EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2013
EMA/PRAC/291178/2013
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Agenda of meeting on 13-16 May 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)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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

13 May 2013, 13:00 – 19:00, room 3/A

14 May 2013, 08:30 – 19:00, room 3/A

15 May 2013, 08:30– 19:00, room 3/A

16 May 2013, 08:30 – 14:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

23 May 2013, 10:30-12:30, room 6/A, 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 on 13-16 May 2013

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 13 May 2013

1.3. Minutes of the previous PRAC meeting on 8-11 April 2013

Status: for adoption

Document: PRAC Final Minutes due for publication on 24 May 2013

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

2.2.1. **Flupirtine** (NAP)

- Review of the benefit-risk balance of flupirtine-containing medicines following notification by Germany of a referral under Article 107i of Directive 2001/83/EC

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)
PRAC Co-Rapporteur: Martin Huber (DE)

2.3. Procedures for finalisation

2.3.1. **Cyproterone**, **ethinylestradiol – DIANE 35** & **other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 mcg** (NAP)

- Review of the benefit-risk balance of cyproterone 2mg/ethinylestradiol 35 mcg-containing medicines following notification by France of a referral under Article 107i of Directive 2001/83/EC

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)
PRAC Co-Rapporteur: Evelyne Falip (FR)

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. 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 risk of dual blockade of the renin angiotensin system through concomitant use of ARBs, ACEi and 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 and adoption of a list of questions and procedure timetable*

Regulatory details:

PRAC Rapporteur: *to be appointed*
PRAC Co-Rapporteur: *to be appointed* (IT)

3.1.2. Strontium ranelate – OSSEOR (CAP), **PROTELOS** (CAP)

- Review of the benefit-risk balance of strontium ranelate-containing medicines following notification by the European Commission of a referral under Article 20(8) of Regulation (EC) No 726/2004, following procedural steps of Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

***Status**: for discussion and adoption of a list of questions and procedure timetable*

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)
PRAC Co-Rapporteur: Harald Herkner (AT)

3.2. Ongoing Procedures

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

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

***Status**: for discussion*

Regulatory details:

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

3.2.2. **Diclofenac** (NAP)

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

***Status**: for discussion and agreement of a list of outstanding issues and revised timetable (or PRAC recommendation to CMDh)*

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)
PRAC Co-Rapporteur: Julie Williams (UK)

3.2.3. **Hydroxyethyl starch** (**HES**), **solutions for infusion** (NAP)

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

***Status**: for discussion and agreement of a list of outstanding issues and revised timetable (or PRAC recommendation to CMDh)*

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)
PRAC Co-Rapporteur: Martin Huber (DE)

3.2.4. **Short-acting beta agonists**: **hexoprenaline** (NAP); **fenoterol** (NAP); **ritodrine** (NAP); **salbutamol** (NAP); **terbutaline** (NAP); **isoxsuprine** (NAP)

- Review of the benefit-risk balance of short-acting beta agonists-containing products in the management of tocolysis and other obstetric indications following notification by Hungary of a referral under Article 31 of Directive 2001/83/EC based on pharmacovigilance data

***Status**: for discussion and agreement of a list of outstanding issues and revised timetable (or PRAC recommendation to CMDh)*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)
PRAC Co-Rapporteurs: Jean-Michel Dogné (BE), Carmela Macchiarulo (IT), Jana Mladá (CZ), Julia Pallos (HU)

3.3. Procedures for finalisation

3.3.1. **Almitrine** (NAP)

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

***Status**: for discussion and agreement of PRAC recommendation to CMDh*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)
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. Agomelatine – **THYMANAX** (CAP), **VALDOXAN** (CAP)

- Signal of QT prolongation

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

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

- Signal of anaphylactic shock

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

4.1.3. Capecitabine – **XELODA** (CAP)

- Signal of convulsion

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

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

- Signal of intereaction with linezolid leading to serotonin syndrome

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

[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.

4.1.5. Efavirenz – **STOCRIN** (CAP), **SUSTIVA** (CAP)

- Signal of interaction with *Ginkgo biloba*

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

4.1.6. Mirabegron – **BETMIGA** (CAP)

- Signal of urinary retention

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)

4.1.7. **Nicardipine** (NAP)

- Signal of acute pulmonary oedema in off-label use during pregnancy

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.1.8. Orlistat – **ALLI** (CAP), **XENICAL** (CAP) and NAP

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

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.1.9. **Sertraline** (NAP)

- Signal of growth retardation in children and adolescents

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.1.10. **Tapentadol** (NAP)

- Signal of suicidal ideation

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

4.2. New signals detected from other sources

None

4.3. Signals follow-up

4.3.1. **Adalimumab – HUMIRA** (CAP)

- Signal of dermatomyositis

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

4.3.2. **Azithromycin** (NAP)

- Signal of potentially fatal heart events

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Terhi Lehtinen (FI)

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

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

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

4.3.4. **Tiotropium bromide** (NAP)

- Signal of increased mortality from cardiovascular disease and all-cause mortality – BMJ publication

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

4.3.5. **Trazodone** (NAP)

- Signal of postural hypotension and somnolence at high starting dose

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Jolanta Gulbinovic (LT)

4.3.6. Vitamin K antagonists: warfarin, phenprocoumon (NAP)

- Signal of interaction with Goji berries (*Lycium barbarum*)

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Afatinib

- 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. Alemtuzumab

- 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. Atosiban

- 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. Autologous peripheral blood mononuclear cells

- 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. Brimonidine

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

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

5.1.6. Cobicistat

- 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. Dexamethasone

- 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. Dolutegravir

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

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

5.1.9. Fenofibrate, simvastatin

- 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. Filgrastim

- 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. Florbetaben (18F)

- 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. Glycopyrronium bromide, indacaterol

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

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

- 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. Human fibrinogen, human thrombin

- 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. Infliximab

- 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. Lomitapide

- 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. Memantine

- 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. Mercaptine

- 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. Misoprostol

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

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

5.1.19. Mixture of polynuclear iron (III)-oxyhydroxide, sucrose and starches

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

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

5.1.20. 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*

5.1.21. Pomalidomide

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

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

5.1.22. Radium-223

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

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

5.1.23. Serelaxin

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

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

5.1.24. Somatropin

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

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

5.1.25. Tilmanocept

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

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

5.1.26. Travoprost

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

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

5.1.27. 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*

5.2. Medicines already authorised

RMP in the context of a PSUR procedure

5.2.1. Capecitabine – XELODA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 6.1.4.

5.2.2. Eribulin – HALAVEN (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 6.1.12.

5.2.3. Eslicarbazepine acetate – ZEBINIX (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 6.1.13.

5.2.4. Fidaxomicin – **DIFICLIR** (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 6.1.15.

5.2.5. Linagliptin – **TRAJENTA** (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 6.1.26.

5.2.6. 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 6.1.27.

5.2.7. Melatonin – **CIRCADIN** (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: Maria Alexandra Pêgo (PT)

See also 6.1.28.

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

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

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

See also 6.1.29.

5.2.9. Miglustat – ZAVESCA (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 6.1.31.

5.2.10. Prucalopride succinate – RESOLOR (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

See also 6.1.41.

5.2.11. Sodium oxybate – XYREM (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: Maria Alexandra Pêgo (PT)

See also 6.1.44.

5.2.12. Sulphur hexafluoride – SONOVUE (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 6.1.45.

5.2.13. Thalidomide – THALIDOMIDE CELGENE (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 6.1.47.

RMP in the context of a variation

5.2.14. Atazanavir – REYATAZ (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

5.2.15. Crizotinib – XALKORI (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

5.2.16. Darunavir – PREZISTA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

5.2.17. Emtricitabine, **rilpivirine**, **tenofovir – EVIPLERA** (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

5.2.18. Everolimus – VOTUBIA (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: Martin Huber (DE)

5.2.19. Fampridine – FAMPYRA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

5.2.20. Insulin human – INSUMAN (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: Jean-Michel Dogné (BE)

5.2.21. Natalizumab – TYSABRI (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)

5.2.22. Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) – PANDEMRIX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

5.2.23. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) – PREVENAR 13 (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)

5.2.24. Pramipexole – OPRYMEA (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)

5.2.25. Ranibizumab – LUCENTIS (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

5.2.26. 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)

5.2.27. Sugammadex – BRIDION (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

5.2.28. Tocilizumab - ROACTEMRA (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: Brigitte Keller-Stanislawski (DE)

5.2.29. Trastuzumab - HERCEPTIN (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: Brigitte Keller-Stanislawski (DE)

5.2.30. Voriconazole – VFEND (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

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

None

RMP in the context of a stand-alone RMP procedure

5.2.31. Capsaicin – QUTENZA (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: Maria Alexandra Pêgo (PT)

5.2.32. Ulipristal – ESMYA (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: Ulla Wändel Liminga (SE)

6. Assessment of 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)

6.1.2. Bazedoxifene – CONBRIZA (CAP)

- Evaluation of a PSUR procedure

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

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.3. **Bortezomib – VELCADE** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.4. **Capecitabine – CAPECITABINE ACCORD** (CAP), **ECANSYA** (CAP), **XELODA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 5.2.1.

6.1.5. **Conestat alfa – RUCONEST** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.6. **Darbepoetin alfa – ARANESP** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.7. **Darifenacin hydrobromide – EMSELEX** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.8. Deferasirox – EXJADE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

6.1.9. Desirudin – REVASC (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

6.1.10. Doripenem – DORIBAX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.11. 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)

See also 5.2.2.

6.1.12. Eslicarbazepine acetate – ZEBINIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

See also 5.2.3.

6.1.13. **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)

6.1.14. **Fidaxomicin – DIFICLIR** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

See also 5.2.4.

6.1.15. **Granisetron – SANCUSO** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Jolanta Gulbinovic (LT)

6.1.16. **Hepatitis B vaccine** (**rDNA**) **– HBVAXPRO** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

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

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.18. **Human normal immunoglobulin – HIZENTRA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.19. Human normal immunoglobulin – KIOVIG (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.20. Human normal immunoglobulin – PRIVIGEN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

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

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogné (BE)

6.1.22. Hydrocortisone – PLENADREN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.23. Insulin glulisine – APIDRA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.24. Levodopa, carbidopa, entacapone – LEVODOPA/CARBIDOPA/ENTACAPONE ORION (CAP), STALEVO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

6.1.25. Linagliptin – TRAJENTA (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 5.2.5.

6.1.26. 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 5.2.6.

6.1.27. Melatonin – CIRCADIN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Maria Alexandra Pêgo (PT)

See also 5.2.7.

6.1.28. 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)

See also 5.2.8.

6.1.29. Methylthioninium chloride – METHYLTHIONINIUM CHLORIDE PROVEBLUE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

6.1.30. Miglustat – ZAVESCA (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 5.2.9.

6.1.31. Nicotinic acid, laropiprant – PELZONT, TREDAPTIVE, TREVACLYN

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

6.1.32. Pandemic influenza vaccine (H1N1) (whole virion, inactivated, prepared in cell culture) – CELVAPAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.33. Pandemic influenza vaccine (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)

6.1.34. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - FOCLIVIA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.35. 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)

6.1.36. Pixantrone dimaleate – PIXUVRI (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.37. Posaconazole – NOXAFIL (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

6.1.38. Prepandemic influenza vaccine (**H5N1**) (**surface antigen**, **inactivated**, **adjuvanted**) **– AFLUNOV** (CAP), **PREPANDEMIC INFLUENZA VACCINE** (**H5N1**) (**SURFACE ANTIGEN**, **INACTIVATED**, **ADJUVANTED**) **NOVARTIS VACCINES AND DIAGNOSTIC** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

6.1.39. Prepandemic influenza vaccine (**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)

6.1.40. Prucalopride succinate – RESOLOR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

See also 5.2.10.

6.1.41. Regadenoson – RAPISCAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

6.1.42. Shingles (herpes zoster) vaccine (live) – ZOSTAVAX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

6.1.43. Sodium oxybate – XYREM (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Maria Alexandra Pêgo (PT)

See also 5.2.11.

6.1.44. Sulphur hexafluoride – SONOVUE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.12.

6.1.45. 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)

6.1.46. Thalidomide – THALIDOMIDE CELGENE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

See also 5.2.13.

6.1.47. 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. Interferon beta 1a – AVONEX (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

6.2.2. Imatinib – GLIVEC (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

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

- Evaluation of a follow-up to a PSUR procedure

[3] Follow up procedures as per the conclusions of PSUR procedures, assessed outside next PSUR procedures

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

6.2.4. Temsirolimus – TORISEL (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of post-authorisation safety studies

7.1.1. Alipogene tiparvovec – GLYBERA (CAP)

- PRAC consultation on a PASS protocol included in the pharmacovigilance plan of the RMP in accordance with Article 107m Directive 2001/83/EC

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

7.1.2. Ulipristal – ESMYA (CAP)

- PRAC consultation on a PASS protocol included in the pharmacovigilance plan of the RMP in accordance with Article 107m Directive 2001/83/EC

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel-Liminga (SE)

7.2. Results of post-authorisation safety studies

7.2.1. Human fibrinogen thrombin – EVICEL (CAP)

- PRAC consultation on PASS study results, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

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

- PRAC consultation on PASS study results, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

7.2.3. Oseltamivir – TAMIFLU (CAP)

- PRAC consultation on PASS study results, upon CHMP request

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

Regulatory details:

PRAC Rapporteur: Kirsti Villika (FI)

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. Azacitidine – VIDAZA (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

8.1.3. Iloprost – VENTAVIS (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)

8.1.4. Lacosamide – VIMPAT (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

8.1.5. Olanzapine – ZYPADHERA (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Terhi Lehtinen (FI)

8.1.6. Vildagliptin – JALRA (CAP), **XILIARX** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

8.1.7. Vildagliptin, **metformin – ICANDRA** (CAP), **ZOMARIST** (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

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. Pazopanib – VOTRIENT (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

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

None

10.3. Other requests

10.3.1. Epoetins:
darbepoetin-alfa - ARANESP (CAP), **epoetin-beta - NEORECORMON** (CAP), **epoetin-zeta - RETACRIT SILAPO** (CAP), **epoetin alfa – BINOCRIT** (CAP), **ABSEAMED** (CAP), **EPOETIN ALFA HEXAL** (CAP), **epoetin theta – EPORATIO** (CAP), **methoxy polyethylene glycol-epoetin beta – MIRCERA** (CAP)

- PRAC consultation on the evaluation of a proposal for a joint post-authorisation safety study on target haemoglobin levels in chronic kidney disease patients, upon CHMP request

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

Regulatory details:

PRAC Rapporteur (overall): Martin Huber (DE)
PRAC Rapporteurs: Isabelle Robine (FR), Dolores Montero Corominas (ES)

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Meningococcal group C polysaccharide conjugate vaccine adsorbed (NAP)

- PRAC consultation on a variation, upon Member States' request

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

Regulatory details:

Lead member: Julie Williams (UK)

11.2. Renewals of the marketing authorisation

None

11.3. Other requests

11.3.1. Peritoneal dialysis solutions (NAP)

- PRAC consultation on the results of an epidemiological study pursuant to an obligation imposed in accordance with Article 21a and 22a of Directive 2001/83/EC following completion of a referral procedure under Article 31 of Directive 2001/83/EC

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

Regulatory details:

Lead member: Julie Williams (UK)

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. Reporting of plenary meeting discussed procedures

- Draft figures for the first 6 months of PRAC activity

***Status**: for discussion*

12.2. Pharmacovigilance audits and inspections

12.2.1. Pharmacovigilance Systems and their Quality Systems

None

12.2.2. Pharmacovigilance Inspections

None

12.2.3. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

None

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

12.3.3.1. Consultation on the draft List, version May 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

None

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

None

12.6.2. Changes to EudraVigilance Database and functional specifications

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

12.8.2. Patient Registries

- Proposal to initiate the process of encouraging and supporting joint disease based-registries in accordance with Article 22a of Directive 200/83/EC

***Status**: for discussion*

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

- Concept paper on public hearings

***Status**: for discussion*

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. Human Scientific Committees Working Party with Healthcare Professionals' Organisations (HCPWP)

- Revised mandate, objectives and rules of procedures

***Status**: for discussion and endorsement*

12.13. Interaction within the EU regulatory network

12.13.1. Heads of Medicines Agencies (HMA)

- Call for participation in the Pharmacovigilance Audit Facilitation Group (PAGF)

***Status**: for information*

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. Novel influenza strain (H7N9) in humans

- Preparatory activities

***Status**: for information*

12.14.3. Medication errors workshop

- Final report from the workshop

***Status**: for information*

13. Any other business

None