EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 October 2013
EMA/PRAC/610367/2013 Corr.*
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 7-10 October 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.

Assessment of Periodic Safety Update Reports (PSURs)
(Item 6 of the PRAC agenda)

*** Combined Hormonal Contraceptives status correction on page 11**

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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

7 October 2013, 13:00 – 19:00, room 3/A

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

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

10 October 2013, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

24 October 2013, 09:00-11:00, 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 7-10 October 2013

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 7 October 2013

1.3. Minutes of the previous PRAC meeting on 2-5 September 2013

Status: for adoption

Document: PRAC Final Minutes due for publication by 14 October 2013

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

None

2.3. Procedures for finalisation

2.3.1. **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 and adoption of recommendation to CMDh*

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

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

3.2.1. **Octocog alfa – HELIXATE NEXGEN** (CAP), **KOGENATE BAYER** (CAP)

- Review of the benefit-risk balance following a 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: Brigitte Keller-Stanislawski (DE)
PRAC Co-Rapporteur: Ulla Wändel Liminga (SE)

3.2.2. **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. **Acipimox** (NAP)

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

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Julia Pallos (HU)
PRAC Co-Rapporteur: Line Michan (DK)

3.3.2. **Combined hormonal contraceptives**:

desogestrel, **gestodene, norgestimate**, **etonogestrel, drospirenone**, **dienogest**, **chlormadinone**, **norgestimate** (NAP), **nomegestrol acetate / estradiol – IOA** (CAP), **ZOELY** (CAP), **norelgestromin / ethinylestradiol** - **EVRA** (CAP)

- 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 recommendation to CHMP*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)
PRAC Co-Rapporteur: Evelyne Falip (FR)

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 recommendation to CMDh*

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

3.5.1. **GLP-1 based therapy products** (**glucagon-like-peptide-1** (**GLP-1**) **agonists and dipeptidylpeptidase-4** (**DPP-4**) **inhibitors**) (CAP)

- Follow-up to actions recommended in the completed review on pancreatic risks under Article 5(3) of Regulation (EC) No 726/2004

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)
PRAC Co-Rapporteur: Menno van der Elst (NL)

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. **Aflibercept - EYLEA** (CAP)

- Signal of blindness

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)

4.1.2. **Amiodarone** (NAP)

- Signal of carcinogenicity

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

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

4.1.3. **Cabazitaxel - JEVTANA** (CAP)

- Signal of medication error, potentially leading to inappropriate dose

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

4.1.4. **Cefuroxime** for intracameral use (NAP)

- Signal of eye inflammation and macular oedema

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.1.5. **Doxycycline** (NAP)

- Signal of photo-onycholysis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.1.6. **Exenatide – BYETTA** (CAP), **BYDUREON** (CAP); **liraglutide** - **VICTOZA** (CAP)

- Signal of cholecystitis and cholelithiasis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE), Menno van der Elst (NL)

4.1.7. **Gabapentin** (NAP)

- Signal of hypoglycaemia

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.1.8. **Human papillomavirus vaccine [type 6, 11, 16, 18] (recombinant, absorbed) – GARDASIL** (CAP), **SILGARD** (CAP)

- Signal of postural orthostatic tachycardia syndrome (POTS)

Status: *for discussion*

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

4.1.9. **Human papillomavirus vaccine [type 6, 11, 16, 18] (recombinant, absorbed) – GARDASIL** (CAP), **SILGARD** (CAP)

Human papillomavirus vaccine [type 16, 18] (recombinant, adjuvanted, adsorbed] – CERVARIX (CAP)

- Signal of primary, premature ovarian failure

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Jean-Michel Dogné (BE), Qun-Ying Yue (SE)

4.1.10. Quetiapine (NAP)

- Signal of suicidality in major depressive disorder (MDD) patients

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.2. New signals detected from other sources

4.2.1. Mefloquine (NAP)

- Signal of possibly permanent neurologic (vestibular) side effects

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.3. Signals follow-up and prioritisation

4.3.1. Adalimumab – HUMIRA (CAP); etanercept – ENBREL (CAP); infliximab – REMICADE (CAP)

- Signal of glioblastoma and other brain neoplasms

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Ulla Wändel Liminga (SE) (Humira, Remicade), Julia Dunne (UK) (Enbrel)

4.3.2. Agomelatine – THYMANAX (CAP), VALDOXAN (CAP)

- Signal of QT prolongation

Status*: for discussion*

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

4.3.3. Azithromycin (NAP)

- Signal of potentially fatal heart events

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Terhi Lehtinen (FI)

4.3.4. Clarithromycin (NAP)

- Signal of cardiovascular events

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

4.3.5. Efavirenz - STOCRIN (CAP), **SUSTIVA** (CAP)
Emtricitabine, **efavirenz**, **tenofovir** – **ATRIPLA** (CAP)

- Signal of interaction with Ginkgo biloba

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

4.3.6. Fondaparinux – ARIXTRA (CAP)

- Signal of heparin-induced thrombocytopenia

***Status:** for discussion*

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

4.3.7. Boceprevir – VICTRELIS (CAP); **indinavir – CRIXIVAN** (CAP)
Quetiapine (NAP)

- Signal of drug interaction between protease inhibitors and quetiapine

***Status:** for discussion*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

4.3.8. Orlistat – ALLI (CAP), **XENICAL** (CAP)
Atazanavir - REYATAZ (CAP); **darunavir - PREZISTA** (CAP); **efavirenz – STOCRIN** (CAP), **SUSTIVA** (CAP); **emtricitabine, efavirenz, tenofovir** – **ATRIPLA** (CAP); **emtricitabine, tenofovir - TRUVADA** (CAP); **lopinavir, ritonavir – KALETRA** (CAP)

- Signal of pharmacokinetic drug interaction (at absorption) with highly active antiretroviral therapy (HAART) leading to loss of HAART efficacy

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

4.3.9. **Pandemic H1N1 and seasonal trivalent influenza vaccines** (CAP, NAP)

- Review of latest evidence for Guillain-Barré sydrome (GBS)

Status: *for discussion*

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

4.3.10. **Tapentadol** (NAP)

- Signal of suicidal ideation

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Brimonidine

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

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

5.1.2. Cabozantinib

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

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

5.1.3. Dolutegravir

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

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

5.1.4. Florbetaben (^{18}F)

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

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

5.1.5. Insulin degludec, liraglutide

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

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

5.1.6. Insulin glargine

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

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

5.1.7. Macitentan

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

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

5.1.8. Masitinib

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

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

5.1.9. Misoprostol

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

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

5.1.10. Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches

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

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

5.1.11. Peginterferon beta–1a

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

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

5.1.12. Serelaxin

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

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

5.1.13. Simoctocog alfa

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

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

5.1.14. Tobramycin

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

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

5.1.15. Travoprost

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

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

5.1.16. Vortioxetine

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

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

5.1.17. Zoledronic acid

- 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. Aztreonam – CAYSTON (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 6.1.2.

5.2.2. Betaine – CYSTADANE (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 6.1.4.

5.2.3. Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins – CHONDROCELECT (CAP)

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

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

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

See also 6.1.8.

5.2.4. Cinacalcet – MIMPARA (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 6.1.9.

5.2.5. Dabigatran – PRADAXA (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 6.1.12.

5.2.6. Dexmedetomidine – DEXDOR (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 6.1.13.

5.2.7. Eculizumab – SOLIRIS (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: Dolores Montero Corominas (ES)

See also 6.1.14.

5.2.8. Emtricitabine – EMTRIVA (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 6.1.15.

5.2.9. Emtricitabine, tenofovir disoproxil – TRUVADA (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 6.1.16.

5.2.10. Everolimus – AFINITOR (CAP), **VOTUBIA** (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.

5.2.11. Fingolimod – GILENYA (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: Evelyne Falip (FR)

See also 6.1.22.

5.2.12. Glycopyrronium bromide – ENUREV BREEZHALER (CAP), **SEEBRI BREEZHALER** (CAP), **TOVANOR BREEZHALER** (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: Line Michan (DK)

See also 6.1.25.

5.2.13. Influenza vaccine (H1N1) (surface antigen, inactivated, adjuvanted) – FOCETRIA (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: Carmela Macchiarulo (IT)

See also 6.1.26.

5.2.14. Meningococcal group a, c, w135 and y conjugate vaccine – MENVEO (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 6.1.30.

5.2.15. Methylnaltrexone – RELISTOR (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 6.1.32.

5.2.16. Mifamurtide – MEPACT (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 6.1.33.

5.2.17. Pirfenidone – ESBRIET (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 6.1.38.

5.2.18. Retigabine – TROBALT (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: Line Michan (DK)

See also 6.1.40.

5.2.19. Tacrolimus – PROTOPIC (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: Almath Spooner (IE)

See also 6.1.42.

5.2.20. Telaprevir – INCIVO (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 6.1.45.

5.2.21. Tenofovir disoproxil fumarate – VIREAD (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 6.1.46.

5.2.22. Vandetanib – CAPRELSA (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 6.1.50.

RMP in the context of a variation

5.2.23. A/H5N1 prepandemic influenza vaccine (whole virion, vero-cell derived, inactivated) – VEPACEL (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: Jean-Michel Dogné (BE)

5.2.24. 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)

5.2.25. Denosumab – XGEVA (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)

5.2.26. Dexamethasone – OZURDEX (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: Julie Williams (UK)

5.2.27. Ferumoxytol – RIENSO (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: Martin Huber (DE)

5.2.28. Golimumab – SIMPONI (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: Ulla Wändel Liminga (SE)

5.2.29. Idursulfase – ELAPRASE (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)

5.2.30. Linagliptin, metformin – JENTADUETO (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: Menno van der Elst (NL)

5.2.31. Nilotinib – TASIGNA (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)

5.2.32. Omalizumab – XOLAIR (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. Omalizumab – XOLAIR (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: Qun-Ying Yue (SE)

5.2.34. Pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated) – PANDEMIC INFLUENZA VACCINE H5N1 BAXTER (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)

5.2.35. Peginterferon alfa-2a – PEGASYS (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)

5.2.36. Ranibizumab – LUCENTIS (CAP)

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

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

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

5.2.37. Sorafenib – NEXAVAR (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)

5.2.38. Tacrolimus – ADVAGRAF (CAP), MODIGRAF (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: Almath Spooner (IE)

5.2.39. Tocilizumab – ROACTEMRA (CAP MAA)

- 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: Brigitte Keller-Stanislawski (DE)

5.2.40. Ulipristal – ESMYA (CAP MAA)

- 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)

5.2.41. Voriconazole – VFEND (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)

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

See Bazedoxifene (CONBRIZA) under 8.1.1. ; Eslicarbazepine (ZEBINIX) under 8.1.4. , Japanese encephalitis vaccine (inactivated, adsorbed) (IXIARO) under 8.1.6. , Tacrolimus (MODIGRAF) under 8.1.8.

RMP in the context of a stand-alone RMP procedure

5.2.42. Adefovir dipivoxil – HEPSERA (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: Isabelle Robine (FR)

5.2.43. Epoetin theta – **BIOPOIN** (CAP), **EPORATIO** (CAP)

- Evaluation of an RMP in the context of stand-alone RMP procedures

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

5.2.44. Human papilloma virus [types 16, 18] (**recombinant**, **adjuvanted**, **adsorbed**) – **CERVARIX** (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: Jean-Michel Dogné (BE)

5.2.45. Imiglucerase – **CEREZYME** (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. Pegfilgrastim – **NEULASTA** (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: Julie Williams (UK)

5.2.47. Telbivudine – **SEBIVO** (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: Isabelle Robine (FR)

5.2.48. Temsirolimus – **TORISEL** (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: Martin Huber (DE)

5.2.49. Velaglucerase alfa – VPRIV (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: Martin Huber (DE)

6. Assessment of Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[2]

6.1.1. Aprepitant – EMEND (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.2. Aztreonam – CAYSTON (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.1.

6.1.3. Belimumab – BENLYSTA (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. Betaine – CYSTADANE (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: Martin Huber (DE)

See also 5.2.2.

6.1.5. Bevacizumab – AVASTIN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

6.1.6. Bimatoprost – LUMIGAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

6.1.7. Certolizumab pegol – CIMZIA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.8. Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins – CHONDROCELECT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

See also 5.2.3.

6.1.9. Cinacalcet – MIMPARA (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 5.2.4.

6.1.10. Colestilan – BINDREN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.11. Copper (^{64}Cu) chloride – CUPRYMINA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.12. Dabigatran – PRADAXA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

See also 5.2.5.

6.1.13. Dexmedetomidine – DEXDOR (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.

6.1.14. Eculizumab – SOLIRIS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

See also 5.2.7.

6.1.15. Emtricitabine – EMTRIVA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

See also 5.2.8.

6.1.16. Emtricitabine, tenofovir disoproxil – TRUVADA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

See also 5.2.9.

6.1.17. Enfuvirtide – FUZEON (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.18. Etravirine – INTELENCE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.19. Everolimus – AFINITOR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 5.2.10.

6.1.20. Everolimus – VOTUBIA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 5.2.10.

6.1.21. Exenatide – **BYDUREON** (CAP), **BYETTA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.22. Fingolimod – **GILENYA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)

See also 5.2.11.

6.1.23. Florbetapir (^{18}F) – **AMYVID** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.24. Fosaprepitant – **IVEMEND** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

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

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

See also 5.2.12.

6.1.26. Influenza vaccine (H1N1) (surface antigen, inactivated, adjuvanted) – FOCETRIA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

See also 5.2.13.

6.1.27. Insulin degludec – TRESIBA (CAP)
Insulin degludec, insulin aspart – RYZODEG (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.28. Ipilimumab – YERVOY (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.29. Lapatinib – TYVERB (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.30. Meningococcal group a, c, w135 and y conjugate vaccine – MENVEO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.14.

6.1.31. Mercaptopurine – XALUPRINE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.32. Methylnaltrexone – RELISTOR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 5.2.15.

6.1.33. Mifamurtide – MEPACT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.16.

6.1.34. Olanzapine – ZALASTA (CAP), ZYPREXA (CAP), ZYPREXA VELOTAB (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Terhi Lehtinen (FI)

6.1.35. Olanzapine pamoate – ZYPADHERA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Terhi Lehtinen (FI)

6.1.36. Pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated) – PANDEMIC INFLUENZA VACCINE H5N1 BAXTER (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.37. Panitumumab – VECTIBIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.38. Pirfenidone – ESBRIET (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

See also 5.2.17.

6.1.39. Raltegravir – ISENTRESS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.40. Retigabine – TROBALT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

See also 5.2.18.

6.1.41. Rivaroxaban – XARELTO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.42. Tacrolimus – PROTOPIC (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

See also 5.2.19.

6.1.43. Teduglutide – REVESTIVE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

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

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.45. Telaprevir – INCIVO (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.

6.1.46. Tenofovir disoproxil fumarate – VIREAD (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.21.

6.1.47. Trastuzumab – HERCEPTIN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.48. Travoprost – TRAVATAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

6.1.49. Travoprost, timolol – DUOTRAV (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

6.1.50. Vandetanib – CAPRELSA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.22.

6.1.51. Voriconazole – VFEND (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.52. Zonisamide – ZONEGRAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

6.2. Follow-up to PSUR procedures[3]

6.2.1. Saquinavir – INVIRASE (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Harald Herkner (AT)

6.2.2. Sodium oxybate – XYREM (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

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

7. Post-authorisation Safety Studies (PASS)

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

7.1.1. Deferasirox – EXJADE (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)

7.1.2. 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)

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

7.2.1. Aliskiren – RASILEZ (CAP)

- Evaluation of a PASS protocol

[3] Follow up as per the conclusions of the previous PSUR procedure, assessed outside next PSUR procedure
[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: Carmela Macchiarulo (IT)

7.2.2. Catridecog – NOVOTHIRTEEN (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

7.2.3. Dapagliflozin – FORXIGA (CAP)

- Evaluation of a PASS protocol

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

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

7.2.4. 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)

7.2.5. Insulin degludec – TRESIBA (CAP)

- Evaluation of a PASS protocol

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

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

7.2.6. Linaclotide – CONSTELLA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

7.2.7. Mirabegron – BETMIGA (CAP)

- Evaluation of a PASS protocol

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

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

7.2.8. Pegloticase – KRYSTEXXA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

7.2.9. Rivastigmine – EXELON (CAP), PROMETAX (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

7.2.10. Tenofovir disoproxil – VIREAD (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

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

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

7.5.1. Certolizumab pegol – CIMZIA (CAP)

- Evaluation of a interim PASS results

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

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

7.5.2. Golimumab – SIMPONI (CAP)

- Evaluation of interim PASS results

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

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

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

7.5.3. Golimumab – SIMPONI (CAP)

- Evaluation of interim PASS results

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

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

7.5.4. Vidagliptin – GALVUS (CAP), JALRA (CAP), XILIARX (CAP) Vidagliptin, metformin – EUCREAS (CAP), ICANDRA (CAP), ZOMARIST (CAP)

- Evaluation of interim PASS results

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

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

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

8.1.1. Bazedoxifene – CONBRIZA (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

8.1.2. Bortezomib – VELCADE (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)

8.1.3. Catumaxomab – REMOVAB (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

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

8.1.4. Eslicarbazepine – ZEBINIX (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

8.1.5. Galsulfase – NAGLAZYME (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)

8.1.6. Japanese encephalitis vaccine (inactivated, adsorbed) – IXIARO (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)

8.1.7. Ribavirin – RIBAVIRIN TEVA (CAP), RIBAVIRIN TEVA PHARMA (CAP)

- PRAC consultation on renewals of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

8.1.8. Tacrolimus – MODIGRAF (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

8.1.9. Vandetanib – CAPRELSA (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going 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.

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. **Fingolimod – GILENYA** (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

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

None

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

None

10.4. Other requests

None

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

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. Organisation of the PRAC meetings

- PRAC meeting dates 2016 - 2018

Status: *for information*

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. PSURs Repository

None

12.3.3. Union Reference Date List

12.3.3.1. Consultation on the draft List, version October 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. Consultation on the draft List, version October 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

None

12.7.2. 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

None

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

None

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

- Nomination of Committee representatives for the ENCePP Steering Group

Status: *for discussion*

13. Any other business

13.1.1. EMA new organisation structure

Status*: for information*