7 January 2013
EMA/PRAC/731552/2012
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda of meeting 7-10 January 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)

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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.europa.eu

Chair: June Raine – Vice-Chair: Almath Spooner

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

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

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

10 January 2013, 08:30 – 13:30, room 3/A

1. Introduction

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

1.2. Adoption of agenda of the meeting 7-10 January 2013

Status: for adoption

Document: PRAC Agenda due for publication on 7 January 2013

1.3. Minutes of the previous PRAC meeting on 26-29 November 2012

Status: for adoption

Document: PRAC final Minutes to be published on 11 January 2013

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

2.1. Newly triggered procedures

2.1.1. **Tetrazepam** (NAPs)

- Review of the benefit-risk balance of tetrazepam-containing medicines due to serious cutaneous risks including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema

multiform, DRESS[1]: syndrome: notification by France of a referral under Article 107i of Directive 2001/83/EC

Status: *for initial discussion and Rapporteur appointment*

Regulatory details:

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

2.2. Ongoing Procedures

2.2.1. Laropiprant / nicotinic acid – **PELZONT** (CAP), **TREDAPTIVE** (CAP), **TREVACLYN** (CAPs)

- Review of the benefit-risk balance due to statistically significant increase in the incidence of non-fatal serious adverse events in the laropiprant/nicotinic acid group compared to the statin group following the preliminary results from the study HPS2-THRIVE[2]: ongoing referral under Article 20(8) of Regulation (EC) No 726/2004 following procedural steps of Article 107i of Directive 2001/83/EC

Status: *for adoption of temporary measures and/or PRAC recommendation to the CHMP*

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)
PRAC Co-Rapporteur: Menno van der Elst (NL)

2.3. Procedures for finalisation

None

2.4. Planned public hearings

None

3. EU Referral Procedures for Safety Reasons: Other EU Referral Procedures

3.1. Newly triggered Procedures

None

3.2. Ongoing Procedures

None

3.3. Procedures for finalisation

None

[1] Drug Reaction with Eosinophilia and other Systematic Symptoms
[2] Heart Protection Study 2-Treatment of HDL to Reduce the Incidence of Vascular Events

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

None

4. Signals assessment and prioritisation

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. **Exenatide – BYETTA** (CAP), **BYDUREON** (CAP); **Liraglutide – VICTOZA** (CAP)

- Signal of gastrointestinal stenosis and obstruction

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteurs: Qun-Ying Yue (SE); Menno van der Elst (NL)

4.1.2. **Tiotropium bromide** (NAP)

- Signal of anaphylactic reaction

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.1.3. **Thalidomide - THALIDOMIDE CELGENE** (CAP)

- Signal of posterior reversible encephalopathy syndrome

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

4.2. New signals detected from other sources

None

4.3. Signals follow-up and prioritisation

4.3.1. **Clopidogrel – PLAVIX** (CAP) & **generic products**

- Signal of eosinophilic pneumonia

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Maria Alexandra Pego (PT)

4.3.2. Duloxetine – **ARICLAIM** (CAP), **CYMBALTA** (CAP), **XERISTAR** (CAP), **YENTREVE** (CAP)

- Signal of increased serotonin syndrome due to a potential interaction with aripiprazole

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

4.3.3. Hormonal contraceptives: norelgestromin / ethinylestradiol - EVRA (CAP); **etonogestrel**; **etonogestrel and ethinylestradiol**; **drospirenone and ethinylestradiol** (NAPs)

- Signal of arterial thrombotic events

Status: *for follow-up discussion*

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

4.3.1. Etanercept – ENBREL (CAP)

- Signal of dermatomyositis

Status: *for follow-up discussion*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Afatinib (**dimaleate**)

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.2. Atosiban

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.3. Avanafil

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.4. Bedaquiline

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.5. Fenofibrate / simvastin

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.6. Infliximab

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.7. Infliximab

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.8. Lorcaserin Hydrochloride

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.9. Masitinib mesylate

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.10. Memantine hydrochloride

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.11. Ponatinib

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.12. Regorafenib

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.13. Somatropin

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.14. Telmisartan

- Evaluation of a RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.15. Trastuzumab emtansine

- Evaluation of the RMP in the context of an initial Marketing Authorisation Application procedure

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

5.1.16. Votrioxetine

- Evaluation of the 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. 5-aminolevulinic acid hydrochloride – AMELUZ (CAP)

- Evaluation of a 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 6.1.1.

5.2.2. Ambrisentan – VOLIBRIS (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

See also 6.1.2.

5.2.3. Amifampridine – FIRDAPSE (CAP)

- Evaluation of a 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 6.1.3.

5.2.4. Belatacept – NULOJIX (CAP)

- Evaluation of a 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 6.1.4.

5.2.5. Besilesomab – SCINTIMUN (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

See also: 6.1.5.

5.2.6. Cabazitaxel – JEVTANA (CAP)

- Evaluation of a 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 6.1.8.

5.2.7. Caffeine – PEYONA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Harald Herkner (AT)

See also 6.1.9.

5.2.8. Dasatinib – SPRYCEL (CAP)

- Evaluation of a 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 6.1.11.

5.2.9. Efavirenz / emtricitabine / tenofovir disoproxil – ATRIPLA (CAP)

- Evaluation of a 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 6.1.12.

5.2.10. Fidaxomicin – DIFICLIR (CAP)

- Evaluation of a 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 6.1.13.

5.2.11. Galsulfase – NAGLAZYME (CAP)

- Evaluation of a 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 6.1.14.

5.2.12. Imiglucerase – CEREZYME (CAP)

- Evaluation of a 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 6.1.21.

5.2.13. Liraglutide – VICTOZA (CAP)

- Evaluation of a 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 6.1.22.

5.2.14. Pneumococcal polysaccharide conjugate vaccine – PREVENAR 13 (CAP)

- Evaluation of a 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 6.1.27.

5.2.15. Saxagliptin / metformin hydrochloride – KOMBOGLYZE (CAP)

- Evaluation of a 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 6.1.30. and 5.2.24.

5.2.16. Stavudine – ZERIT (CAP)

- Evaluation of a 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 6.1.32.

5.2.17. Tobramycin – TOBI PODHALER (CAP)

- Evaluation of a 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 6.1.34.

5.2.18. Topotecan – HYCAMTIN (CAP)

- Evaluation of a 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 6.1.35.

RMP in the context of a variation

5.2.19. Bimatoprost / timolol – GANFORT (CAP)

- Evaluation of a RMP in the context of a 60 day-Type II variation

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

5.2.20. Bortezomib – VELCADE (CAP)

- Evaluation of a RMP in the context of a 90 day-Type II variation, extension of indication

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

5.2.21. Natalizumab – TYSABRI (CAP)

- Evaluation of a RMP in the context of a 60-day Type II variation

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.22. Octocog alfa – ADVATE (CAP)

- Evaluation of a RMP in the context of a 60-day Type II variation

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.23. Raltegravir – ISENTRESS (CAP)

- Evaluation of the updated RMP in the context of a 60-day Type II variation

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

5.2.24. Saxagliptin – ONGLYZA (CAP); Saxagliptin / metformin - KOMBOGLYZE (CAP)

- Evaluation of the updated RMP in the context of a Type II variation, extension of indication

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

PRAC Rapporteur: Menno van der Elst (NL)

5.2.25. Tygecycline – TYGACIL (CAP)

- Evaluation of a RMP in the context of a 60-day Type II variation

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

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)

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

5.2.26. Doripenem – DORIBAX (CAP)

- Evaluation of a RMP in the context of a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

See also 9.2.1.

5.2.27. Ranolazine – RANEXA (CAP)

- Evaluation of a RMP in the context of a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

RMP in the context of a stand-alone RMP procedure

5.2.28. Granisetron – SANCUSO (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Jolanta Gulbinovic (LT)

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

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

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.30. Prasugrel – EFIENT (CAP)

- Evaluation of a 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)

5.2.31. Pyronaridine / artesunate – PYRAMAX (CAP)

- Evaluation of a 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)

5.2.32. Topotecan – TOPOTECAN EAGLE (CAP)

- Evaluation of a 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)

5.2.33. Ulipristal – ESMYA (CAP)

- Evaluation of a 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)

6. Assessment of Periodic Safety Update Reports (PSURs)

6.1.1. 5-aminolevulinic acid hydrochloride – AMELUZ (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.2. Ambrisentan – VOLIBRIS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

6.1.3. Amifampridine – FIRDAPSE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.4. Belatacept – NULOJIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

6.1.5. Besilesomab – SCINTIMUN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.6. Bromfenac – YELLOX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

6.1.7. C1 inhibitor (**human**) **– CINRYZE** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.8. Cabazitaxel – JEVTANA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.9. Caffeine – PEYONA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Harald Herkner (AT)

6.1.10. Canakinumab – ILARIS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.11. Dasatinib – SPRYCEL (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

6.1.12. Efavirenz / emtricitabine / tenofovir disoproxil – ATRIPLA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.13. Fidaxomicin – DIFICLIR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.14. Galsulfase – NAGLAZYME (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.15. Gefitinib – IRESSA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

6.1.16. Human normal immunoglobulin – FLEBOGAMMA DIF (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.17. Human papillomavirus vaccine – GARDASIL (CAP), **SILGARD** (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. Hydroxycarbamide – SIKLOS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogne (BE)

6.1.19. Ibandronic acid – BONDENZA (CAP), **BONDRONAT** (CAP), **BONVIVA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (UK)

6.1.20. Influenza vaccine – FLUENZ (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. Imiglucerase – CEREZYME (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.22. Liraglutide – VICTOZA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.23. Nepafenac – NEVANAC (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

6.1.24. Nitric oxide – INOMAX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.25. Paliperidone – INVEGA (CAP), **XEPLION** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.26. Pegaptanib – MACUGEN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogne (BE)

6.1.27. Pneumococcal polysaccharide conjugate vaccine – 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)

6.1.28. Ranibizumab – LUCENTIS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

6.1.29. Roflumilast – DALIRESP (CAP), **DAXAS** (CAP), **LIBERTEK** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)

6.1.30. Saxagliptin / metformin hydrochloride – KOMBOGLYZE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.31. Sildenafil – REVATIO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.32. Stavudine – ZERIT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.33. Ticagrelor – BRILIQUE (CAP), **POSSIA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.34. Tobramycin – TOBI PODHALER (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.35. Topotecan – HYCAMTIN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of post-authorisation safety studies

None

7.2. Results of post-authorisation safety studies

7.2.1. Insulin glargine – **LANTUS** (CAP), **OPTISULIN** (CAP)

- PRAC consultation on PASS study results, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

7.2.2. Pioglitazone – **ACTOS** (CAP), **GLUSTIN** (CAP); **pioglitazone / metformin - COMPETACT** (CAP), **GLUBRAVA** (CAP); **pioglitazone / glimepiride - TANDEMACT** (CAP)

- PRAC consultation on the assessment of interim (and final) data from a Drug Utilisation Study (DUS), upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

8. Product related pharmacovigilance inspections

8.1. List of planned pharmacovigilance inspections

None

8.2. On-going or concluded pharmacovigilance inspection

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

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

9.1.1. Denosumab – **PROLIA** (CAP)

- PRAC consultation on a safety-related type II variation upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

9.1.2. Zonisamide – ZONEGRAN (CAP)

- PRAC consultation on a Type II variation, extension of indication upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

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

9.2.1. Doripenem – DORIBAX (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

9.2.2. Icatibant – FIRAZYR (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

9.2.3. Lapatinib – TYVERB (CAP)

- PRAC consultation on a renewal procedure of the conditional marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

9.2.4. Mecasermin – INCRELEX (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

9.2.5. Methylnaltrexone bromide – RELISTOR (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

9.2.6. Laropiprant / nicotinic acid – PELZONT (CAP), **TREDAPTIVE** (CAP), **TREVACLYN** (CAP)

- PRAC consultation on renewal procedures of the marketing authorisations

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

9.2.7. Pixantrone dimaleate – PIXUVRI (CAP)

- PRAC consultation on a renewal procedure of the conditional marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

9.2.8. Pramipexole – OPRYMEA (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

9.2.9. Ranolazine – RANEXA (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

9.2.10. Sitagliptin / metformin hydrochloride – EFFICIB (CAP), **JANUMET** (CAP), **VELMETIA** (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

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

None

9.4. Other requests

See Insulin glargine 7.2.1. ; Pioglitazone 7.2.2.

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

10.1. Renewals of the Marketing Authorisation

None

10.2. Safety related variations of the marketing authorisation

None

10.3. Other requests

10.3.1. Mycobacterium bovis BCG (Bacillus Calmette-Guerin) **vaccine**, Danish strain 1331, live attenuated - **BCG VACCINE SSI** (NAP)

- PRAC consultation on a stand-alone RMP procedure upon Member State's request

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

Regulatory details:

PRAC Rapporteur: *to be appointed*

11. Organisational, regulatory and methodological matters

11.1. Mandate and organisation of the PRAC

11.2. Pharmacovigilance audits and inspections

11.2.1. Pharmacovigilance Systems and their Quality Systems

None

11.2.2. Pharmacovigilance Inspections

None

11.2.3. Pharmacovigilance Audits

None

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

11.3.1. Periodic Safety Update Reports

None

11.3.2. PSUR Repository

None

11.3.3. Union Reference Date List

11.3.3.1. Consultation on the draft List, version January 2013

Status: *for discussion and agreement of the list*

11.4. Signal Management

11.4.1. Signal Management

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

Status: *for information*

11.5. Adverse Drug Reactions reporting and additional reporting

11.5.1. Management and Reporting of Adverse Reactions to Medicinal Products

None

11.5.2. Additional Monitoring

None

11.5.3. List of Product under Additional Monitoring

None

11.6. Eudravigilance Database

11.6.1. Activities related to the confirmation of full functionality

None

11.6.2. Changes to Eudravigilance Database and functional specifications

None

11.7. Risk Management Plans and Effectiveness of risk Minimisations

11.7.1. Risk Management Systems

11.7.1.1. RMP Flowchart

Status: *for discussion*

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

None

11.8. Post-authorisation Safety Studies

11.8.1. Post-Authorisation Safety Studies

None

11.9. Community Procedures

11.9.1. Referral Procedures for Safety Reasons

None

11.10. Risk communication and Transparency

11.10.1. Public Participation in Pharmacovigilance

None

11.10.2. Safety Communication

- Guideline on good pharmacovigilance practices (GVP) Module XV on safety communication

Status: *for information*

11.11. Continuous pharmacovigilance

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

None

11.11.2. Incident Management

None

11.12. Interaction with EMA Committees and Working Parties

11.12.1. Committees

None

11.12.2. Working Parties

11.12.2.1. Patients and Consumers Working Party (PCWP)

- PCWP Work Plan for 2013

Status: *for discussion and adoption of the draft Work Plan*

11.13. Interaction within the EU regulatory network

None

11.14. Contacts of the PRAC with external parties and inter- status of the EMA with interested parties

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

None

11.14.2. Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) study

Status: *for discussion*

11.14.3. Other Drug Regulatory Authorities outside the EU

- International pharmacovigilance teleconferences and non-EU DRA and PRAC observerships to PRAC

Status: *for discussion*

12. Any other business