4 May 2015
EMA/PRAC/59170/2015
Procedure Management and Committees Support Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 04-07 May 2015

Chair: June Raine – Vice-Chair: Almath Spooner

04 May 2015, 13:00 – 19:00, room 3/A

05 May 2015, 08:30 – 19:00, room 3/A

06 May 2015, 08:30 – 19:00, room 3/A

07 May 2015, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

27 May 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 vary 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).

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1.2. Adoption of agenda of the meeting of 04-07 May 2015

1.3. Adoption of minutes of the previous meeting of 07-10 April 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. Inhaled corticosteroids (ICS)-containing medicinal products indicated in the treatment of chronic obstructive pulmonary disease: beclomethasone (NAP); beclomethasone, formoterol (NAP); budesonide (NAP); budesonide, formoterol – BIRESP SPIROMAX (CAP); BUDESONIDE FORMOTEROL TEVA (CAP); DUORESP SPIROMAX (CAP); VYALER SPIROMAX (CAP); flunisolide, salbutamol (NAP); fluticasone; fluticasone, salmeterol; fluticasone, vilanterol – RELVAR ELLIPTA (CAP); REVINTY ELLIPTA (CAP)

Applicant: Glaxo Group Ltd, Teva Pharma B.V., Teva Pharmaceuticals Europe, various

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

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

3.1.2. Natalizumab – TYSABRI (CAP)

Applicant: Biogen Idec Ltd

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

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 list of questions

3.2. Ongoing procedures

None

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

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Amikacin (NAP)

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

PRAC Rapporteur: to be appointed

Scope: Signal of drug reaction with eosinophilia and systemic symptoms (DRESS)
Action: For adoption of PRAC recommendation
EPITT 18304 – New signal
Lead Member State: EE

4.1.2. Angiotensin-converting enzyme (ACE)-inhibitors: benazepril, captopril, cilazapril, delapril, enalapril, fosinopril, imidapril, lisinopril, moexipril, perindopril, quinapril, ramipril, spirapril, trandolapril, zofenpril (NAP)

Applicant: various

PRAC Rapporteur: to be appointed

[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

Scope: Signal of hallucinations
Action: For adoption of PRAC recommendation
EPITT 18286 – New signal
Lead Member States: IE, NL, PT

4.1.3. Decitabine – DACOGEN (CAP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Patrick Maison

Scope: Signal of organising pneumonia
Action: For adoption of PRAC recommendation
EPITT 18303 – New signal
Lead Member State: FR

4.1.4. Lenalidomide – REVLIMID (CAP)

Applicant: Celgene Europe Limited

PRAC Rapporteur: Arnaud Batz

Scope: Signal of pulmonary alveolar haemorrhage
Action: For adoption of PRAC recommendation
EPITT 18300 – New signal
Lead Member State: FR

4.1.5. Long acting glucagon-like peptide (GLP)-1 agonists: albiglutide – EPERZAN (CAP); dulaglutide - TRULICITY (CAP); exenatide – BYDUREON (CAP); liraglutide – SAXENDA (CAP), VICTOZA (CAP), XULTOPHY (CAP)

Applicant: Novo Nordisk A/S (Saxenda, Victoza, Xultophy), AstraZeneca AB (Bydureon), GlaxoSmithKline Trading Services (Eperzan), Eli Lilly Nederland B.V. (Trulicity)

PRAC Rapporteur: to be appointed

Scope: Signal of medullary thyroid cancer
Action: For adoption of PRAC recommendation
EPITT 18292 – New signal
Lead Member State: NL

4.1.6. Rivaroxaban – XARELTO (CAP)

Applicant: Bayer Pharma AG

PRAC Rapporteur: Qun-Ying Yue

Scope: Signal of pulmonary alveolar haemorrhage
Action: For adoption of PRAC recommendation
EPITT 18291 – New signal
Lead Member State: SE

4.1.7. Tamsulosin (NAP)

Applicant: Astellas Pharma Europe B.V., various

PRAC Rapporteur: to be appointed

Scope: Signal of urinary incontinence
Action: For adoption of PRAC recommendation

EPITT 18317 – New signal
Lead Member State: NL

4.2. New signals detected from other sources

4.2.1. Digoxin (NAP)

Applicant: various

PRAC Rapporteur: to be appointed

Scope: Signal of increased mortality in patients with atrial fibrillation
Action: For adoption of PRAC recommendation
EPITT 18259 – New signal
Lead Member State: IT

4.2.2. Mitotane – LYSODREN (CAP)

Applicant: Laboratoire HRA Pharma, SA

PRAC Rapporteur: Dolores Montero Corominas

Scope: Signal of sex hormone disturbances and development of ovarian macrocysts
Action: For adoption of PRAC recommendation
EPITT 18301 – New signal
Lead Member State: ES

4.3. Signals follow-up and prioritisation

4.3.1. Fingolimod - GILENYA (CAP) - EMEA/H/C/002202/SDA/033

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Arnaud Batz

Scope: Signal of progressive multifocal leukoencephalopathy (PML)
Action: For adoption of PRAC recommendation
EPITT 18241– Follow-up to March 2015

4.3.2. Latanoprost (NAP)

Applicant: Pfizer (Xalatan), various

PRAC Rapporteur: Julie Williams

Scope: Signal of increased reporting of eye disorders, in particular eye irritation, after change of formulation
Action: For adoption of PRAC recommendation
EPITT 18068 – Follow-up to January 2015

4.3.3. Leflunomide – ARAVA (CAP) - EMEA/H/C/000235/SDA/053

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Sabine Straus

Scope: Signal of colitis
Action: For adoption of PRAC recommendation
EPITT 18189 – Follow-up to January 2015

4.3.4. Natalizumab – TYSABRI (CAP) - EMEA/H/C/000603/SDA/062

Applicant: Biogen Idec Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Signal of anaemia
Action: For adoption of PRAC recommendation
EPITT 18137 – Follow-up to December 2014

4.3.5. Olanzapine – ZYPADHERA (CAP) - EMEA/H/C/000890/SDA/024, ZYPREXA (CAP) - EMEA/H/C/000115/SDA/045, ZYPREXA VELOTAB (CAP) - EMEA/H/C/000287/SDA/038

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Signal of angle closure glaucoma
Action: For adoption of PRAC recommendation
EPITT 18159 – Follow-up to January 2015

4.3.6. Recombinant Factor VIII: Antihemophilic factor (recombinant) (NAP) Moroctocog alfa – REFACTO AF (CAP) Octocog alfa – ADVATE (CAP), HELIXATE NEXGEN (CAP), KOGENATE (CAP)

Applicant: Baxter AG (Advate, Recombinate), Bayer Pharma AG (Kogenate, Helixate NexGen), Pfizer Limited (ReFacto AF), various

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Signal of inhibitor development in previously untreated patients (PUP)
Action: For adoption of PRAC recommendation
EPITT 18134 – Follow-up to March 2015

4.3.7. Sildenafil – REVATIO (CAP) - EMEA/H/C/000638/SDA/048

Applicant: Pfizer Limited

PRAC Rapporteur: Menno van der Elst

Scope: Signal of pulmonary haemorrhage in off label paediatric use
Action: For adoption of PRAC recommendation
EPITT 18183 – Follow-up to January 2015

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Asfotase alfa - EMEA/H/C/003794, Orphan

Applicant: Alexion Europe SAS

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

5.1.2. Atazanavir - EMEA/H/C/004048, Generic

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

5.1.3. Atazanavir, cobicistat - EMEA/H/C/003904

Scope: Treatment of human immunodeficiency virus (HIV)-1, in combination with other antiretroviral medicinal products
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.4. Bortezomib - EMEA/H/C/003984, Generic

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

5.1.5. 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

5.1.6. Dinutuximab - EMEA/H/C/002800, Orphan

Applicant: United Therapeutics Europe Ltd

Scope: Treatment of neuroblastoma, treatment of high-risk neuroblastoma
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.7. Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982

Scope: Vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b (Hib)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.8. Evolocumab - EMEA/H/C/003766

Scope: Treatment of hypercholesterolaemia and mixed dyslipidaemia and homozygous familial hypercholesterolaemia
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.9. Idebenone - EMEA/H/C/003834, Orphan

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

Scope: Treatment of Leber's hereditary optic neuropathy (LHON)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.10. Isavuconazole - EMEA/H/C/002734, Orphan

Applicant: Basilea Medical Ltd

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

5.1.11. Lesinurad - EMEA/H/C/003932

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

5.1.12. Lopinavir, ritonavir - EMEA/H/C/004025, Generic

Scope: Treatment of human immunodeficiency virus (HIV-1) infected adults, adolescents and children above the age of 2 years
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.13. Nivolumab - EMEA/H/C/003840

Scope: Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.14. Panobinostat - EMEA/H/C/003725, Orphan

Applicant: Novartis Pharmaceuticals UK Limited

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

5.1.15. Pembrolizumab - EMEA/H/C/003820

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

5.1.16. Plasmodium falciparum circumsprozoite protein fused with hepatitis B surface antigen (rts) and combined with hepatitis B surface antigen(s) in the form of non-infectious virus-like particles (vlps) produced in yeast cells (saccharomyces cerevisiae) by recombinant DNA technology) - EMEA/H/W/002300

Scope: Indicated for active immunisation against malaria
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.17. Pitolisant - EMEA/H/C/002616, Orphan

Applicant: Bioprojet Pharma

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

5.1.18. Pregabalin - EMEA/H/C/004024, Generic

Scope: Treatment of neuropathic pain, epilepsy and generalised anxiety disorder (GAD)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.19. Pregabalin - EMEA/H/C/003900, Generic

Scope: Treatment of epilepsy and generalised anxiety disorder (GAD)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

Applicant: Medac Gesellschaft fuer klinische Spezialpraeparate GmbH

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

5.1.21. 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

5.1.22. Sufentanil - EMEA/H/C/002784, Hybrid

Scope: Management of moderate to severe acute pain
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. Abacavir – ZIAGEN (CAP) - EMEA/H/C/00252/II/0082

Applicant: ViiV Healthcare UK Limited

PRAC Rapporteur: Arnaud Batz

Scope: Updated RMP to remove the important potential risk of viral resistance in children
Action: For adoption of PRAC AR

5.2.2. Linagliptin – TRAJENTA (CAP) – EMEA/H/C/002110/II/0018

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Updated RMP to add cardiac failure as important potential risk
Action: For adoption of PRAC AR

5.2.3. Linagliptin, metformin – JENTADUETO (CAP) - EMEA/H/C/002279/II/0026

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Updated RMP to add cardiac failure as important potential risk
Action: For adoption of PRAC AR

5.2.4. Pioglitazone – ACTOS (CAP) - EMEA/H/C/000285/WS0705/0067; GLUSTIN (CAP) - EMEA/H/C/000286/WS0705/0065 pioglitazone, glimepiride – TANDEMACT (CAP) - EMEA/H/C/000680/WS0705/0042 pioglitazone, metformin – COMPETACT (CAP) - EMEA/H/C/000655/WS0705/0052; GLUBRAVA (CAP) - EMEA/H/C/000893/WS0705/0038

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Almath Spooner

Scope: Change of the due date for reporting of the pan-European multiple database bladder cancer risk characterisation study ER12-9433 from 30 December 2014 to 31 July 2015. In addition, an administrative change has been introduced to include mention of a drug utilisation study using the medical registries in Denmark (Pioglitazone 5019) and associated timelines
Action: For adoption of PRAC AR

5.2.5. Teduglutide – REVESTIVE (CAP) - EMEA/H/C/002345/II/0009

Applicant: NPS Pharma Holdings Limited

PRAC Rapporteur: Torbjorn Callreus

Scope: Updated RMP (version 6.0) to include the results of long-term study CL0600-021, the use of nursing services as a risk minimisation measure effort to decrease adverse events associated with fluid overload and to include updated review of non-clinical risks, clinical exposure data and post-marketing exposure data
Action: For adoption of PRAC AR

5.2.6. Vemurafenib – ZELBORAF (CAP) - EMEA/H/C/002409/II/0021/G

Applicant: Roche Registration Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Updated RMP in order to update the following information: proposal to consider fulfilled MEA 004 (category 3) and MEA 018 (Category 4); proposal to extend the timelines of MEA 006 (category 3); to include amendments as required in procedure EMEA/H/C/2409/II/018 (opinion in March 2015) and MEA 015 (opinion in December 2012). Furthermore, the MAH take the opportunity to provide data on the ongoing study for MEA010 for information, to correct a mistake found in RMP v.7 and v.8 where study GO27826 had been misclassified as a category 3 PAM being instead a category 4 PAM and to update data in modules S.I, S.III, S.V and S.VI up to DLP of PBRER 1057994 (16 August 2014)
Action: For adoption of PRAC AR

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

5.3.1. Bosutinib – BOSULIF (CAP) - EMEA/H/C/002373/II/0014/G

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

Scope: Update of SmPC section 4.5 to include further information related to concomitant use of Bosulif with CYP3A inhibitors based on the results of study B1871041, and to reflect the results of study B1871043, submitted to fulfil MEA 003.2, and undertaken to investigate the drug interaction potential with regard to bosutinib being a P-gp inhibitor. The package leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.2. Buprenorphine, naloxone – SUBOXONE (CAP) - EMEA/H/C/000697/X/0029

Applicant: RB Pharmaceuticals Ltd

PRAC Rapporteur: Martin Huber

Scope: Line extension to add 12mg/3mg and 16mg/4mg sublingual tablets
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.3. Enzalutamide – XTANDI (CAP) - EMEA/H/C/002639/II/0015

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Dolores Montero Corominas

Scope: Update of SmPC sections 4.2, 4.4 and 5.2 to update the safety and pharmacokinetic information on hepatic impairment after finalisation of study 9785-CL-0404. The package leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.4. Fingolimod – GILENYA (CAP) - EMEA/H/C/002202/II/0032

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Arnaud Batz

Scope: Update of SmPC section 4.4 to include precautionary statements on cryptococcal meningitis and of section 4.8 to reflect cryptococcal infections, including isolated cases of cryptococcal meningitis. In addition, the marketing authorisation holder took the opportunity to make minor editorial change in SmPC section 4.5 to align with other SmPC sections
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.5. Golimumab – SIMPONI (CAP) - EMEA/H/C/000992/II/0061

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 to add a new therapeutic indication for non-radiographic axial spondyloarthritis. The package leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.6. Human coagulation factor VIII, human von Willebrand factor – VONCENTO (CAP) - EMEA/H/C/002493/II/0008/G

Applicant: CSL Behring GmbH

PRAC Rapporteur: Sabine Straus

Scope: Extension of indication to include prophylactic treatment of patients with von Willebrand disease (VWD). In addition the MAH submitted data to support the treatment of paediatric patients with VWD
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.7. 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. SmPC sections 4.1, 4.2, 4.4, 4.8, and 5.1 and the package leaflet are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.8. Ibrutinib – IMBRUVICA (CAP) - EMEA/H/C/003791/II/0001

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Julie Williams

Scope: Extension of indication for the treatment of adult patients with Waldenström macroglobulinaemia (WM). SmPC sections 4.1, 4.2, 4.8 and 5.1 and the package leaflet are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.9. Ibrutinib – IMBRUVICA (CAP) - EMEA/H/C/003791/II/0007/G

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Julie Williams

Scope: Group of variations to submit several non-clinical studies reports. Accordingly, update of section 4.5 of the SmPC regarding BRCP inhibition, update of section 4.5 of the SmPC to delete the CYP3A4 inhibition statement, update of wording regarding the coadministration with transport substrates/inhibitors in section 5.2 of the SmPC.
The Package Leaflet has been updated accordingly and an updated RMP version 3.5 is proposed
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of SmPC sections 4.4, 4.5, 4.6 and 4.8 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 is updated accordingly. In addition, the Marketing authorisation holder took the opportunity to revise Annex II D to bring it in line with Annex 10 of the RMP
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.11. Insulin glargine – ABASAGLAR (CAP) - EMEA/H/C/002835/II/0003/G

Applicant: Eli Lilly Regional Operations GmbH

PRAC Rapporteur: Carmela Macchiarulo

Scope: Introduction of a new KwikPen capable of delivering a maximum dose of 80 units (1 pre-filled pen), a new pack-size of 2 pre-filled pens (Kwikpen, 1 to 80 unit injection), a new pack-size of 5 pre-filled pens (Kwikpen, 1 to 80 unit injection) and of a new multipack of 10 (2x5) pre-filled pens (Kwikpen, 1 to 80 unit injection)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.12. 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. SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.2 as well as the package leaflet are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.13. Nelarabine – ATRIANCE (CAP) - EMEA/H/C/000752/II/0027

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Torbjorn Callreus

Scope: Final study report from a post-marketing surveillance study in the indicated patient population under 21 years of age receiving 650 mg/m^2 dose of nelarabine (study PGA111081) and data from drug use investigation of ArranonG intravenous injection 250mg (paediatric study OTH112279). This variation intends to fulfil ANX II specific obligation SOB 004.2 and Article 46 of the paediatric legislation
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.14. Nonacog alfa – BENEFIX (CAP) - EMEA/H/C/000139/II/0131

Applicant: Pfizer Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of SmPC sections 4.2, 5.1, and 5.2 to update the posology with once-weekly prophylaxis regimen. The package leaflet is also updated
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.15. Perampanel – FYCOMPA (CAP) - EMEA/H/C/002434/II/0016

Applicant: Eisai Europe Ltd

PRAC Rapporteur: Julie Williams

Scope: Extension of indication as adjunctive treatment of primary generalised tonic-clonic seizures in patients with epilepsy aged 12 years and older. SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 and the package leaflet are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.16. Pertuzumab – PERJETA (CAP) - EMEA/H/C/002547/II/0010

Applicant: Roche Registration Ltd

PRAC Rapporteur: Doris Stenver

Scope: Extension of the indication in combination with trastuzumab and docetaxel for the neoadjuvant treatment of patients with human epidermal growth factor receptor (HER) 2-positive, locally advanced, inflammatory, or early stage breast cancer (> 2 cm in diameter) as part of the treatment for early breast cancer. SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.17. Pneumococcal polysaccharide conjugate vaccine (adsorbed) – SYNFLORIX (CAP) - EMEA/H/C/000973/II/0096/G

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Qun-Ying Yue

Scope: Grouped variations to update SmPC section 5.1 with effectiveness data against pneumococcal vaccine serotypes and against vaccine related serotype 19A, and to update

SmPC section 4.4 to include information on the immune response against serotype 19A observed in infants and children. In addition, extensions of the due dates for MEA 009: study 10PN-PD-DIT-034 (111634) and MEA 018.5: study 10PN-PD-DIT-064 (114056)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.18. Ramucirumab – CYRAMZA (CAP) - EMEA/H/C/002829/II/0003, Orphan

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Extension of indication to include the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with progression after platinum-based chemotherapy. SmPC sections 4.1, 4.2, 4.8, 5.1 and 5.2 and the package leaflet are updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.19. Regorafenib – STIVARGA (CAP) - EMEA/H/C/002753/II/0008

Applicant: Bayer Pharma AG

PRAC Rapporteur: Sabine Straus

Scope: Update of SmPC section 5.1 to reflect final results from study 15808 (Concur; randomized, double blind, placebo controlled phase III study of regorafenib plus best supportive care (BSC) versus placebo plus BSC in Asian subjects with metastatic CRC who have progressed after Standard therapy)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.20. Shingles (herpes zoster) vaccine (live) – ZOSTAVAX (CAP) - EMEA/H/C/000674/X/0085

Applicant: Sanofi Pasteur MSD SNC

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Line extension to add a new route of administration 'intramuscular' to all presentations
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.21. Thiotepa – TEPADINA (CAP) - EMEA/H/C/001046/II/0018

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

PRAC Rapporteur: Arnaud Batz

Scope: Update of SmPC section 4.8 to update the safety information on pulmonary arterial hypertension with an uncommon frequency. The package leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.22. 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 new study report BO22227 (Hannah) regarding non inferior trastuzumab exposure and clinical efficacy of a q3w regimen of Herceptin subcutaneous compared to Herceptin intravenous
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.23. Ustekinumab – STELARA (CAP) - EMEA/H/C/000958/II/0042

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Julie Williams

Scope: Extension of indication to add the treatment of moderate to severe plaque psoriasis in paediatric patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. SmPC sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 and the package leaflet are 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. Abiraterone – ZYTIGA (CAP) - PSUSA/00015/201410

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Dolores Montero Corominas

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

6.1.2. Alipogene tiparvovec – GLYBERA (CAP) - PSUSA/10056/201410

Applicant: uniQure biopharma B.V.

PRAC Rapporteur: Julie Williams

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

6.1.3. Arsenic trioxide – TRISENOX (CAP) - PSUSA/00235/201409

Applicant: Teva B.V.

PRAC Rapporteur: Arnaud Batz

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

6.1.4. Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor (sipuleucel-T) – PROVENGE (CAP) - PSUSA/10065/201410

Applicant: Dendreon UK Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.5. Bazedoxifene – CONBRIZA (CAP) - PSUSA/00302/201410

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

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

6.1.6. Budesonide, formoterol – BIRESP SPIROMAX (CAP), DUORESP SPIROMAX (CAP) - PSUSA/10202/201410

Applicant: Teva Pharma B.V.

PRAC Rapporteur: Torbjorn Callreus

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

6.1.7. Ceftaroline fosamil – ZINFORO (CAP) - PSUSA/10013/201410

Applicant: AstraZeneca AB

PRAC Rapporteur: Julie Williams

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

6.1.8. Cholic acid – KOLBAM (CAP) - PSUSA/10182/201410

Applicant: ASK Pharmaceuticals GmbH

PRAC Rapporteur: Rafe Suvarna

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

6.1.9. Dapagliflozin – FORXIGA (CAP) - PSUSA/10029/201410

Applicant: AstraZeneca AB

PRAC Rapporteur: Qun-Ying Yue

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

6.1.10. Decitabine – DACOGEN (CAP) - PSUSA/09118/201411

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Patrick Maison

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

6.1.11. Deferasirox – EXJADE (CAP) - PSUSA/00939/201410

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Arnaud Batz

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

6.1.12. Defibrotide – DEFITELIO (CAP) - PSUSA/10086/201410

Applicant: Gentium S.p.A.

PRAC Rapporteur: Julie Williams

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

6.1.13. Delamanid – DELTYBA (CAP) - PSUSA/10213/201410

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Rafe Suvarna

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

6.1.14. Dihydroartemisinin, piperaquine – EURARTESIM (CAP) - PSUSA/01069/201410

Applicant: Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.

PRAC Rapporteur: Julie Williams

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

6.1.15. 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); HEXAXIM (Art 58); HEXYON (CAP) - PSUSA/10091/201410

Applicant: Sanofi Pasteur

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.16. Eltrombopag – REVOLADE (CAP) - PSUSA/01205/201409

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Dolores Montero Corominas

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

6.1.17. Empagliflozin – JARDIANCE (CAP) - PSUSA/10219/201410

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Miguel-Angel Macia

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

6.1.18. Eribulin – HALAVEN (CAP) - PSUSA/01254/201411

Applicant: Eisai Europe Ltd.

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.19. Eslicarbazepine – ZEBINIX (CAP) - PSUSA/01267/201410

Applicant: Bial - Portela & Cª, S.A.

PRAC Rapporteur: Martin Huber

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

6.1.20. Fenofibrate, pravastatin – PRAVAFENIX (CAP) - PSUSA/01363/201410

Applicant: Laboratoires SMB s.a.

PRAC Rapporteur: Arnaud Batz

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

6.1.21. Granisetron – SANCUSO (CAP) - PSUSA/10101/201410

Applicant: ProStrakan Limited

PRAC Rapporteur: Jolanta Gulbinovic

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

6.1.22. Human fibrinogen, human thrombin – EVICEL (CAP) - PSUSA/01627/201410

Applicant: Omrix Biopharmaceuticals N. V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.23. Hydrocortisone – PLENADREN (CAP) - PSUSA/09176/201411

Applicant: ViroPharma SPRL

PRAC Rapporteur: Qun-Ying Yue

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

6.1.24. Insulin aspart – NOVOMIX (CAP), NOVORAPID (CAP) - PSUSA/01749/201409

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Qun-Ying Yue

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

6.1.25. Ivabradine – CORLENTOR (CAP), PROCORALAN (CAP) - PSUSA/01799/201410

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Menno van der Elst

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

6.1.26. Lurasidone – LATUDA (CAP) - PSUSA/10114/201410

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Qun-Ying Yue

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

6.1.27. Macitentan – OPSUMIT (CAP) - PSUSA/10115/201410

Applicant: Actelion Registration Ltd.

PRAC Rapporteur: Dolores Montero Corominas

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

6.1.28. Meningococcal group a, c, w135 and y conjugate vaccine – NIMENRIX (CAP) - PSUSA/10044/201410

Applicant: GlaxoSmithKline Biologicals S.A.

PRAC Rapporteur: Rafe Suvarna

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

6.1.29. Micafungin – MYCAMINE (CAP) - PSUSA/02051/201410

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

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

6.1.30. Miglustat – ZAVESCA (CAP) - PSUSA/02062/201410

Applicant: Actelion Registration Ltd.

PRAC Rapporteur: Qun-Ying Yue

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

6.1.31. Obinutuzumab – GAZYVARO (CAP) - PSUSA/10279/201410

Applicant: Roche Registration Ltd

PRAC Rapporteur: Julie Williams

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

6.1.32. Ocriplasmin – JETREA (CAP) - PSUSA/10122/201410

Applicant: ThromboGenics NV

PRAC Rapporteur: Julie Williams

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

6.1.33. Ofatumumab – ARZERRA (CAP) - PSUSA/02202/201410

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Doris Stenver

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

6.1.34. Pasireotide – SIGNIFOR (CAP) - PSUSA/09253/201410

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Qun-Ying Yue

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

6.1.35. Pazopanib – VOTRIENT (CAP) - PSUSA/02321/201410

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Doris Stenver

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

6.1.36. Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) – AFLUNOV (CAP), FOCLIVIA (CAP), PREPANDEMIC INFLUENZA VACCINE (H5N1) (SURFACE ANTIGEN, INACTIVATED, ADJUVANTED) NOVARTIS VACCINES AND DIAGNOSTIC (CAP) - PSUSA/10008/201410

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

PRAC Rapporteur: Carmela Macchiarulo

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

6.1.37. Propranolol – HEMANGIOL (CAP) - PSUSA/10250/201410

Applicant: Pierre Fabre Dermatologie

PRAC Rapporteur: Dolores Montero Corominas

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

6.1.38. Prucalopride – RESOLOR (CAP) - PSUSA/02568/201410

Applicant: Shire Pharmaceuticals Ireland Ltd.

PRAC Rapporteur: Rafe Suvarna

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

6.1.39. Regadenoson – RAPISCAN (CAP) - PSUSA/02616/201410

Applicant: Rapidscan Pharma Solutions EU Ltd.

PRAC Rapporteur: Julie Williams

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

6.1.40. Siltuximab – SYLVANT (CAP) - PSUSA/10254/201410

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.41. Sirolimus – RAPAMUNE (CAP) - PSUSA/02710/201409

Applicant: Pfizer Limited

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.42. Thalidomide – THALIDOMIDE CELGENE (CAP) - PSUSA/02919/201410

Applicant: Celgene Europe Limited

PRAC Rapporteur: Arnaud Batz

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

6.1.43. Tocilizumab – ROACTEMRA (CAP) - PSUSA/02980/201410

Applicant: Roche Registration Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.44. Turoctocog alfa – NOVOEIGHT (CAP) - PSUSA/10138/201410

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.45. Umeclidinium bromide – INCRUSE (CAP) - PSUSA/10263/201410

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Carmela Macchiarulo

Scope of procedure: 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. Melatonin – CIRCADIN (CAP), NAP - PSUSA/01963/201409

Applicant: Rad Neurim Pharmaceuticals EEC Ltd., various

PRAC Rapporteur: Magda Pedro

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

6.3. PSUR procedures including Nationally Approved Products (NAPs) only

6.3.1. Adapalene, benzoyl peroxide (NAP) – PSUSA/00000059/201409

Applicant: various

PRAC Lead: Ulla Wändel Liminga

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

6.3.2. Atenolol, chlortalidone (NAP) – PSUSA/00000260/201409

Applicant: various

PRAC Lead: Tatiana Magalova

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Hexaminolevulinate hydrochloride (NAP) – PSUSA/00001606/201409

Applicant: various

PRAC Lead: Qun-Ying Yue

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

6.4. Follow-up to PSUR procedures

6.4.1. Ambrisentan – VOLIBRIS (CAP) - EMEA/H/C/000839/LEG 026

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Dolores Montero Corominas

Scope: MAH response to PRAC recommendation on PSUV/0040, as adopted in Jan 2015
Action: For adoption of advice to CHMP

6.4.2. Insulin lispro – HUMALOG (CAP) - EMEA/H/C/000088/LEG 026; LIPROLOG (CAP) - EMEA/H/C/000393/LEG 026

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Julie Williams

Scope: MAH response to PRAC recommendation on PSUV/0128, as adopted in Dec 2014.
Action: For adoption of advice to CHMP

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[2]

7.1.1. Afamelanotide – SCENESSE (CAP) - EMEA/H/C/PSP/0022

Applicant: Clinuvel (UK) Limited

PRAC Rapporteur: Valerie Strassmann

Scope: PASS protocol for study CUV-PA001: disease registry to assess long-term safety and generate data on the clinical benefits of afamelanotide 16mg implant in patients with erythropoietic protoporphyria (EPP) and for a retrospective study comparing long term safety data and outcome endpoints in patients receiving and not receiving afamelanotide, or having discontinued the use of afamelanotide
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.2. Dexamfetamine (NAP) - EMEA/H/N/PSP/0018

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Julie Williams

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

Scope: 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

7.1.3. Dexamfetamine (NAP) - EMEA/H/N/PSP/021

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Julie Williams

Scope: 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

7.1.4. Ivabradine – CORLENTOR (CAP), PROCORALAN (CAP) - EMEA/H/C/PSP/J/0019

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Menno van der Elst

Scope: PASS protocol for a drug utilisation study (DUS) in selected European countries: multinational, retrospective, observational study to assess effectiveness of risk-minimisation measures
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.5. Ospemifene – SENSHIO (CAP) - EMEA/H/C/PSP/0023

Applicant: Shionogi Limited

PRAC Rapporteur: Julie Williams

Scope: 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

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[3]

7.2.1. Apixaban – ELIQUIS (CAP) - EMEA/H/C/002148/MEA 021.2

Applicant: Bristol-Myers Squibb / Pfizer EEIG

PRAC Rapporteur: Menno van der Elst

Scope: Revised PASS protocol for a study CV185365, in response to MEA 021.1 as adopted in January 2015
Action: For adoption of advice to CHMP

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

7.2.2. Conjugated estrogens, bazedoxifene – DUAVIVE (CAP) - EMEA/H/C/002314/MEA 002

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

Scope: PASS protocol for an active surveillance of conjugated estrogens, bazedoxifene (CE/BZA) using US healthcare data (study B2311060)
Action: For adoption of advice to CHMP

7.2.3. Conjugated estrogens, bazedoxifene – DUAVIVE (CAP) - EMEA/H/C/002314/MEA 003

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

Scope: PASS protocol for a drug utilisation study (study no. B2311061)
Action: For adoption of advice to CHMP

7.2.4. Empagliflozin – JARDIANCE (CAP) - EMEA/H/C/002677/MEA 002

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Miguel-Angel Macia

Scope: Protocol for a post-authorisation safety study in patients with type 2 diabetes mellitus to assess the risk of acute liver injury, hospitalisation for acute kidney injury, hospitalisation for urinary tract infection, and the risk of genital infections, among patients treated with empagliflozin compared to patients treated with other sodium-glucose linked transporters (SGLT)2 inhibitors or dipeptidyl peptidase-4 (DPP-4) inhibitors
Action: For adoption of advice to CHMP

7.2.5. Ibrutinib – IMBRUVICA (CAP) - EMEA/H/C/003791/MEA 023

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Julie Williams

Scope: Protocol for a PASS study PCYC-PMR-2060-04: enhanced pharmacovigilance to evaluate the risks of haemorrhage with the administration of ibrutinib
Action: For adoption of advice to CHMP

7.2.6. Insulin detemir – LEVEMIR (CAP) - EMEA/H/C/000528/MEA 045.3

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Doris Stenver

Scope: Revised PASS protocol for diabetes pregnancy registry (NN304-4016)
Action: For adoption of advice to CHMP

7.2.7. Insulin glargine – LANTUS (CAP) - EMEA/H/C/000284/MEA 051.2

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Revised protocol for a differentiation study [UK SoloStar Differentiation Study: Test in patients with Type 1 or Type 2 diabetes in the UK, to evaluate the ease of differentiating between SoloStar pens containing different types of insulin]
Action: For adoption of advice to CHMP

7.2.8. Insulin glulisine – APIDRA (CAP) - EMEA/H/C/000557/MEA 037.2

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Revised protocol for a differentiation study [UK SoloStar Differentiation Study: Test in patients with Type 1 or Type 2 diabetes in the UK, to evaluate the ease of differentiating between SoloStar pens containing different types of insulin]

7.2.9. Naloxegol – MOVENTIG (CAP) - EMEA/H/C/002810/MEA 002

Applicant: AstraZeneca AB

PRAC Rapporteur: Almath Spooner

Scope: Protocol for an observational PASS: drug utilisation in selected European populations (study D2288R00081)
Action: For adoption of advice to CHMP

7.2.10. Naloxegol – MOVENTIG (CAP) - EMEA/H/C/002810/MEA 004

Applicant: AstraZeneca AB

PRAC Rapporteur: Almath Spooner

Scope: Protocol for an observational PASS among patients aged 18 years and older diagnosed with cancer pain and treated with opioids chronically (study D2288R00082)
Action: For adoption of advice to CHMP

7.2.11. Naloxegol – MOVENTIG (CAP) - EMEA/H/C/002810/MEA 006

Applicant: AstraZeneca AB

PRAC Rapporteur: Almath Spooner

Scope: Protocol for an observational PASS among patients aged 18 years and older diagnosed with non-cancer pain and treated with opioids chronically (study D2288R00084)
Action: For adoption of advice to CHMP

7.2.12. Tenofovir– VIREAD (CAP) - EMEA/H/C/000419/MEA 265.4

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Arnaud Batz

Scope: MAH's response to MEA 265.3 as adopted in December 2014, including a revised PASS protocol for study GS-EU-174-1403, a pharmacoepidemiology study to define the long-term safety profile of tenofovir disoproxil fumarate and describe the management of associated renal and bone toxicity in Chronic Hepatitis B -infected adolescents aged 12 to <18 years in Europe

7.2.13. Voriconazole – VFEND (CAP) - EMEA/H/C/000387/MEA 087.2

Applicant: Pfizer Limited

PRAC Rapporteur: Sabine Straus

Scope: MAH's response to MEA 087.1 as adopted in November 2014, including revised PASS protocol for study A1501020, evaluating the effectiveness of risk minimisation measures (RMMs) that aim to reduce the risks of phototoxicity, squamous cell carcinoma (SCC) of the skin and hepatic toxicity in patients receiving voriconazole in the EU
Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[4]

None

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

7.4.1. 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

7.4.2. Etanercept – ENBREL (CAP) - EMEA/H/C/000262/II/0182 (without RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Final report of the STORK study, which is a retrospective study to evaluate pregnancy outcomes associated with and without etanercept use among pregnant women with chronic inflammatory arthritis or psoriasis
Action: For adoption of PRAC Assessment Report

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

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Julie Williams

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

7.4.4. Tocilizumab – ROACTEMRA (CAP) - EMEA/H/C/000955/II/0049 (with RMP)

Applicant: Roche Registration Limited

[4] In accordance with Article 107p-q of Directive 2001/83/EC
[5] 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

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Final clinical study report for study WA22762 (SUMACTA) in order to fulfil MEA 044. As a consequence of the analyses of the final study results a revised RMP (version 16.6) has been submitted
Action: For adoption of PRAC Assessment Report

7.4.5. Tocilizumab – ROACTEMRA (CAP) - EMEA/H/C/000955/II/0050 (with RMP)

Applicant: Roche Registration Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Final clinical study report for study WA18221 'Tender' in order to address the post-authorisation measure MEA 036. An update RMP version 16.4 was provided as part of the application
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[6]

7.5.1. Abatacept – ORENCIA (CAP) - EMEA/H/C/000701/MEA 046.2

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kirsti Villikka

Scope: Annual update for study IM101240: observational registry of abatacept in patients with juvenile idiopathic arthritis (JIA registry)
Action: For adoption of advice to CHMP

7.5.2. Abatacept – ORENCIA (CAP) - EMEA/H/C/000701/MEA 048.3

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kirsti Villikka

Scope: Annual report on the juvenile idiopathic arthritis (JIA) registry, an observational registry of abatacept in patients with juvenile idiopathic arthritis
Action: For adoption of advice to CHMP

7.5.3. Belimumab – BENLYSTA (CAP) - EMEA/H/C/002015/MEA 003.9

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Second interim report on a safety registry evaluating the incidence of all-cause mortality and adverse events of special interest in patients with systemic lupus erythematosus
Action: For adoption of advice to CHMP

7.5.4. Saxagliptin – ONGLYZA (CAP) - EMEA/H/C/001039/MEA 033 Saxagliptin, metformin – KOMBOGLYZE (CAP) – EMEA/H/C/002059/MEA 010

Applicant: AstraZeneca AB

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

PRAC Rapporteur: Menno van der Elst

Scope: First interim analysis of PASS study CV181-099ST: comparison of risk of major cardiovascular events between patients with type 2 diabetes initiating saxagliptin and those initiating other oral anti-diabetic treatments
Action: For adoption of advice to CHMP

7.5.5. Saxagliptin – ONGLYZA (CAP) - EMEA/H/C/001039/MEA 034 Saxagliptin, metformin – KOMBOGLYZE (CAP) – EMEA/H/C/002059/MEA 011

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: First interim analysis of PASS study CV181-100ST: comparison of risk of hospitalisation with acute liver failure between patients with type 2 diabetes initiating saxagliptin and those initiating other oral anti-diabetic treatments
Action: For adoption of advice to CHMP

7.5.6. Saxagliptin – ONGLYZA (CAP) - EMEA/H/C/001039/MEA 035 Saxagliptin, metformin – KOMBOGLYZE (CAP) – EMEA/H/C/002059/MEA 014

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: First interim analysis of PASS study CV181-103ST: comparison of risk of hospitalisation with severe hypersensitivity (including severe cutaneous reactions) between patients with type 2 diabetes initiating saxagliptin and those initiating other oral anti-diabetic treatments
Action: For adoption of advice to CHMP

7.5.7. Saxagliptin – ONGLYZA (CAP) - EMEA/H/C/001039/MEA 036 Saxagliptin, metformin – KOMBOGLYZE (CAP) – EMEA/H/C/002059/MEA 012

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: First interim analysis of PASS study CV181-101ST: comparison of risk of hospitalisation with infection between patients with type 2 diabetes initiating saxagliptin and those initiating other oral anti-diabetic treatments
Action: For adoption of advice to CHMP

7.5.8. Saxagliptin – ONGLYZA (CAP) - EMEA/H/C/001039/MEA 037 Saxagliptin, metformin – KOMBOGLYZE (CAP) – EMEA/H/C/002059/MEA 013

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: First interim analysis of PASS study CV181-157ST: comparison of risk of hospitalisation with acute kidney injury between patients with type 2 diabetes initiating saxagliptin and those initiating other oral anti-diabetic treatments
Action: For adoption of advice to CHMP

7.5.9. Ulipristal – ESMYA (CAP) - EMEA/H/C/002041/MEA 004.4

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Interim study results on a retrospective drug utilisation chart review study on Esmya prescription patterns (PGL11-020)
Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Interferon beta-1a – REBIF (CAP) - EMEA/H/C/000136/MEA 039.2

Applicant: Merck Serono Europe Limited

PRAC Rapporteur: Qun-Ying Yue

Scope: MAH's response to MEA-039.1 [Feasibility study report, EPID multiple sclerosis pregnancy study / ER12-9430] following the adoption of a request for supplementary information (RSI) as adopted in September 2014
Action: For adoption of advice to CHMP

7.6.2. Interferon beta-1b – EXTAVIA (CAP) - EMEA/H/C/000933/MEA 019.2

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Julie Williams

Scope: MAH's response to MEA-019.1 [Feasibility study report, EPID multiple sclerosis pregnancy study / ER12-9430] request for supplementary information (RSI) as adopted in September 2014
Action: For adoption of advice to CHMP

7.6.3. Ketoconazole – KETOCONAZOLE HRA (CAP) - EMEA/H/C/003906/ANX 002

Applicant: Laboratoire HRA Pharma

PRAC Rapporteur: Viola Macolić Šarinić

Scope: Submission of a feasibility study for a PASS: multi-country, observational registry to collect clinical information on patients with Cushing syndrome patients exposed with ketoconazole (preferably using the existing European Registry on Cushing's syndrome (ERCUSYN) registry where feasible), to assess drug utilisation patterns and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of ketoconazole
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. Agalsidase alfa – REPLAGAL (CAP) - EMEA/H/C/000369/S/0086 (without RMP)

Applicant: Shire Human Genetic Therapies AB

PRAC Rapporteur: Sabine Straus

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

8.1.2. 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

8.2. Conditional renewals of the marketing authorisation

8.2.1. Crizotinib – XALKORI (CAP) - EMEA/H/C/002489/R/0026 (without RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Arnaud Batz

Scope: Conditional renewal of the marketing authorisation
Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Vernakalant – BRINAVESS (CAP) - EMEA/H/C/001215/R/0023 (without RMP)

Applicant: Cardiome UK Limited

PRAC Rapporteur: Menno van der Elst

Scope: Five-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. List of planned 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

None

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

None

10.3. Other requests

10.3.1. Saxagliptin – KOMBOGLYZE (CAP) – EMEA/H/C002059/LEG 015; ONGLYZA (CAP) – EMEA/H/C/001039/LEG 038

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

None

11.2. Other requests

11.2.1. Gadolinum containing contrast agents (GdCA) (NAP, CAP)

Applicant: various

Lead member: Rafe Suvarna

Scope: PRAC consultation on a post-authorisation measure resulting from the 2010 Article 20 and Article 31 referral procedures for gadolinium-containing contrast agents
Action: For adoption of advice to CHMP

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. Competence and experience of Committee members - recommendation to National Competent Authorities in appointment process

Action: For discussion

12.2. Coordination with EMA scientific committees or CMDh-v

12.2.1. Appointment of CHMP liaison person for PRAC lead variations

Action: For discussion

12.3. Coordination with EMA working parties / working groups / drafting groups

12.3.1. Biostatistics Working Party - statistical reporting of safety data in product information

Action: For discussion

12.3.2. Blood Products Working Party - Guideline on the clinical investigation of recombinant and human plasma-derived factor IX products and overview of comments – revision

Action: For discussion

12.3.3. Blood Products Working Party - Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products and guideline on core SmPC for human plasma-derived and recombinant coagulation factor VIII products – revision

Action: For discussion

12.3.4. Blood Products Working Party - Haemophilia registries – workshop

Action: For discussion

12.3.5. Cardiovascular Working Party - cardiovascular risk of medicinal products for the treatment of cardiovascular and metabolic diseases

Action: For discussion

12.3.6. Post-authorisation efficacy study (PAES) - draft scientific guidance

Action: For discussion

12.4. Cooperation within the EU regulatory network

12.4.1. European Union network training centre

Action: For information

12.5. Cooperation with international regulators

None

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

None

12.7. PRAC work plan

None

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) and 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. Periodic safety update single assessment (PSUSA) - publication

Action: For discussion

12.10.5. Union Reference Date List – Consultation on the draft list

Action: For adoption of the revised list (version May 2015)

12.11. Signal management

12.11.1. Medical literature monitoring project - inclusion and exclusion criteria in support of the screening and review process

Action: For discussion

12.11.2. Medical literature monitoring project - launch of the EMA service - status update

Action: For discussion

12.11.3. Signal Management: feedback from Signal Management Review Technical (SMART) Working Group

Action: For discussion

12.11.4. Statistical guideline: update

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 of the list (version May 2015)

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

12.15.1.1. Facilitating joint post-authorisation studies between marketing authorisation holders (MAHs)

Action: For discussion

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public hearings: outcome of the public consultation

Action: For adoption

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Others

None

13. Any other business

13.1. European Commission report on the performance of pharmacovigilance tasks

Action: For discussion

Explanatory notes

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

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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/

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