4 February 2013
EMA/PRAC/729256/2012
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda of meeting

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.ema.europa.eu/

Chair: June Raine – Vice-Chair: Almath Spooner

4 February 2013, 13:00 – 19:00, room 3/A

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

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

7 February 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 the agenda of the meeting on 4-7 February 2013

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 4 February 2013

1.3. Adoption of the minutes of the previous PRAC meeting on 7-10 January 2013

Status: for adoption

Document: PRAC Final Minutes to be published on 8 February 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

None

2.4. Planned public hearings

None

2.5. Other

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

- Follow-up of finalised referral under Article 20(8) of Regulation (EC) No 726/2004 following procedural steps of Article 107i of Directive 2001/83/EC

Status: *for discussion*

Regulatory details:

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

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

3.1. Newly triggered Procedures

3.1.1. Combined oral contraceptives:
Third generation: progestins-containing products (NAP)
Fourth generation: chlormadinone-, dienogest-, drospirenone- and nomegestrol-containing products (NAP), **nomegestrol acetate / estradiol – IOA** (CAP), **ZOELY** (CAP)

- Review of the benefit-risk balance of oral contraceptives third and fourth generations due to the risk of venous thrombotic events: notification by France of a referral under Article 31 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*

3.2. Ongoing Procedures

None

3.3. Procedures for finalisation

None

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

None

4. Signals assessment and prioritisation

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. **Basiliximab – SIMULECT** (CAP)

- Signal of cardiovascular instability resulting in fatal outcome following off-label use in heart transplantation

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

4.1.2. **Thiocolchicoside** (NAP)

- Signal of potential genotoxicity

Status: *for initial discussion and Rapporteur appointment*

Regulatory details:

PRAC Rapporteur: *to be appointed*

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

- Signal of food interaction with grapefruit juice

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

4.1.4. **Tramadol** (NAP)

- Signal of hypoglycaemia

Status: *for initial discussion and Rapporteur appointment*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.2. New signals detected from other sources

4.2.1. **Tolvaptan - SAMSCA** (CAP)

- Signal of serious liver injury associated with high dose tolvaptan in patients with polycystic kidney disease

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

4.2.2. **Zolpidem** (NAP)

- Signal of next-morning impaired mental alertness, including impaired driving ability

Status: *for initial discussion and Rapporteur appointment*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.3. Signals follow-up and prioritisation

4.3.1. **Domperidone** (NAP)

- Signal of cardiotoxicity

Status: *for discussion and Rapporteur appointment*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.3.2. **Roxithromycin** (NAP)

- Signal of hearing disorders

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

4.3.3. **Roxithromycin** (NAP)

- Signal of rhabdomyolysis secondary to interaction with statins

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

4.3.4. **Sugammadex - BRIDION** (CAP)

- Signal of respiratory symptoms unrelated to hypersensitivity reaction

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Alogliptin

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

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

5.1.2. Alogliptin, metformin

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

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

5.1.3. Alogliptin, pioglitazone

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

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

5.1.4. Autologous cultured chondrocytes

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

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

5.1.5. Autologous oral mucosal epithelial cells

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

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

5.1.6. Dimethyl fumarate

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

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

5.1.7. Imatinib

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

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

5.1.8. Indacaterol maleate, glycopyrronium

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

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

5.1.9. Influenza Vaccine (tetravalent live attenuated, nasal)

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

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

5.1.10. Lomitapide

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

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

5.1.11. Lurasidone

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

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

5.1.12. Perflubutane

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

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

5.1.13. Tobramycin

- Evaluation of a 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. Axitinib – **INLYTA** (CAP)

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

See also 6.1.4.

5.2.2. Dronedarone – **MULTAQ** (CAP)

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

See also 6.1.9.

5.2.3. Epoetin Theta – **BIOPOIN** (CAP), **EPORATIO** (CAP)

- Evaluation of RMP in the context of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

See also 6.1.10.

5.2.4. **Fampridine – FAMPYRA** (CAP)

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.11.

5.2.5. **Methoxy polyethylene glycolepoetin beta – MIRCERA** (CAP)

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

See also 6.1.15.

5.2.6. **Orlistat – ALLI** (CAP)

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

See also 6.1.17.

5.2.7. **Ribavirin – REBETOL** (CAP)

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

See also 6.1.24.

5.2.8. **Romiplostim – NPLATE** (CAP)

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

See also 6.1.25.

5.2.9. **Rotavirus vaccine**, **live**, **attenuated – ROTARIX** (CAP)

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

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogne (BE)

See also 6.1.26.

5.2.10. Saxagliptin – ONGLYZA (CAP)

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

See also 6.1.27.

5.2.11. Sitagliptin, **metformin – EFFICIB** (CAP), **JANUMET** (CAP), **RISTFOR** (CAP), **VELMETIA** (CAP)

- Evaluation of a RMP in the context of PSUR procedures

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

See also 6.1.28.

RMP in the context of a variation

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

- Evaluation of a RMP in the context of type II variations

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.13. Belatacept – NULOJIX (CAP)

- Evaluation of a RMP in the context of a type II variation

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

5.2.14. Bortezomib – VELCADE (CAP)

- Evaluation of a RMP in the context of a type II variation

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

5.2.15. Canakinumab – ILARIS (CAP)

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.16. Daranuvir – PREZISTA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

5.2.17. Fampridine – FAMPYRA (CAP)

- Evaluation of a RMP in the context of a type II variation

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

5.2.18. Golimumab – SIMPONI (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

5.2.19. Human Fibrinogen, human thrombin – EVICEL (CAP)

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.20. Insulin aspart – NOVORAPID (CAP)

- Evaluation of a RMP in the context of a type II variation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.21. Leflunomide – LEFLUNOMIDE MEDAC (CAP)

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

5.2.22. Natalizumab – TYSABRI (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

5.2.23. Velagluserase alfa – VPRIV (CAP)

- Evaluation of a RMP in the context of a type II variation

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

5.2.24. Sugammadex – BRIDION (CAP)

- Evaluation of a RMP in the context of a type II variation

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

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

5.2.25. Pazopanib – VOTRIENT (CAP)

- Evaluation of a RMP in the context of a conditional renewal procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

See also 9.2.2.

5.2.26. Sugammadex – BRIDION (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

See also 9.2.3.

RMP in the context of a stand-alone RMP procedure

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

5.2.28. Fentanyl - INSTANYL (CAP)

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

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)

5.2.29. Fesoterodine – TOVIAZ (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: Miguel-Angel Macia (ES)

5.2.30. Human fibrinogen, human thrombin – EVICEL (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)

5.2.31. Hydroxycarbamide – SIKLOS (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: Jean-Michel Dogne (BE)

5.2.32. Ibandronic acid – BONDENZA (CAP), BONDRONAT (CAP), BONVIVA (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)

5.2.33. Paliperidone – INVEGA (CAP), XEPLION (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

5.2.34. Pioglitazone – ACTOS (CAP), **GLUSTIN** (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

5.2.35. Pioglitazone – GLIDIPION (CAP), **PIOGLITAZONE ACTAVIS** (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

5.2.36. Pioglitazone – PAGLITAZ (CAP), **PIOGLITAZONE KRKA** (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

5.2.37. Pioglitazone – PIOGLITAZONE TEVA (CAP), **PIOGLITAZONE TEVA PHARMA** (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

5.2.38. Pioglitazone – SEPIOGLIN (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: Almath Spooner (IE)

5.2.39. Pioglitazone, **glimepiride – TANDEMACT** (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: Almath Spooner (IE)

5.2.40. Pioglitazone, **metformin – COMPETACT** (CAP), **GLUBRAVA** (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: Almath Spooner (IE)

5.2.41. Somatropin – NUTROPINAQ (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: Line Michan (DK)

5.2.42. Sunitinib – SUTENT (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: Carmela Macchiarulo (IT)

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

5.2.44. Telmisartan, **hydrochlorothiazide – KINZALKOMB** (CAP), **MICARDISPLUS** (CAP), **PRITORPLUS** (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

6. Assessment of Periodic Safety Update Reports (PSURs)

6.1.1. Agalsidase alfa – REPLAGAL (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.2. Aripiprazole – ABILIFY (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Margarida Guimaraes (PT)

6.1.3. Atazanavir – REYATAZ (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.4. Axitinib – INLYTA (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

6.1.5. Corifollitropin alfa – ELONVA (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.6. D-alfa-tocopherol – VEDROP (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.7. Desloratidine, pseudoephedrine – AERINAZE (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogne (BE)

6.1.8. Dexamethasone – **OZURDEX** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.9. Dronedarone – **MULTAQ** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.10. Epoetin Theta – **BIOPOIN** (CAP), **EPORATIO** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

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

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.12. Icatibant – **FIRAZYR** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.13. Idursulfase – **ELAPRASE** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.14. Ioflupane (**123 I**) – **DATSCAN** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.15. Methoxy polyethylene glycolepoetin beta – **MIRCERA** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

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

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)

6.1.17. Orlistat – ALLI (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.18. Palonosetron – ALOXI (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

6.1.19. Peginterferon alfa 2a - PEGASYS (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.20. Pioglitazone – ACTOS (CAP), **GLUSTIN** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

6.1.21. Pioglitazone, **glimepiride - TANDEMACT** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

6.1.22. Pioglitazone, **metformin – COMPETACT** (CAP), **GLUBRAVA** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

6.1.23. **Pyronaridine**, **artesunate – PYRAMAX**

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.24. **Ribavirin – REBETOL** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.25. **Romiplostim – NPLATE** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

6.1.26. **Rotavirus vaccine**, **live**, **attenuated – ROTARIX** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogne (BE)

6.1.27. **Saxagliptin – ONGLYZA** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.28. **Sitagliptin, metformin – EFFICIB** (CAP), **JANUMET** (CAP), **RISTFOR** (CAP), **VELMETIA** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.29. **Sulesomab – LEUKOSCAN** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.30. **Telithromycin – KETEK** (CAP)

- Evaluation of a PSUR procedure

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of post-authorisation safety studies

7.1.1. **Alipogene tiparovec – GLYBERA** (CAP)

- Evaluation of a protocol for a PASS

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

7.1.2. **Teduglutide – REVESTIVE** (CAP)

- Evaluation of a protocol for a PASS

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

7.2. Results of post-authorisation safety studies

None

8. Product related pharmacovigilance inspections

8.1. List of planned pharmacovigilance inspections

None

8.2. 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.

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. **Telaprevir – INCIVO** (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: Qun-Ying Yue (SE)

See also Sugammadex 4.3.4.

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

9.2.1. Histamine dihydrochloride – CEPLENE (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

9.2.2. Pazopanib – VOTRIENT (CAP)

- PRAC consultation on a renewal procedure of the conditional marketing authorisation, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

9.2.3. Sugammadex – BRIDION (CAP)

- PRAC consultation on a renewal procedure of the marketing authorisation, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

9.2.4. Trabectedin – YONDELIS (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

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

None

9.4. Other requests

9.4.1. **Iron containing intravenous** (**IV**) **medicinal products** (NAP)

- PRAC consultation on an Article 31 referral procedure upon CHMP's request

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

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)
PRAC Co-Rapporteur: Qun-Ying Yue (SE)

9.4.2. **Phentermine**, **topiramate**

- PRAC consultation on an evaluation of an initial marketing authorisation procedure, upon CHMP's request

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

9.4.3. **Telaprevir – INCIVO** (CAP)

- PRAC consultation on a study protocol upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

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

See Roxithromycin 4.3.1.

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

None

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. PSURs Repository

None

11.3.3. Union Reference Date List

11.3.3.1. Consultation on the draft List, version February 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

11.5.3.1. Update on Creation and maintenance of the List

Status: *For discussion*

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

None

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

- Guideline on good pharmacovigilance practices (GVP) Module XV on Risk Minimisation Measures: Selection of Tools and Effectiveness Indicators

Status: *for discussion*

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

None

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

11.12.2. Paediatric Committee (PDCO)

- Collection of Pregnancy Data for New or Commonly Used Drugs during Pregnancy

Status: *for discussion*

11.12.3. Working Parties

None

11.13. Interaction within the EU regulatory network

None

11.13.1. Implementation of the pharmacovigilance legislation: feedback from the EMA Management Board dated December 2012

Status: *for discussion*

11.14. Contacts of the PRAC with external parties and interaction 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

- Proposals for drug safety priorities for EC DG Research Framework Programme 8 (FP8) funding in Work Programme 2014

Status: *for discussion*

12. Any other business

None