7 September 2015
EMA/PRAC/596669/2015
Procedure Management and Committees Support Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 07-10 September 2015

Chair: June Raine – Vice-Chair: Almath Spooner

07 September 2015, 13:00 – 19:00, room 3/A

08 September 2015, 08:30 – 19:00, room 3/A

09 September 2015, 08:30 – 19:00, room 3/A

10 September 2015, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

24 September 2015, 10:00 – 12:00, room 6/B, via teleconference

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised.

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

Note on access to documents

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 7-10 September 2015. See (current) September 2015 PRAC minutes (to be published post October 2015 PRAC meeting).

1.2. Adoption of agenda of the meeting on 7-10 September 2015

1.3. Adoption of the minutes of the previous meeting on 6-9 July 2015

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

2.4. Planned public hearings

None

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

3.1. Newly triggered procedures

3.1.1. Fusafungine (NAP), for nasal and oral solution

Applicant: Les Laboratoires Servier, various

PRAC Rapporteur: To be appointed; PRAC Co-rapporteur: To be appointed

Scope: Review of the benefit-risk balance following notification by Italy of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data
Action: For adoption of a list of questions and a timetable for the procedure

3.2. Ongoing procedures

3.2.1. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (CAP)
Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – GARDASIL (CAP), SILGARD (CAP)
Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) – GARDASIL 9 (CAP) - EMEA/H/A-20/1421

MAH(s): GlaxoSmithKline Biologicals S.A. (Cervarix), Sanofi Pasteur MSD SNC (Gardasil, Gardasil 9), Merck Sharp & Dohme Limited (Silgard)

PRAC Rapporteur: Julie Williams; PRAC Co-rapporteurs: Jean-Michel Dogné, Qun-Ying Yue

Scope: Review to further clarify the safety profile of human papillomavirus (HPV) vaccines following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data
Action: For adoption of a revised timetable and discussion for the organisation of a Scientific Advisory Group (SAG)

3.2.2. Natalizumab – TYSABRI (CAP) - EMEA/H/A-20/1416

Applicant: Biogen Idec Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski; PRAC Co-rapporteur: Carmela Macchiarulo

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20(8) of Regulation (EC) No 726/2004, based on pharmacovigilance data
Action: For adoption of a recommendation or a list of outstanding issues

3.3. Procedures for finalisation

None

3.4. Article 5(3) of Regulation (EC) No 726/2004 as amended: PRAC advice on CHMP request

None

3.5. Others

3.5.1. Ambroxol (NAP); bromhexine (NAP) - EMEA/H/A-31/1397

MAH(s): Boehringer Ingelheim, various

PRAC Rapporteur: Margarida Guimarães
PRAC Co-rapporteurs: Jean-Michel Dogné, Jan Neuhauser

Scope: Revision of recommendations of a referral procedure under Article 31 of Directive 2001/83/EC adopted in January 2015, at the request of the European Commission
Action: For discussion and/or adoption of a revised recommendation

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Daptomycin – CUBICIN (CAP)

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Julie Williams

Scope: Signal of acute generalised exanthematous pustulosis (AGEP)
Action: For adoption of PRAC recommendation
EPITT 18412 – New signal
Lead MS: UK

4.1.2. Levetiracetam – KEPPRA (CAP), NAP

Applicant: UCB Pharma SA, various

PRAC Rapporteur: To be appointed

Scope: Signal of encephalopathy
Action: For adoption of PRAC recommendation
EPITT 18423 – New signal
Lead MS: BE

4.1.3. Methotrexate (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of progressive multifocal leukoencephalopathy (PML), JC virus infection
Action: For adoption of PRAC recommendation
EPITT 18473 – New signal
Lead MS: DK

4.1.4. Paracetamol, phenylephrine (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of pharmacokinetic drug interaction: increased bioavailability of phenylephrine when co-administered with paracetamol
Action: For adoption of PRAC recommendation
EPITT 18474 – New signal
Lead MS: BE

4.1.5. Peginterferon alfa-2a – PEGASYS (CAP)

Applicant: Roche Registration Limited

[1] 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

PRAC Rapporteur: Qun-Ying Yue

Scope: Signal of Guillain-Barré syndrome (GBS)
Action: For adoption of PRAC recommendation
EPITT 18402 – New signal
Lead MS: SE

4.1.6. Pemetrexed – ALIMTA (CAP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Corinne Fechant

Scope: Signal of scleroderma
Action: For adoption of PRAC recommendation
EPITT 18383 – New signal
Lead MS: FR

4.1.7. Tyrosine kinase inhibitors (TKI): bosutinib – BOSULIF (CAP); dasatinib - SPRYCEL (CAP); imatinib – GLIVEC (CAP); nilotinib – TASIGNA (CAP); ponatinib – ICLUSIG (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG (Sprycel), Novartis Europharm Ltd (Glivec, Tasigna), Pfizer Limited (Bosulif), Ariad Pharma Ltd (Iclusig)

PRAC Rapporteur: To be appointed

Scope: Signal of hepatitis B virus (HBV) reactivation
Action: For adoption of PRAC recommendation
EPITT 18405 – New signal
Lead MS: UK, ES, DK, DE

4.1.8. Regorafenib – STIVARGA (CAP)

Applicant: Bayer Pharma AG

PRAC Rapporteur: Sabine Straus

Scope: Signal of haemolysis
Action: For adoption of PRAC recommendation
EPITT 18437 – New signal
Lead MS: NL

4.1.9. Regorafenib – STIVARGA (CAP)

Applicant: Bayer Pharma AG

PRAC Rapporteur: Sabine Straus

Scope: Signal of acute pancreatitis
Action: For adoption of PRAC recommendation
EPITT 18440 – New signal
Lead MS: NL

4.1.10. Sunitinib – SUTENT (CAP)

Applicant: Pfizer Limited

PRAC Rapporteur: Carmela Macchiarulo

Scope: Signal of pneumatosis intestinalis
Action: For adoption of PRAC recommendation
EPITT 18396 – New signal
Lead MS: IT

4.2. New signals detected from other sources

4.2.1. Clozapine (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of myocarditis
Action: For adoption of PRAC recommendation
EPITT 18414 – New signal
Lead MS: UK

4.2.2. Thioctic acid (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of insulin autoimmune syndrome
Action: For adoption of PRAC recommendation
EPITT 18406 – New signal
Lead MS: HR

4.3. Signals follow-up and prioritisation

4.3.1. Amikacin (NAP)

Applicant: Bristol-Myers Squib, B. Braun Melsungen AG

PRAC Rapporteur: Maia Uusküla

Scope: Signal of drug reaction with eosinophilia and systemic symptoms (DRESS)
Action: For adoption of PRAC recommendation
EPITT 18304 – Follow-up to May 2015

4.3.2. Bisphosphonates: alendronic acid (NAP); alendronic acid, colecalciferol - ADROVANCE (CAP), FOSAVANCE (CAP), VANTAVO (CAP); etidronic acid (NAP); ibandronic acid – BONDRONAT (CAP), BONVIVA (CAP); neridronic acid (NAP); pamidronic acid (NAP); risedronic acid (NAP); tiludronic acid (NAP); zoledronic acid – ACLASTA (CAP), ZOMETA (CAP)
Denosumab – PROLIA (CAP), XGEVA (CAP)

Applicant: Amgen Europe B.V. (Prolia, Xgeva), Merck Sharp & Dohme Limited (Adrovance, Fosavance, Vantavo), Novartis Europharm Ltd (Aclasta, Zometa), Roche Registration Ltd (Bondronat, Bonviva), various

PRAC Rapporteur: Julie Williams

Scope: Signal of osteonecrosis of the external auditory canal

Action: For adoption of PRAC recommendation
EPITT 18256 – Follow-up to March 2015

4.3.3. Digoxin (NAP)

Applicant: various

PRAC Rapporteur: Carmela Macchiarulo

Scope: Signal of mortality in patients with atrial fibrillation
Action: For adoption of PRAC recommendation
EPITT 18259 – Follow-up to May 2015

4.3.4. Hormone replacement therapy medicinal products containing oestrogens or oestrogens and progestogens in combination (NAP); bazedoxifene, oestrogens conjugated – DUAVIVE (CAP)

Applicant: Pfizer Limited (Duavive), various

PRAC Rapporteur: Menno van der Elst

Scope: Signal of increased risk of ovarian cancer
Action: For adoption of PRAC recommendation
EPITT 18258 – Follow-up to June 2015

4.3.5. Leflunomide – ARAVA (CAP) – EMEA/H/C/000235/SDA/055, LEFLUNOMIDE WINTHROP (CAP) – EMEA/H/C/001129/SDA/024

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Sabine Straus

Scope: Signal of pulmonary hypertension
Action: For adoption of PRAC recommendation
EPITT 18221 – Follow-up to April 2015

4.3.6. Lenalidomide – REVLIMID (CAP) – EMEA/H/C/000717/SDA/045

Applicant: Celgene Europe Limited

PRAC Rapporteur: Corinne Fechant

Scope: Signal of pulmonary alveolar haemorrhage
Action: For adoption of PRAC recommendation
EPITT 18300 – Follow-up to May 2015

4.3.7. Liraglutide – SAXENDA (CAP) – EMEA/H/C/003780/SDA/012, VICTOZA (CAP) – EMEA/H/C/001026/SDA/034; liraglutide, insulin degludec - XULTOPHY (CAP) – EMEA/H/C/002647/SDA/002

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Menno van der Elst

Scope: Signal of medullary thyroid cancer
Action: For adoption of PRAC recommendation
EPITT 18292 – Follow-up to May 2015

4.3.8. Tamsulosin (NAP)

Applicant: Astellas Pharma Europe B.V., various

PRAC Rapporteur: Sabine Straus

Scope: Signal of urinary incontinence
Action: For adoption of PRAC recommendation
EPITT 18317 – Follow-up to May 2015

4.3.9. Trabectedin – YONDELIS (CAP) - EMEA/H/C/000773/SDA/028

Applicant: Pharma Mar, S.A.

PRAC Rapporteur: Torbjörn Callreus

Scope: Signal of capillary leak syndrome
Action: For adoption of PRAC recommendation
EPITT 18115 – Follow-up to April 2015

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Aripiprazole - EMEA/H/C/004021

Generic

Scope: Treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.2. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ADA) cDNA sequence - EMEA/H/C/003854, Orphan

Applicant: GlaxoSmithKline Trading Services, ATMP[2]

Scope: Treatment of severe combined immunodeficiency
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.3. Betulae cortex dry extracts - EMEA/H/C/003938

Scope: Treatment of partial thickness wounds
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.4. Blinatumomab - EMEA/H/C/003731, Orphan

Applicant: Amgen Europe B.V.

Scope: Treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

[2] Advanced-therapy medicinal product

5.1.5. Brivaracetam - EMEA/H/C/003898

Scope: Treatment of partial-onset seizures
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.6. Carfilzomib - EMEA/H/C/003790, Orphan

Applicant: Amgen Europe B.V.

Scope: Treatment of multiple myeloma
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.7. Cinacalcet - EMEA/H/C/004014

Generic

Scope: Treatment of secondary hyperparathyroidism and hypercalcaemia
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.8. Cobimetinib - EMEA/H/C/003960

Scope: Treatment of metastatic melanoma
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.9. Dapaglifozin - EMEA/H/C/004161

Scope: Treatment of diabetes mellitus type 2
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.10. Dapaglifozin, metformin - EMEA/H/C/004162

Scope: Treatment of diabetes mellitus type 2
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.11. Efmoroctocog alfa - EMEA/H/C/003964, Orphan

Applicant: Biogen Idec Ltd

Scope: Treatment of haemophilia A
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.12. Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide - EMEA/H/C/004042

Scope: Treatment of human immunodeficiency virus (HIV)-1
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.13. Eptifibatide - EMEA/H/C/004104

Generic

Scope: Prevention of early myocardial infarction
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.14. Etanercept - EMEA/H/C/004007

Biosimilar

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

5.1.15. Fentanyl - EMEA/H/C/002715

Scope: Treatment of acute moderate to severe post-operative pain
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.16. Ferric maltol - EMEA/H/C/002733

Scope: Treatment of iron deficiency anaemia
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.17. Glycerol phenylbutyrate - EMEA/H/C/003822, Orphan

Applicant: Horizon Therapeutics Limited

Scope: Treatment of patients with urea cycle disorders
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.18. Human fibrinogen, human thrombin - EMEA/H/C/003914

Scope: Supportive treatment for improvement of haemostasis and as a suture support in vascular surgery
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.19. Idarucizumab – EMEA/H/C/003986

Scope: Prevention and treatment of dabigatran-associated haemorrhage
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.20. Levodopa, carbidopa - EMEA/H/C/002611

Scope: Treatment of Parkinson's disease
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.21. Lumacaftor, ivacaftor - EMEA/H/C/003954, Orphan

Applicant: Vertex Pharmaceuticals (U.K.) Ltd.

Scope: Treatment of cystic fibrosis
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.22. Mepolizumab - EMEA/H/C/003860

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

5.1.23. Mercaptamine - EMEA/H/C/003769, Orphan

Applicant: Orphan Europe S.A.R.L.

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

5.1.24. Mercaptamine - EMEA/H/C/004038, Orphan

Applicant: Lucane Pharma

Scope: Treatment of corneal cystine deposits
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.25. Necitumumab - EMEA/H/C/003886

Scope: Treatment of squamous non-small cell lung cancer
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.26. Octocog alfa - EMEA/H/C/004147; EMEA/H/C/003825

Scope: Treatment and prophylaxis of haemophilia A
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.27. Opicapone - EMEA/H/C/002790

Scope: Treatment of Parkinson's disease and motor fluctuations
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.28. Parathyroid hormone - EMEA/H/C/003861, Orphan

Applicant: NPS Pharma Holdings Limited

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

5.1.29. Pemetrexed - EMEA/H/C/003788

Generic

Scope: Treatment of malignant pleural mesothelioma and non-small cell lung cancer
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.30. Pemetrexed - EMEA/H/C/004072

Generic

Scope: Treatment of unresectable malignant pleural mesothelioma metastatic non-small cell lung cancer
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.31. Pemetrexed - EMEA/H/C/004109

Hybrid

Scope: Treatment of malignant pleural mesothelioma and non-small cell lung cancer
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.32. Pemetrexed - EMEA/H/C/003970

Generic

Scope: Treatment of malignant pleural mesothelioma and non-small cell lung cancer (excluding predominantly squamous cell histology)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.33. Pemetrexed - EMEA/H/C/003905

Generic

Scope: Treatment of malignant pleural mesothelioma and non-small cell lung cancer
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.34. Recombinant L-asparaginase - EMEA/H/C/002661, Orphan

Applicant: Medac Gesellschaft fuer klinische Spezialpraeparate GmbH

Scope: Treatment for B/T cell lymphoblastic leukaemia (ALL) or B/T cell lymphoblastic lymphoma (LBL) in combination
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.35. Sacubitril, valsartan - EMEA/H/C/004062

Scope: Treatment of heart failure (NYHA class II-IV)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.36. Selixibag - EMEA/H/C/003774, Orphan

Applicant: Actelion Registration Ltd

Scope: Treatment of pulmonary arterial hypertension (PAH)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.37. Talimogene laherparepvec - EMEA/H/C/002771

ATMP[3]

Scope: Treatment of adults with melanoma that is regionally or distantly metastatic
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. Bazedoxifene – CONBRIZA (CAP) - EMEA/H/C/000913/II/0038

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated RMP version 4.3 in order to reclassify the risks currently listed as potential risks
Action: For adoption of PRAC AR

[3] Advanced-therapy medicinal product

5.2.2. Denosumab – PROLIA (CAP) - EMEA/H/C/001120/II/0051

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of an updated RMP version 12 to reflect the introduction of the patient reminder card on risk of osteonecrosis of the jaw and changes to the SmPC
Action: For adoption of PRAC AR

5.2.3. Denosumab – XGEVA (CAP) - EMEA/H/C/002173/II/0039

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of an updated RMP version 14 to reflect the introduction of the patient reminder card on risk of osteonecrosis of the jaw and changes to the SmPC and DHPC to remind practitioners that unhealed lesions from dental or oral surgery is a contraindication
Action: For adoption of PRAC AR

5.2.1. Filgrastim – FILGRASTIM HEXAL (CAP) - EMEA/H/C/000918/WS0779/0029/G, ZARZIO (CAP) - EMEA/H/C/000917/WS0779/0030/G

Applicant: Sandoz GmbH

PRAC Rapporteur: Julie Williams

Scope: Submission of long term safety and immunogenicity data in additional studies EP06-302 to address post authorisation measure MEA 005. Submission of an updated RMP (version 11.0) to include two important potential risks (extramedullary haematopoiesis and venous thrombotic events) following the request from PSUR13 assessment
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.2.2. Filgrastim – NIVESTIM (CAP) - EMEA/H/C/001142/II/0033

Applicant: Hospira UK Limited

PRAC Rapporteur: Kirsti Villikka

Scope: Submission of an updated RMP (version 9.0) following PRAC recommendations dated 12 March 2015 following the completion of the renewal procedure of Nivestim (EMA/PRAC/153431/2015)
Action: For adoption of PRAC AR

5.2.3. Infliximab – INFLECTRA (CAP) - EMEA/H/C/002778/II/0030

Applicant: Hospira UK Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Submission of an updated RMP in order to add/delete safety concerns in line with the reference product, Remicade and update the status of the category 3 studies, including the change of due date for Post-Authorisation Measure MEA 011 study CT-P13 3.4 (submission of Week 6 clinical study report (CSR)) from May 2015 to December 2016
Action: For adoption of PRAC AR

5.2.4. Infliximab – REMSIMA (CAP) - EMEA/H/C/002576/II/0025

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Rafe Suvarna

Scope: Submission of a revised RMP to include newly identified safety concerns (acute hypersensitivity reaction (including anaphylactic shock); merkel cell carcinoma; melanoma) in line with the RMP for the reference product Remicade, deletion of potential risks (bowel stenosis, stricture, obstruction (in Crohn's Disease)) in line with the RMP for the reference product Remicade, addition of pharmacological class risks as newly identified class risks, update of category 3 studies to reflect current status and to change the due date for MEA 011 study CT-P13 3.4 (week 6 clinical study report (CSR)) from May 2015 to December 2016
Action: For adoption of PRAC AR

5.2.5. Influenza vaccine (split virion, inactivated) – IDFLU (CAP) - EMEA/H/C/000966/WS/0763/0038; INTANZA (CAP) - EMEA/H/C/000957/WS/0763/0040

Applicant: Sanofi Pasteur, Sanofi Pasteur MSD SNC

PRAC Rapporteur: Miguel-Angel Macia

Scope: Submission of a revised RMP (version 9.0) to update the strategy of the enhanced safety surveillance in EEA during 2015-2016 influenza season, the status of GID47 updated and details on clinical study report, results of THIN study and the table of risk minimisation measures updated according to the PRAC assessment report of the RMP 8.0
Action: For adoption of PRAC AR

5.2.6. Meningococcal group B vaccine (rDNA, component, adsorbed) – BEXSERO (CAP) - EMEA/H/C/002333/II/0033

Applicant: Novartis Vaccines and Diagnostics S.r.l.

PRAC Rapporteur: Qun-Ying Yue

Scope: Submission of a revised RMP in order to replace study V72_39OB to monitor the use of Bexsero during pregnancy using the vaccines in pregnancy surveillance system, with study V72_82OB using the United States pregnancy registry
Action: For adoption of PRAC AR

5.2.7. Oseltamivir – TAMIFLU (CAP) - EMEA/H/C/000402/II/0114

Applicant: Roche Registration Ltd

PRAC Rapporteur: Kirsti Villikka

Scope: Proposal of a new and alternative study BV29684 'assessing the safety of prenatal exposure to oseltamivir' as category 3 study (MEA 099) to replace the agreed 2-year extension of the Danish-Swedish registry (NV25577)'
Action: For adoption of PRAC AR

5.2.8. Tenofovir disoproxil – VIREAD (CAP) - EMEA/H/C/000419/II/0154/G

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Isabelle Robine

Scope: Submission of an updated RMP (version 19.0): to remove the pharmacokinetic (PK) sub-study of the category 3 study GSUS-174-0144, to change the agreed due date of the category 3 study GS-US-236-0103, to update in Part II of the antiretroviral pregnancy registry exposure in line with EMA request. In addition, the RMP is updated to reflect the milestones for category 3 studies GS-US-174-0115 and GS-US-174-0144 in line with those already agreed in the paediatric investigation plan (PIP). Finally, the MAH took the opportunity of this procedure to update studies and exposure data as well as update status/milestones of several studies
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.2.9. Zoledronic acid – ACLASTA (CAP) - EMEA/H/C/000595/II/0056

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of an updated RMP (version 11.0) in order to introduce a patient reminder card as an additional risk minimisation measure for the existing identified risk of osteonecrosis of the jaw and to propose indicators to measure the effectiveness of this new measure. Furthermore, the clinical trial exposure data from the Aclasta study ZOL446H2301E2 has been updated
Action: For adoption of PRAC AR

5.2.10. Zoledronic acid – ZOMETA (CAP) - EMEA/H/C/000336/II/0069

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Doris Stenver

Scope: Submission of an updated RMP to include an additional new minimisation measure (introduction of the patient reminder card) as well as to propose indicators to measure its effectiveness. The MAH has also taken the opportunity to add the targeted follow-up checklist for the identified risk hypocalcaemia in Annex 7 of the RMP
Action: For adoption of PRAC AR

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

5.3.1. Abiraterone – ZYTIGA (CAP) - EMEA/H/C/002321/II/0035/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Dolores Montero Corominas

Scope: Grouped variations: submission of clinical study reports (CSRs) associated with four studies listed in the RMP as required additional pharmacovigilance activities to address the important identified risk of cardiac disorders: 1) interim analysis CSR for study ABI-PRO-3002: phase 3, randomized, double-blind, placebo-controlled study of abiraterone acetate (JNJ-212082) plus prednisone in asymptomatic or mildly symptomatic patients with metastatic castration-resistant prostate cancer; 2) final CSR for study JNJ-212082-JPN-201: phase 2 study of JNJ-212082 (abiraterone acetate) in metastatic castration-resistant prostate cancer patients who are chemotherapy-naïve; 3) final CSR for study JNJ-212082-JPN-202: phase 2 study of JNJ-212082 (abiraterone acetate) in metastatic castration-resistant prostate cancer patients who have received docetaxel-based chemotherapy; 4) final analysis CSR for study 212082BCA2001: randomized, open-label study of abiraterone acetate (JNJ-212082) plus prednisone with or without exemestane in postmenopausal women with ER+ metastatic breast cancer progressing after letrozole or anastrozole therapy. An updated EU RMP (version 11.0) is submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.2. Abiraterone – ZYTIGA (CAP) - EMEA/H/C/002321/II/0036/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Dolores Montero Corominas

Scope: Grouped variations: submission of clinical study reports (CSRs) associated with four studies listed in the RMP as required additional pharmacovigilance activities to address missing information in non-white patients: 1) final analysis CSR for study ABI-PRO-3001: phase 3, randomized, double-blind, placebo-controlled study for abiraterone acetate (JNJ-212082) plus prednisone in patients with metastatic castration-resistant prostate cancer who have failed docetaxel-based chemotherapy; 2) final analysis CSR for study 212082PCR3001: open-label study of abiraterone acetate in subjects with metastatic castration-resistant prostate cancer who have progressed after taxane-based chemotherapy; 3) final CSR and addendum for study 212082PCR2007: phase 2 open-label study of abiraterone acetate (JNJ-212082) and prednisolone in patients with advanced prostate cancer who have failed androgen deprivation and docetaxel-based chemotherapy; 4) final CSR for study JNJ-212082-JPN-102: phase 1 study of JNJ-212082 (abiraterone acetate) in chemotherapy-naïve patients with castration-resistant prostate cancer. In addition, interim analysis CSR for study ABI-PRO-3002: phase 3, randomized, double-blind, placebo-controlled study of abiraterone acetate (JNJ-212082) plus prednisone in asymptomatic or mildly symptomatic patients with metastatic castration-resistant prostate cancer is discussed with regard to missing information for use of ZYTIGA in non-white patients. An updated EU RMP (version 11.0) is submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.3. Aflibercept – EYLEA (CAP) - EMEA/H/C/002392/II/0021

Applicant: Bayer Pharma AG

PRAC Rapporteur: Isabelle Robine

Scope: Extension of indication to include a new indication for adult for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated. The Package Leaflet is updated accordingly. In addition, some editorial changes are proposed in section 5.1 of the SmPC, in Annex II and in the Package Leaflet
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.4. Alipogene tiparvovec - GLYBERA (CAP) - EMEA/H/C/002145/II/0038

Applicant: UniQure biopharma B.V.

PRAC Rapporteur: Julie Williams

Scope: Update of section 5.1 of the SmPC based on the final clinical study report (CSR) for study CT-AMT-011-05, a retrospective clinical records review study undertaken to generate further long-term follow-up data on the incidence and severity of acute pancreatitis episodes in lipoprotein lipase deficiency (LPLD) subjects who previously participated in clinical studies with alipogene tiparvovec or AMT-10
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.5. Ambrisentan – VOLIBRIS (CAP) - EMEA/H/C/000839/II/0041

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Dolores Montero Corominas

Scope: Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to include an expanded therapeutic indication for the treatment of pulmonary arterial hypertension (PAH).

In addition, the MAH took the opportunity to update Annex II to reflect a change in the PSUR frequency. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.6. Aprepitant – EMEND (CAP) - EMEA/H/C/000527/X/0049/G

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Extension of indication for the treatment of chemotherapy-induced nausea and vomiting (CINV) in paediatric patients (12 to 17 years) for the 80 mg and 125 mg hard capsules. In addition, update of SmPC sections 4.2 and 5.3 of the 165 mg hard capsule label. Furthermore, addition of a new pharmaceutical form (powder for oral suspension) for the 125 mg strength. Finally, update of sections 5.1 and 5.2 of the SmPC to reflect the paediatric results for prevention of post-operative nausea and vomiting (PONV) in the clinical sections of the 40 mg hard capsules product information. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.7. Atanazavir – REYATAZ (CAP) - EMEA/H/C/000494/II/0096

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Isabelle Robine

Scope: Update of sections 4.2, 4.3, 4.4, 4.5, 4.6, 5.1 and 5.2 of the SmPC in order to provide important information and guidance to prescribers when they consider using unboosted atazanavir (ATV) in line with international guidelines based on study INDUMA/AI424-136. In addition, the MAH took the opportunity to make a minor change in section 4.7 of the SmPC for increased clarity, and minor editorial changes to the SmPC and Package Leaflet. RMP version 9 has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.8. Bivalirudin – ANGIOX (CAP) - EMEA/H/C/000562/II/0062

Applicant: The Medicines Company UK Ltd.

PRAC Rapporteur: Julie Williams

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to update the posology instructions and update the warning of use of bivalirudin in case of haemorrhage. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.9. Capecitabine – XELODA (CAP) - EMEA/H/C/000316/II/0067

Applicant: Roche Registration Limited

PRAC Rapporteur: Martin Huber

Scope: Update of sections 4.3 and 4.4 of the SmPC in order to delete the contraindication regarding patients with known dihydropyrimidine dehydrogenase (DPD) and add information with regard to patients with DPD deficiency. The package leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.10. Ceftaroline fosamil – ZINFORO (CAP) - EMEA/H/C/002252/II/0021

Applicant: AstraZeneca AB

PRAC Rapporteur: Julie Williams

Scope: Submission of the final study report of the multicentre, randomised, double-blind, comparative study to evaluate the efficacy and safety of ceftaroline fosamil (600 mg every 8 hours) versus vancomycin plus aztreonam in the treatment of patients with complicated bacterial skin and soft tissue infections with evidence of systemic inflammatory response or underlying comorbidities. A revised RMP (version 14) is submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.11. Dabigatran – PRADAXA (CAP) - EMEA/H/C/000829/II/0082

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Torbjorn Callreus

Scope: Submission of the final study report for study 1160.166: exploratory study to investigate the pharmacokinetics and effects of dabigatran etexilate in patients with stable severe renal disease (DabiRenal). A revised RMP (version 31.1) is submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.12. Dabigatran – PRADAXA (CAP) - EMEA/H/C/000829/II/0085

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Torbjorn Callreus

Scope: Update of sections 4.2 and 5.1 of the SmPC to add a recommendation to ensure Pradaxa is taken with a meal and/or a proton pump inhibitor such a pantoprazole in case of gastrointestinal symptoms (GIS), based on the results of study 1160.128; a prospective, open label study evaluating the efficacy of two management strategies on GIS in non-valvular atrial fibrillation (NVAF) patients. The Package Leaflet (including the patient alert card) has been updated accordingly. A revised RMP (version 31.2) is submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.13. Daclatasvir – DAKLINZA (CAP) - EMEA/H/C/003768/II/0008/G

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Margarida Guimarães

Scope: Update of sections 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC in order to update the safety information based on the final results of clinical study AI444043. In addition, update of section 4.5 of the SmPC in order to update the safety information based on the final results of clinical study AI444093. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.14. Daclatasvir – DAKLINZA (CAP) - EMEA/H/C/003768/II/0010/G

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Margarida Guimarães

Scope: Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update the safety information based on the final results of clinical study AI444216 (ALLY-2): phase 3 evaluation of daclatasvir plus sofosbuvir in treatment-naive and treatment experienced chronic hepatitis C (genotype 1, 2, 3, 4, 5, or 6) subjects co-infected with human immunodeficiency virus (HIV). The Package Leaflet is updated accordingly. In addition, update of sections 4.2, 4.4, 4.8, 5.1, 5.2 in order to update the safety information based on the final results of clinical study AI444215 (ALLY-1): phase 3 evaluation of daclatasvir, sofosbuvir, and ribavirin in genotype 1-6 chronic hepatitis C infection subjects with cirrhosis

who may require future liver transplant and subjects post-liver transplant. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.15. Deferasirox – EXJADE (CAP) - EMEA/H/C/000670/II/0045

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Corinne Fechant

Scope: Update of section 4.4 of the SmPC based on the results from studies CICL670A2425, CICL670A2426 and CICL670AFR01T and the patient survey. The Package Leaflet and Annex II are updated accordingly. Updated RMP version 11 has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.16. Diphtheria (D) tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and haemophilus influenzae type b (Hib) conjugate vaccine (adsorbed) – HEXACIMA (CAP) - EMEA/H/C/002702/WS/0789; HEXAXIM (Art 58) - EMEA/H/W/002495/WS/0789; HEXYON (CAP) - EMEA/H/C/002796/WS/0789

Applicant: Sanofi Pasteur

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of section 4.8 of the SmPC, upon request by the PRAC following the assessment of PSUSA/10091/201410, to include the adverse drug reactions: 'convulsion with or without fever' and 'anaphylactic reaction'. The Package Leaflet is updated accordingly. A revised RMP (version 10.0) was submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.17. Dolutegravir – TIVICAY (CAP) - EMEA/H/C/002753/II/0014/G

Applicant: ViiV Healthcare

PRAC Rapporteur: Julie Williams

Scope: Update of section 5.1 of the SmPC in order to include additional, long-term efficacy and safety data from week 144 of the Phase III study ING114467 (SINGLE) and week 96 of the Phase IIIb study ING114915 (FLAMINGO). An updated RMP (version 6.0) has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.18. Dolutegravir, abacavir, lamivudine – TRIUMEQ (CAP) - EMEA/H/C/002754/II/0015/G

Applicant: ViiV Healthcare UK Limited

PRAC Rapporteur: Julie Williams

Scope: Update of section 5.1 of the SmPC in order to include additional, long-term efficacy and safety data from week 144 of the Phase III study ING114467 (SINGLE) and week 96 of the Phase IIIb study ING114915 (FLAMINGO). An updated RMP (version 6.0) has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.19. Eculizumab – SOLIRIS (CAP) - EMEA/H/C/000791/II/0077

Applicant: Alexion Europe SAS

PRAC Rapporteur: Dolores Montero Corominas

Scope: Update of sections 4.3 and 4.4 of the SmPC to add the serogroup B vaccine in addition to the serogroups A, C, W135 and Y. In addition, update of section 4.4 of the SmPC to remove the reference to tetravalent or conjugated vaccines. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.20. Emtricitabine – EMTRIVA (CAP) - EMEA/H/C/000533/WS/0792; tenofovir disoproxil – VIREAD (CAP) - EMEA/H/C/000419/WS0792 tenofovir disoproxil, emtricitabine – EVIPLERA (CAP) - EMEA/H/C/002312/WS0792; TRUVADA (CAP) - EMEA/H/C/000594/WS0792 tenofovir disoproxil, emtricitabine, efavirenz – ATRIPLA (CAP) - EMEA/H/C/000797/WS0792 tenofovir disoproxil, emtricitabine, elvitegravir, cobicistat – STRIBILD (CAP) - EMEA/H/C/002574/WS0792

Applicant: Bristol-Myers Squibb and Gilead Sciences International Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Update of section 4.4 of the SmPC in order to delete the human immunodeficiency virus (HIV) class label wording for mitochondrial dysfunction following the review of existing data on mitochondrial toxicity including the Mitochondrial Toxicity in Children (MITOC) Study. The Package Leaflet of Viread, Truvada and Emtriva were updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.21. Emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA (CAP) - EMEA/H/C/002312/II/0063/G

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Menno van der Elst

Scope: Update of section 4.8 of the SmPC in order to add safety information regarding severe skin reactions with systemic symptoms. The Package Leaflet and the RMP (version 10.0) are updated accordingly. In addition, update of the RMP in alignment with the RMP for the mono-component rilpivirine (RPV) by deleting an important missing information safety concern (drug-drug interactions) and update the RMP to amend the potential risk safety concern (off-label use) to reflect the use for the product and not the single component RPV
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.22. Etanercept – ENBREL (CAP) - EMEA/H/C/000262/II/0184

Applicant: Pfizer Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Update of section 4.6 of the SmPC in order to update the information on the effects of etanercept on pregnancy and lactation. The Package Leaflet and the RMP are updated accordingly. In addition, the MAH took the opportunity to update the RMP in reference to past approved variations
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.23. Etravirine – INTELENCE (CAP) - EMEA/H/C/000900/II/0042

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Isabelle Robine

Scope: Update of sections 4.2, 4.4, 5.1 and 5.2 of the SmPC in order to update the safety information of the TMC114HIV3015 study. In addition, the MAH took the opportunity to include information on the removal of gastric lavage in section 4.9 of the SmPC
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.24. Golimumab – SIMPONI (CAP) - EMEA/H/C/000992/II/0065/G

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information based on review of all available safety data. The Package Leaflet and RMP are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.25. Human fibrinogen, human thrombin – EVICEL (CAP) - EMEA/H/C/000898/II/0032

Applicant: Omrix Biopharmaceuticals N. V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of sections 4.2 and 4.8 of the SmPC in order to update the safety information and the frequencies of adverse drug reactions (ADR) already reported in the Product Information based on the final study report for a prospective, single-arm, observational, non-interventional study for Evicel when used as an adjunct to haemostasis in vascular surgery. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.26. Human normal immunoglobulin - KIOVIG (CAP) - EMEA/H/C/000628/II/0065/G

Applicant: Baxter AG

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of section 4.4 of the SmPC in order to include further information to avoid thromboembolic events and renal complications and to update information on aseptic meningitis syndrome. New information is also provided on possible false positive testing of assays used for diagnosis of fungal infections depending on detection of beta-D-glucans. In addition, update of section 4.8 of the SmPC in order to update the safety information and to change frequencies of existing adverse drug reactions as revealed in several clinical studies in which Kiovig was used as investigational medicinal product. The Package Leaflet is updated accordingly. Finally, the MAH took the opportunity to update the RMP in reference to the new warning for the false positive testing for ß-d-glucan and including the changes requested during assessment of procedure EMEA/H/C/0000628/II/0056.
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.27. Human rotavirus, live attenuated – ROTARIX (CAP) - EMEA/H/C/000639/II/0078

Applicant: GlaxoSmithKline Biologicals S.A.

PRAC Rapporteur: Jean-Michel Dogné
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.28. Human thrombin, human fibrinogen – TACHOSIL (CAP) - EMEA/H/C/000505/II/0057

Applicant: Takeda Austria GmbH

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Extension of indication for the use of Tachosil as suture line sealing in dura mater closure. As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC and the Package leaflet are updated
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.29. Infliximab – REMICADE (CAP) - EMEA/H/C/000240/II/0188

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.4, 4.5, 4.6 and 4.8 of the SmPC in order to include updated pregnancy information following submission of the final report of the Pregnancy and Infant Outcomes Registry and additional reports on infections and agranulocytosis in neonates and infants in utero exposure to Remicade. The Package Leaflet is updated accordingly. Furthermore, the Patient Alert Card which is part of Annex III A is updated accordingly. In addition, the MAH took the opportunity to revise Annex II D to bring it in line with Annex 10 of the RMP. An updated RMP (version 11.0) has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.30. Infliximab – REMICADE (CAP) - EMEA/H/C/000240/II/0191

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.4 to add a warning on possible causal relationship between infliximab and cervical cancer and 4.8 of the SmPC in order to add cervical cancer with frequency category 'rare' as a new adverse drug reaction (ADR) identified from post marketing experience. These updates address LEG 135.7. The Package Leaflet is updated accordingly. An updated RMP (version 12.0) has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.31. Ivacaftor – KALYDECO (CAP) - EMEA/H/C/002494/II/0027

Applicant: Vertex Pharmaceuticals (U.K.) Ltd.

PRAC Rapporteur: Miguel-Angel Macia

Scope: Extension of indication to include the treatment of cystic fibrosis in patients aged 18 years and older who have a R117H mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Consequently, changes are proposed to sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC. The Package Leaflet is updated accordingly

5.3.32. Ivacaftor – KALYDECO (CAP) - EMEA/H/C/002494/X/0034/G

Applicant: Vertex Pharmaceuticals (U.K.) Ltd.

PRAC Rapporteur: Miguel-Angel Macia

Scope: Line extension to include a new pharmaceutical form (granules) in two new strengths (50 mg and 75 mg unit doses) to enable administration of Kalydeco to patients

aged 2 to less than 6 years of age. Consequently, changes to SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.2 are proposed to provide clarity and relevant updates in line with the proposed paediatric extension application. The Package Leaflet is updated accordingly

5.3.33. Insulin degludec, liraglutide – XULTOPHY (CAP) - EMEA/H/C/002647/II/0009

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Menno van der Elst

Scope: Update of section 5.1 of the SmPC based on the results from 26-week trials assessing efficacy and safety of Xultophy compared to insulin glargine in patients with type 2 diabetes mellitus inadequately controlled on insulin glargine and metformin. Consequently, sections 4.4 and 4.8 of the SmPC have also been updated. The Package Leaflet and RMP are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.34. Liraglutide – VICTOZA (CAP) - EMEA/H/C/001026/II/0032

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Menno van der Elst

Scope: Submission of the final study report from the liraglutide 10-week juvenile toxicity study. Consequently, an updated RMP is submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.35. Lomitapide – LOJUXTA (CAP) - EMEA/H/C/002578/X/0016

Applicant: Aegerion Pharmaceuticals Limited

PRAC Rapporteur: Menno van der Elst

Scope: Line extension to add three new strengths: 30 mg, 40 mg and 60 mg hard capsules
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.36. Macitentan – OPSUMIT (CAP) - EMEA/H/C/002697/II/0007/G

Applicant: Actelion Registration Ltd

PRAC Rapporteur: Dolores Montero Corominas

Scope: Submission of final study report for studies AC-055C301/DUAL-1 and AC-055C302/DUAL-2, two completed Phase 3 studies in patients with digital ulcers associated with systemic sclerosis. An updated RMP has been submitted accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.37. Nintedanib – OFEV (CAP) - EMEA/H/C/003821/WS/0766; VARGATEF (CAP) - EMEA/H/C/002569/WS/0766

Applicant: Boehringer Ingelheim Pharma GmbH & Co. KG

PRAC Rapporteur: Leonidas Klironomos

Scope: Update of sections 4.2, 4.4 and 5.2 of the SmPC in order to include further information related to patients with hepatic impairment based on the clinical study reports (CSRs) of studies 1199.37, 1199.39 and 1199.200. A revised RMP was provided as part of the application; RMP version 2.0 for Ofev and RMP version 3.0 for Vargatef
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.38. Nivolumab – OPDIVO (CAP) - EMEA/H/C/003985/II/0001

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Extension of indication to include treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been revised accordingly. Further, Annex II has been updated to include a post-authorisation efficacy study as a new obligation in line with the agreed Annex II for Nivolumab BMS. In addition, the MAH took the opportunity to make editorial changes in the SmPC, Annex II, labelling and Package Leaflet. A revised RMP (version 2.0) is provided accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.39. Perampanel – FYCOMPA (CAP) - EMEA/H/C/02434/II/0023

Applicant: Eisai Europe Ltd.

PRAC Rapporteur: Julie Williams

Scope: Update of sections 4.5 and 5.2 in order to update the safety information based on the results of a mass balance study
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.40. Pyronaridine, artesunate – PYRAMAX (Art 58) - EMEA/H/W/002319/II/0002

Applicant: Shin Poong Pharmaceutical Co.

PRAC Rapporteur: Isabelle Robine

Scope: Update of SmPC section 4.1 to remove restrictions on repeated course of treatment in any individual and use only in areas of low transmission with evidence of artesmisinin resistance, based on further clinical experience. Consequent changes in SmPC sections 4.2, 4.4, 4.8 and the Package Leaflet are also included. In addition, update of SmPC Section 4.2 in relation to dosing in mild to moderate renal impairment
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.41. Pyronaridine, artesunate – PYRAMAX (Art 58) - EMEA/H/W/002319/X/0008/G

Applicant: Shin Poong Pharmaceutical Co.

PRAC Rapporteur: Isabelle Robine

Scope: Line Extension to add a new paediatric formulation 60 mg/20 mg granules for oral suspension. The product information for Pyramax 180 mg/60 mg film coated tablets has also been updated with data submitted for the line extension
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.42. Ramucirumab – CYRAMZA (CAP) - EMEA/H/C/002829/II/0003

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Extension of indication to include a new indication for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with progression after

platinum-based chemotherapy for Cyramza. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.43. Ramucirumab – CYRAMZA (CAP) - EMEA/H/C/002829/II/0004

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Extension of indication to include the use of Cyramza in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.44. Retigabine – TROBALT (CAP) - EMEA/H/C/001245/R/0036

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Doris Stenver

Scope: 5-year renewal of the marketing authorisation
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.45. Sofosbuvir – SOVALDI (CAP) - EMEA/H/C/002798/II/0015

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Julie Williams

Scope: Submission of the final study report to investigate the safety and efficacy of GS-7977 and ribavirin for 24 weeks in subjects with recurrent chronic hepatitis C virus (HCV) post liver transplant (GS-US-334-0126). The submission of this study fulfils MEA 005. An updated RMP (version 3.0) is proposed accordingly
Action: For adoption of PRAC Assessment Report

5.3.46. Thiotepa – TEPADINA (CAP) - EMEA/H/C/001046/II/0021

Applicant: Adienne S.r.l. S.U.

PRAC Rapporteur: Corinne Fechant

Scope: Update of section 4.8 of the SmPC to add the new adverse drug reaction (ADR) 'toxic skin reactions' with an unknown frequency. The Package Leaflet is updated accordingly. A revised RMP version 12 was provided as part of the application
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.47. Trametinib – MEKINIST (CAP) - EMEA/H/C/002643/II/0006/G

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Julie Williams

Scope: Update of sections 4.5 and 5.2 of the SmPC in order to update the safety information based on new preclinical data provided to fulfil four nonclinical post-authorisation measures (REC 001, MEA 004, MEA 005 and MEA 006). Moreover, an updated RMP (version 10) has been submitted

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

5.3.48. Trametinib – MEKINIST (CAP) - EMEA/H/C/002643/II/0007

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Julie Williams

Scope: Update of sections 4.2 and 5.3 of the SmPC in order to update the safety information based on new preclinical data from an oral juvenile toxicity study in rats. Moreover, an updated RMP (version 10) has been submitted
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.49. Trastuzumab – HERCEPTIN (CAP) - EMEA/H/C/000278/II/0092

Applicant: Roche Registration Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of SmPC sections 4.4, 4.8 and 5.1 to reflect the results of a new study report BO22227 (Hannah) regarding non inferior trastuzumab exposure and clinical efficacy of a q3w regimen of Herceptin subcutaneous (SC) compared to Herceptin intravenous (IV). An updated RMP has been provided
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.50. Trastuzumab – HERCEPTIN (CAP) - EMEA/H/C/000278/II/0093

Applicant: Roche Registration Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of section 5.1 of the SmPC in order to update the safety information of Herceptin 600 mg solution for injection (EU/1/00/145/002 and EU/1/00/145/003) in line with the interim report of study MO28048 (SafeHER) submitted. The RMP is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.51. Vemurafenib – ZELBORAF (CAP) - EMEA/H/C/002409/II/0023

Applicant: Roche Registration Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of section 4.5 of the SmPC in order to update the drug-drug interaction information following finalisation of study GO28394 (phase I, open-label, multicentre, 3-period, fixed sequence study to investigate the effect of vemurafenib on the pharmacokinetics of a single dose of digoxin in patients with BRAFV600 mutation-positive metastatic malignancy – MEA 013)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.52. Vemurafenib – ZELBORAF (CAP) - EMEA/H/C/002409/II/0024/G

Applicant: Roche Registration Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.4, 4.5 and 4.8 of the SmPC in order to update information on the risk of potentiation of radiation toxicity and updating the risk of progression of cancers

with RAS mutations with information on progression of pre-existing pancreatic adenocarcinoma with KRAS mutation. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

6. Periodic safety update reports (PSURs)

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

6.1.1. Aclidinium bromide – BRETARIS GENUAIR (CAP); EKLIRA GENUAIR (CAP) - PSUSA/09005/201501

Applicant: AstraZeneca AB

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.2. Aflibercept – ZALTRAP (CAP) - PSUSA/10019/201502

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.3. Agomelatine – THYMANAX (CAP), VALDOXAN (CAP) - PSUSA/00071/201502

Applicant: Servier (Ireland) Industries Ltd, Les Laboratoires Servier

PRAC Rapporteur: Kristin Thorseng Kvande

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.4. Ataluren – TRANSLARNA (CAP) - PSUSA/10274/201501

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.5. Axitinib – INLYTA (CAP) - PSUSA/10022/201501

Applicant: Pfizer Limited

PRAC Rapporteur: Ingebjørg Buajordet

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.6. Betaine anhydrous – CYSTADANE (CAP) - PSUSA/00390/201502 (with RMP)

Applicant: Orphan Europe S.A.R.L.

PRAC Rapporteur: Valerie Strassmann

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.7. Bevacizumab – AVASTIN (CAP) - PSUSA/00403/201502

Applicant: Roche Registration Ltd

PRAC Rapporteur: Doris Stenver

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.8. Bosutinib – BOSULIF (CAP) - PSUSA/10073/201503

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.9. Brentuximab vedotin – ADCETRIS (CAP) - PSUSA/10039/201502

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.10. Brimonidine – MIRVASO (CAP) - PSUSA/10093/201502 (with RMP)

Applicant: Galderma International

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.11. Carglumic acid – CARBAGLU (CAP) - PSUSA/00564/201501 (with RMP)

Applicant: Orphan Europe S.A.R.L.

PRAC Rapporteur: Magda Pedro

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.12. Cobicistat – TYBOST (CAP) - PSUSA/10081/201502

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.13. Cobicistat, elvitegravir, emtricitabine, tenofovir disoproxil – STRIBILD (CAP) - PSUSA/10082/201502

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.14. Colistimethate sodium – COLOBREATHE (CAP) - PSUSA/09112/201502

Applicant: Forest Laboratories UK Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.15. Collagenase clostridium histolyticum – XIAPEX (CAP) - PSUSA/00871/201502

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.16. Copper (^{64}Cu) chloride – CUPRYMINA (CAP) - PSUSA/10040/201502

Applicant: SparkleSRL

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.17. Crizotinib – XALKORI (CAP) - PSUSA/10042/201502

Applicant: Pfizer Limited

PRAC Rapporteur: Corinne Fechant

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.18. Dabrafenib – TAFINLAR (CAP) - PSUSA/10084/201502

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.19. Daclatasvir – DAKLINZA (CAP) - PSUSA/10295/201501

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Margarida Guimarães

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.20. Dapagliflozin, metformin – XIGDUO (CAP) - PSUSA/10294/201501 (with RMP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.21. Degarelix – FIRMAGON (CAP) - PSUSA/00944/201502 (with RMP)

Applicant: Ferring Pharmaceuticals A/S

PRAC Rapporteur: Corinne Fechant

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.22. Dexamethasone – OZURDEX (CAP) - PSUSA/00985/201501 (with RMP)

Applicant: Allergan Pharmaceuticals Ireland

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.23. Dolutegravir - TIVICAY (CAP) - abacavir, dolutegravir –TRIUMEQ (CAP) - PSUSA/10075/201501 (with RMP)

Applicant: ViiV Healthcare, ViiV Healthcare UK Limited

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.24. Elosulfase alfa – VIMIZIM (CAP) - PSUSA/10218/201502

Applicant: BioMarin Europe Ltd

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.25. Elvitegravir – VITEKTA (CAP) - PSUSA/02577/201502

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.26. Emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA (CAP) - PSUSA/09142/201502

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.27. Enzalutamide – XTANDI (CAP) - PSUSA/10095/201502

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Dolores Montero Corominas

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.28. Epoetin zeta – RETACRIT (CAP), SILAPO (CAP) - PSUSA/01241/201412

Applicant: Hospira UK Limited, Stada Arzneimittel AG

PRAC Rapporteur: Valerie Strassmann

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.29. Etanercept – ENBREL (CAP) - PSUSA/01295/201502

Applicant: Pfizer Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.30. Fampridine – FAMPYRA (CAP) - PSUSA/01352/201501 (with RMP)

Applicant: Biogen Idec Ltd.

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.31. Fingolimod – GILENYA (CAP) - PSUSA/01393/201502

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Isabelle Robine

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.32. Florbetaben (^{18}F) – NEURACEQ (CAP) - PSUSA/10094/201502

Applicant: Piramal Imaging Limited

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.33. Gadoversetamide – OPTIMARK (CAP) - PSUSA/01508/201501

Applicant: Mallinckrodt Deutschland GmbH

PRAC Rapporteur: Almath Spooner

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.34. Gimeracil, oteracil potassium, tegafur – TEYSUNO (CAP) - PSUSA/02875/201501

Applicant: Nordic Group B.V.

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.35. Human coagulation factor VIII, von Willebrand factor – VONCENTO (CAP) - PSUSA/10102/201502

Applicant: CSL Behring GmbH

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action n: For adoption of recommendation to CHMP

6.1.36. Idelalisib – ZYDELIG (CAP) - PSUSA/10303/201503

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.37. Infliximab – INFLECTRA (CAP), REMSIMA (CAP) - PSUSA/10106/201501

Applicant: Hospira UK Limited, Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.38. Ingenol mebutate – PICATO (CAP) - PSUSA/10035/201501

Applicant: Leo Pharma A/S

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.39. Ivacaftor – KALYDECO (CAP) - PSUSA/09204/201501

Applicant: Vertex Pharmaceuticals (U.K.) Ltd.

PRAC Rapporteur: Miguel-Angel Macia

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.40. Lipegfilgrastim – LONQUEX (CAP) - PSUSA/10111/201501

Applicant: Sicor Biotech UAB

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.41. Lixisenatide – LYXUMIA (CAP) - PSUSA/10017/201501

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Qun-Ying Yue

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.42. Lomitapide – LOJUXTA (CAP) - PSUSA/10112/201501

Applicant: Aegerion Pharmaceuticals Limited

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.43. Loxapine – ADASUVE (CAP) - PSUSA/10113/201502

Applicant: Alexza UK Ltd.

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.44. Meningococcal group B vaccine (rDNA, component, adsorbed) – BEXSERO (CAP) - PSUSA/10043/201501

Applicant: Novartis Vaccines and Diagnostics S.r.l.

PRAC Rapporteur: Qun-Ying Yue

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.45. Mifamurtide – MEPACT (CAP) - PSUSA/02059/201503 (with RMP)

Applicant: Takeda France SAS

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.46. Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches – VELPHORO (CAP) - PSUSA/10296/201502

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.47. Modified vaccinia ankara virus – IMVANEX (CAP) - PSUSA/10119/201501

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.48. Nalmefene – SELINCRO (CAP) - PSUSA/10120/201502

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.49. Nilotinib – TASIGNA (CAP) - PSUSA/02162/201501

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Doris Stenver

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.50. Nitisinone – ORFADIN (CAP) - PSUSA/02169/201502

Applicant: Swedish Orphan Biovitrum International AB

PRAC Rapporteur: Carmela Macchiarulo

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.51. Nonacog gamma – RIXUBIS (CAP) - PSUSA/10320/201412

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.52. Palifermin – KEPIVANCE (CAP) - PSUSA/02265/201501 (with RMP)

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.53. Peginterferon beta-1a – PLEGRIDY (CAP) - PSUSA/10275/201501 (with RMP)

Applicant: Biogen Idec Ltd

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.54. Pegloticase – KRYSTEXXA (CAP) - PSUSA/10046/201501

Applicant: Crealta Pharmaceuticals Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.55. Pemetrexed – ALIMTA (CAP) - PSUSA/02330/201502 (with RMP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Corinne Fechant

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.56. Perampanel – FYCOMPA (CAP) - PSUSA/09255/201501

Applicant: Eisai Europe Ltd.

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.57. Pirfenidone – ESBRIET (CAP) - PSUSA/02435/201502 (with RMP)

Applicant: Roche Registration Limited

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.58. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) – PREVENAR 13 (CAP) - PSUSA/09263/201501 (with RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Qun-Ying Yue

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.59. Pomalidomide – IMNOVID (CAP) - PSUSA/10127/201502 (with RMP)

Applicant: Celgene Europe Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.60. Prasugrel – EFIENT (CAP) - PSUSA/02499/201502 (with RMP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Torbjorn Callreus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.61. Pyronaridine, artesunate – PYRAMAX (Art 58) – EMEA/H/W/002319/PSUV/0010

Applicant: Shin Poong Pharmaceutical Co., Ltd.

PRAC Rapporteur: Isabelle Robine

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.62. Ranolazine – RANEXA (CAP) - PSUSA/02611/201501

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Qun-Ying Yue

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.63. Rivastigmine – EXELON (CAP); PROMETAX (CAP); RIVASTIGMINE 1A PHARMA (CAP); RIVASTIGMINE HEXAL (CAP); RIVASTIGMINE SANDOZ (CAP) - PSUSA/02654/201501

Applicant: Novartis Europharm Ltd, 1 A Pharma GmbH, Hexal AG, Sandoz GmbH

PRAC Rapporteur: Isabelle Robine

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.64. Rufinamide – INOVELON (CAP) - PSUSA/02671/201501

Applicant: Eisai Ltd

PRAC Rapporteur: Isabelle Robine

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.65. Ruxolitinib – JAKAVI (CAP) - PSUSA/10015/201502

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.66. Silodosin – SILODYX (CAP), UROREC (CAP) - PSUSA/02701/201501

Applicant: Recordati Ireland Ltd.

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.67. Simoctocog alfa – NUWIQ (CAP) - PSUSA/10276/201501

Applicant: Octapharma AB

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.68. Tacrolimus – ENVARSUS (CAP) - PSUSA/10337/201501

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Almath Spooner

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.69. Teduglutide – REVESTIVE (CAP) - PSUSA/09305/201502

Applicant: NPS Pharma Holdings Limited

PRAC Rapporteur: Torbjorn Callreus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.70. Trastuzumab emtansine – KADCYLA (CAP) - PSUSA/10136/201502

Applicant: Roche Registration Limited

PRAC Rapporteur: Doris Stenver

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.71. Ulipristal acetate – ESMYA (CAP) - PSUSA/09325/201502

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.72. Velaglucerase alfa – VPRIV (CAP) - PSUSA/03103/201502 (with RMP)

Applicant: Shire Pharmaceuticals Ireland Ltd.

PRAC Rapporteur: Valerie Strassmann

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.73. Vismodegib – ERIVEDGE (CAP) - PSUSA/10140/201501

Applicant: Roche Registration Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

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

6.2.1. Estradiol, nomegestrol acetate – ZOELY (CAP), NAP - PSUSA/02182/201501

Applicant: Teva B.V., various

PRAC Rapporteur: Corinne Fechant

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.2.2. Nitric oxide – INOMAX (CAP), NAP - PSUSA/02172/201412

Applicant: Linde Healthcare AB, various

PRAC Rapporteur: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.2.3. Orlistat – ALLI (CAP), XENICAL (CAP), NAP - PSUSA/02220/201502

Applicant: Glaxo Group Ltd, Roche Registration Ltd, various

PRAC Rapporteur: Corinne Fechant

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.2.4. Pregabalin – LYRICA (CAP), PREGABALIN PFIZER (CAP), NAP - PSUSA/02511/201501

Applicant: Pfizer Limited, various

PRAC Rapporteur: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.2.5. Repaglinide – NOVONORM (CAP), PRANDIN (CAP), NAP - PSUSA/02618/201412

Applicant: Novo Nordisk A/S, various

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

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

6.3.1. Alpha-1-antitrypsin (NAP) - PSUSA/00108/201412

Applicant: various

PRAC Lead: Doris Stenver

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.2. Altizide, spironolactone (NAP) – PSUSA/02781/201501

Applicant: various

PRAC Lead: Viola Macolić Šarinić

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.3. Amisulpride (NAP) - PSUSA/00167/201501

Applicant: various

PRAC Lead: Almath Spooner

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.4. Androstanolone (NAP) - PSUSA/00212/201412

Applicant: various

PRAC Lead: Corinne Fechant

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.5. Atovaquone (NAP) - PSUSA/00265/201411

Applicant: various

PRAC Lead: Isabelle Robine

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.6. Azelastine (NAP) - PSUSA/00277/201412

Applicant: various

PRAC Lead: Marianne Lunzer

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.7. Betahistine (NAP) - PSUSA/00389/201412

Applicant: various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.8. Calcitriol (NAP) - PSUSA/00000495/201501

Applicant: various

PRAC Lead: Carmela Macchiarulo

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.9. Celecoxib (NAP) - PSUSA/00616/201412

Applicant: various

PRAC Lead: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.10. Cyproheptadine (NAP) - PSUSA/00000902/201412

Applicant: various

PRAC Lead: Julia Pallos

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.11. Delapril (NAP) - PSUSA/00000946/201501

Applicant: various

PRAC Lead: Carmela Macchiarulo

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.12. Desmopressin (NAP) - PSUSA/00000964/201412

Applicant: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.13. Domperidone (NAP) - PSUSA/00001158/20150

Applicant: various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.14. Enalapril, nitrendipine (NAP) - PSUSA/00001213/201501

Applicant: various

PRAC Lead: Dolores Montero Corominas

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.15. Ethinylestradiol, gestodene (transdermal application) (NAP) - PSUSA/00010145/201502

Applicant: various

PRAC Lead: Isabelle Robine

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.16. 5-Fluorouracil (intravenous application) (NAP) - PSUSA/00000007/201412

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.17. 5-Fluorouracil (topical application) (NAP) - PSUSA/00010000/201412

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.18. Flupirtine (NAP) - PSUSA/00010225/201501

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.19. Furosemide (NAP) - PSUSA/00001491/201501

Applicant: various

PRAC Lead: Margarida Guimarães

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.20. Gasiloxe (NAP) - PSUSA/00010283/201501

Applicant: various

PRAC Lead: Miguel-Angel Macia

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Glatiramer (NAP) - PSUSA/00001529/201411

Applicant: various

PRAC Lead: Julie Williams

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.22. Hydrochlorothiazide, ramipiril (NAP) - PSUSA/00001660/201501

Applicant: various

PRAC Lead: Carmela Macchiarulo

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.23. Hydrochlorothiazide, spironolactone (NAP) - PSUSA/00001662/201501

Applicant: various

PRAC Lead: Viola Macolić Šarinić

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.24. Levonorgestrel (NAP) - PSUSA/00001856/201412

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.25. Lormetazepam (NAP) - PSUSA/00001910/201412

Applicant: various

PRAC Lead: Marianne Lunzer

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.26. Magnesium sulphate, sodium sulphate, potassium sulphate (NAP) - PSUSA/00010239/201502

Applicant: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.27. Methylprednisolone (NAP) - PSUSA/00002026/201411

Applicant: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure
Action: For adoption of an updated recommendation to CMDh

6.3.28. Phenylephrine (NAP) - PSUSA/00002378/201501

Applicant: various

PRAC Lead: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.29. Potassium para aminobenzoate (NAP) - PSUSA/00010130/201502

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For discussion: Preliminary PRAC Rapporteur AR

6.3.30. Pseudoephedrine, triprolidine (NAP) - PSUSA/00003047/201412

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.31. Reviparin (NAP) - PSUSA/00002634/201501

Applicant: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.32. Roxithromycin (NAP) - PSUSA/00002669/201412

Applicant: various

PRAC Lead: Carmela Macchiarulo

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.33. Rubella vaccine (live, attenuated) (NAP) - PSUSA/00002670/201501

Applicant: various

PRAC Lead: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.34. Tetanus vaccine (NAP) - PSUSA/00002910/201501

Applicant: various

PRAC Lead: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.35. Tizanidine (NAP) - PSUSA/00002977/201412

Applicant: various

PRAC Lead: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.36. Tobramycin (nebuliser solution) (NAP) - PSUSA/00009316/201412

Applicant: various

PRAC Lead: Carmela Macchiarulo

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.3.37. Valproic acid, sodium valproate, valproate pivoxil, valproate semisodium, valpromide, valproate bismuth, calcium valproate, valproate magnesium (NAP) – PSUSA/03090/201501

Applicant: various

PRAC Lead: Sabine Straus

Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Alogliptin – VIPIDIA (CAP) - EMEA/H/C/002182/LEG 009 alogliptin, metformin - VIPDOMET (CAP) - EMEA/H/C/002654/LEG 008 alogliptin, pioglitazone – INCRESYNC (CAP) - EMEA/H/C/002178/LEG 008

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Menno van der Elst

Scope: MAH's response to PSUSA/00010061/201410 following PRAC adoption in April 2015
Action: For adoption of recommendation to CHMP

6.4.2. Arsenic trioxide – TRISENOX (CAP) - EMEA/H/C/000388/LEG 049

Applicant: Teva B.V.

PRAC Rapporteur: Corinne Fechant

Scope: MAH's responses to PSUSA/00000235/201409/0053
Action: For adoption of advice to CHMP

6.4.3. Botulinium B toxin – NEUROBLOC (CAP) - EMEA/H/C/000301/LEG 062

Applicant: Eisai Ltd

PRAC Rapporteur: Magda Pedro

Scope: MAH's response to EMEA/H/C/PSUSA/00000428/201406 following PRAC outcome in February 2015
Action: For adoption of advice to CHMP

6.4.4. Dibotermin alfa – INDUCTOS (CAP) - EMEA/H/C/000408/LEG 070

Applicant: Medtronic BioPharma B.V.

PRAC Rapporteur: Menno van der Elst

Scope: MAH's response to EMEA/H/C/PSUSA/00001034/201409 as adopted in April 2015
Action: For adoption of advice to CHMP

6.4.5. Iloprost – VENTAVIS (CAP) - EMEA/H/C/000474/LEG 037

Applicant: Bayer Pharma AG

PRAC Rapporteur: Isabelle Robine

Scope: MAH's response to EMEA/H/C/474/PSUSA/00001724/201409 as adopted in April 2015
Action: For adoption of advice to CHMP

6.4.6. Infliximab – REMICADE (CAP) - EMEA/H/C/000240/LEG 153

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Cumulative review of weight changes in patients treated with Remicade (infliximab)
Action: For adoption of advice to CHMP

6.4.7. Leflunomide – ARAVA (CAP) - EMEA/H/C/000235/LEG 056; LEFLUNOMIDE WINTHROP (CAP) - EMEA/H/C/001129/LEG 023

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Sabine Straus

Scope: MAH's response to EMEA/H/C/000235/PSUSA/00001837/201409/0064 following PRAC adoption in April 2015
Action: For adoption of advice to CHMP

6.4.8. Mycophenolate mofetil – CELLCEPT (CAP) - EMEA/H/C/000082/LEG 038

Applicant: Roche Registration Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: MAH's response to EMEA/H/C/PSUSA/00002099/201405 on Drug Safety Report for Haemolytic Anaemia (DUS 1065479) and Interstitial Lung Disease (DUS 1065477)
Action: For adoption of advice to CHMP

6.4.9. Sirolimus – RAPAMUNE (CAP) - EMEA/H/C/000273/LEG 052

Applicant: Pfizer Limited

PRAC Rapporteur: Ulla Wändel Liminga

Scope: MAH's responses to (EMEA/H/C/PSUSA/00002710/201409) as adopted in May 2015 following PRAC
Action: For adoption of advice to CHMP

6.4.10. Temozolomide – TEMODAL (CAP) - EMEA/H/C/000229/LEG 040

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Martin Huber

Scope: MAH's responses to (EMEA/H/C/PSUSA/00002886/201407): cumulative review on the concomitant use of live vaccines and temozolomide
Action: For adoption of advice to CHMP

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[4]

7.1.1. Afamelanotide – SCENESSE (CAP) – EMEA/H/C/PSP/0022.1

Applicant: Clinuvel (UK) Limited

PRAC Rapporteur: Valerie Strassmann

Scope: Revised PASS protocol for study CUV-PA001: disease registry to assess long-term safety and generate data on the clinical benefits of afamelanotide 16 mg implant in patients with erythropoietic protoporphyria (EPP)
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.2. Chlormadinone acetate, ethinyl estradiol (NAP) – EMEA/H/N/PSP/0012.2

Applicant: Gideon Richter, various

PRAC Rapporteur: Valerie Strassmann

Scope: Revised joint PASS protocol (following conclusion of Article31 referral procedure for combined hormonal contraceptives with CHMP opinion adopted in November 2013) to study the risk of venous thromboembolism (VTE) associated with chlormadinone/ethinylestradiol (CMA/EE) containing products

[4] In accordance with Article 107n of Directive 2001/83/EC

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

7.1.3. Dexamfetamine (NAP) – EMEA/H/N/PSP/0018.1

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Julie Williams

Scope: Revised protocol for a post-authorisation safety study to evaluate the long-term safety profile of dexamfetamine in children with attention deficit hyperactivity disorder (ADHD), specifically targeting key issues such as cardiovascular events, growth and psychiatric related adverse events
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.4. Dexamfetamine (NAP) – EMEA/H/N/PSP/0021.1

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Julie Williams

Scope: Revised protocol for a drug utilisation study of dexamfetamine to follow the use of prescribed dexamfetamine in the European Union using multiple data sources
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.5. Domperidone (NAP) – EMEA/H/N/PSP/0016.1

Applicant: Janssen (Motilium), various

PRAC Rapporteur: Isabelle Robine

Scope: Revised PASS protocol for a study is to characterise prescribers' knowledge, understanding and extent of awareness regarding the new safety information for domperidone following the change in SmPC and the distribution of DHPC. The secondary objective of the study is to characterise the extent to which domperidone is prescribed for conditions that are not labelled
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.6. Ospemifene – SENSHIO (CAP) - EMEA/H/C/PSP/0023.1

Applicant: Shionogi Limited

PRAC Rapporteur: Julie Williams

Scope: Revised protocol for a post-authorisation safety study to evaluate the incidence of venous thromboembolism and other adverse events, as agreed in the risk management plan, in vulvar and vaginal atrophy (VVA) patients treated with ospemifene as compared to: 1) patients newly prescribed selective oestrogen receptor modulators (SERMs) for oestrogen-deficiency conditions or breast cancer prevention; 2) the incidence in untreated VVA patients
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.7. Thiocolchicoside (NAP) - EMEA/H/N/PSP/j/0030

Applicant: Sanofi-Aventis Recherche & Développement, various

PRAC Rapporteur: To be appointed

Scope: Drug utilisation study to characterise prescribing practices for the medicinal products during typical clinical use in representative groups of prescribers and to assess main reasons for prescription
Action: For adoption of procedure timetable

7.1.8. Valproate (NAP) - EMEA/H/N/ PSP/j/0029

Applicant: Sanofi Aventis R&D, various

PRAC Rapporteur: Sabine Straus

Scope: PASS protocol for a drug utilisation study (DUS) to assess the effectiveness of the risk minimisation measures and to further characterise the prescribing patterns for valproate
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[5]

7.2.1. Aflibercept – ZALTRAP (CAP) - EMEA/H/C/002532/MEA 002.2

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Ulla Wändel Liminga

Scope: MAH's responses to MEA 002.1 [PASS protocol for study OZONE OBS13597] adopted in September 2013
Action: For adoption of advice to CHMP

7.2.2. Apremilast – OTEZLA (CAP) - EMEA/H/C/003746/MEA 005

Applicant: Celgene Europe Limited

PRAC Rapporteur: Dolores Montero Corominas

Scope: Evaluation of a PASS protocol to collect long-term data, as required in the RMP, by using the PsoBest registry
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2.3. Apremilast – OTEZLA (CAP) - EMEA/H/C/003746/MEA 006

Applicant: Celgene Europe Limited

PRAC Rapporteur: Dolores Montero Corominas

Scope: Evaluation of a PASS protocol to investigate several safety concerns, as required in the RMP, using the CPRD (UK) database
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2.4. Bromelain enriched proteolytic enzyme preparation from ananas comosus – NEXOBRID (CAP) - EMEA/H/C/002246/MEA 003.2

Applicant: MediWound Germany GmbH

PRAC Rapporteur: Valerie Strassmann

[5] 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

Scope: Evaluation of a revised PASS protocol (MW2013-06-01) for a drug utilisation study to further evaluate the effectiveness of the risk minimisation activities (including evaluation of educational and training materials)

Action: For adoption of advice to CHMP

7.2.5. Buprenorphine, naloxone – SUBOXONE (CAP) - EMEA/H/C/000697/MEA 023.4

Applicant: RB Pharmaceuticals Ltd

PRAC Rapporteur: Martin Huber

Scope: MAH's responses to MEA 023.3 [protocol for safety study PE-US-005-Suboxone mortality study in the UK with the Health Improvement Network database (THIN)], request for supplementary information (RSI) as adopted in March 2013
Action: For adoption of advice to CHMP

7.2.6. Canakinumab – ILARIS (CAP) - EMEA/H/C/001109/MEA/037.3

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: MAH's response to MEA-037.2 [non-interventional study collecting safety and efficacy data from systemic juvenile idiopathic arthritis (SJIA) patients enrolled in Pharmachild JIA registry, revised protocol, study no. CACZ885G2401] as adopted in June 2015
Action: For adoption of PRAC Assessment Report

7.2.7. Crizotinib – XALKORI (CAP) - EMEA/H/C/002489/MEA 011.3

Applicant: Pfizer Limited

PRAC Rapporteur: Corinne Fechant

Scope: Revised PASS protocol for study A8081038 to estimate the incidence rate and incidence proportion over a 3-year period of observation for hepatotoxicity, pneumonitis/interstitial lung disease (ILD), QTc prolongation related events, bradycardia, and visual disorder among lung cancer patients receiving crizotinib prescriptions
Action: For adoption of advice to CHMP

7.2.8. Crizotinib – XALKORI (CAP) - EMEA/H/C/002489/MEA 022

Applicant: Pfizer Limited

PRAC Rapporteur: Corinne Fechant

Scope: PASS protocol for studies to evaluate the effectiveness of the patient information brochure (PIB) and therapeutic management guide (TMG). It consists of: 1) study A8081049: cross-sectional study to evaluate the effectiveness of the TMG among physician; 2) study A8081050: a cross-sectional study to evaluate the effectiveness of the PIB among non-small cell lung cancer (NSCLC) patients receiving Xalkori treatment in Europe
Action: For adoption of advice to CHMP

7.2.9. Eliglustat – CERDELGA (CAP) - EMEA/H/C/003724/MEA 005.1

Applicant: Genzyme Europe BV

PRAC Rapporteur: Dolores Montero Corominas

Scope: Drug utilisation study for eliglustat in Europe using electronic healthcare records (final protocol for US DUS study report / ELIGLC06913)
Action: For adoption of advice to CHMP

7.2.10. Eliglustat – CERDELGA (CAP) - EMEA/H/C/003724/MEA 006

Applicant: Genzyme Europe BV

PRAC Rapporteur: Dolores Montero Corominas

Scope: Drug utilisation study for eliglustat in the US population using the MarketScan database (final protocol for US DUS study report / ELIGL C06912)
Action: For adoption of advice to CHMP

7.2.11. Empagliflozin – JARDIANCE (CAP) - EMEA/H/C/002677/MEA 002.1

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Miguel-Angel Macia

Scope: MAH's response to MEA 002 [PASS protocol for BI study no. 1245.96] request for supplementary information (RSI) as adopted in May 2015
Action: For adoption of advice to CHMP

7.2.12. Epoetin zeta – RETACRIT (CAP) - EMEA/H/C/000872/MEA 031.1

Applicant: Hospira UK Limited

PRAC Rapporteur: Valerie Strassmann

Scope: PASS protocol for a PASCO II (PMS-830-09-0082): post-authorisation safety cohort observation of Silapo (epoetin zeta) administered subcutaneously for the treatment of renal anaemia
Action: For adoption of advice to CHMP

7.2.13. Florbetaben (^{18}F) – NEURACEQ (CAP) - EMEA/H/C/002553/MEA 001.3

Applicant: Piramal Imaging Limited

PRAC Rapporteur: Julie Williams

Scope: MAH's responses to MEA. 001.2 [revised PASS protocol for study no. FBB-01_03_13] as adopted in April 2015
Action: For adoption of advice to CHMP

7.2.14. Flutemetamol (^{18}F) – VIZAMYL (CAP) - EMEA/H/C/002557/MEA 003.1

Applicant: GE Healthcare Ltd

PRAC Rapporteur: Julie Williams

Scope: MAH's responses to MEA-003 [PASS protocol for a drug utilisation study as an additional pharmacovigilance activity to further characterize the safety concern (GE067-028)] as adopted in March 2015
Action: For adoption of advice to CHMP

7.2.15. Hydrocortisone – PLENADREN (CAP) - EMEA/H/C/002185/MEA 005.1

Applicant: ViroPharma SPRL

PRAC Rapporteur: Qun-Ying Yue

Scope: PASS protocol for study SWE-DUS (study no.: 10918 -404 (SHP617-404): a Swedish, retrospective, study progress reports to be provided on a yearly basis evaluating the pattern of Plenadren use from as part of the PSURs Swedish quality registries
Action: For adoption of advice to CHMP

7.2.16. Ibrutinib – IMBRUVICA (CAP) - EMEA/H/C/003791/MEA 023.1

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Julie Williams

Scope: Updated protocol for a PASS study PCYC-PMR-2060-04: enhanced pharmacovigilance to evaluate the risks of haemorrhage with the administration of ibrutinib

7.2.17. Insulin human – INSUMAN (CAP) - EMEA/H/C/000201/MEA 047.1

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Jean-Michel Dogné

Scope: MAH's response to MEA 047 [PASS protocol for study HUBIN-C-06380] as adopted in April 2015
Action: For adoption of advice to CHMP

7.2.18. Liraglutide – SAXENDA (CAP) - EMEA/H/C/003780/MEA 014

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Menno van der Elst

Scope: Drug utilisation study (DUS) protocol (study No. NN8022-4241): in-market utilisation of liraglutide used for weight management in Europe: a retrospective medical record review study
Action: For adoption of advice to CHMP

7.2.19. Liraglutide – SAXENDA (CAP) - EMEA/H/C/003780/MEA 015

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Menno van der Elst

Scope: Drug utilisation study (DUS) protocol (study No. NN8022-4246): in-market utilisation of liraglutide used for weight management in the UK: a study in the CPRD primary care database
Action: For adoption of advice to CHMP

7.2.20. Rituximab – MABTHERA (CAP) - EMEA/H/C/000165/MEA 093

Applicant: Roche Registration Ltd

PRAC Rapporteur: Doris Stenver

Scope: PASS protocol on long-term surveillance study of rituximab-treated patients with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)
Action: For adoption of advice to CHMP

7.2.21. Sofosbuvir, ledipasvir – HARVONI (CAP) - EMEA/H/C/003850/MEA 013

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Margarida Guimarães

Scope: Drug utilisation study (DUS) protocol (study number GS-EU-337-1820): an observational drug utilisation study of ledipasvir/sofosbuvir and tenofovir disoproxil fumarate with pharmacokinetic enhancer co-administration in adults co-infected with chronic hepatitis C and human immunodeficiency (HIV)-1 infections
Action: For adoption of advice to CHMP

7.2.22. Tocilizumab – ROACTEMRA (CAP) - EMEA/H/C/000955/MEA 041.4

Applicant: Roche Registration Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Revised paediatric registry protocol: observational safety and effectiveness study of patients with polyarticular juvenile idiopathic arthritis treated with tocilizumab
Action: For adoption of advice to CHMP

7.2.23. Vernakalant – BRINAVESS (CAP) - EMEA/H/C/001215/MEA 026

Applicant: Cardiome UK Limited

PRAC Rapporteur: Menno van der Elst

Scope: PASS protocol for vernakalant intravenous (IV) sterile concentrate prospective safety registry study: a prospective observational registry study to characterise normal conditions of use, dosing and safety following administration of vernakalant IV sterile concentrate (study 6621 049-00)
Action: For adoption of advice to CHMP

7.2.24. Voriconazole – VFEND (CAP) - EMEA/H/C/000387/MEA 091.1

Applicant: Pfizer Limited

PRAC Rapporteur: Sabine Straus

Scope: MAH's response to MEA-091 [PASS protocol for study A1501103] as adopted in April 2015
Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[6]

None

[6] In accordance with Article 107p-q of Directive 2001/83/EC

7.4. Results of PASS non-imposed in the marketing authorisation(s)[7]

7.4.1. Abacavir – ZIAGEN (CAP) - EMEA/H/C/000252/WS/0769 (without RMP)

Applicant: ViiV Healthcare UK Limited

PRAC Rapporteur: Isabelle Robine

Scope: Submission of final clinical study report (CSR) for mitochondrial toxicity in children (MITOC) study (WE027/WWE112888). The MAH took also the opportunity to respond to a LEG on mitochondrial dysfunction to address the request on revision of class labelling of antiretrovirals on mitochondrial toxicity
Action: For adoption of PRAC Assessment Report

7.4.2. Aliskiren – RASILEZ (CAP) - EMEA/H/C/000780/WS/0807 (without RMP); aliskiren, hydrochlorothiazide – RASILEZ HCT (CAP) – EMEA/H/C/000964/WS/0807 (without RMP)

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Carmela Macchiarulo

Scope: Submission of final results of the non-interventional (NIS) aliskiren study SPP100A2418 on the incidence of colorectal hyperplasia and gastrointestinal cancer in aliskiren treated patients
Action: For adoption of PRAC Assessment Report

7.4.3. Anidulafungin – ECALTA (CAP) - EMEA/H/C/000788/II/0030 (without RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Sabine Straus

Scope: Submission of final study results of study A8851030: retrospective cohort study of the risk of severe hepatic injury in hospitalised patients treated with echinocandins for candida infections
Action: For adoption of PRAC Assessment Report

7.4.4. Bivalirudin – ANGIOX (CAP) - EMEA/H/C/000562/II/0058 (without RMP)

Applicant: The Medicines Company UK Ltd.

PRAC Rapporteur: Julie Williams

Scope: Study report for the study entitled: 'exposure and adverse event assessment (EAEA) for protocol TMC-BIV-07-01 bivalirudin (Angiomax) as a procedural anticoagulant in the paediatric population undergoing intravascular procedures for congenital heart disease' to update information on paediatric population

Action: For adoption of PRAC Assessment Report

7.4.5. Dabigatran – PRADAXA (CAP) - EMEA/H/C/000829/II/0079/G (with RMP)

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Torbjorn Callreus

[7] 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

Scope: Submission of the final clinical study report (CSR) for study 1160.84: observational cohort study undertaken to evaluate the safety and efficacy of Pradaxa in patients with moderate renal impairment (creatinine clearance 30-50 ml/min) undergoing elective total hip replacement surgery or total knee replacement surgery. An updated RMP (version 31.0) was submitted accordingly
Action: For adoption of PRAC Assessment Report

7.4.6. Etanercept – ENBREL (CAP) - EMEA/H/C/000262/II/0182 (with RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Submission of the final report of the STORK study: retrospective study to evaluate pregnancy outcomes associated with and without etanercept use among pregnant women with chronic inflammatory arthritis or psoriasis, as listed in RMP part III
Action: For adoption of PRAC Assessment Report

7.4.7. Human rotavirus, live attenuated – ROTARIX (CAP) - EMEA/H/C/000639/II/0062 (with RMP)

Applicant: GlaxoSmithKline Biologicals S.A.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the final report of genetic stability study EPI-ROTA-014 VS BE – 112560 that addresses the post-approval measure ME2 005.2: monitoring for the potential occurrence of genetic drifts and shifts in the vaccine strain in post-marketing settings
Action: For adoption of PRAC Assessment Report

7.4.8. Insulin detemir – LEVEMIR (CAP) - EMEA/H/C/000528/WS/0784 (with RMP) liraglutide – SAXENDA (CAP) - EMEA/H/C/003780/WS/0784; VICTOZA (CAP) - EMEA/H/C/001026/WS/0784 - (with RMP)

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Menno van der Elst

Scope: Submission of final results for the database study NN2211-3880: a health care database study using the clinical practice research datalink (CPRD) to evaluate and monitor the safety of liraglutide
Action: For adoption of PRAC Assessment Report

7.4.9. Lamivudine – EPIVIR (CAP) - EMEA/H/C/000107/WS/0769 (without RMP), LAMIVUDINE VIIV (Art 58) - EMEA/H/W/000673/WS/0769 (without RMP); lamivudine, abacavir – KIVEXA (CAP) - EMEA/H/C/000581/WS/0769 (without RMP); lamivudine, abacavir, zidovudine – TRIZIVIR (CAP) - EMEA/H/C/000338/WS/0769 (without RMP); lamivudine, zidovudine – COMBIVIR (CAP) - EMEA/H/C/000190/WS/0769 (without RMP)

Applicant: ViiV Healthcare UK Limited

PRAC Rapporteur: Isabelle Robine

Scope: Submission of final clinical study report (CSR) for mitochondrial toxicity in children (MITOC) study (WE027/WWE112888). The MAH took also the opportunity to respond to a LEG on mitochondrial dysfunction to address the request on revision of class labelling of antiretrovirals on mitochondrial toxicity

Action: For adoption of PRAC Assessment Report

7.4.10. Moroctocog alfa – REFACTO AF (CAP) - EMEA/H/C/000232/II/0127/G (with RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Doris Stenver

Scope: Submission of a post-marketing study in subjects with haemophilia A, study B1831078 and consequential update of the RMP. In addition, introduction of missing information in the RMP as previously agreed with PRAC: 'patients receiving anti-fibrinolytic agents, medications known to influence platelet function and concomitant therapy with immunosuppressive drugs' and 'patients with genetic polymorphisms'
Action: For adoption of PRAC Assessment Report

7.4.11. Raltegravir – ISENTRESS (CAP) - EMEA/H/C/000860/II/0052 (without RMP)

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Julie Williams

Scope: Submission of the fifth and final report of the five-year EuroSIDA post-authorisation observational study
Action: For adoption of PRAC Assessment Report

7.4.12. Regorafenib – STIVARGA (CAP) - EMEA/H/C/002573/II/0013 (without RMP)

Applicant: Bayer Pharma AG

PRAC Rapporteur: Sabine Straus

Scope: Submission of the final clinical study report for study 16675 single-centre, open-label, non-randomized, two-period sequential treatment study to assess the effect of neomycin on the pharmacokinetics of regorafenib in healthy male subjects. The data does not require an update of the product information. An updated RMP is included
Action: For adoption of PRAC Assessment Report

7.4.13. Tolvaptan – SAMSCA (CAP) - EMEA/H/C/000980/II/0020 (without RMP)

Applicant: Otsuka Pharmaceutical Europe Ltd

PRAC Rapporteur: Julie Williams

Scope: Submission of the final study report for Samsca PASS (FUM 004): a multi-centre multi-national observational post-authorisation safety study to document the drug utilisation of Samsca and to collect information on the safety of Samsca when used in routine medical practice
Action: For adoption of PRAC Assessment Report

7.4.14. Vildagliptin – GALVUS (CAP) - EMEA/H/C/000771/WS/0791, JALRA (CAP) - EMEA/H/C/001048/WS/0791, XILIARX (CAP) - EMEA/H/C/001051/WS/0791 (with RMP)
Vildagliptin, metformin – EUCREAS (CAP) - EMEA/H/C/000807/WS/0791, ICANDRA (CAP) - EMEA/H/C/001050/WS/0791, ZOMARIST (CAP) - EMEA/H/C/001049/WS/0791 (with RMP)

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Qun-Ying Yue

Scope: Submission of the final results of PASS study CLAF237A2401 to add the study results and to include the 'rhabdomyolysis' under the current potential risk as 'muscle events/myopathy/rhabdomyolysis, in particular with concurrent statin use' following the PRAC recommendation EMA/PRAC/716523/2014. An updated RMP (version 13.0) is submitted accordingly
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[8]

7.5.1. Apixaban – ELIQUIS (CAP) - EMEA/H/C/002148/MEA 012.3

Applicant: Bristol-Myers Squibb / Pfizer EEIG

PRAC Rapporteur: Menno van der Elst

Scope: Second interim report on a drug utilisation study (DUS) to monitor the potential off label use with apixaban: study of the utilisation patterns in Sweden (study B066017) and in the Netherlands (study B066018)
Action: For adoption of advice to CHMP

7.5.2. Canagliflozin – INVOKANA (CAP) - EMEA/H/C/002649/MEA 005.2

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Valerie Strassmann

Scope: MAH's responses to MEA 004.1 and 005.1 [canagliflozin independent data monitoring committee (IDMC) status reports for the DIA3008 CANVAS study], request for supplementary information (RSI) as adopted in April 2015
Action: For adoption of advice to CHMP

7.5.3. Canagliflozin – INVOKANA (CAP) - EMEA/H/C/002649/MEA 005.3

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Valerie Strassmann

Scope: Six-monthly status report of the canagliflozin independent data monitoring committee (IDMC) for the DIA3008 CANVAS study as requested in the RMP additional pharmacovigilance activity
Action: For adoption of advice to CHMP

7.5.4. Canagliflozin – INVOKANA (CAP) - EMEA/H/C/002649/MEA 006

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Valerie Strassmann

Scope: Status report 1 of the canagliflozin independent data monitoring committee (IDMC) for the NE-3001 CREDENCE study as requested in the RMP additional pharmacovigilance activity
Action: For adoption of advice to CHMP

[8] In line with the revised variations regulation for any submission before 4 August 2013

7.5.5. Canagliflozin, metformin - VOKANAMET (CAP) - EMEA/H/C/002656/MEA 004.2

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Menno van der Elst

Scope: MAH's responses to MEA 004.1 [canagliflozin independent data monitoring committee (IDMC) status reports for the DIA3008 CANVAS study], request for supplementary information (RSI) as adopted in April 2015
Action: For adoption of advice to CHMP

7.5.6. Canagliflozin, metformin – VOKANAMET - EMEA/H/C/002656/MEA 005

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Menno van der Elst

Scope: Status report 1 of the canagliflozin independent data monitoring committee (IDMC) for the NE-3001 CREDENCE study as requested in the RMP additional pharmacovigilance activity
Action: For adoption of advice to CHMP

7.5.7. Collagenase clostridium histolyticum – XIAPEX (CAP) - EMEA/H/C/002048/MEA 015.1

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Martin Huber

Scope: Interim clinical study report for study Auxilium B1531005: non-interventional post approval commitment study to evaluate the outcomes of the various treatment options for Dupuytren's contracture
Action: For adoption of advice to CHMP

7.5.8. Data Collection on Adverse Events of Anti-HIV[9] Drugs (D:A:D) study - PRAC evaluation of D:A:D data merger results

Applicant: various

PRAC Representatives: Filip Josephson, Deborah Ashby

Scope: Evaluation of the fifteen data merger
Action: For adoption of advice to CHMP

7.5.9. Efavirenz – SUSTIVA (CAP) - EMEA/H/C/000249/MEA 079.2

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Margarida Guimarães

Scope: Second annual report for malignant events associated with efavirenz: diagnostic consulting network (DCN) report dated June 2015
Action: For adoption of PRAC Assessment Report

[9] Human immunodeficiency virus

7.5.10. Efavirenz, emtricitabine, tenofovir disoproxil – ATRIPLA (CAP) - EMEA/H/C/000797/MEA 039.2

Applicant: Bristol-Myers Squibb and Gilead Sciences Ltd

PRAC Rapporteur: Martin Huber

Scope: Second annual report for malignant events associated with efavirenz: diagnostic consulting network (DCN) report dated June 2015
Action: For adoption of PRAC Assessment Report

7.5.11. Eltrombopag – REVOLADE (CAP) - EMEA/H/C/001110/MEA 022.1

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Dolores Montero Corominas

Scope: Interim report of the study measuring the effectiveness of eltrombopag educational materials for hepatitis C associated thrombocytopenia
Action: For adoption of advice to CHMP

7.5.12. Filgrastim – FILGRASTIM HEXAL (CAP) - EMEA/H/C/000918/MEA 007; ZARZIO (CAP) – EMEA/H/C/000917/MEA 007

Applicant: Hexal AG

PRAC Rapporteur: Julie Williams

Scope: Submission of fourth interim report of study EP06-501 after four years of treatment: a non-interventional, prospective, long-term observational study to assess the safety and effectiveness of Zarzio/Filgrastim Hexal administered to healthy unrelated stem cell donors for peripheral blood progenitor cell mobilisation
Action: For adoption of advice to CHMP

7.5.13. Indacaterol – HIROBRIZ BREEZHALER (CAP) - EMEA/H/C/001211/MEA 015.1; ONBREZ BREEZHALER (CAP) - EMEA/H/C/001114/MEA 017.1; OSLIF BREEZHALER (CAP) - EMEA/H/C/002576/MEA 015.1

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Torbjorn Callreus

Scope: MAH's response [comments on fourth interim study report of US PASS] to request for supplementary information (RSI) as adopted in March 2015
Action: For adoption of advice to CHMP

7.5.14. Infliximab – INFLECTRA (CAP) - EMEA/H/C/002778/MEA 007

Applicant: Hospira UK Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Annual safety and efficacy interim analysis for registry CT-P13 4.2: an observational, prospective cohort study to evaluate safety and efficacy of Inflectra in patients with rheumatoid arthritis (EU and Korea)
Action: For adoption of advice to CHMP

7.5.15. Infliximab – INFLECTRA (CAP) - EMEA/H/C/002778/MEA 010

Applicant: Hospira UK Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Annual safety and efficacy interim analysis for registry CT-P13 4.3: an observational, prospective cohort study to evaluate the safety and efficacy of Inflectra in patients with Crohn's disease (CD), and ulcerative colitis (UC) (EU and Korea)
Action: For adoption of advice to CHMP

7.5.16. Infliximab – REMSIMA (CAP) - EMEA/H/C/002576/MEA 007

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Rafe Suvarna

Scope: Annual safety and efficacy interim analysis for registry CT-P13 4.2: an observational, prospective cohort study to evaluate safety and efficacy of Remsima in patients with rheumatoid arthritis (EU and Korea)
Action: For adoption of advice to CHMP

7.5.17. Infliximab – REMSIMA (CAP) - EMEA/H/C/002576/MEA 010

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Rafe Suvarna

Scope: Annual report on a registry CT-P13 4.3: an observational, prospective cohort study to evaluate the safety and efficacy in patients with Crohn's disease (CD), and ulcerative colitis (UC) (EU and Korea)
Action: For adoption of advice to CHMP

7.5.18. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (CAP) - EMEA/H/C/000758/MEA 041.4

Applicant: Novartis Influenza Vaccines Marburg GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Two year interim report on study V58_30OB, an observational study to investigate the safety of Optaflu vaccination in adults in routine clinical care in the UK using the THIN database
Action: For adoption of advice to CHMP

7.5.19. Mannitol – BRONCHITOL (CAP) – EMEA/H/C/001252/ANX 002.6

Applicant: Pharmaxis Pharmaceuticals Limited

PRAC Rapporteur: Julie Williams

Scope: Fifth interim analysis of the cystic fibrosis (CF) study
Action: For adoption of advice to CHMP

7.5.20. Tenofovir – VIREAD (CAP) - EMEA/H/C/000419/MEA 256.4

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Isabelle Robine

Scope: Interim results for a drug utilisation study (DUS) in human immunodeficiency virus (HIV)-1 and hepatitis B virus (HBV)-infected paediatric patients to follow-up the effectiveness of the risk minimisation measures
Action: For adoption of PRAC Assessment Report

7.5.21. Trastuzumab emtansine – KADCYLA (CAP) - EMEA/H/C/002389/MEA 011.1

Applicant: Roche Registration Limited

PRAC Rapporteur: Doris Stenver

Scope: Second annual interim report on an observational study of pregnancy and pregnancy outcomes in women with breast cancer treated with Herceptin or Perjeta in combination with Herceptin during pregnancy or within 6 months prior to conception
Action: For adoption of advice to CHMP

7.5.22. Vernakalant – BRINAVESS (CAP) - EMEA/H/C/001215/LEG 027

Applicant: Cardiome UK Limited

PRAC Rapporteur: Menno van der Elst

Scope: Follow-up on case report of hypotension
Action: For adoption of advice to CHMP

7.6. Other

7.6.1. Eliglustat – CERDELGA (CAP) - EMEA/H/C/003724/ANX 001

Applicant: Genzyme Europe BV

PRAC Rapporteur: Dolores Montero Corominas

Scope: Concept protocol for a prospective multicentre observational post authorisation safety sub-registry to characterize the long-term safety profile of eliglustat of adult patients with Gaucher disease
Action: For adoption of advice to CHMP

7.6.2. Ketoconazole – KETOCONAZOLE HRA (CAP) - EMEA/H/C/003906/ANX 002.1

Applicant: Laboratoire HRA Pharma

PRAC Rapporteur: Viola Macolic Sarinic

Scope: MAH's responses to ANX 002 [results of ercusyn feasibility study] as adopted in May 2015
Action: For adoption of advice to CHMP

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/0036 (without RMP)

Applicant: BioMarin Europe Ltd

PRAC Rapporteur: Julie Williams

Scope: Annual reassessment of the marketing authorisation
Action: For adoption of advice to CHMP

8.1.2. Laronidase – ALDURAZYME (CAP) - EMEA/H/C/000477/S/0054 (without RMP)

Applicant: Genzyme Europe BV

PRAC Rapporteur: Rafe Suvarna

Scope: Annual reassessment of the marketing authorisation
Action: For adoption of advice to CHMP

8.2. Conditional renewals of the marketing authorisation

None

8.3. Renewals of the marketing authorisation

8.3.1. Cabazitaxel – JEVTANA (CAP) - EMEA/H/C/002018/R/0030 (with RMP)

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Corinne Fechant

Scope: 5-year renewal of the marketing authorisation
Action: For adoption of advice to CHMP

8.3.2. Fingolimod – GILENYA (CAP) - EMEA/H/C/002202/R/0036 (with RMP)

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Isabelle Robine

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.

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

10.1. Safety related variations of the marketing authorisation

10.1.1. Mycophenolate mofetil – CELLCEPT (CAP) – EMEA/H/C/000082/II/0121

Applicant: Roche Registration Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Update of sections 4.4 and 4.6 of the SmPC in order to add a warning for pregnant women and update the safety information related to pregnancy
Action: For adoption of advice to CHMP

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

None

10.3. Other requests

10.3.1. Antiretroviral medicinal products:

Abacavir –ZIAGEN (CAP) - EMEA/H/C/000252/LEG 089.1; abacavir, lamivudine – KIVEXA (CAP) - EMEA/H/C/000581/LEG 045.1; abacavir, lamivudine, zidovudine – TRIZIVIR (CAP) - EMEA/H/C/000338/LEG 090.1; atazanavir– REYATAZ (CAP) - EMEA/H/C/000494/LEG 080.1; darunavir – PREZISTA (CAP) - EMEA/H/C/000707/LEG 070.1; efavirenz – STOCRIN (CAP) - EMEA/H/C/000250/LEG 071.1, SUSTIVA (CAP) - EMEA/H/C/000249/LEG 080.1; efavirenz, emtricitabine, tenofovir disoproxil – ATRIPLA (CAP) - EMEA/H/C/000797/LEG 040.1; elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil – STRIBILD (CAP) - EMEA/H/C/002574/LEG 014.1; emtricitabine – EMTRIVA (CAP) - EMEA/H/C/000533/LEG 049.1; emtricitabine, tenofovir disoproxil – TRUVADA (CAP) - EMEA/H/C/000594/LEG 043.1; emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA (CAP) - EMEA/H/C/002312/LEG 031.1; etravirine – INTELENCE (CAP) - EMEA/H/C/000900/LEG 048.1; fosamprenavir – TELZIR (CAP) - EMEA/H/C/000534/LEG 076.1; indinavir – CRIXIVAN (CAP) - EMEA/H/C/000128/LEG 039.1; lamivudine – EPIVIR (CAP) - EMEA/H/C/000107/LEG 052.1, LAMIVUDINE VIIV (Art 58) - EMEA/H/W/000673/LEG 007.1; lamivudine, zidovudine – COMBIVIR (CAP) - EMEA/H/C/000190/LEG 038.1; lopinavir, ritonavir –ALUVIA (Art 58) - EMEA/H/W/000764/LEG 031.1, KALETRA (CAP) - EMEA/H/C/000368/LEG 118.1; nevirapine – VIRAMUNE (CAP) - EMEA/H/C/000183/LEG 061.1; rilpivirine – EDURANT (CAP) - EMEA/H/C/002264/LEG 026.1; ritonavir – NORVIR (CAP) - EMEA/H/C/000127/LEG 049.1; saquinavir – INVIRASE (CAP) - EMEA/H/C/000113/LEG 065.1; stavudine – ZERIT (CAP) - EMEA/H/C/000110/LEG

060.1; tenofovir disoproxil – VIREAD (CAP) - EMEA/H/C/000419/LEG 270.1; tipranavir - APTIVUS (CAP) - EMEA/H/C/000631/LEG 068.1

Applicant: AbbVie Ltd (Kaletra, Norvir), Boehringer Ingelheim International GmbH (Aptivus, Viramune), Bristol-Myers Squibb Pharma EEIG (Reyataz, Sustiva, Zerit), Bristol-Myers Squibb and Gilead Sciences Ltd.(Atripla), Gilead Sciences International Ltd.(Emtriva, Eviplera, Stribild, Truvada, Tybost, Viread), Janssen-Cilag International N.V.(Edurant, Intelence, Prezista), Merck Sharp & Dohme Ltd (Crixivan, Isentress, Stocrin), Roche Registration Ltd. (Invirase), ViiV Healthcare UK Limited (Celsentri, Combivir, Epivir, Lamivudine Viiv, Kivexa, Telzir, Trizivir, Ziagen)

PRAC Rapporteur (lead): Qun-Ying Yue; PRAC Co-Rapporteur: Isabelle Robine; Julie Williams

Scope: Review of class labelling on mitochondrial dysfunction, lactic acidosis and lipodystrophy
Action: For adoption of advice to CHMP

10.3.2. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (CAP) Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – GARDASIL (CAP), SILGARD (CAP)

MAH(s): GlaxoSmithKline Biologicals S.A. (Cervarix), Sanofi Pasteur MSD SNC (Gardasil), Merck Sharp & Dohme Limited (Silgard)

PRAC Rapporteurs: Jean-Michel Dogné (Cervarix), Qun-Ying Yue (Gardasil, Silgard)

Scope: PRAC consultation on the preliminary results of a pharmacoepidemiological study on the safety-in-use of human papillomavirus vaccines (HPV)
Action: For adoption of advice to CHMP

10.3.3. Saxagliptin – ONGLYZA (CAP) – EMEA/H/C/001039/LEG 038.1; saxagliptin, metformin - KOMBOGLYZE (CAP) – EMEA/H/C002059/LEG 015.1

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: PRAC consultation on the assessment of data on mortality from the SAVOR study
Action: For adoption of advice to CHMP

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Androstanolone (NAP)

Applicant: Besins Healthcare (Andractim), various

PRAC Lead: Corinne Fechant

Scope: PRAC consultation on the relevance of the PRAC recommendation on testosterone and cardiovascular safety from the article 31 referral for androstanolone

Action: For adoption of advice to Member States

11.2. Other requests

11.2.1. Antiretroviral medicinal products (NAP)

Applicant: Teva Pharma B.V., Mikle-Pharm GmBH

PRAC Rapporteur: Martin Huber

Scope: PRAC consultation on initial marketing authorisation applications for generic medicinal products and the need for the applicants to participate in the Antiretroviral Pregnancy Registry
Action: For adoption of advice to Member States

11.2.2. Quetiapine (NAP) - NL/H/PSUR/0021/005

Applicant: AstraZeneca (Seroquel), various

PRAC Lead: Sabine Straus

Scope: PRAC consultation on a PSUR worksharing procedure regarding a signal of possible misuse and abuse
Action: For adoption of advice to Member States

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC assessors training course – draft agenda

Action: For discussion

12.2. Coordination with EMA Scientific Committees or CMDh-v

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

12.3.1. Post-authorisation efficacy studies (PAES) – regulatory and procedural questions and answers document

Action: For discussion

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

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

None

12.7. PRAC work plan

12.7.1. PRAC work plan 2016 - development

Action: For discussion

12.8. Planning and reporting

None

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)

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

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

12.13.1.1. EudraVigilance stakeholder change management plan

Action: For discussion

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

12.14.1.1. Good Pharmacovigilance Practice (GVP) Module V and RMP template for industry updates

Action: For discussion

12.14.1.2. Summaries of risk management plans (RMP) - report on pilot testing

Action: For discussion

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

Action: For discussion

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

Action: For discussion

12.15.3. Post-authorisation Safety Studies and additional monitoring imposed to originator products - applicability to generic products

Action: For discussion

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

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

13. Any other business

13.1. Good Pharmacovigilance Practice (GVP) Chapter P.II. on biologicals

Action: For discussion

13.2. Good Pharmacovigilance Practice (GVP) on medication errors - Good practice guide on recording, coding, reporting and assessment of medication errors (GPG I), Good practice guide on risk minimisation and prevention of medication errors (GPG I) and Good practice guide on risk minimisation and prevention of medication errors, addendum on risk minimisation strategy for high strength and fixed combination insulin products (GPG II Addendum)

Action: For adoption

13.3. Good Pharmacovigilance Practice (GVP) Module XII on safety-related actions on authorised medicinal products

Action: For discussion

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/