EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 November 2012
EMA/PRAC/519419/2012
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda of meeting 26-29 November 2012

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

26 November 2012, 12:30 – 19:00, room 2/A

27 November 2012, 09:00 – 19:00, room 2/A

28 November 2012, 09:00 – 19:00, room 2/A

29 November 2012, 09:00 – 13:00, room 2/A

1. Introduction

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

1.2. Adoption of agenda of the meeting of 26-29 November 2012

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 26 November 2012

1.3. Minutes of the previous PRAC meeting on 29-31 October 2012

Status: for adoption

Document: PRAC Final Minutes to be published on 30 November 2012

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

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

3.1. Newly triggered Procedures

3.1.1. **Hydroxyethyl starch** (HES) (NAPs)

- Review of the risk/benefit balance of HES-containing products: due to higher risk of mortality in septic patients and higher risk of negative effects on renal function in Intensive Care Patients: notification by Germany 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*

3.1.2. **Short-acting beta agonists**: **hexoprenaline - fenoterol - ritodrine - salbutamol - terbutaline** (NAPs)

- Review of the risk/benefit balance of short-acting beta agonists: due to cardiovascular adverse drug reactions following use in obstetric indications: notification by Hungary of a referral under Article 31 of Directive 2001/83/EC

Status: *for 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. **Agomelatine – VALDOXAN, THYMANAX** (CAP)

- Signal of angioedema

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

4.1.2. **Atanazavir – REYATAZ** (CAP)

- Signal of angioedema

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

4.1.3. **Capsaicin** patch – **QUTENZA** (CAP)

- Signal of severe burns

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

Regulatory details:

PRAC Rapporteur: Maria Alexandra Pego (PT)

4.1.4. **Leflunomide – ARAVA** (CAP)

- Signal of myositis

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

4.1.5. **Nicardipine** (NAPs)

- Signal of thrombocytopenia

Status: *for initial discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.2. New signals detected from other sources

None

4.3. Signals follow-up and prioritisation

4.3.1. **Adalimumab – HUMIRA** (CAP)

- Signal of dermatomyositis

Status: *for follow-up discussion*

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

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

- Signal of arterial thrombotic events

Action: *for follow-up discussion*

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

4.3.3. **Infliximab – REMICADE** (CAP)

- Signal of dermatomyositis

Status: *for follow-up discussion*

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

4.3.4. **Influenza vaccines -** (NAPs)

- Signal of extensive limb swelling (ELS)

Status: *for follow-up discussion*

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Autologous Cultured Chondrocytes

- 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. Autologous Peripheral Blood Mononuclear Cells Activated With Pap-Gm-Csf

- 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. Bosentan

- 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. Dabrafenib

- 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. Delamanid

- 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. Dimethyl Fumarate

- 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. Diphtheria, Tetanus, Pertussis (Acellular, Component)

- 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. Enzalutamide

- 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. Hepatitis B, Surface Antigen

- 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. Human Coagulation Factor VIII / Von Willebrand Factor

- 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. Imatinib

- 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. Modified Vaccinia Ankara Virus

- 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. Telmisartan

- 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

5.2.1. Abatacept – ORENCIA (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: Kirsti Villikka (FI)
PRAC Co-Rapporteur: Julia Pallos (HU)

5.2.2. Boceprevir – VICTRELIS (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 6.1.3.

5.2.3. Denosumab – PROLIA (CAP), XGEVA (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 6.1.5.

5.2.4. Dibotermin Alfa - INDUCTOS (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)
PRAC Co-Rapporteur: Kirsti Villikka (FI)

5.2.5. Duloxetine - **ARICLAIM** (CAP), **CYMBALTA** (CAP), **XERISTAR** (CAP), **YENTREVE** (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: Dolores Montero (ES)
PRAC Co-Rapporteur: Qun-Ying Yue (SE)

5.2.6. Eslicarbazepine acetate - ZEBINIX (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)
PRAC Co-Rapporteur: Jana Mlada (CZ)

5.2.7. Everolimus – VOTUBIA (CAP)

- Evaluation of an RMP in the context of a line extension procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (ES)
PRAC Co-Rapporteur: Julie Williams (UK)

5.2.8. Fosamprenavir - TELZIR (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)
PRAC Co-Rapporteur: Jacqueline Genoux-Hames (LU)

5.2.9. Imatinib – GLIVEC (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 (ES)

See also 6.1.8.

5.2.10. Insulin human – INSUMAN (CAP)

- Evaluation of an RMP in the context of a line extension procedure

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

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogne (BE)
PRAC Co-Rapporteur: Sabine Straus (NL)

5.2.11. Lopinavir / ritonavir – KALETRA (CAP), **ALUVIA**

- 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)
PRAC Co-Rapporteur: Jacqueline Genoux-Hames (LU)

5.2.12. Natalizumab - TYSABRI (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)
PRAC Co-Rapporteur: Carmela Macchiarulo (IT)

See also 6.1.10.

5.2.13. Pazopanib – VOTRIENT (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)
PRAC Co-Rapporteur: Sabine Straus (NL)

5.2.14. Pregabalin – LYRICA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)
PRAC Co-Rapporteur: Maria Alexandra Pego (PT)

5.2.15. Pandemic influenza vaccine (h5n1) A/Vietnam/1194/2004 NIBRG-14 (H5N1) (split virion, inactivated, adjuvanted) – ADJUPANRIX (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)
PRAC Co-Rapporteur: Sabine Straus (NL)

See also 6.1.11.

5.2.16. Pandemic influenza vaccine (h5n1) A/Indonesia/05/2005 PR8 IBCDC-RG2 (H5N1) (split virion, inactivated, adjuvanted) – PREPANDRIX (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 6.1.12.

5.2.17. Ranibizumab – LUCENTIS (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)
PRAC Co-Rapporteur: Dolores Montero (ES)

5.2.18. Tenofovir Disoproxil Fumarate – VIREAD (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)
PRAC Co-Rapporteur: Miguel Angel Macia (ES)

5.2.19. Tolvaptan – SAMSCA (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)
PRAC Co-Rapporteur: Carmela Macchiarulo (IT)

See also 6.1.18.

5.2.20. Ulipristal – ELLAONE (CAP)

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

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

Regulatory details:

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

See also: 6.1.19.

5.2.21. Varenicline – CHAMPIX (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)
PRAC Co-Rapporteur: Sabine Straus (NL)

See also: 6.1.20.

6. Assessment of Periodic Safety Update Reports (PSURs)

6.1.1. Apixaban – ELIQUIS (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.2. Azacitidine – VIDAZA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.3. Boceprevir – **VICTRELIS** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.4. Capsaicin – **QUTENZA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Maria Alexandra Pego (PT)

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

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.6. Eribulin – **HALAVEN** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

6.1.7. Human hepatitis B immunoglobulin – **ZUTECTRA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.8. Imatinib – **GLIVEC** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

6.1.9. Interferon Beta 1-a – AVONEX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero (ES)

6.1.10. Natalizumab - TYSABRI (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.11. Pandemic influenza vaccine (h5n1) A/Vietnam/1194/2004 NIBRG-14 (H5N1) (split virion, inactivated, adjuvanted) – ADJUPANRIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.12. Pandemic influenza vaccine (h5n1) A/Indonesia/05/2005 PR8 IBCDC-RG2 (H5N1) (split virion, inactivated, adjuvanted) – PREPANDRIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.13. Piperaquine tetraphosphate / dihydroartemisinin – EURARTESIM (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.14. Rilpivirine – EDURANT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

6.1.15. Rosiglitazone – AVANDIA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.16. Tafamidis – VYNDAQEL (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)

6.1.17. Temsirolimus – TORISEL (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.18. Tolvaptan – SAMSCA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.19. Ulipristal – ELLAONE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.1.20. Varenicline – CHAMPIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

7. Post-authorisation Safety Studies (PASS)

7.1. Post-authorisation safety studies protocols

7.1.1. Aclidinium Bromide - EKLIRA GENUAIR; BRETARIS GENUAIR (CAP)

- Evaluation of a protocol for a PASS to evaluate the risk of cardiovascular endpoints

Status: *for discussion and agreement of PRAC letter of endorsement/objection/notification that study is a clinical trial*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)
PRAC Co-Rapporteur: Adam Przybylkowski (PL)

7.2. Results of post-authorisation safety studies

None

8. Product related pharmacovigilance inspections

8.1. List of planned pharmacovigilance inspections

8.1.1. Risk-based programme for routine pharmacovigilance inspections of Marketing Authorisation Holders (MAHs) connected with human centrally authorised products

Status: *for discussion and agreement of the programme*

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 considered confidential and it 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. Cinacalcet – MIMPARA (CAP)

- PRAC consultation in 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. Dabigatran – PRADAXA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

9.1.3. Parecoxib – DYNASTAT (CAP)

- PRAC consultation in a safety-related type II variation 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. Ofatumumab – ARZERRA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

9.2.2. Teriparatide – FORSTEO (CAP)

- PRAC consultation in a renewal procedure of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

9.2.3. Tocofersolan D-Alpha-Tocopheryl Polyethylene Glycol Succinate – VEDROP (CAP)

- PRAC consultation in an annual reassessment procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

9.2.4. Vandetanib – CAPRELSA (CAP)

- PRAC consultation in a conditional renewal procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

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

None

9.4. Other requests

9.4.1. Loxapine

- PRAC consultation in a drug utilisation study (DUS) protocol upon CHMP request

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

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

- PRAC consultation in a final protocol for a Pan European Observational Study of Pioglitazone and Risk of Bladder Cancer, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

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

None

11. Organisational, regulatory and methodological matters

11.1. Mandate and organisation of the PRAC

11.1.1. Rules of Procedure of the PRAC

Status: *for discussion and adoption of the revised Rules of Procedure*

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 December 2012

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

None

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

- Adapting format of EMA 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. Inter-Status with EMA Committees and Working Parties

11.12.1. Committees

None

11.12.2. Working Parties

- Working Group on Quality Review of Documents (QRD): Revised mandate – interaction with PRAC

Status: *for information*

11.12.3. Other

- Summary of Product Characteristics (SmPC) Advisory Group – Revision of webpage and member list update

Status: *for information*

11.13. Inter-Status 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. Other

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

Status: *for discussion and agreement of the proposals in advance of CHMP discussion/adoption*

12. Any other business

- Management and circulation of documents

Status: *for information*