EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 November 2013
EMA/PRAC/676915/2013
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 4-7 November 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.ema.europa.eu/

Chair: June Raine – Vice-Chair: Almath Spooner

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

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

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

7 November 2013, 08:30 – 13:30, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

21 November 2013, 10:30-12:30, room 2/B, via teleconference

Table of contents

1. Introduction

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

1.2. Adoption of agenda of the meeting of 4-7 November 2013

Status: for adoption

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

1.3. Minutes of the previous PRAC meeting on 7-10 October 2013

Status: for adoption

Document: PRAC final Minutes due for publication by 15 November 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

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

3.1. Newly triggered Procedures

None

3.2. Ongoing Procedures

3.2.1. Agents acting on the renin-angiotensin system (CAP, NAP): **angiotensin receptor blockers** (**ARBs**), **angiotensin converting enzyme inhibitors** (**ACEi**), **direct renin inhibitors** (**aliskiren**)

- Review of the risks of dual blockade of the renin angiotensin system through concomitant use of ARBs, ACEi or aliskiren-containing medicines following notification by Italy of a referral under Article 31 of Directive 2001/83/EC based on pharmacovigilance data

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)
PRAC Co-Rapporteur: Margarida Guimarães (PT), Martin Huber (DE), Tatiana Magálová (SK), Dolores Montero Corominas (ES), Almath Spooner (IE), Menno van der Elst (NL), Julie Williams (UK), Qun-Ying Yue (SE)

3.3. Procedures for finalisation

3.3.1. Acipimox (NAP)

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

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

Regulatory details:

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

3.3.2. Diacerein (NAP)

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

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

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)
PRAC Co-Rapporteur: Evelyne Falip (FR)

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

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Adalimumab - HUMIRA (CAP)

- Signal of missed dose due to malfunction of the pre-filled pen device

Status: *for discussion*

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

4.1.2. Bupropione (NAP)

- Signal of pancytopenia

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

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

- Signal of angioedema

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

4.1.4. Goserelin (NAP)

- Signal of long duration flushing and hyperhidrosis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.1.5. Leflunomide - ARAVA (CAP)

- Signal of drug reaction with eosinophilia and systemic symptoms (DRESS)

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

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

4.1.6. Teriparatide - **FORSTEO** (CAP)

- Signal of anaphylactic shock

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

4.2. New signals detected from other sources

4.2.1. **Paracetamol** (NAP)

- Signal of drug-induced Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP)

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.2.2. **Calcium channel blockers** (CAP, NAP):
Aliskiren, amlodipine - RASILAMLO (CAP)
Amlodipine, valsartan - **COPALIA,** (CAP), **DAFIRO** (CAP), **EXFORGE** (CAP), **IMPRIDA** (CAP)
Amlopdine, valsartan, hydrochlorothiazide - **COPALIA HCT** (CAP), **DAFIRO HCT** (CAP), **EXFORGE HCT** (CAP);
Telmisartan, amlodipine - ONDUARP (CAP), **TWYNSTA** (CAP)

- Signal of calcium-channel blockers and breast cancer risk

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.3. Signals follow-up and prioritisation

4.3.1. **Bevacizumab - AVASTIN** (CAP)

- Signal of anaphylactic shock

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

4.3.2. **HMG-CoA Reductase Inhibitors**:
simvastatin (NAP); **simvastatin/ezetimibe** (NAP); **simvastatin/fenofibrate – CHOLIB** (CAP)

- Signal of risk of myopathy and rhabdomyolysis associated with high doses – follow-up to previous PhVWP review

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

4.3.3. **Lenograstim** (NAP)

- Signal of (systemic) capillary leak syndrome (CLS)

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

4.3.4. **Levetiracetam – KEPPRA** (CAP)

- Signal of hyponatraemia and inappropriate antidiuretic hormone secretion (SIADH)

***Status**: for discussion*

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

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Albiglutide

- 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. Ataluren

- 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. Brimonidine tartare, brinzolamide

- 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. Cholic acid

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

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

5.1.5. Colecalciferol, strontium ranelate

- 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. Dapagliflozin, metformin

- 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. Dolutegravir

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

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

5.1.8. Etarfolatide

- 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. Folic acid

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

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

5.1.10. Follitropin alfa

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

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

5.1.11. Laquinimod

- 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. Nalfurafine

- 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. Perflubutane

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

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

5.1.14. Riociguat

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

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

5.1.15. Sofosbuvir

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

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

5.1.16. Trametinib

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

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

5.1.17. Umeclidinium bromide, vilanterol

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

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

5.1.18. Vintafolide

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

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

5.1.19. Zoledronic acid

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

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

5.2. Medicines already authorised

RMP in the context of a PSUR procedure

5.2.1. Abiraterone – ZYTIGA (CAP)

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

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

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

See also 6.1.1.

5.2.2. Ceftaroline fosamil – ZINFORO (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 6.1.5.

5.2.3. Cidofovir – VISTIDE (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: Margarida Guimarães (PT)

See also 6.1.6.

5.2.4. Dapagliflozin – FORXIGA (CAP)

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

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

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

See also 6.1.8.

5.2.5. Febuxostat – ADENURIC (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: Harald Herkner (AT)

See also 6.1.10.

5.2.6. Fenofibrate, pravastatin – PRAVAFENIX (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

See also 6.1.11.

5.2.7. Fesoterodine – TOVIAZ (CAP)

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

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

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

See also 6.1.12.

5.2.8. Histamine dihydrochloride – CEPLENE (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

See also 6.1.15.

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

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

See also PRAC agenda, Minutes October 2013

5.2.10. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 6.1.16.

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

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

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

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

See also 6.1.17.

5.2.12. Ivabradine – CORLENTOR (CAP), **PROCORALAN** (CAP)

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

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

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

See also 6.1.18.

5.2.13. Japanese encephalitis vaccine (inactivated, adsorbed) – IXIARO (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: Brigitte Keller-Stanislawski (DE)

See also 6.1.19.

5.2.14. Mannitol – BRONCHITOL (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 6.1.20.

5.2.15. Orlistat – XENICAL (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

See also 6.1.24.

5.2.16. Pasireotide – SIGNIFOR (CAP)

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

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

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

See also 6.1.25.

5.2.17. Regadenoson – RAPISCAN (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 6.1.27.

5.2.18. Sunitinib – SUTENT (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

See also 6.1.29.

5.2.19. Tadalafil – **ADCIRCA** (CAP), **CIALIS** (CAP)

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

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

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

See also 6.1.30.

RMP in the context of a variation

5.2.20. Abiraterone – **ZYTIGA** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

5.2.21. Bazedoxifene – **CONBRIZA** (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

5.2.22. Bevacizumab – **AVASTIN** (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

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

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

5.2.24. Dasatinib – SPRYCEL (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.25. Icatibant – FIRAZYR (CAP)

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

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

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

5.2.26. Iloprost – VENTAVIS (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

5.2.27. Imatinib – IMATINIB ACTAVIS (CAP)

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

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

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

5.2.28. Indacaterol – HIROBRIZ BREEZHALER (CAP), ONBREZ BREEZHALER (CAP), OSLIF BREEZHALER (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

5.2.29. Insulin lispro – HUMALOG (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

5.2.30. Measles, mumps, rubella and varicella vaccine (live) – PROQUAD (CAP)

- Evaluation of an RMP in the context of a variation

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

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

5.2.31. Ponatinib – ICLUSIG (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

5.2.32. Pazopanib – VOTRIENT (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.33. Prasugrel – EFIENT (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.34. Rituximab – MABTHERA (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

5.2.35. Tocilizumab – ROACTEMRA (CAP)

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

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

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

5.2.36. Ulipristal – ESMYA (CAP)

- Evaluation of an RMP in the context of a variation

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

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

5.2.37. Ulipristal acetate – **ELLAONE** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

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

Not applicable

RMP in the context of a stand-alone RMP procedure

5.2.38. Telmisartan – **MICARDIS** (CAP), **KINZALMONO** (CAP), **PRITOR** (CAP)

- Evaluation of a stand-alone RMP

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[2]

6.1.1. Abiraterone – **ZYTIGA** (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.1.

6.1.2. Alipogene tiparvovec – **GLYBERA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.3. Bortezomib – **VELCADE** (CAP)

- Evaluation of a PSUR procedure

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.4. Catumaxomab – REMOVAB (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. Ceftaroline fosamil – ZINFORO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.2.

6.1.6. Cidofovir – VISTIDE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

See also 5.2.3.

6.1.7. Cytarabine – DEPOCYTE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

6.1.8. Dapagliflozin – FORXIGA (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.4.

6.1.9. Decitabine – DACOGEN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

6.1.10. Febuxostat – ADENURIC (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Harald Herkner (AT)

See also 5.2.5.

6.1.11. Fenofibrate, pravastatin – PRAVAFENIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

See also 5.2.6.

6.1.12. Fesoterodine – TOVIAZ (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.7.

6.1.13. Golimumab – SIMPONI (CAP)

- Evaluation of a PSUR procedure

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

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

6.1.14. Granisetron – SANCUSO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Jolanta Gulbinovic (LT)

6.1.15. Histamine dihydrochloride – CEPLENE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

See also 5.2.8.

6.1.16. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

See also 5.2.10.

6.1.17. Insulin glargine – LANTUS (CAP), OPTISULIN (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.11.

6.1.18. Ivabradine – CORLENTOR (CAP), PROCORALAN (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.12.

6.1.19. Japanese encephalitis vaccine (inactivated, adsorbed) – IXIARO (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.13.

6.1.20. Mannitol – **BRONCHITOL** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.14.

6.1.21. Meningococcal group a, c, w135 and y conjugate vaccine – **NIMENRIX** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

6.1.22. Ocriplasmin – **JETREA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

6.1.23. Ofatumumab – **ARZERRA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

6.1.24. Orlistat – **XENICAL** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Evelyne Falip (FR)

See also 5.2.15.

6.1.25. Pasireotide – **SIGNIFOR** (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.16.

6.1.26. Pazopanib – **VOTRIENT** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

6.1.27. Regadenoson – **RAPISCAN** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

See also 5.2.17.

6.1.28. Retapamulin – **ALTARGO** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

6.1.29. Sunitinib – **SUTENT** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

See also 5.2.18.

6.1.30. Tadalafil – **ADCIRCA** (CAP), **CIALIS** (CAP)

- Evaluation of a PSUR procedure

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

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

See also 5.2.19.

6.1.31. Telmisartan – KINZALMONO (CAP), **MICARDIS** (CAP), **PRITOR** (CAP), **TELMISARTAN TEVA** (CAP), **TELMISARTAN TEVA PHARMA** (CAP), **TOLURA** (CAP), NAPs
Telmisartan, hydrochlorothiazide – KINZALKOMB (CAP), **MICARDIS PLUS** (CAP), **PRITOR PLUS (**CAP), **TOLUCOMBI** (CAP), NAP

- Evaluation of a PSUSA procedure

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.32. Telmisartan, amlodipine – ONDUARP (CAP), **TWYNSTA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

6.1.33. Tocilizumab – ROACTEMRA (CAP)

- Evaluation of a PSUR procedure

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

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

6.2. Follow-up to PSUR procedures[3]

6.2.1. Pneumococcal polysaccharide conjugate vaccine (adsorbed) – SYNFLORIX (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

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

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

- Evaluation of a follow-up to a PSUR procedure

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

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

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

7. Post-authorisation Safety Studies (PASS)

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

7.1.1. Imatinib – GLIVEC (CAP)

- Evaluation of an imposed PASS protocol

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

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

7.1.2. Lomitapide – LOJUXTA (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

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

7.2.1. Adalimumab – HUMIRA (CAP)

- Evaluation of a PASS protocol

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

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

7.2.2. Certolizumab pegol – CIMZIA (CAP)

- Evaluation of a PASS protocol

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

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

7.2.3. Dapagliflozin – FORXIGA (CAP)

- Evaluation of a PASS protocol

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

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

7.2.4. Emtricitabine, rilpivirine, tenofovir disproxil – EVIPLERA (CAP)

- Evaluation of a PASS protocol

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

7.2.5. Human normal immunoglobulin – PRIVIGEN (CAP)

- Evaluation of a PASS protocol

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

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

7.2.6. Loxapine – ADASUVE (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

7.2.7. Mifamurtide – MEPACT (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

7.2.8. Nalmefene – SELINCRO (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

7.2.9. Nalmefene – SELINCRO (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

7.2.10. Romiplostim – NPLATE (CAP)

- Evaluation of a PASS protocol

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

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

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

None

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

None

7.5. Interim results of imposed and non-imposed PASS and results of non-imposed PASS submitted before the entry into force of the revised variations regulation[8]

7.5.1. **Adalimumab – HUMIRA** (CAP)

- Evaluation of interim PASS results

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

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

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

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

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

8.1.2. **Bosutinib – BOSULIF** (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

8.1.3. **Canakinumab – ILARIS** (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

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

8.1.4. Capsaicin – **QUTENZA** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Maria Alexandra Pêgo (PT)

8.1.5. Ofatumumab – **ARZERRA** (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

8.1.6. Rivastigmine – **NIMVASTID** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Evelyne Falip (FR)

8.1.7. Ulipristal acetate – **ELLAONE** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

Disclosure of information on results of pharmacovigilance inspections could undermine the protection of the purpose of these inspections, investigations and audits. Therefore such information is not reported in the agenda.

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

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

10.1.1. Temozolomide – TEMODAL (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

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

None

10.3. Other requests

10.3.1. Delamanid

- PRAC consultation on a re-examination procedure of an initial marketing authorisation

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

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

None

12.2. Pharmacovigilance audits and inspections

None

12.2.1. Pharmacovigilance Systems and their Quality Systems

None

12.2.2. Pharmacovigilance Inspections

None

12.2.3. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

None

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

12.3.3.1. Consultation on the draft List, version November 2013

Status: *for discussion and agreement of the list*

12.4. Signal Management

12.4.1. Signal Management

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

Status: *for information*

12.5. Adverse Drug Reactions reporting and additional reporting

12.5.1. Management and Reporting of Adverse Reactions to Medicinal Products

None

12.5.2. Additional Monitoring

None

12.5.3. List of Product under Additional Monitoring

12.5.3.1. Consultation on the draft List, version November 2013

Status: *for discussion and agreement of the list*

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

None

12.6.2. Changes to EudraVigilance Database and functional specifications

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

None

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Risk communication and Transparency

12.10.1. Public Participation in Pharmacovigilance

None

12.10.2. Safety Communication

None

12.11. Continuous pharmacovigilance

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

None

12.11.2. Incident Management

None

12.12. Interaction with EMA Committees and Working Parties

12.12.1. Committees

None

12.12.2. Blood Products Working Party

12.12.2.1. Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration: consultation on the ongoing revision

Status: *for discussion*

12.12.2.2. Guideline on core SmPC for plasma-derived fibrin sealant / haemostatic products: consultation on the ongoing revision

Status: *for discussion*

12.13. Interaction within the EU regulatory network

None

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

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

None

12.14.2. Others

None

13. Any other business

13.1.1. Awareness session on the new pharmacovigilance training resource

Status*: for information*