02 September 2013
EMA/PRAC/534993/2013
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda of the meeting on 2-5 September 2013

Explanatory notes

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

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

(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.
The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.
The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.
RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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 8 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/

Chair: June Raine – Vice-Chair: Almath Spooner

2 September 2013, 13:00 – 19:00, room 3/A

3 September 2013, 08:30 – 19:00, room 3/A

4 September 2013, 08:30– 19:00, room 3/A

5 September 2013, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

19 September 2013, 10:30 – 12:30, room 2/B, via teleconference

Table of contents

1. Introduction

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

1.2. Adoption of agenda of the meeting of 2-5 September 2013

Status: for adoption

1.3. Minutes of the previous PRAC meeting on 8-11 July 2013

Status: for adoption

2. EU Referral Procedures for Safety Reasons: Urgent EU Procedures

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

2.2.1. **Hydroxyethyl starch** (**HES**), **solutions for infusion** (NAP)

- Review of the benefit-risk balance following notification by the United Kingdom of a referral under Article 107i of Directive 2001/83/EC

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Jana Mladá (CZ)
PRAC Co-Rapporteur: Julie Williams (UK)

2.3. Procedures for finalisation

2.3.1. **Solutions for parenteral nutrition**, **combination - NUMETA G13%E and NUMETA G16%E EMULSION FOR INFUSION and associated names** (NAP)

- Review of the benefit-risk following notification by Sweden of a referral under Article 107i of Directive 2001/83/EC

***Status**: for discussion and adoption of PRAC recommendation to CMDh*

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)
PRAC Co-Rapporteur: Ulla Wändel Liminga (SE)

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. **Aceclofenac** (NAP)

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

Status: *for discussion and adoption of a list of questions and procedure timetable*

Regulatory details:
PRAC Rapporteur: *to be appointed*
PRAC Co-Rapporteur: *to be appointed*

3.1.2. **Bromocriptine** (NAP)

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

Status: *for discussion and adoption of a list of questions and procedure timetable*

Regulatory details:
PRAC Rapporteur: *to be appointed*
PRAC Co-Rapporteur: *to be appointed*

3.2. Ongoing Procedures

3.2.1. **Strontium ranelate – OSSEOR** (CAP), **PROTELOS** (CAP)

- 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, following procedural steps of Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)
PRAC Co-Rapporteur: Harald Herkner (AT)

3.3. Procedures for finalisation

3.3.1. **Short-acting beta agonists**:
hexoprenaline (NAP); **fenoterol** (NAP); **ritodrine** (NAP); **salbutamol** (NAP); **terbutaline** (NAP); **isoxsuprine** (NAP)

- Review of the benefit-risk balance of the obstetric indications following notification by Hungary of a referral under Article 31 of Directive 2001/83/EC based on pharmacovigilance data

Status: *for discussion and adoption of PRAC recommendation to CMDh*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)
PRAC Co-Rapporteurs: Jean-Michel Dogné (BE), Carmela Macchiarulo (IT), Jana Mladá (CZ), Julia Pallos (HU)

3.4. Re-examination procedures

3.4.1. **Hydroxyethyl starch** (**HES**), **solutions for infusion** (NAP)

- Re-examination procedure of the PRAC recommendation following the review of the benefit-risk balance following notification by Germany of a referral under Article 31 of Directive 2001/83/EC based on pharmacovigilance data

***Status**: for discussion and adoption of a procedure timetable and list of questions to ad-hoc expert group*

Regulatory details:

PRAC Rapporteur: Tatiana Magálová (SK)
PRAC Co-Rapporteur: Brigitte Keller-Stanislawski (DE-PEI)

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

None

3.6. Others

3.6.1. **Dihydrocodeine** (NAP)

- Follow-up of finalised referral for codeine-containing medicines under Article 31 of Directive 2001/83/EC based on pharmacovigilance data

***Status:** for discussion*

Regulatory details:

Lead member: Dolores Montero Corominas (ES)

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. **Chloroquine** (NAP), **hydroxychloroquine** (NAP)

- Signal of hypoglycaemia

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.1.2. **Denosumab – PROLIA** (CAP), **XGEVA** (CAP)

- Signal of vasculitis

[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.

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

4.1.3. Dexmedetomidine – DEXDOR (CAP)

- Signal of infantile apnoeic attack

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

4.1.4. Fingolimod – GILENYA (CAP)

- Signal of spontaneous abortion and blighted ovum

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

4.1.5. Interferon beta 1a – AVONEX (CAP), REBIF (CAP) Interferon beta 1b - BETAFERON (CAP), EXTAVIA (CAP)

- Signal of thrombotic microangiopathy (TMA)

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.1.6. Triamcinolone acetonide (NAP)

- Signal of postmenopausal haemorrhage

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.1.7. Ustekinumab – STELARA (CAP)

- Signal of dermatitis exfoliative

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

4.1.8. Vemurafenib – ZELBORAF (CAP)

- Signal of renal failure

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

4.2. New signals detected from other sources

None

4.3. Signals follow-up and prioritisation

4.3.1. **Brentuximab vedotin - ADCETRIS** (CAP)

- Signal of pulmonary toxicity

***Status:** for information*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

4.3.2. **Nicardipine** (NAP)

- Signal of acute pulmonary oedema in off-label use during pregnancy

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. 4-aminosalicylic acid

5.1.2. Aripiprazole

5.1.3. Ataluren

5.1.4. Balugrastim

5.1.5. Bedaquiline

5.1.6. Canagliflozin

5.1.7. Cholic acid

5.1.8. Dapagliflozin, metformin

5.1.9. Dexamethasone

5.1.10. Elvitegravir

5.1.11. Fluticasone, vilanterol

5.1.12. Influenza vaccine (tetravalent, live attenuated, nasal)

5.1.13. Levetiracetam

5.1.14. Levodopa, carbidopa, entacapone

5.1.15. Lidocaine, prilocaine

5.1.16. Macitentan

5.1.17. Masitinib

5.1.18. Memantine

5.1.19. Obinutuzumab

5.1.20. Oseltamivir

5.1.21. Radium-223

5.1.22. Recombinant human n-acetylgalactosamine-6-sulfatase (RHGALNS)

5.1.23. Simeprevir

5.1.24. Sofosbuvir

5.1.25. Tacrolimus

5.1.26. Trastuzumab emtansine

5.1.27. Turoctocog alfa

5.1.28. Umeclidinium bromide

5.1.29. Umeclidinium bromide, vilanterol

- Evaluation of an RMP in the context of an initial marketing authorisation application procedure

Status: *for discussion and agreement of advice to CHMP*

5.2. Medicines already authorised

RMP in the context of a PSUR procedure

5.2.1. Aclidinium bromide – BRETARIS GENUAIR (CAP), EKLIRA GENUAIR (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 6.1.1.

5.2.2. Anidulafungin – ECALTA (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.8.

5.2.3. Asenapine – SYCREST (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 6.1.9.

5.2.4. Axitinib – INLYTA (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

See also 6.1.10.

5.2.5. Brentuximab vedotin – ADCETRIS (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.12.

5.2.6. Ceftaroline fosamil – ZINFORO (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.6.

5.2.7. Clofarabine – EVOLTRA (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

See also 6.1.17.

5.2.8. Collagenase clostridium histolyticum – XIAPEX (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

See also 6.1.19.

5.2.9. Degarelix – FIRMAGON (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

See also 6.1.21.

5.2.10. Dronedarone – MULTAQ (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Menno van der Elst (NL)

See also 6.1.23.

5.2.11. **Emtricitabine**, **rilpivirine**, **tenofovir disoproxil – EVIPLERA** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.24.

5.2.12. **Etanercept – ENBREL** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

See also 6.1.27.

5.2.13. **Fampridine – FAMPYRA** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.28.

5.2.14. **Ivacaftor – KALYDECO** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Miguel-Angel Macia (ES)

See also 6.1.33.

5.2.15. **Linagliptin**, **metformin – JENTADUETO** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Menno van der Elst (NL)

See also 6.1.35.

5.2.16. Nilotinib – TASIGNA (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

See also 6.1.36.

5.2.17. Prasugrel – EFIENT (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

See also 6.1.46.

5.2.18. Pregabalin – LYRICA (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.47.

5.2.19. Pyronaridine, artesunate – PYRAMAX (Art 58)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

See also 6.1.48.

5.2.20. Ranolazine – RANEXA (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

See also 6.1.49.

5.2.21. Rotigotine – **LEGANTO** (CAP), **NEUPRO** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Maria Alexandra Pêgo (PT)

See also 6.1.52.

5.2.22. Ruxolitinib – **JAKAVI** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

See also 6.1.54.

5.2.23. Silodosin – **SILODYX** (CAP), **UROREC** (CAP)

- Evaluation of an RMP in the context of a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 6.1.56.

RMP in the context of a variation

5.2.24. Anakinra – **KINERET** (CAP)

- Evaluation of an RMP in the context of a variation, line extension

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.25. Bortezomib – **VELCADE** (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

5.2.26. Catridecacog – NOVOTHIRTEEN (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

5.2.27. Certolizumab pegol – CIMZIA (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

5.2.28. Dabigatran – PRADAXA (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.29. Denosumab – XGEVA (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

5.2.30. Doxorubicin – CAELYX (CAP)

- Evaluation of an RMP in the context of a variation

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

5.2.31. Human normal immunoglobulin – HIZENTRA (CAP)

- Evaluation of an RMP in the context of a variation

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.32. Insulin aspart – NOVORAPID (CAP)

- Evaluation of an RMP in the context of a variation

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.33. Ipilimumab – YERVOY (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

5.2.34. Peginterferon alfa-2B – PEGINTRON (CAP), VIRAFERONPEG (CAP)

- Evaluation of an RMP in the context of a variation, worksharing procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.35. Pramipexole – OPRYMEA (CAP)

- Evaluation of an RMP in the context of a variation, line extension

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.36. Ribavirin – REBETOL (CAP)

- Evaluation of an RMP in the context of a variation

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

5.2.37. Ulipristal – ESMYA (CAP)

- Evaluation of an RMP in the context of a variation

Status*: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

5.2.38. Vinflunine – JAVLOR (CAP)

- Evaluation of an RMP in the context of a variation, extension of indication

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

RMP in the context of a renewal of the marketing authorisation, conditional renewal or annual reassessment

See Aliskiren, hydrochlorothiazide (RASILEZ HCT) 8.1.1. , Filgrastim (FILGRASTIM HEXAL/ZARZIO) 8.1.4. ;Human fibrogen, human thrombin (EVICEL) 8.1.5. , Pneumococcal polysaccharide conjugate vaccine (SYNFLORIX) 8.1.11.

RMP in the context of a stand-alone RMP procedure

5.2.39. Atosiban – TRACTOCILE (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

5.2.40. Colestilan – BINDREN (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.41. Imatinib – GLIVEC (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Dolores Montero Corominas (ES)

5.2.42. Pneumococcal polysaccharide conjugate vaccine (**13-valent**, **adsorbed**) **–PREVENAR 13** (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.43. Rituximab – MABTHERA (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.44. Sirolimus – RAPAMUNE (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

5.2.45. Tegafur, gimeracil, oteracil – TEYSUNO (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

5.2.46. Vardenafil – LEVITRA (CAP), VIVANZA (CAP)

- Evaluation of an RMP in the context of a stand-alone RMP procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Miguel-Angel Macia (ES)

6. Assessment of Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[2]

6.1.1. A/H5N1 prepandemic influenza vaccine (whole virion, vero-cell derived, inactivated) – VEPACEL (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Jean-Michel Dogné (BE)

6.1.2. Aclidinium bromide – BRETARIS GENUAIR (CAP), EKLIRA GENUAIR (CAP)

- Evaluation of a PSUR procedure

[2] Where a regulatory action is recommended (variation, suspension or revocation of the terms of Marketing Authorisation(s)), the assessment report and PRAC recommendation are transmitted to the CHMP for adoption of an opinion. Where PRAC recommends the maintenance of the terms of the marketing authorisation(s), the procedure finishes at the PRAC level.

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.1.

6.1.3. **Aflibercept – ZALTRAP** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.4. **Agomelatine – THYMANAX** (CAP), **VALDOXAN** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.5. **Aliskiren**, **amlodipine – RASILAMLO** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.6. **Aliskiren**, **hydrochlorothiazide – RASILEZ HCT** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.7. **Alitretinoin – PANRETIN** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.8. **Anidulafungin – ECALTA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.2.

6.1.9. Asenapine – SYCREST (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.3.

6.1.10. Axitinib – INLYTA (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

See also 5.2.4.

6.1.11. Azilsartan medoxomil – EDARBI (CAP), IPREZIV (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Menno van der Elst (NL)

6.1.12. Brentuximab vedotin – ADCETRIS (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.5.

6.1.13. ^{13}C-urea – HELICOBACTER TEST INFAI (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Harald Herkner (AT)

6.1.14. Caspofungin – CANCIDAS (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Jean-Michel Dogné (BE)

6.1.15. Catridecacog – NOVOTHIRTEEN (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.1.16. Ceftaroline fosamil – ZINFORO (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.6.

6.1.17. Clofarabine – EVOLTRA (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.7.

6.1.18. Colistimethate sodium – COLOBREATHE (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

6.1.19. Collagenase clostridium histolyticum – XIAPEX (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

See also 5.2.8.

6.1.20. Crizotinib – XALKORI (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.1.21. Degarelix – FIRMAGON (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.9.

6.1.22. Dexamethasone – OZURDEX (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.23. Dronedarone – MULTAQ (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Menno van der Elst (NL)

See also 5.2.10.

6.1.24. Emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.11.

6.1.25. Entacapone – COMTAN (CAP), COMTESS (CAP), ENTACAPONE ORION (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

6.1.26. Epoetin zeta – RETACRIT (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

6.1.27. Etanercept – ENBREL (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

See also 5.2.12.

6.1.28. Fampridine – FAMPYRA (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.13.

6.1.29. Filgrastim – FILGRASTIM HEXAL (CAP), ZARZIO (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.30. Gadoversetamide – OPTIMARK (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

6.1.31. Hepatitis B (rDNA) vaccine (adjuvanted, adsorbed) – FENDRIX (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Jean-Michel Dogné (BE)

6.1.32. Insulin analogue human recombinant – **ACTRAPHANE** (CAP), **ACTRAPID** (CAP), **INSULATARD** (CAP), **MIXTARD** (CAP), **PROTAPHANE** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

6.1.33. Ivacaftor – **KALYDECO** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Miguel-Angel Macia (ES)

See also 5.2.14.

6.1.34. Lenalidomide – **REVLIMID** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.1.35. Linagliptin, metformin – **JENTADUETO** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Menno van der Elst (NL)

See also 5.2.15.

6.1.36. Nilotinib – **TASIGNA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

See also 5.2.16.

6.1.37. Nitisinone – **ORFADIN** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.38. **Nomegestrol**, **estradiol – IOA** (CAP), **ZOELY** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

6.1.39. **Octocog alfa – ADVATE** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.40. **Paclitaxel – ABRAXANE** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

6.1.41. **Pegfilgrastim – NEULASTA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.42. **Perampanel – FYCOMPA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.43. **Perflutren – OPTISON** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.44. Pioglitazone – ACTOS (CAP), **GLUSTIN** (CAP)
Pioglitazone, **glimepiride – TANDEMACT** (CAP)
Pioglitazone, **metformin – COMPETACT** (CAP), **GLUBRAVA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

6.1.45. Pneumococcal polysaccharide conjugate vaccine (**13-valent**, **adsorbed**) **– PREVENAR 13** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.46. Prasugrel – EFIENT (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

See also 5.2.17.

6.1.47. Pregabalin – LYRICA (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.18.

6.1.48. Pyronaridine, **artesunate – PYRAMAX** (Art 58)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.19.

6.1.49. Ranolazine – **RANEXA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

See also 5.2.20.

6.1.50. Rasagiline – **AZILECT** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Maria Alexandra Pêgo (PT)

6.1.51. Rivastigmine – **EXELON** (CAP), **PROMETAX** (CAP), **RIVASTIGMINE 1A PHARMA** (CAP), **RIVASTIGMINE HEXAL** (CAP), **RIVASTIGMINE SANDOZ** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

6.1.52. Rotigotine – **LEGANTO** (CAP), **NEUPRO** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Maria Alexandra Pêgo (PT)

See also 5.2.21.

6.1.53. Rufinamide – **INOVELON** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

6.1.54. Ruxolitinib – **JAKAVI** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

See also 5.2.22.

6.1.55. Samarium (^{153}Sm) lexidronam pentasodium – **QUADRAMET** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.56. Silodosin – **SILODYX** (CAP), **UROREC** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.23.

6.1.57. Sugammadex – **BRIDION** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

6.1.58. Ulipristal – **ESMYA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.59. Vardenafil – **LEVITRA** (CAP), **VIVANZA** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Miguel-Angel Macia (ES)

6.1.60. Velaglucerase alfa – **VPRIV** (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

6.1.61. Vemurafenib – ZELBORAF (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.62. Yttrium (^{90}Y) chloride – YTTRIGA (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion and agreement of recommendation to CHMP*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

6.2. Follow-up to PSUR procedures[3]

6.2.1. Adefovir dipivoxil – HEPSERA (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.2.2. Dabigatran – PRADAXA (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

6.2.3. Interferon beta-1a – AVONEX (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Dolores Montero Corominas (ES)

6.2.4. Irbesartan – APROVEL (CAP), IRBESARTAN ZENTIVA (CAP), KARVEA (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Dolores Montero Corominas (ES)

[3] Follow up as per the conclusions of the previous PSUR procedure, assessed outside next PSUR procedure.

6.2.5. Levetiracetam – KEPPRA (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Jean-Michel Dogné (BE)

6.2.6. Lopinavir, ritonavir – ALUVIA (Art 58), KALETRA (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.2.7. Maraviroc – CELSENTRI (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

6.2.8. Micafungin – MYCAMINE (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

6.2.9. Ribavirin – REBETOL (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.2.10. Thalidomide – THALIDOMIDE CELGENE (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.2.11. Trastuzumab – HERCEPTIN (CAP)

- Evaluation of a follow-up to a PSUR procedure

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

7. Post-authorisation Safety Studies (PASS)

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

7.1.1. Glycopyrronium bromide – **ENUREV BREEZHALER** (CAP), **SEEBRI BREEZHALER** (CAP), **TOVANOR BREEZHALER** (CAP)

- Evaluation of an imposed PASS protocol

Status: *for discussion and agreement of PRAC letter of endorsement/objection/notification*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

7.1.2. Lenalidomide – **REVLIMID** (CAP)

- Evaluation of an imposed PASS protocol

Status: *for discussion and agreement of PRAC letter of endorsement/objection/notification*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

7.1.3. Rivaroxaban – **XARELTO** (CAP)

- Evaluation of an imposed PASS protocol

Status: *for discussion and agreement of PRAC letter of endorsement/objection/notification*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

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

7.2.1. Aflibercept – **ZALTRAP** (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

7.2.2. Aripiprazole – **ABILIFY** (CAP)

- Evaluation of a PASS protocol

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

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

7.2.3. Bivalirudin – ANGIOX (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

7.2.4. Bromelain enriched proteolytic enzyme preparation from ananas comosus – NEXOBRID (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

7.2.5. Deferasirox – EXJADE (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

7.2.6. Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil – STRIBILD (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

7.2.7. Enzalutamide – XTANDI (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Dolores Montero Corominas (ES)

7.2.8. Etanercept – ENBREL (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

7.2.9. Glycopyrronium bromide – **ENUREV BREEZHALER** (CAP), **SEEBRI BREEZHALER** (CAP), **TOVANOR BREEZHALER** (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

7.2.10. Human normal immunoglobulin – **HYQVIA** (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

7.2.11. Orlistat – **ALLI** (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

7.2.12. Tocilizumab – **ROACTEMRA** (CAP)

- Evaluation of a PASS protocol

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

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

None

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

None

[6] In accordance with Article 107p-q of Directive 2001/83/EC
[7] In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

7.5. Interim results of imposed and non-imposed PASS and results of non-imposed PASS[8]

7.5.1. Caffeine – PEYONA (CAP)

- Evaluation of interim PASS results

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Harald Herkner (AT)

7.5.2. Etanercept – ENBREL (CAP)

- Evaluation of PASS study results

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

7.5.3. Fentanyl – INSTANYL (CAP)

- Evaluation of PASS results

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

7.5.4. Mannitol – BRONCHITOL (CAP)

- Evaluation of interim PASS results

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

7.5.5. Paliperidone – INVEGA (CAP)

- Evaluation of interim PASS results

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

7.5.6. Romiplostim – NPLATE (CAP)

- Evaluation of interim PASS results

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Dolores Montero Corominas (ES)

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

7.5.7. **Ulipristal – ESMYA** (CAP)

- Evaluation of interim PASS results

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE)

8. Renewals of the Marketing Authorisation, Conditional Renewals and Annual Reassessments

8.1.1. **Aliskiren**, **hydrochlorothiazide – RASILEZ HCT** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

Status*: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

8.1.2. **Amifampridine – FIRDAPSE** (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

Status*: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

8.1.3. **Degarelix – FIRMAGON** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

Status*: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

8.1.4. **Filgrastim – FILGRASTIM HEXAL** (CAP), **ZARZIO** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

Status*: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

8.1.5. **Human fibrogen**, **human thrombin – EVICEL** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

Status*: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

8.1.6. Ibandronic acid – BONVIVA (CAP)

- PRAC consultation on a renewal of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

8.1.7. Laronidase – ALDURAZYME (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

8.1.8. Mifamurtide – MEPACT (CAP)

- PRAC consultation on a renewal of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

8.1.9. Moroctocog alfa – REFACTO AF (CAP)

- PRAC consultation on a renewal of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

8.1.10. Nelarabine – ATRIANCE (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

8.1.11. Pneumococcal polysaccharide conjugate vaccine – SYNFLORIX (CAP)

- PRAC consultation on a renewal of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

8.1.12. Prasugrel – EFIENT (CAP)

- PRAC consultation on a renewal of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

8.1.13. Sapropterin – KUVAN (CAP)

- PRAC consultation on a renewal of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

8.1.14. Ziconotide – PRIALT (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

***Status**: for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Jean-Michel Dogné (BE)

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

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

10.1. Safety related variations of the marketing authorisation (MA)

10.1.1. Cetuximab – ERBITUX (CAP)

- PRAC consultation on a safety-related variation, upon CHMP request

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

10.2. Timing and message content in relation to MS safety announcements

None

10.3. Other requests

10.3.1. Gadolinium-containing products (NAP, CAP)

- PRAC consultation on a post-authorisation measure, upon CHMP request

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur (lead): Julie Williams (UK)

10.3.2. **Interferon beta-1a – AVONEX** (CAP)

- PRAC consultation on a post-authorisation measure, upon CHMP request

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Dolores Montero Corominas (ES)

10.3.3. **Interferon beta-1a – REBIF** (CAP)

- PRAC consultation on a post-authorisation measure, upon CHMP request

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)

10.3.4. **Interferon beta-1b – BETAFERON** (CAP), **EXTAVIA** (CAP)

- PRAC consultation on a post-authorisation measure, upon CHMP request

Status: *for discussion and agreement of advice to CHMP*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. **Nebivolol** (NAP)

- PRAC consultation on a PSUR worksharing procedure, on Member State's request

Status: *for discussion and agreement of advice to Member States*

Regulatory details:
Lead member: Menno van der Elst (NL)

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

None

12.2. Pharmacovigilance audits and inspections

12.2.1. Pharmacovigilance Systems and their Quality Systems

None

12.2.2. Pharmacovigilance Inspections

None

12.2.3. Pharmacovigilance Audits

None

12.3. Periodic Safety Update Reports & Union Reference Date (EURD) List

12.3.1. Periodic Safety Update Reports

None

12.3.2. PSUR Repository

None

12.3.3. Union Reference Date List

12.3.3.1. Consultation on the draft List, version September 2013

Status: *for discussion and agreement of the list*

12.4. Signal Management

12.4.1. Signal Management

- Feedback from Signal Management Review Technical (SMART) Working Group

Status: *for information*

12.5. Adverse Drug Reactions reporting and additional reporting

12.5.1. Management and Reporting of Adverse Reactions to Medicinal Products

None

12.5.2. Additional Monitoring

12.5.2.1. Additional monitoring and black symbol: next steps on communication

Status: *for information*

12.5.2.2. Consultation on the draft List, version September 2013

Status: *for discussion and agreement of the list*

12.5.3. List of Product under Additional Monitoring

None

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

None

12.6.2. Changes to EudraVigilance Database and functional specifications

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

12.7.2. Champions in the review of the assessment process of RMPs

- Progress report on the activity

Status: *for discussion*

12.7.3. Tools, Educational Materials and Effectiveness Measurement for Risk Minimisation

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

None

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Risk communication and Transparency

12.10.1. Public Participation in Pharmacovigilance

None

12.10.2. Safety Communication

None

12.11. Continuous pharmacovigilance

12.11.1. Continuous Pharmacovigilance, Ongoing Benefit-Risk Evaluation, Regulatory Status and Planning of Public Communication

12.11.1.1. Benefit risk tables as part of the evaluation of marketing authorisation applications for new substances, pilot phase

Status: *for information*

12.11.2. Incident Management

None

12.12. Interaction with EMA Committees and Working Parties

12.12.1. Committees

None

12.12.2. Working Parties

None

12.13. Interaction within the EU regulatory network

None

12.14. Contacts of the PRAC with external parties and interaction of the EMA with interested parties

12.14.1. EMA Pharmacovigilance Clusters with Drug Regulatory Authorities

- Announcement of a new pharmacovigilance cluster

Status: *for discussion*

12.14.2. European Network Centres for Pharmacoepidemiology and Pharmacovigilance (**ENCePP**)

- Proposal for an EMA funded study on antidepressant exposure in utero and subsequent childhood autism spectrum disorders

Status: *for discussion*

12.14.3. Guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

None

12.14.4. Others

None

13. Any other business

None