7 April 2014
EMA/PRAC/210339/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 7-10 April 2014

Chair: June Raine – Vice-Chair: Almath Spooner

7 April 2014, 13:00 – 19:00, room 3/A

8 April 2014, 08:30 – 19:00, room 3/A

9 April 2014, 08:30– 19:00, room 3/A

10 April 2014, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

24 April 2014, 10:00 - 12:00, room 6/A, via teleconference

Health and Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regards to therapeutic indications listed against products it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised and start of referrals will also be available.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

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

1.2. Adoption of agenda of the meeting of 7-10 April 2014

Status: *for adoption*

Document: PRAC Agenda Rev.3 due for publication on 7 April 2014

1.3. Minutes of the previous PRAC meeting on 3-6 March 2014

Status: *for adoption*

Document: PRAC Final Minutes due for publication by 18 April 2014

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

2.1. Newly triggered procedures

2.1.1. Methadone oral solutions containing povidone (NAP)

- Review of the benefit-risk balance following notification by Norway of a referral under Article 107i 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*

Administrative details:
MAH(s): various
Triggering MS: NO
Documents:
For adoption: List of Questions (LoQ), procedure timetable

2.2. Ongoing Procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered Procedures

3.1.1. **Ambroxol** (NAP); **bromhexine** (NAP)

- Review of the benefit-risk balance following notification by Belgium 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*

Administrative details:
MAH(s): Boehringer Ingelheim, various
Triggering MS: BE
Documents:
For adoption: List of Questions (LoQ), procedure timetable

3.1.2. **Codeine** (NAP)

- Review of the benefit-risk balance of codeine indicated for the treatment of cough in paediatric patients following notification by Germany 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*

Administrative details:
MAH(s): various
Triggering MS: DE
Documents:
For adoption: List of Questions (LoQ), procedure timetable

3.1.3. **Testosterone** (NAP)

- Review of the benefit-risk balance following notification by Estonia 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*

Administrative details:
MAH(s): various
Triggering MS: EE
Documents:
For adoption: List of Questions (LoQ), procedure timetable

3.2. Ongoing Procedures

3.2.1. Valproate and related substances: sodium valproate, valproic acid, valproate semisodium, valpromide (NAP)

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

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)
PRAC Co-Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number: EMEA/H/A-31/1387
MAH(s): sanofi-aventis GmbH, various
Triggered by: UK
Documents:
For adoption: List of outstanding issues (LoOI), revised timetable

3.3. Procedures for finalisation

3.3.1. 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 the 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-Rapporteurs: Margarida Guimarães (PT), Valerie Strassmann (DE), Tatiana Magálová (SK), Dolores Montero Corominas (ES), Almath Spooner (IE), Menno van der Elst (NL), Julie Williams (UK), Qun-Ying Yue (SE)

Administrative details:
Procedure number: EMEA/H/A-31/1370
EPITT 13359 – Follow up March 2014
PRAC Co-Rapporteurs (responsibility per substance): Margarida Guimarães (PT) (lisinopril); Carmela Macchiarulo (IT) (delapril, telmisartan, aliskiren, moexipril); Tatiana Magálová (SK) (spirapril, quinapril); Dolores Montero Corominas (ES) (fosinopril, irbesartan); Almath Spooner (IE) (benazepril, cilazapril, perindopril); Valerie Strassmann (DE) (ramipril, eprosartan, olmesartan); Menno van der Elst (NL) (trandolapril, losartan, azilsartan); Julie Williams (UK) (captopril, imidapril, zofenopril, candesartan); Qun-Ying Yue (SE) (enalapril, valsartan)
MAH(s): Actavis (Telmisartan Actavis, Actelsar HCT), Bayer Smith Kline Beecham (Kinzalmono, Kinzalkomb, Pritor, Pritor Plus), Boehringer Ingelheim (Micardis, Micardis Plus, Onduarp, Twynsta), Krka (Ifirmasta, Ifirmacombi, Tolura), Novartis (Copalia, Copalia HCT, Exforge, Exforge HCT, Dafiro, Dafiro HCT, Imprida), Novartis Europharm Ltd (Rasilamlo, Rasilez, Rasilez HCT, Rasitrio), Pharmathen S.A. (Sabervel), Sanofi-Winthrop / BMS (Aprovel, CoAprovel, Irbesartan Zentiva, Irbesartan HCT Zentiva, Karvea, Karvezide), Takeda (Edarbi, Ipreziv), Teva Pharma / Pharmachemie (Irbesartan Teva, Irbesartan HCT Teva, Telmisartan Teva, Telmisartan Teva Pharma), various
Oral explanations: *Not applicable*
Documents:
For adoption: PRAC AR, PRAC recommendation

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. Aripiprazole – **ABILIFY** (CAP), **ABILIFY MAINTENA** (CAP)

- Signal of diplopia

***Status**: for discussion*

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT), Qun-Ying Yue (SE)

Administrative details:
EPITT 17913 – New signal
MAH(s): Otsuka Pharmaceutical Europe Ltd
Leading MS: PT
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. Imatinib - **GLIVEC** (CAP), NAP

- Signal of decreased estimated glomerular filtration rate (eGFR)

***Status:** for discussion*

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

Administrative details:
EPITT 17946 – New signal
MAH: Novartis Europharm Ltd
Documents:
For adoption: PRAC recommendation

4.2.2. Sodium containing formulations of effervescent, dispersible and soluble medicines (NAP)

- Signal of cardiovascular events

***Status:** for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

[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

Administrative details:
EPITT 17931 – New signal
MAH: various
Leading MS: UK
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. **Adalimumab - HUMIRA** (CAP)

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

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

Administrative details:
EPITT 17701 – Follow up November 2013
MAH: AbbVie Ltd.
Documents:
For adoption: PRAC recommendation

4.3.2. **Clindamycin** (NAP)

- Signal of possible drug interaction with warfarin leading to international normalised ratio (INR) increased

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 17700 – Follow up December 2013
MAHs: Pfizer, various
Documents:
For adoption: PRAC recommendation

4.3.3. **Fentanyl, transdermal patch** (NAP)

- Signal of accidental exposure

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
EPITT 17778 – Follow up December 2013
MAHs: Janssen-Cilag, various
Leading MS: NL
Documents:
For adoption: PRAC recommendation

4.3.4. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - CERVARIX (CAP)

- Signal of complex regional pain syndrome (CRPS) linked to the process of vaccination

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogné (BE)

Administrative details:
EPITT 17644 – Follow up December 2013
MAHs: GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC recommendation

4.3.5. Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – GARDASIL (CAP), **SILGARD** (CAP)

- Signal of complex regional pain syndrome (CRPS) linked to the process of vaccination

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:
EPITT 17645– Follow up December 2013
MAHs: Sanofi Pasteur MSD, SNC (Gardasil), Merck Sharp & Dohme Limited (Silgard)
Documents:
For adoption: PRAC recommendation

4.3.6. Levonorgestrel-releasing intrauterine device (IUD) (NAP)

- Signal of risk of uterine perforation – Final study results of EURAS-IUD study

Status: *for discussion and Rapporteur appointment*

Regulatory details:

PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 2706 – Follow up PhVWP March 2012
MAHs: Bayer, various
Leading MS: DE
Documents:
For adoption: PRAC recommendation

4.3.7. Simvastatin (NAP)

- Signal of myopathy and rhabdomyolysis associated with high doses

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 13849 – Follow up November 2013

MAHs: Bayer various
Documents:
For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Allogenic human heterologous liver cells

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

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

Administrative details:
Product number(s): EMEA/H/C/003750, *Orphan, ATMP*
Intended indication: Treatment of urea cycle disorders (UCD)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.2. Apremilast

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

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

Administrative details:
Product number(s): EMEA/H/C/003746
Intended indication: Treatment of psoriatic arthritis and psoriasis
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.3. Brinzolamide

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

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

Administrative details:
Product number(s): EMEA/H/C/003698
Intended indication: Treatment of open-angle glaucoma or ocular hypertension
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.4. Cangrelor

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

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

Administrative details:
Product number(s): EMEA/H/C/003773
Intended indication: Reduction of thrombotic cardiovascular events (including stent thrombosis) in adult patients with coronary artery disease undergoing percutaneous coronary intervention (PCI); Maintenance of P2Y12 inhibition in adult patients with acute coronary syndromes or in patients with stents who are at increased risk for thrombotic events (such as stent thrombosis) when oral P2Y12 therapy is interrupted due to surgery ('bridging') during the pre-operative period
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.5. Ciclosporin

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

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

Administrative details:
Product number(s): EMEA/H/C/002066
Intended indication: Treatment of dry eye disease in adult patients with severe keratitis that does not improve despite treatment with tear substitutes
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.6. Clopidogrel, acetylsalicylic acid

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

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

Administrative details:
Product number(s): EMEA/H/C/002272
Intended indication: Prevention of atherothrombotic events
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.7. Daklatasavir

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

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

Administrative details:
Product number(s): EMEA/H/C/003768
Intended indication: Treatment of chronic hepatitis C virus (HCV)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.8. Dalbavancin

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

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

Administrative details:
Product number(s): EMEA/H/C/002840
Intended indication: Treatment of complicated skin and soft tissue infections (cSSTI)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.9. Dasiprotimut-T

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

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

Administrative details:
Product number(s): EMEA/H/C/002772*, Orphan*
Intended indication: Treatment of non-Hodgkin's lymphoma (FL)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.10. Dinutuximab

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

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

Administrative details:
Product number(s): EMEA/H/C/002800*, Orphan*
Intended indication: Treatment of high-risk neuroblastoma
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.11. Human alfa-1 proteinase inhibitor

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

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

Administrative details:
Product number(s): EMEA/H/C/002739
Intended indication: Maintenance treatment to slow the underlying destruction of lung tissue leading to emphysema in adults with alpha$_1$-proteinase inhibitor deficiency (also called alpha$_1$-antitrypsin deficiency) with clinically evident lung disease
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.12. Ketoconazole

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

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

Administrative details:
Product number(s): EMEA/H/C/003800*, Orphan*
Intended indication: Treatment of Cushing's syndrome
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.13. Levofloxacin

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

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

Administrative details:
Product number(s): EMEA/H/C/002789, *Orphan*
Intended indication: Treatment of chronic pulmonary infections
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.14. Obinutuzumab

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

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

Administrative details:
Product number(s): EMEA/H/C/002799, *Orphan*
Intended indication: Treatment of chronic lymphocytic leukaemia
Documents:

For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.15. Recombinant L-asparaginase

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

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

Administrative details:
Product number(s): EMEA/H/C/002661, *Orphan*
Intended indication: Combination therapy for B/T cell lymphoblastic leukaemia (ALL) or B/T cell lymphoblastic lymphoma (LBL)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.16. Safinamide

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

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

Administrative details:
Product number(s): EMEA/H/C/002396
Intended indication: Treatment of Parkinson's disease (PD)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.17. Tadalafil

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

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

Administrative details:
Product number(s): EMEA/H/C/003787*, Generic*
Intended indication: Treatment of erectile dysfunction in adult males
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.18. Tolvaptan

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

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

Administrative details:
Product number(s): EMEA/H/C/002788*, Orphan*
Intended indication: Treatment of autosomal dominant polycystic kidney disease (ADPKD)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.19. Trametinib

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

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

Administrative details:
Product number(s): EMEA/H/C/002643

Intended indication: Treatment of unresectable or metastatic melanoma with a BRAF V600 mutation
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.20. Vorapaxar

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

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

Administrative details:
Product number(s): EMEA/H/C/002814
Intended indication: Reduction of atherothrombotic events
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2. Medicines already authorised

RMP in the context of a variation[2] – PRAC-led procedures

5.2.1. Dabigatran – PRADAXA (CAP)

- Evaluation of an RMP in the context of a variation

Status: *for discussion and adoption of PRAC Assessment Report*

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/II/0062
Procedure scope: Update to the RMP (version 28.4) following modification to study 1160 - 144 (post-authorisation non-interventional study aiming to evaluate potential off-label use of dabigatran etexilate in Europe)
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC AR

5.2.2. Panitumumab – VECTIBIX (CAP)

- Evaluation of an RMP in the context of a variation

Status: *for discussion adoption of PRAC Assessment Report*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000741/II/0056
Procedure scope: Update to the RMP (version 12) to amend important identified and potential risks, address PRAC recommendations, enhance the Physicians education brochure (PEB), provide an update on the European Society of Pathologists (ESP) external Quality Assurance (EQA) programme and revise the timelines for category 1 and category 3 clinical studies
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC AR

[2] In line with the revised variation regulation for submissions as of 4 August 2013

RMP in the context of a variation – CHMP-led procedures

5.2.3. Alogliptin – VIPIDIA (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)

Administrative details:
Procedure number(s): EMEA/H/C/002182/II/0005
Procedure scope: Update of SmPC section 4.4 of to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.4. Alogliptin, metformin – VIPDOMET (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)

Administrative details:
Procedure number(s): EMEA/H/C/002654/II/0006
Procedure scope: Update of SmPC section 4.1 to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.5. Alogliptin, pioglitazone – INCRESYNC (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)

Administrative details:
Procedure number(s): EMEA/H/C/002178/II/0006
Procedure scope: Update of SmPC section 4.1 to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.6. Belimumab – BENLYSTA (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)

Administrative details:
Procedure number(s): EMEA/H/C/002015/II/0023
Procedure scope: Update of SmPC section 4.4 to add a warning regarding progressive multifocal leukoencephalopathy (PML)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.7. Canagliflozin – INVOKANA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002649/II/0005
Procedure scope: Update of the SmPC with new clinical data collected from the CANVAS (DIA3008) study, to reclassify bone fracture as an adverse drug reaction (ADR)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.8. 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)

Administrative details:
Procedure number(s): EMEA/H/C/000707/II/0063
Procedure scope: Update of SmPC section 4.1 for the 100mg/ml oral suspension and the 400mg, 800mg film-coated tablets with information on the use of darunavir with cobicistat as pharmacokinetic enhancer
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.9. Denosumab – PROLIA (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)

Administrative details:
Procedure number(s): EMEA/H/C/001120/II/0030

Procedure scope: Extension of indication to add treatment of osteoporosis in men at increased risk of fracture. As a consequence the MAH proposes to update SmPC sections 4.1 and 5.1
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.10. Denosumab – PROLIA (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)

Administrative details:
Procedure number(s): EMEA/H/C/001120/II/0036
Procedure scope: Update of SmPC section 4.4 upon request by PRAC following the assessment of PSU/027, to revise the warnings on osteonecrosis of the jaw (ONJ)
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.11. Denosumab – PROLIA (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)

Administrative details:
Procedure number(s): EMEA/H/C/001120/II/0037
Procedure scope: Update of the SmPC, upon request by PRAC following the assessment of PSU 027, to refine the warnings on hypocalcaemia including a description of the clinical manifestations of severe symptomatic hypocalcaemia and increases in parathyroid hormone in sections 4.4 and 4.8, and to add musculoskeletal pain as an identified risk in section 4.8 further to post-marketing experience
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.12. Denosumab – XGEVA (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)

Administrative details:
Procedure number(s): EMEA/H/C/002173/II/0027
Procedure scope: Update of the SmPC, upon request by PRAC following the assessment of PSU/014, to revise the warnings in section 4.4 on osteonecrosis of the jaw (ONJ), and to add information in sections 4.4 and 4.8 on the incidence of ONJ based on duration of exposure
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.13. Denosumab – XGEVA (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)

Administrative details:
Procedure number(s): EMEA/H/C/002173/II/0028
Procedure scope: Update of the SmPC, upon request by PRAC following the assessment of PSU 014, to refine the warnings on hypocalcaemia including a description of the clinical manifestations of severe symptomatic hypocalcaemia and increases in parathyroid hormone in sections 4.4 and 4.8, and to add musculoskeletal pain as an identified risk in section 4.8 further to post-marketing experience. Further, sections 4.2 and 5.3 of the SmPC have been updated with respect to recommendations for monitoring of calcium levels, and information regarding patients with renal impairment
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.14. Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil – STRIBILD (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002574/II/0022
Procedure scope: Update of SmPC sections 4.2, 4.4 and 4.8 to revise recommendations to initiate/discontinue treatment based on creatinine levels and to update safety data as a result of the interim 48 weeks data from the GS-US-236-0118 study. Consequently Annex II.D 'Conditions or Restrictions with regard to the Safe and Effective Use of the Medicinal Product' is updated. The MAH included additional analyses using the pooled Week 144 safety analysis set from the GS-US-236-0102 and GS-US-236-0103 studies to support this variation. The Management Plan (RMP) has been updated accordingly
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.15. Exenatide – BYDUREON (CAP), BYETTA (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002020/II/0019, EMEA/H/C/000698/II/0043
Procedure scope: Update of SmPC section 4.4 of to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.16. Ferumoxytol – RIENSO (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: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002215/II/0008
Procedure scope: Extension of indication to all cause iron deficiency anaemia when oral therapy is ineffective or inappropriate or where there is a need for rapid iron repletion
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.17. Filgrastim – GRASTOFIL (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)

Administrative details:
Procedure number(s): EMEA/H/C/002150/II/0003/G
Procedure scope: Inclusion of the paediatric population in the currently approved indication for use in adults, as per the reference product SmPC, and to introduce graduations on the syringe barrel enabling use of the Grastofil in accordance with the paediatric posology. Sections 4.1, 4.2, 4.8 of the SmPC and Section 3.0 of the Package Leaflet are proposed to be updated to include the paediatric population. In addition, Sections 5.1 and 6.6 of the SmPC have been updated in alignment with the Neupogen PI
MAH(s): Apotex Europe BV
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.18. Fingolimod – GILENYA (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: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002202/II/0021
Procedure scope: Modification of SmPC section 4.1 to extend the patient population from patients with high disease activity despite treatment with a beta-interferon (IFN) to patients with high disease activity despite treatment with a disease modifying therapy (DMT)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.19. Insulin lispro – HUMALOG (CAP), LIPROLOG (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: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000088/X/0125, EMEA/H/C/000393/X/0092
Procedure scope: Addition of a new strength (200 U/ml KwikPen presentation)
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.20. Ivacaftor – KALYDECO (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: Miguel-Angel Macia (ES)

Administrative details:
Procedure number(s): EMEA/H/C/002494/II/0009, *Orphan*
Procedure scope: Update of SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 to extend the indication in the treatment of cystic fibrosis to patients aged 6 years and older who have other gating (class III) mutation in the CFTR gene than G551D
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.21. Linagliptin, metformin – JENTADUETO (CAP), **TRAJENTA** (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: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002279/WS0524/0017, EMEA/H/C/002110/WS0524/0014
Procedure scope: Update of the product information with regard to pancreatic events, following the CHMP conclusions on the Art 5(3) procedure
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.22. Liraglutide – VICTOZA (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)

Administrative details:
Procedure number(s): EMEA/H/C/001026/II/0027

Procedure scope: Update of SmPC section 4.4 to implement the conclusions of Art 5(3) referral procedure on GLP-1 based products and pancreatic safety
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.23. Lixisenatide – LYXUMIA (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)

Administrative details:
Procedure number(s): EMEA/H/C/002445/II/0003
Procedure scope: Update of SmPC section 4.4 to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.24. Lopinavir, ritonavir – ALUVIA (Art 58), KALETRA (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)

Administrative details:
Procedure number(s): EMEA/H/W/000764/II/0084, EMEA/H/C/000368/II/0143
Procedure scope: Update of SmPC sections 4.2, 4.6 and 5.2 for 200 mg/50 mg film-coated tablets and 100 mg/25 mg film-coated tablets to include a dosing recommendation for HIV-1-infected women during pregnancy and postpartum as well to include additional information relevant to the use of Lopinavir/ritonavir (LPV/r). In addition, the MAH proposes to update SmPC section 4.6 of the oral solution and film-coated tablets with the results from the most recent interim report from the Antiretroviral Pregnancy Registry (APR)
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.25. Meningococcal group a, c, w 135 and y conjugate vaccine – MENVEO (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)

Administrative details:
Procedure number(s): EMEA/H/C/001095/II/0040
Procedure scope: Update of SmPC section 4.5 with information on co-administration with hepatitis A and B vaccines
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.26. Olanzapine – **ZYPREXA** (CAP), **ZYPREXA VELOTAB** (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: Terhi Lehtinen (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000115/WS0485/0110, EMEA/H/C/000287/WS0485/0085
Procedure scope: Update of the SmPC to reflect the results of study HGMX, long-term, open-label, Safety Study of Oral Olanzapine in Adolescents with bipolar I Disorder (Manic or Mixed Episodes) or Schizophrenia. Updates are proposed to the SmPC in order to reflect the level of data now available in this patient population
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.27. Pneumococcal polysaccharide conjugate vaccine (adsorbed) – **SYNFLORIX** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000973/II/0075
Procedure scope: Update of SmPC section 4.8 to include Kawasaki's disease following the assessments of EMEA/H/C/973/PSU045 and EMEA/H/C/973/LEG045.1, in which an association between Synflorix and Kawasaki's disease could not be ruled out
MAH(s): GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.28. Rituximab – **MABTHERA** (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)

Administrative details:
Procedure number(s): EMEA/H/C/000165/II/0089
Procedure scope: Update of SmPC sections 4.2 and 4.8 to reflect change in infusion rate for RA patients and add infusion reactions as undesirable effect. Submission of RMP version 9.4
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.29. Saxagliptin, metformin – **KOMBOGLYZE** (CAP), **ONGLYZA** (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: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002059/WS0528/0015, EMEA/H/C/001039/WS0528/0025
Procedure scope: Update of SmPC section 4.4 to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.30. Sitagliptin – JANUVIA (CAP), **RISTABEN** (CAP), **TESAVEL** (CAP), **XELEVIA** (CAP)
sitagliptin, metformin - **EFFICIB** (CAP), **JANUMET** (CAP), **RISTFOR** (CAP), **VELMETIA** (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: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000722/WS0534/0039, EMEA/H/C/001234/WS0534/0029, EMEA/H/C/000910/WS0534/0039, EMEA/H/C/000762/WS0534/0043
EMEA/H/C/000896/WS0535/0058, EMEA/H/C/000861/WS0535/0057, EMEA/H/C/001235/WS0535/0043, EMEA/H/C/000862/WS0535/0061
Procedure scope: Update to SmPC section 4.4 and updated RMP to implement the CHMP recommendation of Art 5(3) referral procedure on GLP-1-based therapies and pancreatic safety. The RMP is also updated to include rhabdomyolysis as a potential risk as outcome of post-authorisation measure LEG 006.2
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.31. 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)

Administrative details:
Procedure number(s): EMEA/H/C/000955/II/0032
Procedure scope: Extension of indication to the treatment in combination with methotrexate (MTX) of severe, active and progressive RA in adults not previously treated with MTX
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.32. Vildagliptin – GALVUS (CAP), **JALRA** (CAP), **XILIARX** (CAP)
vildagliptin, metformin – EUCREAS (CAP), **ICANDRA** (CAP), **ZOMARIST** (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: Qun-Ying Yue (SE)

Administrative details:
Procedure number(s): EMEA/H/C/000771/WS0518/0035, EMEA/H/C/001048/WS0518/0034, EMEA/H/C/001051/WS0518/0033
EMEA/H/C/000807/WS0518/0039, EMEA/H/C/001050/WS0518/0039, EMEA/H/C/001049/WS0518/0039
Procedure scope: Update of the SmPC and PL to implement the recommendations of Art 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.33. Vinflunine – JAVLOR (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: Rafe Suvarna (UK)

Administrative details:
Procedure number(s EMEA/H/C/000983/II/0011
Procedure scope: Extension of indication to include: in combination with capecitabine for the treatment of adult patients with locally advanced or metastatic breast cancer previously treated with or resistant to an anthracycline and who are taxane resistant
MAH(s): Pierre Fabre Médicament
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.34. 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)

Administrative details:
Procedure number(s): EMEA/H/C/000387/II/0097
Procedure scope: Update of SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 to include information pertaining to the proposed new indication in prophylaxis of invasive fungal infections in high risk hematopoietic stem cell transplant recipients
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.35. Zoledronic acid – ZOLEDRONIC ACID TEVA (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: Ulla Wändel Liminga (ES)

Administrative details:
Procedure number(s): EMEA/H/C/002439/X/0008
Procedure scope: Addition of a new pharmaceutical form, solution for infusion with three new presentations
MAH(s): Teva Pharma B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

RMP evaluated in the context of a PSUR procedure

See also Bivalirudin under 6.1.4. , Eculizumab under 6.1.14. , Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil under 6.1.15. , Etravirine under 6.1.16. , Fingolimod under 6.1.18. , 6.1.19., Glycopyrronium bromide under 6.1.19. , Ritonavir under 6.1.35. , Strontium ranelate under 6.1.37. , Trastuzumab under 6.1.38. , Vinflunine under 6.1.48.

RMP evaluated in the context of PASS results

See also Dolutegravir under 7.4.1. , Ivacaftor under 7.4.2. ; Retigabine under 7.4.3.

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

5.2.36. Alendronic acid, colecalciferol – VANTAVO (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001180/R/0019
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.37. Bivalirudin – ANGIOX (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000562/R/005
MAH(s): The Medicines Company UK Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

RMP in the context of a stand-alone RMP procedure

5.2.38. Mannitol – BRONCHITOL (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: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001252/RM 011.1
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.39. Pegfilgrastim – NEULASTA (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: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000420/RM 055.1
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[3]

6.1.1. Aliskiren – RASILEZ (CAP)
aliskiren, amlodipine – RASILAMLO (CAP)
aliskiren, hydrochlorothiazide – RASILEZ HCT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000780/PSU 035, EMEA/H/C/002073/PSU 008, EMEA/H/C/000964/PSU 032
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Aztreonam – CAYSTON (CAP), NAP

- Evaluation of a PSUSA[4] procedure

[3] 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
[4] PSUR single assessment, referring to CAP, NAP

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00000283/201309
MAH(s): Gilead Sciences International Ltd (Cayston), A. Menarini Industrie Farma (Primbactam), Bristol-Myers Squibb (Azactam)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Belimumab – BENLYSTA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002015/PSU 018
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Bivalirudin – ANGIOX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000562/PSU 024 (with RMP version 11)
MAH(s): The Medicines Company UK Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Bosutinib – BOSULIF (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002373/PSU 009
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Brinzolamide – AZOPT (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000267/PSU 014
MAH(s): Alcon Laboratories (UK) Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Cetuximab – ERBITUX (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000558/PSU 051
MAH(s): Merck KGaA
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Collagenase clostridium histolyticum – XIAPEX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002048/PSU 021
MAH(s): Auxilium UK Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.1. Colestilan – BINDREN (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002377/PSU 004
MAH(s): Mitsubishi Pharma Europe Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Dabigatran – **PRADAXA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/PSU 039
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Daptomycin – **CUBICIN** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000637/PSU 029
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Deferiprone – **FERRIPROX** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000236/PSU 060
MAH(s): Apotex Europe BV
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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)

Administrative details:
Procedure number(s): EMEA/H/C/001120/PSU 037, EMEA/H/C/002173/PSU 015
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Dexmedetomidine – DEXDOR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002268/PSU 004
MAH(s): Orion Corporation
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Eculizumab – SOLIRIS (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000791/PSU 044 (with RMP version 10.0)
MAH(s): Alexion Europe SAS
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil – STRIBILD (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002574/PSU 009 (with RMP version 1.0)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Etravirine – INTELENCE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000900/PSU 046 (with RMP version 9.0)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Everolimus – VOTUBIA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002311/PSU 005
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Fingolimod – GILENYA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002202/PSU 021 (with RMP version 7.0)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002691/PSU 007 (with RMP version 3.1), EMEA/H/C/002430/PSU 007 (with RMP version 3.1), EMEA/H/C/002690/PSU 007 (with RMP version 3.1)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed) – AMBIRIX (CAP), **TWINRIX ADULT** (CAP), **TWINRIX PAEDIATRIC** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000426/PSU 030, EMEA/H/C/000112/PSU 053, EMEA/H/C/000129/PSU 051
MAH(s): GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Iloprost – **VENTAVIS** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000474/PSU 035
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000240/PSU 143
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Influenza vaccine (split virion, inactivated) – **IDFLU** (CAP), **INTANZA** (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000966/PSU 029, EMEA/H/C/000957/PSU 029
MAH(s): Sanofi Pasteur, Sanofi Pasteur MSD, SNC
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. Ipilimumab – **YERVOY** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002213/PSU 022
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Lapatinib – TYVERB (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000795/PSU 035
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Leflunomide – ARAVA (CAP), **LEFLUNOMIDE MEDAC** (CAP), **LEFLUNOMIDE RATIOPHARM** (CAP), **LEFLUNOMIDE TEVA** (CAP), **LEFLUNOMIDE WINTHROP** (CAP), **REPSO** (CAP), NAP

- Evaluation of a PSUSA[5] procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001837/201309
MAH(s): Sanofi-aventis Deutschland GmbH (Arava, Leflunomide Winthrop), Medac (Leflunomide Medac), Ratiopharm GmbH (Leflunomide Ratiopharm), Teva Pharma B.V. (Lefunomide Teva, Repso), Aptil Pharma Limited (Leflunomide), Apotex Europe B.V. (Leflunomide), Cipla (EU) Limited (Leflunomide), Generics UK Ltd (leflunomide), Hexal AG (Leflunomide), Laboratorios Normon, S.A. (Leflunomide), Pharmathen S.A. (Leflon), Sigapharm GmbH (Fevol), Stada Arzneimittel AG (Leflunomide)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUSA[6] procedure

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

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

[5] PSUR single assessment, referring to CAP, NAP
[6] PSUR single assessment, referring to CAP, NAP

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001936/201309
MAH(s): Sanofi Pasteur MSD, SNC (Proquad)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Mecasermin – INCRELEX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000704/PSU 052
MAH(s): Ipsen Pharma
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Memantine – AXURA (CAP), **EBIXA** (CAP), **MEMANTINE MERZ** (CAP), NAP

- Evaluation of a PSUSA[7] procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001967/201309
MAH(s): Merz Pharmaceuticals GmbH (Axura, Memantine Merz), H. Lundbeck A/S (Ebixa), Aristo Pharma GmbH (Memantin NeuroPharma), Neuraxpharm Arzneimittel GmbH (Memantinhydrochlorid-neuraxpharm)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Midazolam – BUCCOLAM (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002267/PSU 008
MAH(s): ViroPharma SPRL
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Orlistat – ALLI (CAP), **XENICAL** (CAP), NAP

- Evaluation of a PSUSA[8] procedure

[7] PSUR single assessment, referring to CAP, NAP
[8] PSUR single assessment, referring to CAP, NAP

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00002220/201308
MAH(s): Glaxo Group Ltd (alli), Roche Registration Ltd (Xenical), Teva Pharmaceuticals Europe BV (Orlistat 123ratio), Sanofi (Orlsitat Zentiva), Teva Pharmaceuticals Polska Sp. z.o.o (Orlistat Teva), Hexal AG (Orlistat Sandoz, Orlistat Hexal 60and 120mg), Zentiva (Orlistat Zentiva), ZF Polpharma SA (Orlistat Polpharma, Slimella 60/120mg, Orlimax 120mg)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Pirfenidone – ESBRIET (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002154/PSU 007
MAH(s): InterMune UK Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. Pandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture) – PANDEMIC INFLUENZA VACCINE H5N1 BAXTER (CAP)
Prepandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture)- VEPACEL (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001200/PSU 024, EMEA/H/C/002089/PSU 003
MAH(s): Baxter AG, Baxter Innovations GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. Retigabine – TROBALT (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001245/PSU 007
MAH(s): Glaxo Group Ltd
Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Ritonavir – NORVIR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000127/PSU 047 (with RMP version 5.0)
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Rivaroxaban – XARELTO (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000944/PSU 031
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Strontium ranelate – OSSEOR (CAP), PROTELOS (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000561/PSU 036 (with RMP version 13.0), EMEA/H/C/000560/PSU 036 (with RMP version 13.0)
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Sulfur hexafluoride – SONOVUE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000303/PSU 028

MAH(s): Bracco International B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Teduglutide – REVESTIVE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002345/PSU 005
MAH(s): NPS Pharma Holdings Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Tegafur, gimeracil, oteracil – TEYSUNO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001242/PSU 008
MAH(s): Nordic Group B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Telaprevir – INCIVO (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002313/PSU 004
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Telavancin – VIBATIV (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001240/PSU 013
MAH(s): Clinigen Healthcare Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. Teriparatide – **FORSTEO** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000425/PSU 047
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Trabectedin – **YONDELIS** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000773/PSU 027
MAH(s): Pharma Mar, S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Trastuzumab – **HERCEPTIN** (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000278/PSU 093 (with RMP version 12.0)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.39. Vandetanib – **CAPRELSA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002315/PSU 015
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.40. Vernakalant – BRINAVESS (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001215/PSU 008
MAH(s): Cardiome UK Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.41. Vinflunine – JAVLOR (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000983/PSU 015 (with RMP version 13.0)
MAH(s): Pierre Fabre Médicament
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.42. Zoledronic acid – ACLASTA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Ulla Wändel Liminga (SE)

Administrative details:
Procedure number(s): EMEA/H/C/000595/PSU 032
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.43. Zoledronic acid – ZOMETA (CAP), **ZOLEDRONIC ACID MEDAC** (CAP), **ZOLEDRONIC ACID HOSPIRA** (CAP), NAP

- Evaluation of a PSUSA[9] procedure

[9] PSUR single assessment, referring to CAP, NAP

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00003149/201308
MAH(s): Novartis Europharm Ltd (Zometa), Medac (Zoledronic Acid Medac), Hospira (Zoledronic Acid Hospira), PH&T (Zoledronic Acid PHT), Sandoz B.V (Zoledronic acid)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[10]

6.2.1. Filgrastim – **FILGRASTIM HEXAL** (CAP), **ZARZIO** (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:

Procedure number(s): EMEA/H/C/000918/LEG 013.1, EMEA/H/C/000917/LEG 013.1
Procedure scope: MAH's response to PSUR#6 (PSU 013) RSI adopted in September 2013
MAH(s): Hexal AG
Documents:
For adoption: Updated PRAC Rap AR

6.2.2. Pegfilgrastim – **NEULASTA** (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000420/LEG 056
Procedure scope: MAH's response to PSUV-0071 (PSU-053 and RMP-055) RSI adopted at PRAC in September 2013
MAH(s): Amgen Europe B.V.
Documents:
For adoption: Updated PRAC Rap AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[11]

7.1.1. Deferasirox – **EXJADE** (CAP)

- Evaluation of an imposed PASS protocol

[10] Follow up as per the conclusions of the previous PSUR procedure, assessed outside next PSUR procedure
[11] In accordance with Article 107n of Directive 2001/83/EC

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000670/ANX/038.3
Procedure scope: Evaluation of MAH's response to ANX 038.2 as adopted by PRAC on 15 January 2014 via written procedure including a revised PASS protocol for study CICL670E2422: observational cohort study in paediatric non transfusion dependant-thalassaemia (NTDT) patients over 10 years
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.2. Indacaterol, glycopyrronium bromide – ULTIBRO BREEZHALER (CAP), XOTERNA BREEZHALER (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002679/ANX 002, EMEA/H/C/003755/ANX 002
Procedure scope: PASS Protocol of Study QVA149A2402: a multinational multi-database cohort study to assess RMP specified safety outcomes in association with indacaterol, glycopyrronium bromide in Europe
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.3. Lenalidomide – REVLIMID (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000717/ANX 041.3, EMEA/H/C/000717/ANX 041.4
Procedure scope: MAH's responses to ANX-041.1 and ANX-041.2 [PASS Protocol CC-5013-MDS-012 / Drug Utilisation Study] as adopted at PRAC in January 2014
MAH(s): Celgene Europe Limited
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.4. Levonorgestrel (NAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
Lead member: Ulla Wändel Liminga (SE)

Administrative details:
Procedure scope: Evaluation of an updated PASS protocol entitled EURAS-LCS12: European Active Surveillance Study of LCS-12 for non-CAP: Jaydess and Luadei (levonorgestrel). The objective of the study is to assess among new users the risks of certain events associated with the use of LCS12 compared with established IUDs (Mirena, copper IUDs) during standard clinical practice. In addition, drug utilisation patterns are described
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.5. Modified vaccinia Ankara virus – IMVANEX (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002596/SOB 002
Procedure scope: PASS protocol of studies POX-MVA-038 (observational, non-interventional post-authorisation safety study for the prophylactic vaccination with Imvanex in adults) and POX-MVA-039: (observational, non-interventional post-authorisation safety and efficacy study for the prophylactic vaccination with Imvanex following re-emergence of circulating smallpox infections)
MAH(s): Bavarian Nordic A/S
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.6. Teicoplanin (NAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
Procedure scope: Evaluation of an imposed PASS protocol to evaluate the safety of higher loading dose of 12mg/kg bid
MAH(s): Sanofi Aventis
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[12]

7.2.1. Aripiprazole – ABILIFY MAINTENA (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002755/MEA 002
Procedure scope: PASS protocol for a non-interventional, non-imposed study (Study No. 15893N) related to Extrapyramidal symptoms in patients treated with Abilify Maintena: cohort study with a 2-year follow-up using European automated healthcare databases
MAH(s): Otsuka Pharmaceutical Europe Ltd
Documents:
For adoption: PRAC advice

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)

Administrative details:
Procedure number(s): EMEA/H/C/001037/MEA 004.1
Procedure scope: MAH's response to MEA-004 RSI (reports CDP870-028 and CDP870-051) as adopted in September 2013
MAH(s): UCB Pharma SA
Documents:
For adoption: PRAC advice

7.2.3. Dabigatran – PRADAXA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/MEA 041
Procedure scope: Revised PASS protocol for study 1160.149 to evaluate the effectiveness of the risk minimisation activities in the treatment of stroke prevention in atrial fibrillation (SPAF)
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC advice

7.2.4. Golimumab – SIMPONI (CAP)

- Evaluation of a PASS protocol

[12] 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: Ulla Wändel Liminga (SE)

Administrative details:
Procedure number(s): EMEA/H/C/000992/MEA 026
Procedure scope: PASS protocol MK-8259 (non-interventional observational PASS in treatment of ulcerative colitis using Nordic national health registries
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.2.5. Lipegfilgrastim – LONQUEX (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002556/MEA 004
Procedure scope: PASS protocol Study XM22-ONC-50002: Prescribing patterns of lipegfilgrastim (Lonquex) in the EU
MAH(s): Teva Pharma B.V.
Documents:
For adoption: PRAC advice

7.2.6. Radium Ra223 – XOFIGO (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002653/MEA 10
Procedure scope: Final draft protocol for a non-interventional post-authorisation safety study (NIS PASS) with RMP version 1.0
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC advice

7.2.7. Rivastigmine – EXELON (CAP), **PROMETAX** (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000169/MEA 034.1, EMEA/H/C/000255/MEA 035
Procedure scope: Updated PASS protocol – MHA's response to RSI as adopted at PRAC in October 2013
MAH(s): Novartis Europharm Ltd

Documents:
For adoption: PRAC advice

7.2.8. Trastuzumab – HERCEPTIN (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000278/MEA 095
Procedure scope: PASS protocol BO29159: interventional phase IV safety clinical trial with prospective cardiac monitoring in patients with metastatic breast cancer (MBC)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC advice

7.2.9. Ustekinumab – STELARA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000958/MEA 022.8
Procedure scope: PASS protocol of a PSOLAR (PSOriasis Longitudinal Assessment and Registry), an international prospective cohort study/registry program designed to collect data on Psoriasis (PSO) patients that are eligible to receive systemic therapies, including generalised phototherapy and biologics
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC advice

7.2.10. Vernakalant – BRINAVESS (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001215/MEA 003.3
Procedure scope: Revised PASS protocol of a study SPECTRUM - change to target enrolment
MAH(s): Cardiome UK Limited
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[13]

None

[13] In accordance with Article 107p-q of Directive 2001/83/EC

7.4. Results of PASS non-imposed in the marketing authorisation(s)[14]

7.4.1. Dolutegravir – TIVICAY (CAP)

- Evaluation of PASS results

***Status**: for discussion and adoption of PRAC Assessment Report*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002753/II/0001 (with RMP)
Procedure scope: Submission of data from a physiologically-based pharmacokinetic model in fulfilment of the MEA 4 regarding the potential for a drug-drug interaction with midazolam
MAH(s): ViiV Healthcare
Documents:
For adoption: PRAC AR

7.4.2. Ivacaftor – KALYDECO (CAP)

- Evaluation of PASS results

***Status**: for discussion and adoption of PRAC Assessment Report*

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

Administrative details:
Procedure number(s): EMEA/H/C/002494/II/0015/G (with RMP)
Procedure scope: Submission of final study reports for studies VX08-770-102 and VX08-770-104 covering results from the post-treatment, 2-year, observational long-term follow up
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd
Documents:
For adoption: PRAC AR

7.4.3. Retigabine – TROBALT (CAP)

- Evaluation of PASS results

***Status**: for discussion and adoption of PRAC Assessment Report*

Regulatory details:
PRAC Rapporteur: Line Michan (DK)
Procedure number(s): EMEA/H/C/001245/II/0025 (with RMP)
Procedure scope: Submission of the final study report for a non-interventional PASS (WEUKBRE5744)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC AR

[14] 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

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[15]

7.5.1. Cobicistat – TYBOST (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002572/MEA 013
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.2. Efavirenz, emtricitabine, tenofovir disoproxil – ATRIPLA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000797/MEA 038
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Bristol-Myers Squibb and Gilead Sciences Ltd
Documents:
For adoption: PRAC advice

7.5.3. Elvitegravir – VITEKTA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002577/MEA 009
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.4. Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil– STRIBILD (CAP)

- Evaluation of interim PASS results

[15] In line with the revised variations regulation for any submission before 4 August 2013

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002574/MEA 013
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.5. Emtricitabine – EMTRIVA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000533/MEA 047
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.6. Emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002312/MEA 028
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.7. Emtricitabine, tenofovir disoproxil – TRUVADA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000594/MEA 040
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.8. Infliximab – REMICADE (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000240/MEA 089.11
Procedure scope: Interim study reports of the remaining EU rheumatoid arthritis registries: ARTIS and RABBIT cohort 2
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.5.9. Glycopyrronium bromide – ENUREV BREEZHALER (CAP), SEEBRRI BREEZHALER (CAP), TOVANOR BREEZHALER (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002691/ANX 001.3, EMEA/H/C/002430/ANX 001.3, EMEA/H/C/002690/ANX 001.3
Procedure scope: First interim result of an imposed non interventional PASS study (CNVA237A2402T): multinational database cohort study to assess adverse cardiovascular outcomes and mortality in association with inhaled NVA237
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.5.10. Ivacaftor – KALYDECO (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002494/ANX 001.1
Procedure scope: First interim results of a 5-year long-term observational study (PASS study ENCEPP/SDPP/4270) with ivacaftor in patients with cystic fibrosis, including also microbiological and clinical endpoints (e.g. exacerbations)
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC advice

7.5.11. Tenofovir disoproxil – VIREAD (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000419/MEA 267
Procedure scope: Interim report of the Antiretroviral Pregnancy Registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

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

8.1.1. Everolimus – VOTUBIA (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)

Administrative details:
Procedure number(s): EMEA/H/C/002311/R/0024 (without RMP)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

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

- PRAC consultation on a variation worksharing procedure, on CHMP request

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

Regulatory details:
Lead member: Ulla Wändel Liminga (SE)

Administrative details:
Procedure number(s): EMEA/H/C/001120/II/0036, EMEA/H/C/001120/II/0037, EMEA/H/C/001120/II/0027, EMEA/H/C/001120/II/0028
Procedure scope: see under 5.2.10. , 5.2.11., 5.2.12., 5.2.13.
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC Advice

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

None

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

None

10.4. Other requests

None

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Cyproterone, ethinylestradiol (NAP)

- PRAC consultation on a variation worksharing procedure, on Member State's request

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

Regulatory details:
Lead member: Menno van der Elst (NL)

Administrative details:
Procedure scope: Assessment of the MAH's responses relating to the assessment of RMP of all cyproterone, ethinylestradiol (2 mg/0.035 mg) containing products, authorised in Europe and belonging to MAH Bayer
MAH(s): Bayer
Documents:
For adoption: PRAC Advice

11.1.2. Flucloxacillin (NAP)

- PRAC consultation on a variation procedure, on Member State's request

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

Regulatory details:
Lead member: Sabine Straus (NL)

Administrative details:
Procedure scope: PRAC consultation on a variation proposing the addition of a warning in SmPC section 4.4 of Flucloxacillin and Floxapen to exercise special caution regarding drug induced liver injury in subjects with HLA-B*5701 haplotype
MAH(s): Actavis Group PTC
Documents:

For adoption: PRAC advice

11.1.3. Triptorelin (NAP)

- PRAC consultation on a variation worksharing procedure, on Member State's request

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

Regulatory details:
Lead member: Martin Huber (DE)

Administrative details:
Procedure scope: PRAC consultation on a variation proposing the addition of a new warning associated with long-term androgen deprivation therapy which may prolong the QT interval
MAH(s): Laboratoires Pharmaceutiques Sodia, various
Documents:
For adoption: PRAC Advice

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. Cefepime (NAP)

- PRAC consultation on a PSUR worksharing procedure, on Member State's request

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

Regulatory details:
Lead member: Margarida Guimarães (PT)

Administrative details:
Procedure number(s): PT/H/PSUR/0008/001
Procedure scope: PRAC consultation on an ongoing PSUR worksharing procedure and request for PRAC advice regarding association of Cefepime with increased all-cause mortality compared to other β–lactam antibacterials
MAH(s): Bayer, various
Documents:
For adoption: PRAC Advice

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC Work Programme

- Draft PRAC Work Programme 2014-2015

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

12.2.3.1. Pharmacovigilance Audit Facilitation Group (PAFG)

- Standardisation for preparing, performing and reporting pharmacovigilance audits to European Commission

Status: *for discussion*

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

12.3.1. PSUR single assessment of substances contained in both centrally and nationally authorised products (PSUSA)

- Handling of submissions of PSURs in a PSUSA

Status: *for discussion*

12.3.2. Periodic Safety Update Reports

None

12.3.3. PSURs Repository

None

12.3.4. Union Reference Date List

- Consultation on the draft List, version April 2014

Status: *for discussion and agreement of the list*

Documents:
For adoption: Revised EURD 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

12.5.2. Individual Case Safety Report (ICSR) standard

- Draft EU ICSR Implementation Guide

Status: *for discussion*

12.5.3. Additional Monitoring

None

12.5.4. List of Product under Additional Monitoring

- Consultation on the draft List, version April 2014

Status: *for information*

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

- Principles for RMP revised process

Status*: for discussion*

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

- Qualitative and quantitative review of studies aimed to evaluate the effectiveness of additional risk minimisation measures

Status*: for discussion*

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

12.12.1.1. Paediatric Committee (PDCO)

- Concept paper on revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population

Status: *for adoption*

12.12.2. Working Parties

12.12.2.1. Patients and Consumers Working Party (PCWP)
Healthcare Professionals Working Party (HCPWP)

- Feedback from joint meeting Workshop on regulatory and methodological standards to improve benefit/risk evaluation of medicines

Status: *for discussion*

12.12.2.2. Vaccine Working Party (VWP)

- Draft interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU

Status: *for discussion*

12.13. Interaction within the EU regulatory network

12.13.1. European Commission: Directorate General for Health & Consumers (DG SANCO)

- Delegated Regulation on Post-Authorisation Efficacy Studies (PAES)

Status: *for discussion*

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. EMA move in 2014 to new building

Status: *for discussion*

13.2. EMA reorganisation

- New organisational model

Status: *for discussion*

13.3. Marketing Authorisation Applications planned for the remainder of 2014

Status: *for information*