National des Données de Santé

³² In accordance with Article 107p-q of Directive 2001/83/EC

7.4. Results of PASS non-imposed in the marketing authorisation(s)³³

7.4.1. Bazedoxifene - CONBRIZA (CAP) - EMEA/H/C/000913/II/0052

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Submission of the final clinical study report (CSR) for study B1781044 (listed as a category 3 study in the RMP): a study to estimate the incidence and to compare the risks of endometrial hyperplasia and endometrial cancer in postmenopausal women initiating either Duavive (estrogens conjugated/bazedoxifene) or estrogen + progestin (E+P) combination hormone replacement therapy (HRT)

Action: For adoption of PRAC Assessment Report

7.4.2. Concentrate of proteolytic enzymes enriched in bromelain - NEXOBRID (CAP) - EMEA/H/C/002246/II/0047, Orphan

Applicant: MediWound Germany GmbH

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report from study MW2013-06-01 (listed as a category 3 study in the RMP): an international, observational retrospective, data-collection study assessing efficacy of applied risk-minimisation measures in burn patients treated with NexoBrid (concentrate of proteolytic enzymes enriched in bromelain). The RMP (version 7.0) is updated accordingly. In addition, the MAH took the opportunity to bring the RMP in line with revision 2 of GVP module V on 'Risk management systems' and to change the due dates for: 1) study MW2013-06-01 (listed as a category 3 study in the RMP): a drug utilisation study (DUS) for further evaluation of the effectiveness of the risk minimisation activities; 2) study MW2010-03-02 (DETECT) (listed as a category 3 study in the RMP): a multicentre, multinational, randomized, controlled, open-label study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) as compared to standard of care (SOC) treatment

Action: For adoption of PRAC Assessment Report

7.4.3. Deferasirox - EXJADE (CAP) - EMEA/H/C/000670/II/0068

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report related to the physician survey (NO6987) conducted for Exjade (deferasirox) to assess the impact of educational materials on the prescribers' awareness of doses and biological monitoring recommendations and to assess the awareness and appropriate use of both formulations (dispersible tablets and film-coated tablets). The RMP (version 17.1) is updated accordingly

Action: For adoption of PRAC Assessment Report

³³ In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

7.4.4. [Dolutegravir, rilpivirine - JULUCA \(CAP\) - EMEA/H/C/004427/WS1810/0028; dolutegravir - TIVICAY \(CAP\) - EMEA/H/C/002753/WS1810/0061; dolutegravir, abacavir, lamivudine - TRIUMEQ \(CAP\) - EMEA/H/C/002754/WS1810/0082](#)

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report for study 201177 (EuroSIDA) (listed as a category 3 study in the RMP): a prospective observational cohort study to monitor and compare the occurrence of hypersensitivity reactions (HSR) and hepatotoxicity in patients receiving dolutegravir (with or without abacavir) and other integrase inhibitors (with or without abacavir)

Action: For adoption of PRAC Assessment Report

7.4.5. [Duloxetine - CYMBALTA \(CAP\) - EMEA/H/C/000572/WS1879/0084; DULOXETINE LILLY \(CAP\) - EMEA/H/C/004000/WS1879/0021; YENTREVE \(CAP\) - EMEA/H/C/000545/WS1879/0069](#)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the results of study F1J-MC-B034: an observational pregnancy registry to monitor women exposed to duloxetine during pregnancy. As a consequence, the RMP (version 14.0) is updated accordingly

Action: For adoption of PRAC Assessment Report

7.4.6. [Estrogens conjugated, bazedoxifene - DUAVIVE \(CAP\) - EMEA/H/C/002314/II/0025](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Submission of the final clinical study report (CSR) for study B2311061 (listed as a category 3 study in the RMP): a non-interventional EU drug utilisation study (DUS) to describe baseline characteristics and utilisation patterns of EU patients initiating Duavive (estrogens conjugated/bazedoxifene) or oestrogen + progestin (E+P) combination hormone replacement therapy (HRT) (in fulfilment of MEA 003)

Action: For adoption of PRAC Assessment Report

7.4.7. [Lenvatinib - KISPLYX \(CAP\) - EMEA/H/C/004224/WS1861/0037/G; LENVIMA \(CAP\) - EMEA/H/C/003727/WS1861/0037/G](#)

Applicant: Eisai GmbH

PRAC Rapporteur: Annika Folin

Scope: Grouped variations consisting of: 1) submission of the final clinical study report (CSR) for study E7080-G000-201 (study 201): evaluation of the long-term safety of lenvatinib in medullary and iodine-131 refractory, unresectable differentiated thyroid carcinoma (DTC) stratified by histology (in fulfilment of MEA 001 for Lenvima (lenvatinib), and from initial opinion/marketing authorisation for Kisplyx (lenvatinib)); 2) submission of the final CSR for study E7080-G000-303 (study 303): evaluation of the long-term safety of lenvatinib in

patients with radioiodine refractory differentiated thyroid cancer (RR-DTC) in a randomized, double-blind, placebo-controlled phase 3 study (in fulfilment of MEA 004 for Lenvima (lenvatinib) and MEA 002 for Kisplyx (lenvatinib)); 3) submission of an updated integrated summary of safety (ISS) including data from DTC subjects in study 201, study 303 and study E7080-J081-208 (study 208): long-term safety profile of lenvatinib in Japanese patients with advanced thyroid cancer. The RMP (version 12) is updated accordingly

Action: For adoption of PRAC Assessment Report

7.4.8. [Meningococcal group B vaccine \(recombinant, component, adsorbed\) - BXSERO \(CAP\) - EMEA/H/C/002333/II/0092](#)

Applicant: GSK Vaccines S.r.l

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of the final report from study V72_38OB (listed as a category 3 study in the RMP): an observational study conducted by Public Health England (PHE) to assess Bexsero (meningococcal group B vaccine (recombinant, component, adsorbed)) effectiveness and impact in infants in the UK upon introduction of the vaccine in the infant National Immunisation Programme (NIP) administered at 2, 4 and 12 months of age. The RMP (version 8.0) is updated accordingly

Action: For adoption of PRAC Assessment Report

7.4.9. [Meningococcal group B vaccine \(recombinant, component, adsorbed\) - BXSERO \(CAP\) - EMEA/H/C/002333/II/0093](#)

Applicant: GSK Vaccines S.r.l

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of the final report from study V72_82OB (listed as a category 3 study in the RMP): an observational study on the safety of Bexsero (meningococcal group B vaccine (recombinant, component, adsorbed)) in pregnant women and their offspring to evaluate pregnancy outcomes among women immunised with the vaccine within 30 days prior to the last menstrual period (LMP) or at any time during pregnancy. The RMP (version 8.0) is updated accordingly

Action: For adoption of PRAC Assessment Report

7.4.10. [Nitisinone - ORFADIN \(CAP\) - EMEA/H/C/000555/II/0074](#)

Applicant: Swedish Orphan Biovitrum International AB

PRAC Rapporteur: Amelia Cupelli

Scope: Submission of the final report from study Sobi.NTBC-005 (listed as a category 3 study in the RMP): a non-interventional PASS to evaluate the long-term safety of Orfadin (nitisinone) treatment in hereditary tyrosinaemia type 1 (HT-1) patients in standard clinical care. The RMP (version 5.3) is updated accordingly

Action: For adoption of PRAC Assessment Report

7.4.11. Rasagiline - AZILECT (CAP) - EMEA/H/C/000574/WS1749/0084; RASAGILINE RATIOPHARM (CAP) - EMEA/H/C/003957/WS1749/0016

Applicant: Teva B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Submission of the final report from study TV1030-CNS-50024 (listed as a category 3 study in the RMP): a non-interventional retrospective cohort study which was conducted using the United States Medicare research database to assess the potential risk of melanoma associated with the use of rasagiline mesylate in patients with Parkinson's disease

Action: For adoption of PRAC Assessment Report

7.4.12. Susoctocog alfa - OBIZUR (CAP) - EMEA/H/C/002792/II/0034

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Submission of the final report for the survey among healthcare professionals (HCPs) to assess their knowledge on dosing and administration of Obizur (susoctocog alfa) in 6 European countries

Action: For adoption of PRAC Assessment Report

7.5. Interim results of imposed and non-imposed PASS submitted before the entry into force of the revised variation regulation

7.5.1. Alirocumab - PRALUENT (CAP) - EMEA/H/C/003882/MEA 017.6

Applicant: Sanofi-aventis groupe

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: MAH's response to MEA 017.5 [third interim report for study ALIROC07997: a non-interventional safety study using healthcare databases to monitor the safety of Praluent (alirocumab) in patients affected with human immunodeficiency virus (HIV)] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.5.2. Apremilast - OTEZLA (CAP) - EMEA/H/C/003746/MEA 008

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Eva Segovia

Scope: Yearly report for study CC 10004 PSA-012: evaluation of the long-term safety and safety outcomes for psoriatic arthritis patients treated with Otezla (apremilast) in the British Society for Rheumatology Psoriatic Arthritis Register (BSRBR-PsA)

Action: For adoption of advice to CHMP

7.5.3. Brodalumab - KYNTHEUM (CAP) - EMEA/H/C/003959/MEA 002.4

Applicant: LEO Pharma A/S

PRAC Rapporteur: Eva Segovia

Scope: Interim report for study NIS-KYNTHEUM-1345: an observational PASS investigating the risk of suicidal behaviour, serious infections, major adverse cardiovascular events (MACE) and malignancy in psoriasis patients treated with brodalumab. The brodalumab assessment of hazards: a multinational safety (BRAHMS) study in electronic healthcare databases [final report expected in Q3 2030]

Action: For adoption of advice to CHMP

7.5.4. Empagliflozin - JARDIANCE (CAP) - EMEA/H/C/002677/MEA 002.10

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Eva Segovia

Scope: Second annual progress report for study 1245.96: an observational cohort study using existing data assessing the risks of acute liver injury, acute kidney injury and chronic kidney disease, severe complications of urinary tract infection, genital infection, and diabetic ketoacidosis in patients with type 2 diabetes mellitus (T2DM) treated with empagliflozin compared with patients treated with other sodium-glucose cotransporter-2 (SGLT2) inhibitors or with dipeptidyl peptidase-4 (DPP-4) inhibitors [final clinical study report (CSR) expected in Q3 2021]

Action: For adoption of advice to CHMP

7.5.5. Empagliflozin - JARDIANCE (CAP) - EMEA/H/C/002677/MEA 010.3

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Eva Segovia

Scope: Fourth monitoring interim report for study 1245.97: a non-interventional PASS assessing the risk of urinary tract malignancies in relation to empagliflozin exposure in patients with type 2 diabetes mellitus (T2DM): a multi-database European study [final clinical study report (CSR) expected in June 2021]

Action: For adoption of advice to CHMP

7.5.6. Empagliflozin, metformin - SYNJARDY (CAP) - EMEA/H/C/003770/MEA 003.7

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Eva Segovia

Scope: Second annual progress report for study 1245.96: an observational cohort study using existing data assessing the risks of acute liver injury, acute kidney injury and chronic kidney disease, severe complications of urinary tract infection, genital infection, and diabetic ketoacidosis in patients with type 2 diabetes mellitus (T2DM) treated with empagliflozin compared with patients treated with other sodium-glucose cotransporter-2 (SGLT2) inhibitors or with dipeptidyl peptidase-4 (DPP-4) inhibitors [final clinical study report (CSR) expected in Q3 2021]

Action: For adoption of advice to CHMP

7.5.7. Empagliflozin, metformin - SYNJARDY (CAP) - EMEA/H/C/003770/MEA 006.5

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Eva Segovia

Scope: Fourth monitoring interim report for study 1245.97: a non-interventional PASS assessing the risk of urinary tract malignancies in relation to empagliflozin exposure in patients with type 2 diabetes mellitus (T2DM): a multi-database European study [final clinical study report (CSR) expected in June 2021]

Action: For adoption of advice to CHMP

7.5.8. Hydrocortisone - PLENADREN (CAP) - EMEA/H/C/002185/MEA 009.3

Applicant: Shire Services BVBA

PRAC Rapporteur: Annika Folin

Scope: Interim report for study SHP617-400 (EU AIR): a non-interventional (PASS) registry study: A European multicentre, multi-country, post-authorisation observational study (registry) of patients with chronic adrenal insufficiency

Action: For adoption of advice to CHMP

7.5.9. Nomegestrol acetate, estradiol - ZOELY (CAP) - EMEA/H/C/001213/ANX 011.6

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Adrien Inoubli

Scope: MAH's response to ANX 011.5 [fourth interim report for study P08291 (PRO-E2): a prospective observational controlled cohort study to assess the risk of venous thromboembolic events (VTE) and arterial thromboembolic events (ATE) in nomegestrel/estradiol users compared with the VTE risk in users of combined oral contraceptives containing levonorgestrel (as imposed in accordance with Article 10(a) of Regulation (EC) No 726/2004)] as per the request for supplementary information (RSI) adopted in May 2020

Action: For adoption of advice to CHMP

7.5.10. Ospemifene - SENSHIO (CAP) - EMEA/H/C/002780/ANX 001.9

Applicant: Shionogi B.V.

PRAC Rapporteur: Kirsti Villikka

Scope: Fifth annual interim report for a PASS (ENCEPP/SDPP/8585) (listed as a category 1 study in Annex II and the RMP): an observational retrospective cohort study of ospemifene utilising existing databases in Germany, Italy, Spain, and the United States to evaluate the incidence of venous thromboembolism and other adverse events in vulvar and vaginal atrophy (VVA) patients treated with ospemifene as compared to: 1) patients newly prescribed selective oestrogen receptor modulators (SERM) for oestrogen-deficiency conditions or breast cancer prevention and; 2) the incidence in untreated VVA patients [final report expected in February 2021]

Action: For adoption of advice to CHMP

7.5.11. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - MOSQUIRIX (Art 58³⁴) - EMEA/H/W/002300/MEA 002.3

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: Scientific Opinion Holder (SOH)'s response to MEA 002.2 [interim result for study EPI-MAL-002: a prospective study to estimate the incidence of diseases specified as adverse events of special interest (AESI) leading to hospitalisation or death, and of meningitis in infants and young children in sub-Saharan Africa prior to implementation of Mosquirix (RTS, S/AS01E) [final clinical study report due in December 2022]] as per the request for supplementary information (RSI) adopted in February 2020

Action: For adoption of advice to CHMP

7.5.12. Selexipag - UPTRAVI (CAP) - EMEA/H/C/003774/MEA 003.2

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Adrien Inoubli

Scope: Interim/progress report for study AC-065A403 (EDUCATE) (listed a category 3 study in the RMP): evaluation of the risk minimisation measures for medication errors with Uptravi during the titration phase in patients with pulmonary arterial hypertension (PAH) in Clinical prAcTicE

Action: For adoption of advice to CHMP

7.5.13. Tolvaptan - JINARC (CAP) - EMEA/H/C/002788/ANX 002.2

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: MAH's response to ANX 002.1 [interim report for study 156-12-299: a non-interventional PASS to investigate the risks of hepatotoxicity, basal cell carcinoma and glaucoma associated with the use of Jinarc (tolvaptan). In addition, the study investigates pregnancy outcomes in patients treated with Jinarc (tolvaptan), patterns of medicinal product utilisation especially with regards to off-label use and use in patients over 50 years old as well as adverse drug reactions (ADRs) associated with long term use of Jinarc (tolvaptan) [final clinical study report (CSR) expected by: Q1/2026]] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.5.14. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 022.20

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 022.19 [ninth annual report for study C0168Z03 (PSOLAR: PSOriasis Longitudinal Assessment and Registry): an international prospective cohort

³⁴ Article 58 of Regulation (EC) No 726/2004 allows the Committee for Medicinal Products for Human Use (CHMP) to give opinions, in co-operation with the World Health Organisation (WHO) on medicinal products for human use that are intended exclusively for markets outside of the European Union (EU)

study/registry programme designed to collect data on psoriasis (PSO) patients that are eligible to receive systemic therapies, including generalised phototherapy and biologics] as per the request for supplementary information (RSI) adopted in April 2020

Action: For adoption of advice to CHMP

7.5.15. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 024.14

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Rhea Fitzgerald

Scope: Tenth annual interim report for study CNTO1275PSO4007 (Nordic pregnancy research initiative) (C0743T): exposure to ustekinumab during pregnancy in patients with psoriasis: a review and analysis of birth outcomes from the Swedish, Danish, and Finnish medical birth registers

Action: For adoption of advice to CHMP

7.5.16. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 045.5

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Rhea Fitzgerald

Scope: First interim report for study RRA-20745: an observational PASS to describe the safety of ustekinumab and other Crohn's disease treatments in a cohort of patients with Crohn's disease

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Emicizumab - HEMLIBRA (CAP) - EMEA/H/C/004406/MEA 005.1

Applicant: Roche Registration GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: MAH's response to MEA 005 [Evaluation of the MAH's assessment of a letter to the editor in the New England Journal of Medicine (NEJM) entitled 'deaths associated with emicizumab in patients with hemophilia A' published in November 2019] as per the request for supplementary information (RSI) adopted in April 2020

7.6.2. Pegfilgrastim - NEULASTA (CAP) - EMEA/H/C/000420/MEA 060.3

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Menno van der Elst

Scope: MAH's response to MEA 060.2 [six-monthly summary report of medication error events reported with the on body injector in the EU market, as requested in the conclusions of variation II/093/G finalised in February 2018] as per the request for supplementary information (RSI) adopted in October 2019] as per the request for supplementary information (RSI) adopted in March 2020

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

None

7.8. Ongoing Scientific Advice

7.9. Final Scientific Advice (Reports and Scientific Advice letters)

None

8. Renewals of the marketing authorisation, conditional renewal and annual reassessments

8.1. Annual reassessments of the marketing authorisation

8.1.1. Amifampridine - FIRDAPSE (CAP) - EMEA/H/C/001032/S/0066 (without RMP)

Applicant: SERB SA

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Zanamivir - DECTOVA (CAP) - EMEA/H/C/004102/S/0006 (without RMP)

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.2. Conditional renewals of the marketing authorisation

8.2.1. Ixazomib - NINLARO (CAP) - EMEA/H/C/003844/R/0021 (without RMP)

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Annika Folin

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Obeticholic acid - OCALIVA (CAP) - EMEA/H/C/004093/R/0023 (without RMP)

Applicant: Intercept Pharma International Limited

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.3. Polatuzumab vedotin - POLIVY (CAP) - EMEA/H/C/004870/R/0003 (with RMP)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Annika Folin

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Amlodipine, valsartan - AMLODIPINE-VALSARTAN MYLAN (CAP) - EMEA/H/C/004037/R/0008 (with RMP)

Applicant: Mylan S.A.S

PRAC Rapporteur: Anette Kirstine Stark

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Etanercept - BENEPALI (CAP) - EMEA/H/C/004007/R/0053 (without RMP)

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Eva Segovia

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Ferric maltol - FERACCRU (CAP) - EMEA/H/C/002733/R/0027 (with RMP)

Applicant: Norgine B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Fingolimod - GILENYA (CAP) - EMEA/H/C/002202/R/0063 (without RMP)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Lopinavir, ritonavir - LOPINAVIR/RITONAVIR MYLAN (CAP) - EMEA/H/C/004025/R/0014 (without RMP)

Applicant: Mylan S.A.S

PRAC Rapporteur: Adrien Inoubli

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Lumacaftor, ivacaftor - ORKAMBI (CAP) - EMEA/H/C/003954/R/0056 (with RMP)

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. Pegaspargase - ONCASPAR (CAP) - EMEA/H/C/003789/R/0034 (without RMP)

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Annika Folin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.8. Rasagiline - RASAGILINE MYLAN (CAP) - EMEA/H/C/004064/R/0006 (without RMP)

Applicant: Mylan S.A.S

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.9. Susoctocog alfa - OBIZUR (CAP) - EMEA/H/C/002792/R/0033 (with RMP)

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.10. Talimogene laherparepvec - IMLYGIC (CAP) - EMEA/H/C/002771/R/0039 (without RMP)

Applicant: Amgen Europe B.V. ATMP³⁵

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.3.11. Zonisamide - ZONISAMIDE MYLAN (CAP) - EMEA/H/C/004127/R/0008 (without RMP)

Applicant: Mylan S.A.S

³⁵ Advanced therapy medicinal product

PRAC Rapporteur: Rhea Fitzgerald

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

Disclosure of information on results of pharmacovigilance inspections could undermine the protection of the purpose of these inspections, investigations and audits. Therefore such information is not reported in the agenda.

9.3. Others

None

10. Other safety issues for discussion requested by the CHMP or the EMA

10.1. Safety related variations of the marketing authorisation

None

10.2. Timing and message content in relation to Member States' safety announcements

None

10.3. Other requests

None

10.4. Scientific Advice

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

11. Other safety issues for discussion requested by the Member States

11.1. Safety related variations of the marketing authorisation

11.1.1. Bupropion (NAP) - NL/H/xxxx/WS/397

Applicant(s): GSK R&D (Wellbutrin SR/Wellbutrin XR/Elontril, Zyban/Zyntabac)

PRAC Lead: Liana Gross-Martirosyan

Scope: PRAC consultation on a national worksharing variation assessing a cumulative review of serotonin syndrome from clinical trials, post-marketing sources and literature as discussed at PRAC and agreed by CMDh following the conclusion of the PSUSA procedure (PSUSA/00000461/201812) concluded in September 2019, on request of the Netherlands

Action: For adoption of advice to Member States

11.1.2. Oxaliplatin (NAP) - ES/H/0609/II/052/G

Applicant(s): Pfizer (Oxaliplatin Hospira 5 mg/mL)

PRAC Lead: Eva Segovia

Scope: PRAC consultation on a national grouped type II variation to add a warning on immunosuppressant effects/increased susceptibility to infections associated with vaccines and to include 'focal nodular hyperplasia' as an adverse drug reaction (ADR) to the product information, on request of Spain

Action: For adoption of advice to Member States

11.2. Other requests

11.2.1. Levonorgestrel³⁶ (NAP) - DE/H/PSUFU/00001856/201905

Applicant(s): Bayer (Mirena, Jaydess/Flere/Luadei/Skyla, Kyleena); Gedeon Richter (Levosert)

PRAC Lead: Martin Huber

Scope: PRAC consultation on a PSUR follow-up (PSU FU) procedure on a review of cases reporting meningioma together with a causality assessment, biological plausibility and literature analysis, as discussed at PRAC and agreed by CMDh following the conclusion of the PSUSA procedure (PSUSA/00001856/201905) concluded in January 2020, on request of Germany

Action: For adoption of advice to Member States

³⁶ levonorgestrel intrauterine device (LNG-IUD)

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

None

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

12.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

12.3.1. EMA working parties – reactivation

PRAC lead: Sabine Straus

Action: For discussion

12.4. Cooperation within the EU regulatory network

12.4.1. Coronavirus (COVID-19) pandemic - update

Action: For discussion

12.5. Cooperation with International Regulators

None

12.6. Contacts of the PRAC with external parties and interaction with the Interested Parties to the Committee

12.6.1. Coronavirus (COVID-19) pandemic - multicentre observational study on use of steroids in COVID-19 patients

PRAC lead: Antoine Pariente

Action: For discussion

12.6.2. Coronavirus (COVID-19) pandemic - Covid-19 infection and medicines in pregnancy (CONSIGN) – project outline

EMA lead: Corinne de Vries, Kelly Plueschke

Action: For discussion

12.7. PRAC work plan

12.7.1. PRAC work plan 2020 – mid-year report

PRAC lead: Sabine Straus, Martin Huber

Action: For discussion

12.8. Planning and reporting

- 12.8.1. EU Pharmacovigilance system – quarterly workload measures and performance indicators – Q2 2020 and predictions
-

Action: For discussion

12.9. Pharmacovigilance audits and inspections

- 12.9.1. Pharmacovigilance systems and their quality systems
-

None

- 12.9.2. Pharmacovigilance inspections
-

None

- 12.9.3. Pharmacovigilance audits
-

None

12.10. Periodic safety update reports (PSURs) & Union reference date (EURD) list

- 12.10.1. Periodic safety update reports
-

None

- 12.10.2. Granularity and Periodicity Advisory Group (GPAG)
-

PRAC lead: Menno van der Elst, Maia Uusküla

Action: For discussion

- 12.10.3. PSURs repository
-

None

- 12.10.4. Union reference date list – consultation on the draft list
-

Action: For adoption

12.11. Signal management

- 12.11.1. Signal management – feedback from Signal Management Review Technical (SMART) Working Group
-

PRAC lead: Menno van der Elst

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

12.12.3. List of products under additional monitoring – consultation on the draft list

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

12.14.2. Tools, educational materials and effectiveness measurement of risk minimisations

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

12.15.2. Post-authorisation Safety Studies – non-imposed PASS

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.16.2. Pharmacovigilance referrals roadmap – temporary measures

PRAC lead: Jean-Michel Dogné, Martin Huber, Adrien Inoubli, Ulla Wändel Liminga

Action: For discussion

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Others

12.20.1. Strategy on measuring the impact of pharmacovigilance – PRAC interest group (IG) Impact – risk minimisation effectiveness evaluation: update to assessment report template

PRAC lead: Antoine Pariente

Action: For discussion

13. Any other business

14. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures

(Items 2 and 3 of the PRAC agenda)

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 European Union (EU). For further detailed information on safety related referrals please see:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.

The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.

The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.

RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.

PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

A PASS is a study of an authorised medicinal product carried out to obtain further information on its safety, or to measure the effectiveness of risk management measures. The results of a PASS help regulatory agencies to evaluate the safety and benefit-risk profile of a medicine.

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

Inspections carried out by regulatory agencies to ensure that marketing authorisation holders comply with their pharmacovigilance obligations.

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