7 April 2015
EMA/PRAC/59170/2015
Procedure Management & Business Support Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 07-10 April 2015

Chair: June Raine – Vice-Chair: Almath Spooner

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

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

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

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

Organisational, regulatory and methodological matters (ORGAM)

23 April 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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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

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

3.3.1. Dexibuprofen (NAP); ibuprofen (NAP) - EMEA/H/A-31/1401

Applicant: various

PRAC Rapporteur: Dolores Montero Corominas; PRAC Co-rapporteur: Julie Williams

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

Action: For adoption of a PRAC recommendation to CMDh (or a list of outstanding issues)

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. Etanercept – ENBREL (CAP)

Applicant: Pfizer Limited

PRAC Rapporteur: Rafe Suvarna

Scope: Signal of diarrhoea
Action: For adoption of PRAC recommendation
EPITT 18257 – New signal
Lead Member State: UK

4.1.2. Leflunomide – ARAVA (CAP)

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Sabine Straus

Scope: Signal of pulmonary hypertension
Action: For adoption of PRAC recommendation
EPITT 18221 – New signal
Lead Member State: NL

4.1.3. Sildenafil – REVATIO (CAP)

Applicant: Pfizer Limited

PRAC Rapporteur: Menno van der Elst

Scope: Signal of non-arteritic anterior ischaemic optic neuropathy (NAION)
Action: For adoption of PRAC recommendation
EPITT 18253 – New signal
Lead Member State: NL

[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

4.1.4. Sitagliptin - JANUVIA (CAP), RISTABEN (CAP), TESAVEL (CAP), XELEVIA (CAP) Sitagliptin, metformin hydrochloride – EFFICIB (CAP), JANUMET (CAP), RISTFOR (CAP), VELMETIA (CAP)

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Menno van der Elst

Scope: Signal of intestinal obstruction
Action: For adoption of PRAC recommendation
EPITT 18251 – New signal
Lead Member State: NL

4.2. New signals detected from other sources

4.2.1. Clopidogrel – ISCOVER (CAP), PLAVIX (CAP)

Applicant: Sanofi-aventis groupe (Iscover), Sanofi Clir SNC (Plavix)

PRAC Rapporteur: Margarida Guimarães

Scope: Signal of drug interaction with grapefruit juice leading to potential impairment of therapeutic efficacy
Action: For adoption of PRAC recommendation
EPITT 18289 – New signal
Lead Member State: PT

4.2.2. Oestrogens, selective oestrogen-receptor modulators and tibolone indicated in menopausal hormone decrease: Bazedoxifene – CONBRIZA (CAP), bazedoxifene, oestrogens conjugated – DUAVIVE (CAP); ospemifene – SENSHIO (CAP); raloxifene - EVISTA (CAP), OPTRUMA (CAP);NAP Chlorotrianisene; conjugated estrogens; dienestrol; diethylstilbestrol; estradiol; Estriol; estrogen; estrone; ethinylestradiol; lasofoxifene; methallenestril; Moxestrol; ormeloxifene; promestriene; tibolone - NAP

Applicant: Pfizer Limited (Duavive, Conbriza), Daiichi Sankyo Europe GmbH (Evista), Eli Lilly Nederland B.V. (Optruma), Shionogi Limited (Senshio), various

PRAC Rapporteur: To be appointed

Scope: Signal of increased risk of ovarian cancer
Action: For adoption of PRAC recommendation
EPITT 18258 – New signal
Lead Member State: DE

4.2.3. Temsirolimus – TORISEL (CAP)

Applicant: Pfizer Limited

PRAC Rapporteur: Martin Huber

Scope: Signal of myocardial infarction
Action: For adoption of PRAC recommendation
EPITT 18263 – New signal
Lead Member State: DE

4.2.4. Ziprasidone (NAP)

Applicant: Pfizer, various

PRAC Rapporteur: To be appointed

Scope: Signal of drug reaction with eosinophilia and systemic symptoms (DRESS)
Action: For adoption of PRAC recommendation
EPITT 18222 – New signal
Lead Member State: SE

4.3. Signals follow-up

4.3.1. Daclatasvir – DAKLINZA (CAP) - EMEA/H/C/003768/SDA/013 Sofosbuvir – SOVALDI (CAP) - EMEA/H/C/002798/SDA/019; sofosbuvir, ledipasvir – HARVONI (CAP) - EMEA/H/C/003850/SDA/001

PRAC Rapporteur: Margarida Guimarães

Scope: Signal of arrhythmia
Action: For adoption of PRAC recommendation
EPITT 18177 – Follow-up to January 2015

4.3.2. Interferon alfa-2a (NAP) Interferon alfa-2b – INTRONA (CAP) - EMEA/H/C/000281/SDA/053 Interferon beta-1a – AVONEX (CAP) - EMEA/H/C/000102/SDA/086, REBIF (CAP) - EMEA/H/C/000136/SDA/042 Interferon beta-1b - BETAFERON (CAP) - EMEA/H/C/000081/SDA/023, EXTAVIA (CAP) - EMEA/H/C/000933/SDA/021 Peginterferon alfa-2a - PEGASYS (CAP) - EMEA/H/C/000381/SDA/052 Peginterferon alfa-2b - PEGINTRON (CAP) - EMEA/H/C/000280/SDA/086, VIRAFERONPEG (CAP) - EMEA/H/C/000329/SDA/083 Peginterferon beta-1a – PLEGRIDY (CAP) – EMEA/H/C/002827/SDA/006

Applicant: Biogen Idec (Avonex, Plegridy), Merck Serono Europe Limited (Rebif), Bayer Pharma AG (Betaferon), Novartis Europharm Ltd (Extavia), Merck Sharp & Dohme Limited (IntronA, PegIntron, ViraferonPeg), Roche Registration Ltd (Pegasys, Roferon-A)

PRAC Rapporteur: Qun-Ying Yue

Scope: Signal of pulmonary arterial hypertension
Action: For adoption of PRAC recommendation
EPITT 18059 – Follow-up to December 2014

4.3.3. Pantoprazole – CONTROLOC CONTROL (CAP) - EMEA/H/C/001097/SDA/014, PANTECTA CONTROL (CAP) - EMEA/H/C/001099/SDA/014, PANTOLOC CONTROL (CAP) - EMEA/H/C/001100/SDA/013, PANTOZOL CONTROL (CAP) - EMEA/H/C/001013/SDA/014, SOMAC CONTROL (CAP) - EMEA/H/C/001098/SDA/019

Applicant: Takeda GmbH

PRAC Rapporteur: Rafe Suvarna

Scope: Signal of subacute cutaneous lupus erythematosus (SCLE)
Action: For adoption of PRAC recommendation
EPITT 18119 – Follow-up to November 2014

4.3.4. Sodium containing formulations of effervescent, dispersible and soluble medicines (NAP)

Applicant: various

PRAC Rapporteur: Julie Williams

Scope: Signal of cardiovascular events
Action: For adoption of PRAC recommendation
EPITT 17931 – Follow-up to March 2015

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

Applicant: Pharma Mar, S.A.

PRAC Rapporteur: Torbjorn Callreus

Scope: Signal of capillary leak syndrome
Action: For adoption of PRAC recommendation
EPITT 18115 – Follow-up to December 2014

5. Risk management plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Alirocumab - EMEA/H/C/003882

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

5.1.2. Aripiprazole - EMEA/H/C/003803, 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

5.1.3. Aripiprazole - EMEA/H/C/003899, Generic

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

5.1.4. Edoxaban - EMEA/H/C/002629

Scope: Prevention of stroke, embolism and treatment of venous thromboembolism
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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. Duloxetine - EMEA/H/C/003981, Generic

Scope: Treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalised anxiety disorder
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.7. Duloxetine - EMEA/H/C/003935, Generic

Scope: Treatment of depressive disorder, diabetic neuropathic pain, anxiety disorder
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.8. 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

5.1.9. 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

5.1.10. 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

5.1.11. 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

5.1.12. 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

5.1.13. Lutetium, isotope of mass 177 - EMEA/H/C/002749

Scope: Radiolabelling of carrier molecules
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.14. 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

5.1.15. Nivolumab - EMEA/H/C/003985

Scope: Treatment of advanced (unresectable or metastatic) melanoma in adults
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

Scope: Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.17. 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

5.1.18. Pembrolizumab - EMEA/H/C/003820

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

5.1.19. Pemetrexed - EMEA/H/C/004114, 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

5.1.20. Pregabalin - EMEA/H/C/003962, EMEA/H/C/004078, Generics

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

5.1.21. Pregabalin - EMEA/H/C/004010, EMEA/H/C/004070, Generics

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

5.1.22. Sebelipase alfa - EMEA/H/C/004004, Orphan

Applicant: Synageva BioPharma Ltd

Scope: Treatment of lysosomal acid lipase (LAL) deficiency
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.23. Selexipag - EMEA/H/C/003774

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

5.1.24. Sonidegib - EMEA/H/C/002839

Scope: Treatment of basal cell carcinoma (BCC)
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.25. Susoctocog alfa - EMEA/H/C/002792

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

5.1.26. Tasimelteon - EMEA/H/C/003870, Orphan

Applicant: Vanda Pharmaceuticals Ltd

Scope: Treatment of non-24-hour sleep-wake disorder (non-24)
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. Ataluren – TRANSLARNA (CAP) - EMEA/H/C/002720/II/0005/G

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Sabine Straus

Scope: Submission of non-clinical study 100011749 (Study of Ataluren (PTC124) and M4 metabolite in the β3 binding assay) and non-clinical study 100012124 (Study of ataluren (PTC124) and M4 (PTC-0256858-04) functional activity in a beta-3 adrenergic cellular assay) in fulfilment of MEA 006 and MEA 007
Action: For adoption of PRAC AR

5.2.2. Fluticasone furoate, vilanterol – RELVAR ELLIPTA (CAP) - EMEA/H/C/002673/WS/0713/G; REVINTY ELLIPTA (CAP) - EMEA/H/C/002745/WS/0713/G

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Miguel-Angel Macia

Scope: Update of the RMP to revise due dates of commitments within the pharmacovigilance plan
Action: For adoption of PRAC AR

5.2.3. Interferon beta-1b – BETAFERON (CAP) - EMEA/H/C/000081/II/0100

Applicant: Bayer Pharma AG

PRAC Rapporteur: Julie Williams

Scope: Introduction of an RMP for Betaferon following a signal assessment on thrombotic microangiopathy (TMA) covering the entire class of interferon beta. The RMP for Extavia, informed consent of Betaferon, has already been assessed
Action: For adoption of PRAC AR

5.2.4. Lapatinib – TYVERB (CAP) - EMEA/H/C/000795/II/0041/G

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Revised RMP in order to include general updates in the RMP regarding posology update, addition of some new studies to pharmacovigilance activities and addition of details of three newly available study reports. Timelines have been also changed for study EGF114299 and study EGF117165 and RMP and Annex II have been updated accordingly
Action: For adoption of PRAC AR

5.2.5. Memantine – AXURA (CAP) - EMEA/H/C/000378/WS0668/0067; EBIXA (CAP) - EMEA/H/C/000463/WS0668/0083; MEMANTINE MERZ (CAP) - EMEA/H/C/002711/WS0668/0004

Applicant: Lundbeck A/S

PRAC Rapporteur: Dolores Montero Corominas

Scope: Revised RMP (version 7.1) to reflect the interim results of the prostate cancer study and four finalised studies. This RMP update also introduces changes to the required

additional pharmacovigilance activity regarding the identified potential risk of prostate cancer by adjusting the due dates of agreed milestones
Action: For adoption of PRAC AR

5.2.6. Micafungin – MYCAMINE (CAP) - EMEA/H/C/000734/II/0026

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Revised RMP in order to update the important identified risk of drug interaction; include a second survey that will be conducted in Q1 2015 to further assess the effectiveness of risk minimisation measures as requested by the PRAC in May 2014
Action: For adoption of PRAC AR

5.2.7. Temoporfin – FOSCAN (CAP) - EMEA/H/C/000318/II/0036

Applicant: Biolitec pharma Ltd

PRAC Rapporteur: Sabine Straus

Scope: Submission of a new RMP (version 1.0)
Action: For adoption of PRAC AR

5.2.8. Temozolomide – TEMODAL (CAP) - EMEA/H/C/000229/II/0072

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Martin Huber

Scope: Revised RMP (version 5.0) in order to reclassify hepatobiliary disorders from important potential to important identified risk following the request from PRAC/CHMP in the assessment of variation II/63
Action: For adoption of PRAC AR

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

5.3.1. 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 chemotherapy-induced nausea and vomiting (CINV) in adults to paediatric patients (12 to 17years) for the 80mg and 125mg hard capsules. SmPC section 4.2 and 5.3 of the 165mg hard capsule label, which is consequential. In addition, addition of a new pharmaceutical form (powder for oral suspension) is assessed for 125mg strength. The MAH also submitted a type II variation to reflect the paediatric results for prevention of post-operative nausea and vomiting (PONV) in the clinical sections of 40mg hard capsules label, thus updating SmPC sections 5.1 and 5.2. The Package Leaflet is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.2. Azacitidine – VIDAZA (CAP) - EMEA/H/C/000978/II/0030

Applicant: Celgene Europe Limited

PRAC Rapporteur: Sabine Straus

Scope: Extension of indication to add treatment of adult patients aged 65 years or older who are not eligible for hematopoietic stem cell transplantation (HSCT) with acute myeloid leukaemia (AML) with >30% marrow blasts according to the WHO classification, based on the pivotal phase III study AZA- AML-001. As a consequence, SmPC sections 4.1, 4.4, 4.8 and 5.1 have been updated and the package leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. A revised RMP version 10.0 was provided as part of the application. The application includes a request for an additional year of market protection for a new indication in accordance with Article 10(1) of Directive 2001/83/EC
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.3. Cabazitaxel – JEVTANA (CAP) - EMEA/H/C/002018/II/0029

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Arnaud Batz

Scope: Update of SmPC sections 4.2 and 5.2 in order to update safety and pharmacokinetic information on the use of cabazitaxel in patients with solid tumours with moderately and severely impaired and with normal renal function. Final study report for study POP12251 supportive of these changes has been submitted. The RMP is updated accordingly. In addition, the MAH took the opportunity to update the RMP also for the on-going variation EMEA/H/C/002018/II/0029
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

Applicant: Roche Registration Limited

PRAC Rapporteur: Martin Huber

Scope: Update of SmPC sections 4.3 and 4.4 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

5.3.5. Conestat alfa – RUCONEST (CAP) - EMEA/H/C/001223/R/0023

Applicant: Pharming Group N.V.

PRAC Rapporteur: Rafe Suvarna

Scope: Evaluation of an RMP as part of a five-year renewal of the marketing authorisation
Action: For adoption of advice to CHMP

5.3.6. Dimethyl fumarate – TECFIDERA (CAP) - EMEA/H/C/002601/WS0689/0011/G

Applicant: Biogen Idec Ltd

PRAC Rapporteur: Martin Huber

Scope: Update of SmPC sections 4.4 to add a recommendation to consider interruption of treatment in patients with low lymphocyte counts (<0.5 x 109/L) persisting for more than six months and to monitor lymphocyte counts until recovery. Update of SmPC section 4.8 with information on observed low lymphocyte counts in clinical studies with Tecfidera and progressive multifocal leukoencephalopathy (PML) occurrence in the setting of severe and prolonged lymphopenia. Furthermore, the due dates of two commitments as part of the RMP have been revised
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.7. Enzalutamide – XTANDI (CAP) - EMEA/H/C/002639/II/0018

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Dolores Montero Corominas

Scope: Update of SmPC section 5.1 in order to update the pharmacodynamic properties information regarding overall survival (OS) after analysis of data from the PREVAIL (MDV3100-03) study part of the obligation to conduct post-authorisation measures as reported in Annex II. Annex II is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.8. Ingenol mebutate – PICATO (CAP) - EMEA/H/C/X002275/II/0012

Applicant: Leo Pharma A/S

PRAC Rapporteur: Julie Williams

Scope: Update of SmPC sections 4.2, 4.8 and 5.1 to provide new efficacy and safety data supporting a labelling update that introduces repeat treatment of Picato gel (150 mcg/g and 500 mcg/g), based on trial LP0041-22. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor linguistic amendments
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.9. Ipilimumab – YERVOY (CAP) - EMEA/H/C/002213/II/0028/G

Applicant: Bristol-Myers Squibb Pharma EEIG

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

5.3.10. Japanese encephalitis vaccine (inactivated, adsorbed) – IXIARO (CAP) - EMEA/H/C/000963/II/0065/G

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.1 in order to include data of the clinical trial sponsored by Novartis Vaccines V49_23, testing concomitant use in conventional and accelerated schedules of Ixiaro with Rabipur. Update of SmPC as recommended during the renewal procedure EMEA/H/C/00963/R/0055 with inclusion of relevant data to elderly population
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.11. Levetiracetam – KEPPRA (CAP) - EMEA/H/C/000277/R/0154 (with RMP)

Applicant: UCB Pharma SA

PRAC Rapporteur: Veerle Verlinden

Scope: Evaluation of an RMP as part of a five-year renewal of the marketing authorisation
Action: For adoption of advice to CHMP

5.3.12. Methylnatrexone bromide – RELISTOR (CAP) – EMEA/H/C/000870/II/0030

Applicant: TMC Pharma Services Ltd

PRAC Rapporteur: Valerie Strassmann

Scope: Extension of the indication for the treatment of opioid induced constipation in adult non cancer pain patients. Consequently, SmPC sections 4.1, 4.2, 4.4 and 5.1 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. Nitisinone – ORFADIN (CAP) - EMEA/H/C/000555/X/0041

Applicant: Swedish Orphan Biovitrum International AB

PRAC Rapporteur: Carmela Macchiarulo

Scope: Addition of an oral suspension 4 mg/ml as additional pharmaceutical form
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.14. Pazopanib – VOTRIENT (CAP) - EMEA/H/C/001141/II/0029/G

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Doris Stenver

Scope: Update of SmPC sections 4.4 and 4.8 to add interstitial lung disease (ILD)/pneumonitis. The package leaflet is updated accordingly. Following study VEG 108844 results, update of SmPC section 4.4 to add more information on myocardial dysfunction. Following the review of safety data from the sarcoma studies, the SmPC section 4.4 has been updated to correct the number of reported cases of congestive heart failure (CHF). The RMP is updated accordingly
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.15. Peginterferon alfa-2b – PEGINTRON (CAP) - EMEA/H/C/000280/WS0611/0119; VIRAFERONPEG (CAP) - EMEA/H/C/000329/WS0611/0112 interferon alfa-1b – INTRONA (CAP) - EMEA/H/C/000281/WS0611/0099

Applicant: Merck Sharp & Dohme Limited

PRAC Rapporteur: Qun-Ying Yue

Scope: Update of SmPC section 4.4 with updated information on homicidal ideation and for patients with decompensated liver disease, and update in SmPC section 4.8 with pulmonary fibrosis added as post-marketing adverse experience. The package leaflet is updated accordingly. For Intron A only, the MAH takes the opportunity to implement minor linguistic revisions in various languages arising from an internal quality check
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.16. Pegvisomant – SOMAVERT (CAP) - EMEA/H/C/000409/X/0072

Applicant: Pfizer Limited

PRAC Rapporteur: Arnaud Batz

Scope: Line extension to add 25 mg and 30 mg powder and solvent for solution for injection
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.17. Prucalopride – RESOLOR (CAP) - EMEA/H/C/001012/II/0034

Applicant: Shire Pharmaceuticals Ireland Ltd

PRAC Rapporteur: Rafe Suvarna

Scope: Extension of indication to include the male population on the basis of the completion of the clinical study SPD555-302. Consequently, the MAH proposed to update SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2. The package leaflet is updated accordingly. An updated RMP (version 12) is also provided with this submission
Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.18. Sodium oxybate – XYREM (CAP) - EMEA/H/C/000593/R/0054

Applicant: UCB Pharma Ltd.

PRAC Rapporteur: Magda Pedro

Scope: Evaluation of an RMP as part of a five-year renewal of the marketing authorisation
Action: For adoption of advice to CHMP

5.3.19. 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 in order 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

5.3.20. Tigecycline – TYGACIL (CAP) - EMEA/H/C/000644/II/0092

Applicant: Pfizer Limited

PRAC Rapporteur: Miguel-Angel Macia

Scope: Addition of a new restricted indication in children of eight year-old and older. SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 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

5.3.21. Ulipristal – ESMYA (CAP) - EMEA/H/C/002041/II/0028

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Extension of indication including updates to SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 in order to extend the current indication to long term (repeated intermittent) treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. 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)[2]

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

6.1.1. Afatinib – GIOTRIF (CAP) - EMEA/H/C/002280/PSUSA/10054/201409

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.2. Albiglutide – EPERZAN (CAP) - EMEA/H/C/002735/PSUSA/10175/201409

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Julie Williams

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

6.1.3. Alemtuzumab – LEMTRADA (CAP) - EMEA/H/C/003718/PSUSA/10055/201409

Applicant: Genzyme Therapeutics Ltd

PRAC Rapporteur: Torbjorn Callreus

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

6.1.4. Aliskiren - RASILEZ (CAP) - EMEA/H/C/000780/PSUSA/00089/201409; aliskiren, amlodipine – RASILAMLO (CAP) - EMEA/H/C/002073/PSUSA/00089/201409; aliskiren, hydrochlorothiazide - RASILEZ HCT (CAP) - EMEA/H/C/000964/PSUSA/00089/201409

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Carmela Macchiarulo

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

6.1.5. Alogliptin - VIPIDIA (CAP) - EMEA/H/C/002182/PSUSA/10061/201410; alogliptin, metformin - VIPDOMET (CAP) - EMEA/H/C/002654/PSUSA/10061/201410; alogliptin, pioglitazone – INCRESYNC (CAP) - EMEA/H/C/002178/PSUSA/10061/201410

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Menno van der Elst

[2] PRAC is responsible for adopting recommendations are on PSUR assessment for single centrally authorised product and of EU PSUR single assessment. The EU PSUR single assessment, referred also as PSUSA, is the assessment of PSURs for medicinal products subject to different marketing authorisations containing the same active substance or the same combination of active substances

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

6.1.6. Antithrombin alfa – ATRYN (CAP) - EMEA/H/C/000587/PSUSA/00224/201407

Applicant: GTC Biotherapeutics UK Limited

PRAC Rapporteur: Arnaud Batz

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

6.1.7. Aztreonam – CAYSTON (CAP) - EMEA/H/C/000996/PSUSA/00283/201409

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Sabine Straus

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

6.1.8. Bedaquiline – SIRTURO (CAP) - EMEA/H/C/002614/PSUSA/10074/201409

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Qun-Ying Yue

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

6.1.9. Belimumab – BENLYSTA (CAP) - EMEA/H/C/002015/PSUSA/09075/201409

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.10. Bivalirudin – ANGIOX (CAP) - EMEA/H/C/000562/PSUSA/00421/201409

Applicant: The Medicines Company UK Ltd.

PRAC Rapporteur: Julie Williams

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

6.1.11. Cabozantinib – COMETRIQ (CAP) - EMEA/H/C/002640/PSUSA/10180/201409

Applicant: TMC Pharma Services Ltd

PRAC Rapporteur: Sabine Straus

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

6.1.12. Cetuximab – ERBITUX (CAP) - EMEA/H/C/000558/PSUSA/00635/201409

Applicant: Merck KGaA

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.13. Cholic acid – ORPHACOL (CAP) - EMEA/H/C/001250/PSUSA/10208/201409

Applicant: Laboratoires CTRS - Boulogne Billancourt

PRAC Rapporteur: Rafe Suvarna

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

6.1.14. Colestilan – BINDREN (CAP) - EMEA/H/C/002377/PSUSA/10016/201409

Applicant: Mitsubishi Tanabe Pharma Europe Ltd

PRAC Rapporteur: Qun-Ying Yue

Scope: Evaluation of a PSUR/PSUSA procedure
Action: For adoption of PRAC Rapporteur AR

6.1.15. Dabigatran etexilate – PRADAXA (CAP) - EMEA/H/C/000829/PSUSA/00918/201409

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Torbjorn Callreus

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

6.1.16. Daptomycin – CUBICIN (CAP) - EMEA/H/C/000637/PSUSA/00931/201409

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Julie Williams

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

6.1.17. Denosumab – PROLIA (CAP) - EMEA/H/C/001120/PSUSA/00954/201409

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.18. Denosumab – XGEVA (CAP) - EMEA/H/C/002173/PSUSA/09119/201409

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.19. Dibotermin alfa – INDUCTOS (CAP) - EMEA/H/C/000408/PSUSA/01034/201409

Applicant: Medtronic BioPharma B.V.

PRAC Rapporteur: Menno van der Elst

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

6.1.20. Eculizumab – SOLIRIS (CAP) - EMEA/H/C/000791/PSUSA/01198/201410

Applicant: Alexion Europe SAS

PRAC Rapporteur: Dolores Montero Corominas

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

6.1.21. Etravirine – INTELENCE (CAP) - EMEA/H/C/000900/PSUSA/01335/201409

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Patrick Maison

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

6.1.22. Florbetapir (^{18}F) – AMYVID (CAP) - EMEA/H/C/002422/PSUSA/10032/201410

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Valerie Strassmann

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

6.1.23. Glycopyrronium bromide – ENUREV BREEZHALER (CAP) - EMEA/H/C/002691/PSUSA/10047/201409; SEEBRI BREEZHALER (CAP) - EMEA/H/C/002430/PSUSA/10047/201409; TOVANOR BREEZHALER (CAP) - EMEA/H/C/002690/PSUSA/10047/201409

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Torbjorn Callreus

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

6.1.24. Glycopyrronium bromide, indacaterol – ULTIBRO BREEZHALER (CAP) - EMEA/H/C/002679/PSUSA/10105/201409; ULUNAR BREEZHALER (CAP) - EMEA/H/C/003875/PSUSA/10105/201409; XOTERNA BREEZHALER (CAP) - EMEA/H/C/003755/PSUSA/10105/201409

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Torbjorn Callreus

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

6.1.25. Hepatitis A (inactivated) and hepatitis B (rDNA) (hab) vaccine (adsorbed) – AMBIRIX (CAP) - EMEA/H/C/000426/PSUSA/01593/201409; TWINRIX ADULT (CAP) - EMEA/H/C/000112/PSUSA/01593/201409; TWINRIX PAEDIATRIC (CAP) - EMEA/H/C/000129/PSUSA/01593/201409

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Rafe Suvarna

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

6.1.26. Human fibrinogen, human thrombin – EVARREST (CAP) - EMEA/H/C/002515/PSUSA/10103/201409

Applicant: Omrix Biopharmaceuticals N. V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.27. Iloprost – VENTAVIS (CAP) - EMEA/H/C/000474/PSUSA/01724/201409

Applicant: Bayer Pharma AG

PRAC Rapporteur: Arnaud Batz

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

6.1.28. Insulin degludec, insulin aspart – RYZODEG (CAP) - EMEA/H/C/002499/PSUSA/10036/201409; TRESIBA (CAP) - EMEA/H/C/002498/PSUSA/10036/201409

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Qun-Ying Yue

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

6.1.29. Insulin human – INSUMAN (CAP) - EMEA/H/C/000201/PSUSA/10107/201409

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Jean-Michel Dogné

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

6.1.30. Ipilimumab – YERVOY (CAP) - EMEA/H/C/002213/PSUSA/09200/201409

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sabine Straus

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

6.1.31. Lapatinib – TYVERB (CAP) - EMEA/H/C/000795/PSUSA/01829/201409

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.32. Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) – PANDEMRIX (CAP) - EMEA/H/C/000832/PSUSA/02277/201409

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Rafe Suvarna

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

6.1.33. Panitumumab – VECTIBIX (CAP) - EMEA/H/C/000741/PSUSA/02283/201409

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Julie Williams

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

6.1.34. Para-aminosalicylic acid – GRANUPAS (CAP) - EMEA/H/C/002709/PSUSA/10171/201410

Applicant: Lucane Pharma

PRAC Rapporteur: Julie Williams

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

6.1.35. Pneumococcal polysaccharide conjugate vaccine (7-valent, adsorbed) – PREVENAR (CAP) - EMEA/H/C/000323/PSUSA/02452/201408

Applicant: Pfizer Limited

PRAC Rapporteur: Jean-Michel Dogné

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

6.1.36. Regorafenib – STIVARGA (CAP) - EMEA/H/C/002573/PSUSA/10133/201409

Applicant: Bayer Pharma AG

PRAC Rapporteur: Sabine Straus

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

6.1.37. Retigabine – TROBALT (CAP) - EMEA/H/C/001245/PSUSA/02624/201409

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Doris Stenver

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

6.1.38. Riociguat – ADEMPAS (CAP) - EMEA/H/C/002737/PSUSA/10174/201409

Applicant: Bayer Pharma AG

PRAC Rapporteur: Julie Williams

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

6.1.39. Rivaroxaban – XARELTO (CAP) - EMEA/H/C/000944/PSUSA/02653/201409

Applicant: Bayer Pharma AG

PRAC Rapporteur: Qun-Ying Yue

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

6.1.40. Strontium ranelate – OSSEOR (CAP) - EMEA/H/C/000561/PSUSA/09301/201409; PROTELOS (CAP) - EMEA/H/C/000560/PSUSA/09301/201409

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Ulla Wändel Liminga

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

6.1.41. Sulfur hexafluoride – SONOVUE (CAP) - EMEA/H/C/000303/PSUSA/02822/201409

Applicant: Bracco International B.V.

PRAC Rapporteur: Arnaud Batz

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

6.1.42. Telavancin – VIBATIV (CAP) - EMEA/H/C/001240/PSUSA/02879/201409

Applicant: Clinigen Healthcare Ltd

PRAC Rapporteur: Julie Williams

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

6.1.43. Tenecteplase – METALYSE (CAP) - EMEA/H/C/000306/PSUSA/02888/201408

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Martin Huber

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

6.1.44. Teriflunomide – AUBAGIO (CAP) - EMEA/H/C/002514/PSUSA/10135/201409

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Martin Huber

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

6.1.45. Trabectedin – YONDELIS (CAP) - EMEA/H/C/000773/PSUSA/03001/201409

Applicant: Pharma Mar, S.A.

PRAC Rapporteur: Torbjorn Callreus

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

6.1.46. Trastuzumab – HERCEPTIN (CAP) - EMEA/H/C/000278/PSUSA/03010/201409

Applicant: Roche Registration Ltd

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.1.47. Vandetanib – CAPRELSA (CAP) - EMEA/H/C/002315/PSUSA/09327/201410

Applicant: AstraZeneca AB

PRAC Rapporteur: Arnaud Batz

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

6.1.48. Vinflunine ditartrate – JAVLOR (CAP) - EMEA/H/C/000983/PSUSA/03123/201409

Applicant: Pierre Fabre Médicament

PRAC Rapporteur: Rafe Suvarna

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

6.1.49. Vortioxetine – BRINTELLIX (CAP) - EMEA/H/C/002717/PSUSA/10052/201409

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Veerle Verlinden

Scope: Evaluation of a PSUR/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. Anagrelide – XAGRID (CAP) - EMEA/H/C/000480/PSUSA/00208/201409; NAP

Applicant: Shire Pharmaceutical Contracts Ltd.

PRAC Rapporteur: Arnaud Batz

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

6.2.2. Leflunomide – ARAVA (CAP) - EMEA/H/C/000235/PSUSA/01837/201409; LEFLUNOMIDE MEDAC (CAP) - EMEA/H/C/001227/PSUSA/01837/201409; LEFLUNOMIDE WINTHROP (CAP) - EMEA/H/C/001129/PSUSA/01837/201409; NAP

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Sabine Straus

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

6.2.3. Measles, mumps, rubella and varicella vaccine (live) – PROQUAD (CAP) - EMEA/H/C/000622/PSUSA/01936/201409; NAP

Applicant: Sanofi Pasteur MSD SNC

PRAC Rapporteur: Brigitte Keller-Stanislawski

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

6.2.4. Memantine – AXURA (CAP) - EMEA/H/C/000378/PSUSA/01967/201409; EBIXA (CAP) - EMEA/H/C/000463/PSUSA/01967/201409; MEMANTINE MERZ (CAP) - EMEA/H/C/002711/PSUSA/01967/201409; NAP

Applicant: Merz Pharmaceuticals GmbH

PRAC Rapporteur: Dolores Montero Corominas

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

6.2.5. Zoledronic acid – ZOLEDRONIC ACID MEDAC (CAP) - EMEA/H/C/002359/PSUSA/03149/201408; ZOMETA (CAP) - EMEA/H/C/000336/PSUSA/03149/201408; NAP

Applicant: medac Gesellschaft fur klinische Spezialpraparate mbH

PRAC Rapporteur: Doris Stenver

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

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

None

6.4. Follow-up to PSUR procedures

6.4.1. Rasburicase – FASTURTEC (CAP) - EMEA/H/C/000331/LEG 044

Applicant: Sanofi-Aventis Groupe

PRAC Rapporteur: Sabine Straus

Scope: Provision of cumulative overview of safety data received for the on-going signals of cardiac toxicity, lack of efficacy and hepatobiliary disorders as per CHMP Opinion dated 23 October 2014 for the procedure EMEA/H/C/000331/PSUV/0041
Action: For adoption of an advice to CHMP

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[3]

7.1.1. Chlormadinone, ethinylestradiol (NAP) – EMEA/H/N/PSP/J/0012.1

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

7.1.2. Cyproterone, ethinylestradiol (NAP) – EMEA/H/N/PSP/J/0006.1

Applicant: Bayer Pharma AG (Bayer 35), various

PRAC Rapporteur: Menno van der Elst

Scope: Revised PASS protocol for a drug utilisation study (database DUS) following EC decision dated 25 July 2013 on a referral procedure (EMEA/H/107i/1357)
Action: For adoption of PRAC Assessment Report, PRAC outcome letter

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

7.1.3. Domperidone (NAP) - EMEA/H/N/PSP/J/0016

Applicant: Janssen (Motilium), various

PRAC Rapporteur: Arnaud Batz

Scope: 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

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[4]

7.2.1. Agomelatine – THYMANAX (CAP) - EMEA/H/C/000916/MEA 023.1; VALDOXAN (CAP) - EMEA/H/C/000915/MEA 023.1

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Ingebjørg Buajordet

Scope: Revised PASS protocol for a study using databases in four European countries to assess the incidence of hospitalisation for liver injury in current medical practice in comparison with other antidepressant drugs
Action: For adoption of advice to CHMP

7.2.2. Albiglutide – EPERZAN (CAP) - EMEA/H/C/002735/MEA 002.1

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Julie Williams

Scope: MAH's response to MEA 002 (PASS protocol for an observational study of the risk of acute pancreatitis in subjects exposed to albiglutide, other GLP-1 agonists or DPP-4 inhibitors compared to other antidiabetic agents (protocol PRJ2335)) request for supplementary information (RSI) as adopted in November 2014
Action: For adoption of advice to CHMP

7.2.3. Albiglutide – EPERZAN (CAP) - EMEA/H/C/002735/MEA 003.1

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Julie Williams

Scope: MAH's response to MEA 003 (PASS protocol for a study to assess the risk of thyroid and pancreatic cancers, and malignancy when used in combination with insulins in observational databases of sufficient size that provides long term longitudinal follow up of patients (Protocol PRJ2331)) request for supplementary information (RSI) as adopted in November 2014

7.2.4. Albiglutide – EPERZAN (CAP) - EMEA/H/C/002735/MEA 004.1

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Julie Williams

[4] 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: MAH's response to MEA 004 (PASS protocol for a cohort study to investigate the prescribing of albiglutide among women of child bearing age who have type 2 diabetes (Protocol PRJ2376)) request for supplementary information (RSI) as adopted in November 2014
Action: For adoption of advice to CHMP

7.2.5. Albiglutide – EPERZAN (CAP) - EMEA/H/C/002735/MEA 005.1

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Julie Williams

Scope: MAH's response to MEA 005 (PASS protocol for a retrospective cohort study to assess the utilisation of albiglutide among women of child bearing age in the U.S. (protocol PRJ2379)) request for supplementary information (RSI) as adopted in November 2014
Action: For adoption of advice to CHMP

7.2.6. Aripiprazole – ABILIFY MAINTENA (CAP) - EMEA/H/C/002755/MEA 005.1

Applicant: Otsuka Pharmaceutical Europe Ltd

PRAC Rapporteur: Qun-Ying Yue

Scope: MAH's response to MEA 005 (PASS protocol No. 31-10-270) request for supplementary information (RSI) as adopted in December 2014
Action: For adoption of advice to CHMP

7.2.7. Dasabuvir – EXVIERA (CAP) - EMEA/H/C/003837/MEA 001

Applicant: AbbVie Ltd.

PRAC Rapporteur: Miguel-Angel Macia

Scope: PASS protocol for a prospective, observational cohort study utilising the Hepatitis C Therapeutic Registry and Research Network (HCV-TARGET) data to evaluate the clinical impact and real world frequency of Grade 3+ ALT elevations in patients being treated for hepatitis C with paritaprevir with ritonavir (paritaprevir/ritonavir), ombitasvir and dasabuvir (3 direct-acting antiviral (DAA) regimen) or paritaprevir/ritonavir and ombitasvir (2-DAA regimen) with or without ribavirin for hepatitis C infection (HCV) (SHORT – evaluation of the potential for and clinical impact of increased ALT in patients using the AbbVie 2-DAA or 3-DAA Regimens in a real world setting)
Action: For adoption of advice to CHMP

7.2.8. Florbetaben (^{18}F) – NEURACEQ (CAP) - EMEA/H/C/002553/MEA 001.2

Applicant: Piramal Imaging Limited

PRAC Rapporteur: Julie Williams

Scope: MAH's response to MEA 001 (revised PASS protocol study no. FBB-01_03_13) adopted in December 2014
Action: For adoption of advice to CHMP

7.2.9. Golimumab – SIMPONI (CAP) - EMEA/H/C/000992/MEA 026.1

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: MAH's response to MEA 026 (protocol MRK-2859, Nordic national register database study) request for supplementary information (RSI) as adopted in April 2014
Action: For adoption of advice to CHMP

7.2.10. Golimumab – SIMPONI (CAP) - EMEA/H/C/000992/MEA 027.2

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: MAH's response to MEA 027.1 (feasibility assessment of Spanish ENEIDA Registry) request for supplementary information (RSI) as adopted in October 2014
Action: For adoption of advice to CHMP

7.2.11. Insulin human – INSUMAN (CAP) - EMEA/H/C/000201/MEA 047

Applicant: Sanofi-aventis Deutschland GmbH

PRAC Rapporteur: Jean-Michel Dogné

Scope: PASS protocol for an European observational cohort of patients with type I diabetes treated via intraperitoneal route with Insuman Implantable 400 IU/mL in Medtronic MiniMed implantable pump (study HUBIN-C-06380)
Action: For adoption of advice to CHMP

7.2.12. Ombitasvir, paritaprevir, ritonavir – VIEKIRAX (CAP) - EMEA/H/C/003839/MEA 001

Applicant: AbbVie Ltd.

PRAC Rapporteur: Miguel-Angel Macia

Scope: Protocol for a prospective, observational cohort study utilising Hepatitis C Therapeutic Registry and Research Network (HCV-TARGET) data to evaluate the clinical impact and real world frequency of grade 3+ ALT elevations in patients being treated for hepatitis C with paritaprevir with ritonavir (paritaprevir/ritonavir), ombitasvir and dasabuvir (3- direct-acting antiviral (DAA) regimen) or paritaprevir/ritonavir and ombitasvir (2-DAA regimen) with or without ribavirin for hepatitis C infection (HCV) (SHORT – evaluation of the potential for and clinical impact of increased ALT in patients using the AbbVie 2-DAA or 3-DAA Regimens in a real world setting)
Action: For adoption of advice to CHMP

7.2.13. Voriconazole – VFEND (CAP) - EMEA/H/C/000387/MEA 091

Applicant: Pfizer Limited

PRAC Rapporteur: Sabine Straus

Scope: Non-interventional PASS protocol A1501103 for an active safety surveillance program to monitor selected events in patients with long-term voriconazole use
Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[5]

None

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

7.4. Results of PASS non-imposed in the marketing authorisation(s)[6]

7.4.1. Emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA (CAP) - EMEA/H/C/002312/II/0053 (without RMP)

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Menno van der Elst

Scope: Submission of the clinical study report (CSR) of the Eviplera/Edurant Healthcare Professionals survey undertaken to gain an understanding of the effectiveness of the current prescribing conditions in minimising the risk associated with taking the products without food/a meal, potentially associated with the risk of development of drug resistance
Action: For adoption of PRAC Assessment Report

7.4.2. Ivacaftor – KALYDECO (CAP) - EMEA/H/C/002494/II/0035 (with RMP)

Applicant: Vertex Pharmaceuticals (U.K.) Ltd

PRAC Rapporteur: Miguel-Angel Macia

Scope: Submission of the final study VX08-770-105 CSR to fulfil the post-authorisation measure ANX 002 and a revised RMP
Action: For adoption of PRAC Assessment Report

7.4.3. Lapatinib – TYVERB (CAP) - EMEA/H/C/000795/II/0042 (with RMP)

Applicant: Glaxo Group Ltd

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of data analysis of the available pharmacokinetic sampling of patients enrolled in LANTERN trial (LAP113130) in comparison to historical data in order to fulfil the MEA 023.4 which is to examine lapatinib dose adjustments with specific CYP3A4 inducers.
Action: For adoption of PRAC Assessment Report

7.4.4. Palivizumab – SYNAGIS (CAP) - EMEA/H/C/000257/II/0098 (without RMP)

Applicant: AbbVie Ltd.

PRAC Rapporteur: Torbjorn Callreus

Scope: Submission of the final study report for study A11-632, an observational study carried out to assess the risk of autoimmune and allergic diseases in high risk children exposed to palivizumab, in fulfilment of the Post Authorisation Measure (REC) FU2 032.4
Action: For adoption of PRAC Assessment Report

7.4.5. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) – PREVENAR 13 (CAP) - EMEA/H/C/001104/II/0116 (without RMP)

Applicant: Pfizer Limited

PRAC Rapporteur: Qun-Ying Yue

Scope: Submission of a final report for an observational safety study of 13-valent pneumococcal conjugate vaccine (13vPnC) administered in routine use to infants and

[6] 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

toddlers. This observational study was conducted as a post-marketing commitment, MEA 012
Action: For adoption of PRAC Assessment Report

7.4.6. Rilpivirine – EDURANT (CAP) - EMEA/H/C/002264/II/0015 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Sabine Straus

Scope: Submission of the clinical study report of the Edurant/Eviplera Healthcare Professionals survey undertaken to gain an understanding of the effectiveness of the current prescribing conditions in minimising the risk associated with taking the products without food/a meal, potentially associated with the risk of development of drug resistance
Action: For adoption of PRAC Assessment Report

7.4.7. Sofosbuvir – SOVALDI (CAP) - EMEA/H/C/002798/II/0015 (with RMP)

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 HCV post liver transplant (GS-US-334-0126). This submission of this study fulfils MEA 005. An updated RMP (version 3.0) is proposed 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[7]

7.5.1. Adefovir dipivoxil – HEPSERA (CAP) - EMEA/H/C/000485/MEA 070.1

Applicant: Gilead Sciences International Ltd

PRAC Rapporteur: Arnaud Batz

Scope: Interim report on the antiretroviral pregnancy registry
Action: For adoption of advice to CHMP

7.5.2. Canagliflozin – INVOKANA (CAP) - EMEA/H/C/002649/MEA 005.1 canagliflozin, metformin – VOKANAMET (CAP) - EMEA/H/C/002656/MEA 004.1

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur (lead): Valerie Strassmann

Scope: Canagliflozin independent data monitoring committee (IDMC) status reports for the DIA3008 CANVAS study
Action: For adoption of advice to CHMP

7.5.3. Denosumab – XGEVA (CAP) - EMEA/H/C/002173/MEA 009.2

Applicant: Amgen Europe B.V.

PRAC Rapporteur Ulla Wändel Liminga

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

Scope: Interim report on an observational cohort study (study 20101363) to monitor the incidence proportion of ONJ and infections leading to hospitalisation in patients with cancer treated with Xgeva or zoledronic acid using health registry data as defined in the protocol
Action: For adoption of advice to CHMP

7.5.4. Fingolimod – GILENYA (CAP) - EMEA/H/C/002202/LEG 012.3

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Arnaud Batz

Scope: Evaluation of yearly report of studies CFTY720D2399, D2403, D2404 and D2406 and annual pooled report of D2403 and D2406
Action: For adoption of advice to CHMP

7.5.5. Fingolimod – GILENYA (CAP) - EMEA/H/C/002202/MEA 014.1

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Arnaud Batz

Scope: Interim results for study D2404: multi-national pregnancy fingolimod exposure registry in multiple sclerosis
Action: For adoption of advice to CHMP

7.5.6. Ivacaftor – KALYDECO (CAP) - EMEA/H/C/002494/ANX 001.2

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

PRAC Rapporteur: Miguel-Angel Macia

Scope: Second interim analysis of a five-year long-term observational study with ivacaftor in patients with cystic fibrosis, including also microbiological and clinical endpoints
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

None

8.2. Conditional renewals of the marketing authorisation

8.2.1. Ataluren – TRANSLARNA (CAP) - EMEA/H/C/002720/R/0007 (without RMP)

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Sabine Straus

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

8.2.2. Everolimus – VOTUBIA (CAP) - EMEA/H/C/002311/R/0033 (without RMP)

Applicant: Novartis Europharm Ltd

PRAC Rapporteur: Martin Huber

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

8.3. Renewals of the marketing authorisation

None

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspection

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

None

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

None

10.3. Other requests

10.3.1. Adrenaline auto-injectors (NAP) - EMEA/H/A-31/1398

Applicant: PharmaSwiss s.r.o., ALK-Abelló A/S, Aptiv Solutions (Lincoln Medical Ltd), Meda Pharma

Lead PRAC member: Rafe Suvarna

Scope: PRAC consultation on a CHMP referral procedure under Article 31 of Directive 2001/83/EC

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

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

None

12.2. Coordination with EMA scientific committees or CMDh-v

12.2.1. Paediatric Committee (PDCO): Guideline on conduct of pharmacovigilance for medicines used by the paediatric population

Action: For discussion

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

12.3.1. Joint Paediatric Committee (PDCO)–PRAC Working Group (WG): Call for nomination

Action: For discussion

12.3.2. Pharmacogenomics Working Party (PGWP): Guideline on key aspects for the use of pharmacogenomics methodologies in the pharmacovigilance evaluation of medicinal products

Action: For discussion

12.4. Cooperation within the EU regulatory network

None

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) & 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

12.10.3.1. PRAC recommendation on the repository audit outcome

Action: For discussion

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

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

12.11. Signal management

12.11.1. Interstitial lung disease (ILD): analysis of geographic clusters of reports

Action: For discussion

12.11.2. Signal management – Feedback from Signal Management Review Technical (SMART) Working Group

Action: For discussion

12.12. Adverse drug reactions reporting and additional monitoring

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 April 2015)

12.12.4. Reporting of adverse drug reactions for donated medicines

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans (RMPs) and effectiveness of risk minimisations

12.14.1. Implementation of the revised RMP assessment process

Action: For discussion

12.14.2. Medication errors: risk minimisation strategy with high strength/fixed combination insulins

Action: For adoption

12.14.3. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Good pharmacovigilance practices (GVP) module VIII (Post-authorisation safety studies)

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

None

13. Any other business

13.1. Pharmacovigilance programme and revised implementation governance

Action: For discussion

13.2. Type II variations: revised procedural timetables

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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