5 May 2014
EMA/PRAC/274254/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 5-8 May 2014

Chair: June Raine – Vice-Chair: Almath Spooner

5 May 2014, 13:00 – 19:00, room 3/A

6 May 2014, 08:30 – 19:00, room 3/A

7 May 2014, 08:30– 19:00, room 3/A

8 May 2014, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

22 May 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. For orphan medicinal products, the applicant name is published as this information is already publicly available.

Note on access to documents

Some documents mentioned in the agenda 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 for the meeting on 5-8 May 2014

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 5 May 2014

1.3. Minutes of the previous PRAC meeting on 7-10 April 2014

Status: for adoption

Document: PRAC Final Minutes due for publication by 16 May 2014

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

2.2.1. Methadone medicinal products containing povidone for oral use (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 to the ad-hoc expert group and procedure timetable*

Regulatory details:

PRAC rapporteur: Qun-Ying Yue (SE)
PRAC Co-rapporteur: Karen Pernille Harg (NO)

Administrative details:
Procedure number: EMEA/H/A-107i/1395
MAH(s): Martindale Pharma, various
Documents:
For adoption: List of questions to ad-hoc expert group, revised timetable

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. **Hydroxyzine** (NAP)

- Review of the benefit-risk balance following notification by Hungary 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): UCB, various
Triggering MS: HU
Documents:
For adoption: List of Questions (LoQ), procedure timetable

3.2. Ongoing Procedures

3.2.1. **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 revised procedure timetable*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)
PRAC Co-Rapporteurs: Jean-Michel Dogné (BE), Harald Herkner (AT)

Administrative details:
MAH(s): Boehringer Ingelheim, various
Documents:
For adoption: Revised timetable

3.2.2. **Ponatinib - ICLUSIG** (CAP)

- Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20(8) of Regulation (EC) No 726/2004, based on pharmacovigilance data

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Rafe Suvarna (UK)
PRAC Co-Rapporteur: Ulla Wändel Liminga (SE)

Administrative details:
Procedure number: EMEA/H/C/002695/A-20/0003
MAH(s): Ariad Pharma Ltd
Documents:
For adoption: List of outstanding issues (LoOI), revised timetable

3.2.3. 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 revised procedure timetable*

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)
PRAC Co-Rapporteur: Maia Uusküla (EE)

Administrative details:
MAH(s): various
Triggering MS: EE
Documents:
For adoption: Revised timetable

3.2.4. 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 questions to patients

3.3. Procedures for finalisation

None

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

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Androgen Deprivation Therapy (ADT) (NAPs)
Abiraterone - **ZYTIGA** (CAP); **degarelix - FIRMAGON** (CAP)

- Signal of QT interval prolongation due to long-term use

[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

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 13886 – New signal
MAH(s): Janssen-Cilag International N.V., Ferring Pharmaceuticals A/S, various
Leading MS: DE
Documents:
For adoption: PRAC recommendation

4.1.2. Atazanavir – REYATAZ (CAP)

- Signal of haemolytic anaemia

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
EPITT 17921 – New signal
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC recommendation

4.1.3. Quetiapine (NAP)

- Signal of possible misuse and abuse

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 17960 – New signal
MAH(s): AstraZeneca, various
Leading MS: NL
Documents:
For adoption: PRAC recommendation

4.1.4. Temozolomide – TEMODAL (CAP)

- Signal of diabetes insipidus

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:
EPITT 17951 – New signal
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. Bisphosphonates (CAP, NAP):
alendronate (NAP); **risedronate** (NAP); **alendronate, colcalciferol – ADROVANCE** (CAP), **FOSAVANCE** (CAP)**, VANTAVO** (CAP)
Strontium ranelate – OSSEOR (CAP), **PROTELOS** (CAP)

- Signal of heart valves disorders

Status*: for discussion*

Regulatory details:

PRAC Rapporteur: *To be appointed*

Administrative details:
EPITT 13832 – New signal
Leading MS: SE, UK
MAH(s): Merck Sharp & Dohme Limited (Adrovance, Fosavance, Vantavo), Les Laboratoires Servier (Osseor, Protelos), various
Documents:
For adoption: PRAC recommendation

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

- Signal of cardiovascular risk

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:
EPITT 17961 – New signal
Leading MS: NL
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC recommendation

4.2.3. Valproic acid (NAP)

- Signal of mitochondrial toxicity

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 17956 – New signal
Leading MS: DE
MAH(s): Neuraxpharm Arzneimittel GmbH, various
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. Azithromycin (NAP)

- Signal of potentially fatal heart events

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Terhi Lehtinen (FI)

Administrative details:
EPITT 16156 – Follow up October 2013
MAH(s): Pfizer, various
Documents:
For adoption: PRAC recommendation

4.3.2. Fentanyl, transdermal patch (NAP)

- Signal of accidental exposure

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
EPITT 17778 – Follow up April 2014
MAH(s): Janssen-Cilag, various
Documents:
For adoption: PRAC recommendation

4.3.3. Fluticasone furoate - AVAMYS (CAP)

- Signal of oral and upper respiratory fungal infection

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Adam Przybylkowski (PL)

Administrative details:
EPITT 17769 – Follow up January 2014
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC recommendation

4.3.4. Leuprorelin, suspension for injection (NAP)

- Signal of medication error - wrong technique in drug usage process

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
EPITT 17753 – Follow up January 2014
MAH(s): Astellas, various
Documents:
For adoption: PRAC recommendation

4.3.5. **Paracetamol** (NAP)

- Signal of drug exposure in pregnancy – publication by *Brandlistuen et al.*; Int. J. Epidemiol., 2013

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Veerle Verlinden (BE)

Administrative details:
EPITT 17796 – Follow up February 2014
MAH(s): Bayer Pharma AG, various
Documents:
For adoption: PRAC recommendation

4.3.6. **Sitagliptin – JANUVIA** (CAP), **RISTABEN** (CAP), **TESAVEL** (CAP), **XELEVIA** (CAP); **Sitagliptin**, **metformin – EFFICIB** (CAP), **JANUMET** (CAP), **RISTFOR** (CAP), **VELMETIA** (CAP); **Angiotensin-converting enzyme (ACE) inhibitors** (NAP)

- Signal of angioedema due to interaction between sitagliptin and ACE inhibitors

Status: *for discussion*

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

Administrative details:
EPITT 17608 – Follow up December 2013
MAH(s): Merck Sharp & Dohme Ltd, various
Documents:
For adoption: PRAC recommendation

4.3.7. **Tiotropium bromide** (NAP)

- Signal of increased mortality from cardiovascular disease and all-cause mortality – results of TIOSPIR[2] trial

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
EPITT 17406 – Follow up December 2013
MAH(s): Boehringer Ingelheim Limited, various
Documents:
For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Balugrastim

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

[2] Tiotropium Safety and Performance in Respimat

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

Administrative details:
Product number(s): EMEA/H/C/002637
Intended indication: Treatment of chemotherapy-induced neutropenia
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.2. Busulfan

- 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/002806, *Generic*
Intended indication: Conditioning treatment prior to conventional haematopoietic progenitor cell transplantation (HPCT)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.3. Liraglutide

- 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/003780
Intended indication: Treatment of obesity
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.4. Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches

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

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

Administrative details:
Product number(s): EMEA/H/C/002705
Intended indication: Control of serum phosphorus levels in patients with end-stage renal disease (ESRD)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.5. Netupitant, palonosetron

- 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/003728
Intended indication: Prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) induced by highly emetogenic chemotherapy (HEC) and moderately emetogenic chemotherapy (MEC)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.6. 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
Applicant: Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.7. Peginterferon beta-1a

- 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/002827
Intended indication: Treatment of relapsing multiple sclerosis
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.8. Perflubutane

- 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/002347
Intended indication: Detection of coronary artery disease (CAD)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.9. Phenylephrine, ketorolac trometamol

- 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/003702
Intended indication: Maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement (ILR) in adults
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.10. Simoctocog alfa

- 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/002813
Intended indication: Treatment and prophylaxis of bleeding (congenital factor VIII deficiency)
Documents:

For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.11. Tacrolimus

- 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/002655*, Hybrid*
Intended indication: Prophylaxis of transplant rejection in adult kidney allograft recipients
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2. Medicines already authorised

RMP in the context of a variation[3] – PRAC-led procedure

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

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000916/II/0018, EMEA/H/C/000915/II/0020
Procedure scope: Update of RMP (version 17.0)
MAH(s): Servier (Ireland) Industries Ltd, Les Laboratoires Servier
Documents:
For adoption: PRAC AR

5.2.2. 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: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/II/0064
Procedure scope: Submission of an updated protocol of the agreed study category 3: 1160.84 (observational cohort study to evaluate safety and efficacy of Pradaxa in patients with moderate renal impairment undergoing elective total hip replacement surgery or total knee replacement surgery)
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC AR

5.2.3. Pegaptanib – **MACUGEN** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogné (BE)

Administrative details:
Procedure number(s): EMEA/H/C/000620/II/0058
Procedure scope: Submission of a revised risk management plan (RMP version 8.2) to update information on the risk minimisation measures and their effectiveness
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC AR

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

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001242/II/0016
Procedure scope: Update of the RMP to modify the post-authorisation phase III clinical study to assess efficacy and safety of Teysuno versus an appropriate triplet comparator in the RMP (MEA 001). In addition the MAH took the opportunity to update the RMP with a new amendment for phase I study TPU-S1119 (MEA 002)
MAH(s): Nordic Group B.V.
Documents:
For adoption: PRAC AR

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

5.2.5. Aflibercept – EYLEA (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/002392/II/0009
Procedure scope: Extension of indication to include the treatment of adult patients with diabetic macular oedema. Consequential updates for SmPC sections 4.2, 4.4, 4.8, 5.1 and 5.2. SmPC section 4.8 was further updated to introduce a single table of adverse drug reactions
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.6. 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/0001
Procedure scope: Update of SmPC sections 4.2, 4.4, 4.8, and 5.1 to reflect results of study 402, a phase 3b, randomized, double-blind, placebo-controlled, event-driven study, designed to demonstrate that no excess risk of a major adverse cardiovascular event (MACE) exists following treatment with alogliptin compared with placebo when added to standard of care in adults with type 2 diabetes mellitus (T2DM) and acute coronary syndrome (ACS)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.7. 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/0002
Procedure scope: Update of SmPC sections 4.4 and 4.8 to reflect results of study 305, a phase 3, randomized, double-blind, active-controlled, 2-year study, designed to assess the efficacy and safety of alogliptin in combination with metformin compared with glipizide in combination with metformin in adults with type 2 diabetes mellitus
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.8. Alogliptin – VIPIDIA (CAP)
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/002182/WS0520/0002, EMEA/H/C/002654/WS0520/0001
Procedure scope: Update of SmPC sections 4.4, 4.8, and 5.1 to reflect results of study 305, a phase 3, randomized, double-blind, active-controlled, 2-year study, designed to assess the efficacy and safety of alogliptin in combination with metformin compared with glipizide in combination with metformin in adults with type 2 diabetes mellitus
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.9. Alogliptin, pioglitazone – INCRESYNC (CAP)
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/002178/WS0519/0003, EMEA/H/C/002654/WS0519/0003
Procedure scope: Update of SmPC sections 4.4, 4.8, and 5.1 to reflect the results of study 402, a phase 3b, randomized, double-blind, placebo-controlled, event-driven study, designed to demonstrate that no excess risk of a major adverse cardiovascular event (MACE) exists following treatment with alogliptin compared with placebo when added to standard of care in adults with type 2 diabetes mellitus and acute coronary syndrome (ACS)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.10. Atazanavir – REYATAZ (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/000494/II/0090
Procedure scope: Update of SmPC sections 4.4 and 4.8 to be in line with the latest CCDS update
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.11. Bevacizumab – AVASTIN (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000582/II/0059
Procedure scope: Update of SmPC section 4.1 in order to extend the indication of Avastin in combination with radiotherapy and temozolomide for the treatment of adult patients with newly diagnosed glioblastoma. Related changes were proposed to SmPC sections 4.2, 4.5, 4.8 and 5.1
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.12. Bevacizumab – AVASTIN (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000582/II/0063
Procedure scope: Extension of indication to include the use of Avastin in combination with chemotherapy (paclitaxel, topotecan or pegylated liposomal doxorubicin) in patients with recurrent, platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube carcinoma based on results of study MO22224 (AURELIA)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.13. Bosutinib – BOSULIF (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002373/II/0001
Procedure scope: Update of SmPC sections 4.2, 4.4 and 5.2 further to the results of a study in patients with renal impairment conducted as a post-authorisation measure
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.14. Cetuximab – ERBITUX (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/000558/II/0066
Procedure scope: Update of SmPC section 5.1 with efficacy data by RAS (KRAS and NRAS) tumour status from the CRYSTAL (EMR 62 202-013) and FIRE3 studies
MAH(s): Merck KGaA
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.15. Dabrafenib – TAFINLAR (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/002604/II/0001/G
Procedure scope: Update of SmPC sections 4.4 and 4.5 with final data from a drug-drug interaction study (BRF113771) and remove a statement in section 4.5 concerning the risk of liver injury following co-administration with paracetamol
MAH(s): GlaxoSmithKline Trading Services
Documents:

For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.16. Darunavir – PREZISTA (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/000707/II/0064
Procedure scope: Update of the SmPC with an extension of indication in treatment naïve children aged 3 to 12 years and changes in the posology of the treatment experienced children aged 3 to 12 years with darunavir resistant-associated mutations (DRV RAMs) based on the data from a 2 week qd substudy of the Phase 2 study TMC114 C228 and results from model-based pharmacokinetic simulations
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.17. Darunavir – PREZISTA (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/000707/II/0067/G
Procedure scope: Grouping of two type II variations:1) Update of SmPC sections 4.3 and 4.5 with information of CYP3A mechanism based interactions; 2) Update of SmPC sections 4.3 and 4.5 with information of CYP2D6 mechanism based interactions
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.18. Denosumab – XGEVA (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/002173/II/0016
Procedure scope: Extension of indication to add the treatment of giant cell tumour of bone in adults or skeletally mature adolescents
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.19. Efavirenz – SUSTIVA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
Procedure number(s): EMEA/H/C/000249/II/0126/G
Procedure scope: Grouped variation consisting of two consequential variations: 1) type II variation to extend the therapeutic indication to include children of 3 months of age to less than 3 year of age and weighing at least 3.5kg; 2) type IB variation to remove the oral solution pharmaceutical form for Sustiva (efavirenz) and as such upgrade the already approved "capsule sprinkle" dosing method as primary means of dosing for young patients and those that cannot swallow capsules and/or tablet
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.20. Golimumab – SIMPONI (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 (SE)

Administrative details:
Procedure number(s): EMEA/H/C/000992/X/0047
Procedure scope: Line extension to include Simponi 12.5 mg/ml solution for infusion
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.21. Iloprost – VENTAVIS (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000474/X/0043
Procedure scope: Addition of a new strength: 20 microgram/ml nebuliser solution (in 30 and 168 ampoules package sizes)
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.22. Mannitol – BRONCHITOL (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/001252/II/0011
Procedure scope: Provision of further qualitative sputum microbiology data from study DPM-B-305
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.23. Ofatumumab – ARZERRA (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001131/II/0023
Procedure scope: Extension of indication to the first line treatment of chronic lymphocytic leukaemia in combination with alkylator-based regimens in patients not eligible for fludarabine-based therapy. As a result, SmPC sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 are updated
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.24. Ponatinib – ICLUSIG (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002695/II/0005/G
Procedure scope: Grouped variations: 1) Update of SmPC section 4.5 to reflect the results from study AP24534-12-107 (open-label, non-randomized, inpatient/outpatient clinical study to assess the effect of rifampicin on the pharmacokinetics of ponatinib, when administered concomitantly in healthy subjects; 2) Update of SmPC sections 4.4, 4.5, 5.2 to reflect the results from study AP24534-12-108 (clinical study to evaluate the effect of multiple doses of lansoprazole on the pharmacokinetics of ponatinib when administered concomitantly to healthy subjects; 3) Update of SmPC sections 4.2, 4.4, 4.5 and 5.2 to reflect the results from study AP24534-12- 109 (evaluation of pharmacokinetics and safety of ponatinib in patients with chronic hepatic impairment and matched healthy subjects; 4) Update of SmPC sections 4.5 to reflect the results from study ARI-001A (simcyp physiologically-based PBPK modelling to determine the impact of different ketoconazole dosing regimens (400 mg QD versus 200 mg BID; pre-dosing with ketoconazole for multiple days versus a single day prior to co-administration of ponatinib) on the pharmacokinetics of ponatinib due to CYP3A4 inhibition); 5) Update of SmPC section 5.2 to reflect the results from study ARP350 (in vitro study to determine whether co-administered drugs that are highly bound to human plasma proteins can displace ponatinib from its binding sites); Submit the results of study ARP395 - a follow up study in which plasma samples from post 24hr collections were analysed to determine metabolite profile; Submit the results of study XT133050 - Study on the potential for ponatinib (at concentrations up to 10 µM) to induce cytochrome P450 (CYP) enzymes in cultured human hepatocytes. In addition, the RMP is submitted to reflect the data submitted and to reflect changes requested as part of variation II/002
MAH(s): Ariad Pharma Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.25. Posaconazole – NOXAFIL (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: Rafe Suvarna (UK)

Administrative details:
Product number(s): EMEA/H/C/000610/X/0033
Intended indication: Line extension to Noxafil 18mg/ml concentrate for solution for infusion
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.26. Ranibizumab – LUCENTIS (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/000715/II/0047
Procedure scope: Update of SmPC section 4.2 to harmonise the administration instructions for Lucentis across indications in line with the available clinical evidence, relevant guidelines and treatment recommendations as well as clinical practice. The proposed posology recommendations for diabetic macular oedema are further supported by the final report of the RETAIN study. In addition, SmPC sections 4.5 and 5.1 were proposed to be updated to reflect RETAIN study data including data on the concomitant treatment with thiazolidinediones. The information in SmPC section 5.1 on the RESTORE study were also proposed to be updated with data from the 2-year extension phase as previously requested by the CHMP in the context of post-authorisation procedure MEA 034
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.27. Regorafenib – STIVARGA (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/002573/II/0001
Procedure scope: Extension of indication to include treatment of patients with gastrointestinal stromal tumours (GIST) who have been previously treated with 2 tyrosine kinase inhibitors. As a consequence, SmPC sections 4.1, 4.2, 4.8 and 5.1 were proposed to be updated
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.28. Saxagliptin – KOMBOGLYZE (CAP),
saxagliptin, metformin – ONGLYZA (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/002059/WS0529/0014/G, EMEA/H/C/001039/WS0529/0024/G
Procedure scope: Update of SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.1 of Onglyza and Komboglyze, respectively, with regard to information from the results from study D1680C00003 (SAVOR), a cardiovascular outcome study, and study D1680L00002 (GENERATION), a study comparing saxagliptin with glimepiride in elderly patients
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

RMP evaluated in the context of a PSUR procedure

See also Alglucosidase alfa (MYOZYME) under 6.1.2. ; Dapagliflozin (FORXIGA) under 6.1.9. ; Decitabine (DACOGEN) under 6.1.10. ; Doripenem (DORIBAX) under 6.1.12. ; Micafungin (MYCAMINE) under 6.1.27. ; Pyronaridine, artesunate (PYRAMAX) under 6.1.36. ; Regadenoson (RAPISCAN) under 6.1.37. ; Sodium oxybate (XYREM) under 6.1.39. ; Thalidomide (THALIDOMIDE CELGENE) under 6.1.41.

RMP evaluated in the context of PASS results

See also Pioglitazone (ACTOS, GLUSTIN), pioglitazone combinations (COMPETACT, GLUBRAVA, TANDEMACT) under 7.4.2.

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

5.2.29. Dronedarone – MULTAQ (CAP)

- Evaluation of an RMP in the context of a 5-renewal of the marketing authorisation

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/001043/R/0030 (with RMP version 9.0)
MAH(s): Sanofi-aventis groupe
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.30. Saxagliptin – ONGLYZA (CAP)

- Evaluation of an RMP in the context of a 5-renewal of the marketing authorisation

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/001039/R/0023 (with RMP version 4.0)
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG

Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

RMP in the context of a stand-alone RMP procedure

5.2.31. Telbivudine – SEBIVO (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000713/RMP 061.1
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

Others

Bisphosphonates, denosumab and risk of osteonecrosis of the jaw (ONJ): consultation with Healthcare Healthcare Professionals Working Group (HPWG) and Patients and Consumers Working Party (PCWP), see under 12.12.2.1.

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[4]

6.1.1. Abiraterone – ZYTIGA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002321/PSUV/0019 (without RMP)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Alglucosidase alfa – MYOZYME (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

[4] 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

Administrative details:
Procedure number(s): EMEA/H/C/000636/PSUV/0036 (with RMP version 7.0)
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Alipogene tiparvovec – GLYBERA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002145/PSUV/0031 (without RMP)
MAH(s): uniQure Biopharma B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Bazedoxifene – CONBRIZA (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/000913/PSUV/0034 (without RMP)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Bortezomib – VELCADE (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/000539/PSUV/0070 (without RMP)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Buprenorphine, naloxone – SUBOXONE (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/000697/PSUV/0023 (without RMP)
MAH(s): RB Pharmaceuticals Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Ceftaroline fosamil – ZINFORO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002252/PSUV/0009 (without RMP)
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Choriogonadotropin alfa – OVITRELLE (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/000320/PSUV/0059 (without RMP)
MAH(s): Merck Serono Europe Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Dapagliflozin – FORXIGA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002322/PSUV/0010 (with RMP version 7.0)
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Decitabine – DACOGEN (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/002221/PSUV/0010 (with RMP version 3.0)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus influenzae type b conjugate vaccine (adsorbed) – HEXACIMA (CAP), **HEXAXIM** (Art 58), **HEXYON** (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/002702/PSUV/0006, EMEA/H/W/002495/PSUV/0015, EMEA/H/C/002796/PSUV/0006 (without RMP)
MAH(s): Sanofi Pasteur
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. Doripenem – DORIBAX (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000891/PSUV/0025 (with RMP version 7.0)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Eltrombopag – REVOLADE (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/001110/PSUV/0016 (without RMP)
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Eslicarbazepine – ZEBINIX (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/000988/PSUV/0043 (without RMP)
MAH(s): Bial - Portela & Cª, S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Exenatide – BYDUREON (CAP), BYETTA (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/002020/PSUV/0018, EMEA/H/C/000698/PSUV/0042 (without RMP)
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Fenofibrate, pravastatin – PRAVAFENIX (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/001243/PSUV/0009 (without RMP)
MAH(s): Laboratoires SMB S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. Ferumoxytol – RIENSO (CAP)

- Evaluation of a PSUR procedure

Status: *for preliminary discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002215/PSUV/0014 (without RMP)
MAH(s): Takeda Pharma A/S
Documents:
For discussion: preliminary PRAC Rapporteur PSUR AR

6.1.18. Florbetapir (^{18}F) – AMYVID (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002422/PSUV/0007 (without RMP)
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Granisetron – SANCUSO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Jolanta Gulbinovic (LT)

Administrative details:
Procedure number(s): EMEA/H/C/002296/PSUV/0030 (without RMP)
MAH(s): ProStrakan Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Human fibrinogen, human thrombin – EVICEL (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/000898/PSUV/0027 (without RMP)
MAH(s): Omrix Biopharmaceuticals N. V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/001208/PSUV/0013, EMEA/H/C/002094/PSUV/0014, EMEA/H/C/002269/PSUV/0009 (without RMP)
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Insulin degludec – TRESIBA (CAP)
Insulin degludec, insulin aspart – RYZODEG (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/002498/PSUV/0007, EMEA/H/C/002499/PSUV/0007 (without RMP)
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Insulin glulisine – APIDRA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000557/PSUV/0055 (without RMP)
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Mannitol – BRONCHITOL (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/001252/PSUV/0010 (without RMP)
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Melatonin – CIRCADIN (CAP), NAP

- Evaluation of a PSUSA[5] procedure

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

Regulatory details:
PRAC Rapporteur: Maria Alexandra Pêgo (PT)

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

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00000283/201309
MAH(s): RAD Neurim Pharmaceuticals EEC Ltd., various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002226/PSUV/0020 (without RMP)
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. Micafungin – MYCAMINE (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/000734/PSUV/0023 (with RMP version 12.0)
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Miglustat – ZAVESCA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000435/PSUV/0044 (without RMP)
MAH(s): Actelion Registration Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Ocriplasmin – JETREA (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/002381/PSUV/0008 (without RMP)
MAH(s): ThromboGenics NV
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Ofatumumab – ARZERRA (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/001131/PSUV/0026 (without RMP)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) – PANDEMRIX (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/000832/PSUV/0070 (without RMP)
MAH(s): GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Panitumumab – VECTIBIX (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/000741/PSUV/0057 (without RMP)
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Pasireotide – SIGNIFOR (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002052/PSUV/0011 (without RMP)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Pazopanib – VOTRIENT (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/001141/PSUV/0024 (without RMP)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Prucalopride succinate – RESOLOR (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/001012/PSUV/0033 (without RMP)
MAH(s): Shire Pharmaceuticals Ireland Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. Pyronaridine, artesunate – PYRAMAX (Art 58)

- 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/W/002319/PSUV/0001 (with RMP version 7.0)
MAH(s)/Scientific Opinion Holder(s): Shin Poong Pharmaceutical Co., Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Regadenoson – RAPISCAN (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/001176/PSU 012 (with RMP version 5.0)
MAH(s): Rapidscan Pharma Solutions EU Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Regorafenib – STIVARGA (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/002573/PSUV/0002 (without RMP)
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.39. Sodium oxybate – XYREM (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Maria Alexandra Pêgo (PT)

Administrative details:
Procedure number(s): EMEA/H/C/000593/PSUV/0049 (with RMP version 6.0)
MAH(s): UCB Pharma Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.40. Tadalafil – ADCIRCA (CAP), CIALIS (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001021/PSUV/0017, EMEA/H/C/000436/PSUV/0074 (without RMP)
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.41. Thalidomide – THALIDOMIDE CELGENE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000823/PSUV/0039 (with RMP version 15.0)
MAH(s): Celgene Europe Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.42. Tocilizumab – ROACTEMRA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000955/PSUV/0036 (without RMP)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[6]

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

- Evaluation of a follow-up to a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000703/LEG 079, EMEA/H/C/000732/LEG 074.1
Procedure scope: MAH's response to PSUR#13 as adopted in January 2014
MAH(s): Sanofi Pasteur MSD, SNC
Documents:
For adoption: Updated PRAC Rap AR

6.2.2. Lopinavir, ritonavir – ALUVIA (Art 58), **KALETRA** (CAP)

- Evaluation of a follow-up to a PSUR procedure

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/LEG 024.2, EMEA/H/C/000368/LEG 105. 2

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

Procedure scope: MAH's response to PSUR#5 as adopted in October 2013 (second request for supplementary information (RSI))
MAH(s): AbbVie Ltd
Documents:
For adoption: Updated PRAC Rap AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[7]

7.1.1. Brentuximab vedotin – ADCETRIS (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002455/SOB 008
Procedure scope: Revised protocol for an imposed PASS (study no. MA25101) to further study Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL), patient populations
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.2. Ethynestradiol, chlormadinone (NAP)

- Evaluation of an imposed PASS protocol

Status: *for appointment of Rapporteur and agreement of timetable*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
Procedure scope: Evaluation of a PASS protocol (following conclusion of Art.31 referral procedure for combined hormonal contraceptives with CHMP opinion adopted in November 2013) to study the risk of venous thromboembolism (VTE) associated with chlormadinone/ethynestradiol (CMA/EE) containing products
MAH(s): Gedeon Richter
Documents:
For adoption: PRAC AR
For adoption: Procedure timetable

7.1.3. Flupirtine (NAP)

- Evaluation of an imposed PASS protocol

Status: *for appointment of Rapporteur and agreement of timetable*

Regulatory details:
PRAC Rapporteur: *to be appointed*

[7] In accordance with Article 107n of Directive 2001/83/EC

Administrative details:
Procedure scope: Protocol for a non-interventional post-authorisation safety study to evaluate the effectiveness of the risk minimisation measures for the use of flupirtine 100 mg immediate-release capsules in daily practice
MAH(s): Meda Pharma
Documents:
For adoption: PRAC AR
For adoption: Procedure timetable

7.1.4. Solutions for parenteral nutrition, combination - NUMETA G16%E EMULSION FOR INFUSION and associated names (NAP)

- Evaluation of an imposed PASS protocol

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

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

Administrative details:
Procedure scope: Evaluation of a PASS protocol (following conclusion of 107i Referral) on a multicentre, non-interventional, uncontrolled, open-label, observational study in children to evaluate serum mg levels associated with the intake of Numeta G 16% E
MAH(s): Baxter
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.5. Teduglutide – REVESTIVE (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002345/ANX 003.7
Procedure scope: Revised PASS protocol for study TED R13-002 (prospective, multi-centre registry for patients with short bowel syndrome)
MAH(s): NPS Pharma Holdings Limited
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)[8]

7.2.1. Aliskiren – RASILEZ (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

[8] 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

Administrative details:
Procedure number(s): EMEA/H/C/000780/MEA 036
Procedure scope: PASS protocol for a multi-database cohort study to assess the incidence rates of colorectal hyperplasia among hypertensive patients (CSPP100A2417)
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC advice

7.2.2. Bivalirudin – ANGIOX (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/000562/MEA 022.2
Procedure scope: Updated PASS protocol for the drug utilisation study EUROVISION 2
MAH(s): The Medicines Company UK Ltd.
Documents:
For adoption: PRAC advice

7.2.3. Elvitegravir – VITEKTA (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/002577/MEA 007
Procedure scope: PASS protocol for a drug utilisation study to determine the use of rifampicin, St. John's wort, carbamazepine, phenobarbital and phenytoin with elvitegravir (EVG) in the post-marketing setting as well as to determine the incidence/prevalence and outcome of medication errors in the post-marketing setting that may result in reduced exposure to elvitegravir
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.2.4. Tocilizumab – ROACTEMRA (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/000955/MEA 041.1, EMEA/H/C/000955/MEA 045
Procedure scope: MEA 041.1: MAH's response to MEA-041 (polyarticular juvenile idiopathic arthritis (pJIA) treatment) as adopted in September 2013; MEA 045: Revised protocol for the EU BSRBR rheumatoid arthritis registry (study WA22479)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[9]

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)[10]

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

- Evaluation of PASS results

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/002073/WS0561/0093, EMEA/H/C/000780/WS0561/0092, EMEA/H/C/000964/WS0561/0062 (without RMP)
Procedure scope: Final study report for non-interventional study CSPP100A2415 (cohort study including a nested case-control analysis using data from the United States IMS PharMetrics Plus health plan claims database – assessing the prevalence and incidence of angioedema among patients with hypertension treated with aliskiren or other antihypertensive medications in the US)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

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

- Evaluation of PASS results

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

Administrative details:
Procedure number(s): EMEA/H/C/000285/WS0541/0061, EMEA/H/C/000286/WS0541/0059, EMEA/H/C/000655/WS0541/0046, EMEA/H/C/000893/WS0541/0032, EMEA/H/C/000680/WS0541/0036 (with RMP version 17)
Procedure scope: Final analysis report of the Kaiser Permanente Northern California (KPNC) non-bladder malignancy study extension (AD4833-403) (post approval commitment)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC AR

[9] In accordance with Article 107p-q of Directive 2001/83/EC
[10] 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[11]

7.5.1. Abatacept – ORENCIA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000701/MEA 046.1, EMEA/H/C/000701/MEA 048.1
Procedure scope: MEA 046.1: Updates of the Rheumatoid Arthritis registries; MEA 048.1: Annual updates of the Juvenile idiopathic arthritis (JIA) registry
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC advice

7.5.2. 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 133.8
Procedure scope: 6th annual report of the paediatric inflammatory bowel disease (IBD) registry in the US and Europe (DEVELOP) collecting data a on long-term safety and efficacy of infliximab and other therapies, safety and efficacy of variable infliximab dosing intervals, episodic therapy, monotherapy, combined infliximab and immunomodulator therapy (AZA/6-MP or MTX)
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.5.3. Paliperidone – INVEGA (CAP)

- Evaluation of interim PASS results

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/000746/MEA 019.1
Procedure scope: MAH's response to MEA 019 (abbreviated CSR - Studies (R076477-SCH-4015 and R076477-SCH-4016 - PILAR)) RSI adopted in September 2013
MAH(s): Janssen-Cilag International
Documents:
For adoption: PRAC advice

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

7.5.4. Raltegravir – **TROBALT** (CAP)

- Evaluation of interim PASS results

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

Regulatory details:

PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001245/REC 017.1
Procedure scope: Fourth quarterly update of discolouration events
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

7.5.5. Tigecycline – **TYGACIL** (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/000644/ANX 058.4
Procedure scope: Interim results of PASS aimed to evaluate Tygacil prescription patterns and monitor superinfections and treatment outcomes
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

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

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

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001032/S/0027, *Orphan* (without RMP)
MAH(s): BioMarin Europe Ltd
Documents:
For adoption: PRAC advice

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

9.1.1 Risk-based programme for routine pharmacovigilance inspections of Marketing Authorisation Holders of Centrally Authorised Products for human use

***Status**: for discussion and agreement of the programme*

Documents:
For adoption: Confidential H-pharmavcovigilance inspection programme 2014-2017 (first revision for 2014) for transmission to CHMP for adoption

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)

None

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

None

10.3. Other requests

10.3.1. Fluticasone furorate, vilanterol – RELVAR ELLIPTA (CAP)

- PRAC consultation on the evaluation of an interventional PASS protocol on CHMP's request

***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/002673/ANX 002.1
Procedure scope: CHMP request for PRAC advice on clinical trial protocol for study HZC115151: interventional post-authorisation safety study to further investigate the risk of pneumonia with Relvar Ellipta compared with other inhaled corticosteroid (ICS)/ long-acting beta2 agonists (LABA) FDC in the treatment of chronic obstructive pulmonary disease (COPD)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

10.3.2. Fluticasone furorate, vilanterol – RELVAR ELLIPTA (CAP)

- PRAC consultation on the evaluation of an interventional PASS protocol on CHMP's request

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/002673/ANX 004.1
Procedure scope: CHMP request for PRAC advice on clinical trial protocol for study HZA115150: interventional post-authorisation safety study to further investigate the risk of pneumonia with Relvar Ellipta compared with other inhaled corticosteroid (ICS)/long-acting beta2 agonists (LABA) FDC in the treatment of asthma
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

10.3.3. Laquinimod

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002546
Intended indication: Treatment of multiple sclerosis
Documents:
For adoption: PRAC advice

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

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

None

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

12.3.1. Periodic Safety Update Reports

None

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

- Consultation on the draft list, version May 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. Monitoring of Medical Literature

- Detailed guide for the monitoring of medical literature and the entry of relevant information into EudraVigilance database

Status: *for adoption*

12.5.3. Additional Monitoring

None

12.5.4. List of Product under Additional Monitoring

- Consultation on the draft List, version May 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

12.7.1.1. Principles for RMP revised process

Status: *for discussion*

12.7.1.2. Progressive multifocal leukoencephalopathy (PML): possibilities for monitoring and labelling

- Possibilities for monitoring and labelling: Development of an evidence-based strategy

Status: *for discussion*

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

None

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Risk communication and Transparency

12.10.1. Public Participation in Pharmacovigilance

None

12.10.2. Safety Communication

None

12.11. Continuous pharmacovigilance

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

None

12.11.2. Incident Management

None

12.12. Interaction with EMA Committees and Working Parties

12.12.1. Committees

None

12.12.2. Working Parties

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

- Effectiveness of risk minimisation measures: consultation on risk of osteonecrosis of the jaw

***Status**: for discussion*

12.13. Interaction within the EU regulatory network

None

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

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

12.14.1.1. ICH E2C R2(R2) Guideline on Periodic Benefit-Risk Evalaution Report

- Publication of ICH Q&A document

***Status**: for information*

12.14.2. Others

None

13. Any other business

13.1. EMA move in 2014 to new building

Status: *for discussion*