06 October 2014
EMA/PRAC/463490/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 6-9 October 2014

Chair: June Raine – Vice-Chair: Almath Spooner

6 October 2014, 13:00 – 19:00, room 3/A

7 October 2014, 08:30 – 19:00, room 3/A

8 October 2014, 08:30 – 19:00, room 3/A

9 October 2014, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

21 October 2014, 10:00 - 12:00, 5/B, 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 regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change 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. The start of referrals will also be announced in the meeting highlights. 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 relate 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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Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures
(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

Signals assessment and prioritisation
(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.
The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.
The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)
(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.
RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Assessment of Periodic Safety Update Reports (PSURs)
(Item 6 of the PRAC agenda)

A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.
PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

Post-authorisation Safety Studies (PASS)
(Item 7 of the PRAC agenda)

A PASS is a study of an authorised medicinal product carried out to obtain further information on its safety, or to measure the effectiveness of risk management measures. The results of a PASS help regulatory agencies to evaluate the safety and benefit-risk profile of a medicine.

Product related pharmacovigilance inspections
(Item 9 of the PRAC agenda)

Inspections carried out by regulatory agencies to ensure that marketing authorisation holders comply with their pharmacovigilance obligations.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

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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 6-9 October 2014

Status: *for adoption*

Document: PRAC Agenda Rev.3 due for publication on 6 October 2014

1.3. Minutes of the previous PRAC meeting on 8-11 September 2014

Status: *for adoption*

Document: PRAC final Minutes due for publication by 19 October 2014

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

None

2.3. Procedures for finalisation

None

2.4. Planned public hearings

None

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

3.1. Newly triggered Procedures

None

3.2. Ongoing Procedures

None

3.3. Procedures for finalisation

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

- Review of the benefit-risk balance following the 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 and agreement of a recommendation to CHMP*

Regulatory details:

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

Administrative details:
Procedure number(s): EMEA/H/C/002695/A-20/0003
MAH(s): Ariad Pharma Ltd
Documents:
For adoption: PRAC AR, PRAC recommendation

3.3.2. **Testosterone** (NAP)

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

Status: *for discussion and agreement of a recommendation to CMD(h)*

Regulatory details:

PRAC Rapporteur: Torbjörn Callréus (DK)
PRAC Co-Rapporteur: Maia Uusküla (EE)

Administrative details:
Procedure number(s): EMEA/H/A-31/1396
MAH(s): various
Documents:
For adoption: PRAC AR, PRAC recommendation

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

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

Status: *for discussion and agreement of a recommendation to CMD(h)*

Regulatory details:

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

Administrative details:
Procedure number(s): EMEA/H/A-31/1387
MAH(s): Sanofi-aventis GmbH, various
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

3.5. Others

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. **Amiodarone** (NAP)

- Signal of Syndrome of Inappropriate Antidiuretic Hormone (SIADH)

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18091 – New signal
MAH(s): various
Lead MS: NL
Documents:
For adoption: PRAC recommendation

4.1.2. **Exenatide - BYETTA** (CAP)

- Signal of goitre and worsening, enlargement of goitre

Status: *for discussion*

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

Administrative details:
EPITT 18077 – New signal
MAH(s): AstraZeneca AB
Lead MS: SE
Documents:
For adoption: PRAC recommendation

4.1.3. **Tocilizumab - ROACTEMRA** (CAP)

- Signal of cholecystitis

[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: Brigitte Keller-Stanislawski (DE)

Administrative details:
EPITT 18092– New signal
MAH(s): Roche Registration Ltd
Lead MS: DE
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. **Aflibercept** – **EYLEA** (CAP)

- Signal of higher systemic exposure compared to ranibizumab after intravitreal injection

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
EPITT 18112 – New signal
MAH(s): Bayer Pharma AG
Lead MS: FR
Documents:
For adoption: PRAC recommendation

4.2.2. **Aripiprazole – ABILIFY** (CAP)

- Signal of hyperprolactinaemia

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
EPITT 18086 – New signal
MAH(s): Otsuka Pharmaceutical Europe Ltd
Lead MS: PT
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. **Atazanavir – REYATAZ** (CAP)

- Signal of haemolytic anaemia

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
EPITT 17921 - Follow-up May 2014
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC recommendation

4.3.2. Valproate and related substances (NAP)

- Signal of mitochondrial toxicity

Status: *for discussion*

Regulatory details:
PRAC Rapporteur*:* Martin Huber (DE)

Administrative details:
EPITT 17956 – Follow-up May 2014
MAH(s): Neuraxpharm Arzneimittel GmbH, Sanofi-Aventis, various
Documents:
For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Afamelanotide

- 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/002548, *Orphan*
Intended indication: Treatment of phototoxicity
Applicant: Clinuvel (UK) Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.2. Bortezomib

- 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/003984, *Generic*
Intended indication(s): Treatment of multiple myeloma
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.3. Docetaxel

- 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/003925, *Generic*
Intended indication(s): Treatment of breast cancer, non-small cell lung cancer, prostate cancer, metastatic gastric adenocarcinoma and head and neck cancer
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.4. Duloxetine

- 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/004000, *informed consent*
Intended indication(s): Treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalised anxiety disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.5. Ex vivo expanded autologous human corneal epithelial cells containing stem 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/002450, *ATMP, Orphan*
Intended indication(s): Treatment of limbal stem cell deficiency
Applicant: Chiesi Farmaceutici S.p.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.6. Glycerol phenylbutyrate

- 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/003822, *Orphan*
Intended indication(s): Treatment of patients with urea cycle disorders
Applicant: Hyperion Therapeutics Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.7. Insulin human

- 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/003858
Intended indication(s): Treatment of diabetes
Documents:

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

5.1.8. 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(s): Treatment of obesity
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.9. Naltrexone, bupropion

- 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/003687
Intended indication(s): Management of obesity
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.10. Olaparib

- 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/003726
Intended indication: Treatment of ovarian cancer
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.11. Paliperidone

- 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/004066, *informed consent*
Intended indication(s): Treatment of schizophrenia in adult patients
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.12. Pembrolizumab

- 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/003820

Intended indication(s): Treatment of unresectable or metastatic melanoma in adults
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 procedure

For adoption: PRAC AR

5.2.1. Desloratadine – AERIUS (CAP), AZOMYR (CAP), NEOCLARITYN (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000313/WS0641/0077, EMEA/H/C/000310/WS0641/0080, EMEA/H/C/000314/WS0641/0075
Procedure scope: Update of the RMP (version 1.0)
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC AR

5.2.2. Elvitegravir, cobicistat, emtricitabine, tenofovir – STRIBILD (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002574/II/0036/G
Procedure scope: Grouped variations to 1) update the RMP with information on applications recently finalised and studies recently concluded, 2) update the due date for a category 3 study (GS-US-236-0140), 3) implement the agreed change in due date for a category 3 study (GS-US-236-0141)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC AR

5.2.3. Everolimus – VOTUBIA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002311/II/0021

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

Procedure scope: Update of the RMP (version 8)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

5.2.4. Fentanyl – **INSTANYL** (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000959/II/0028
Procedure scope: Updated RMP to add a planned study to evaluate the effectiveness of the educational material approved in July 2013 as requested by PRAC and addition of new potential risks as requested by PRAC following the assessment of the latest PSUR and RMP
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC AR

5.2.5. Imiglucerase – **CEREZYME** (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000157/II/0087
Procedure scope: Update of the RMP to reflect the results of the THEME survey, which tested the effectiveness of the educational materials for home infusion, evaluated as PAM 40.7 and to reflect the results of the sixth annual report on the pregnancy and lactation Registry in Gaucher patients, submitted in parallel of the variation as PAM 40.8
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC AR

5.2.6. Influenza vaccine (split viron, inactivated) – **IDFLU** (CAP), **INTANZA** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000966/WS0638/0028, EMEA/H/C/000957/WS0638/0031
Procedure scope: Update of the RMP (version 8)
MAH(s): Sanofi Pasteur MSD SNC
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.7. Insulin human – INSUMAN (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000201/II/0102
Procedure scope: Update of the RMP for Insuman implantable 400 IU/ml version 2.0
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC AR

5.2.8. Rivaroxaban – XARELTO (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000944/II/0034
Procedure scope: Proposal to amend Annex II of the marketing authorization: As an alternative to the study imposed as specific obligation, Bayer proposes to extend and expand the ongoing epidemiological rivaroxaban PASS program to fulfil the CHMP objective on the post approval program for the ACS indication
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC AR

5.2.9. Romiplostim – NPLATE (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000942/II/0045
Procedure scope: Type II variation to remove the existing education programme (both the physician education booklet and dosing calculator) as a condition of the Nplate marketing authorisation. An updated EU RMP (version 14, dated 01 July 2014) is submitted with this variation in Module 1.8.2, in which, distribution of the education material is removed where it is specified as an additional risk minimisation activity, and is replaced by routine risk minimisation only
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC AR

5.2.10. Teduglutide – REVESTIVE (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002345/II/0009, *Orphan*
Procedure scope: Update of the RMP (version 6.0)
MAH(s): NPS Pharma Holdings Limited
Documents:
For adoption: PRAC AR

5.2.11. Temoporfin – FOSCAN (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000318/II/0036
Procedure scope: Submission of a new RMP (version 1.0)
MAH(s): Biolitec Pharma Ltd
Documents:
For adoption: PRAC AR

5.2.12. Ulipristal – ELLAONE (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001027/II/0033
Procedure scope: Submission of the final clinical study report (HRA 2914-012): prospective, multicentre observational study to assess clinical follow-up and outcomes of pregnancies exposed to ulipristal
MAH(s): Laboratoire HRA Pharma, SA
Documents:
For adoption: PRAC AR

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

5.2.13. Adalimumab – HUMIRA (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/000481/II/0134
Procedure scope: Extension of indication to add the treatment of chronic plaque psoriasis in children and adolescents from 4 years of age, based on data from study M04-717: multicentre, randomised, double-dummy, double-blind study evaluating two doses of adalimumab versus methotrexate in paediatric subjects with chronic plaque psoriasis. As a consequence SmPC sections 4.1, 4.2, 4.8, 5.1 and 5.2 of have been updated and the Package Leaflet has been updated accordingly. In addition, the MAH proposed minor editorial changes in the SmPC and Package Leaflet. A revised RMP version 11.2 was included as part of this application
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.14. Ambrisentan – VOLIBRIS (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000839/II/0039, *Orphan*
Procedure scope: Update of SmPC section 4.4 in relation to the current recommendations for liver function and SmPC section 5.1 with data on aminotransferase abnormalities from an analysis of the CSR for PASS 'AMB110094 (VOLT)'. The current 'Health care Professional information' in Annex II has been updated accordingly as well as the Package Leaflet and RMP (revised version 6 provided)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.15. Bedaquiline – SIRTURO (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/002614/II/0002/G
Procedure scope: Grouping of 8 variations for the submission of the final report for non-clinical studies listed as category 3 in the RMP. Update of section 5.3 of the SmPC with the data from the final study report for rat carcinogenicity (TMC207-TOX9596). Submission of the final study reports for the studies 1692-0049281 (FK 10493), 1692-0049280 (FK 10497), 1692-0055447 (FK 10603), 1692-0054807 (FK 10542), 1692-0055364 (FK 10608), 1692-0055365 (FK 10641) and 1692-0055366 (FK 10604) relating to drug-drug interactions with potent inhibitors of drug-metabolising enzymes and transporters. No changes to the product information are proposed based on these data
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.16. Empagliflozin – JARDIANCE (CAP)

- Evaluation of an RMP in the context of a variation

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/002677/II/0002
Procedure scope: Update of SmPC section 4.5 in order to reflect the results of an in vitro study investigating the inhibition of UGT2B7, UGT1A3, UGT1A8, and UGT1A9 by empagliflozin. The RMP was updated to reflect the finalisation of the study and results
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.17. Enzalutamide – XTANDI (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: Dolores Montero Corominas (ES)

Administrative details:
Procedure number(s): (EMEA/H/C/002639/II/0008
Procedure scope: Extension of indication for the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. Consequently, changes are proposed to SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2. The package leaflet is updated accordingly
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.18. Human fibrinogen, human thrombin – EVICEL (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000898/II/0026
Procedure scope: RMP update
MAH(s): Omrix Biopharmaceuticals N. V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.19. Human protein C – CEPROTIN (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/000334/II/0079
Procedure scope: Update of SmPC sections 4.1, 4.2 and 5.1 in order to extend the indication to treatment of patients with Purpura fulminans due to severe acquired protein C deficiency with consequential updates of sections 4.8 and 5.2. Additionally, section 4.6 information has been revised. The PL is updated accordingly
MAH(s): Baxter AG
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/0027
Procedure scope: Extension of indication to include the treatment of cystic fibrosis in patients aged 18 years and older who have a R117H mutation in the CFTR gene. Consequently, changes are proposed to SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 and to the Package Leaflet
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.21. Lamivudine, abacavir – EPIVIR (CAP), LAMIVUDINE VIIV (CAP), ZIAGEN (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000107/WS0578/0092, EMEA/H/W/000673/WS0578/0027, EMEA/H/C/000252/WS0578/0078
Procedure scope: Update of SmPC sections 4.2, 4.8, 5.1 and 5.2 to update the information related to the extension of the once-daily oral administration of abacavir, 3TC and Lamivudine ViiV to HIV-1–infected paediatric patients aged 3 months and older, according to amended weight-band ranges, based on the final clinical study report of the ARROW study. In addition, the safety, pharmacokinetic (PK) and efficacy data support harmonisation with the World Health Organization (WHO) Treatment Guidelines for dosing of ABC scored tablet and 3TC scored tablet in subjects $\geqslant$ 14 kg. The Package Leaflet is updated accordingly
MAH(s): ViiV Healthcare UK Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.22. Nitisinone – ORFADIN (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: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000555/X/0041
Procedure scope: Addition of an oral suspension 4 mg/ml as additional pharmaceutical form
MAH(s): Swedish Orphan Biovitrum International AB
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.23. Oseltamivir – TAMIFLU (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000402/II/0107
Procedure scope: Change of study NV20234 objectives post-authorisation measure in immunocompromised patients. Study NV20234 is a double blinded, randomized, stratified, multicentre trial evaluating conventional and double dose oseltamivir in the treatment of immunocompromised patients with influenza
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.24. Pazopanib – VOTRIENT (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/001141/II/0027/G
Procedure scope: Update of SmPC sections 4.4 and 4.8 in order to update the safety information. The Package Leaflet is updated accordingly
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.25. Peginterferon alfa-2a – PEGASYS (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/000395/II/0075
Procedure scope: Update of SmPC sections 4.1, 4.4 and 4.8 based on data from the long term follow up study to the paediatric study NV17424. The package leaflet is updated accordingly
MAH(s): Roche Registration Ltd
Documents:

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

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

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

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

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:
Procedure number(s): EMEA/H/C/001104/II/0111
Procedure scope: Extension of indication to add pneumonia to the authorised indication for adults (≥18 years of age), based on data from the recently completed community–acquired pneumonia immunisation trial in adults (CAPiTA), which studied the efficacy of Prevenar 13 in preventing vaccine-serotype pneumococcal community-acquired pneumonia (CAP) and vaccine-serotype invasive pneumococcal disease (IPD) in adults aged 65 years and older. As a consequence the MAH proposes to update SmPC sections 4.1, 4.8 and 5.1 and to update the Package Leaflet accordingly
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.27. Riociguat – ADEMPAS (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/002737/II/0001
Procedure scope: Evaluation of non-clinical study reports ph-37417 and ph-37435; in vitro studies undertaken to determine the M-1 potential to inhibit renal efflux transporters MATE1 and MATE2K. A revised RMP version 3.0 was provided as part of the application. No changes to the product information are proposed
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.28. Ritonavir – NORVIR (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: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000127/X/0127
Procedure scope: Line extension for a new oral powder formulation as a replacement for the currently marketed oral solution for a more suitable ritonavir formulation for the paediatric population
MAH(s): AbbVie Ltd.
Documents:

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

5.2.29. Tegafur, gimeracil, oteracil – TEYSUNO (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/001242/II/0018
Procedure scope: Update of SmPC sections 4.1, 4.2 and 5.1 in order to add the use in combination therapy of Teysuno with oxaliplatin (with or without epirubicin) with consequential updates to sections 4.3, 4.4, 4.5, 4.6, 4.8
MAH(s): Nordic Group B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.30. Trastuzumab – KADCYLA (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/002389/II/0006/G
Procedure scope: Grouped variation application to update 1) SmPC section 4.6 of and section 2 of the Package Leaflet in order to change the duration of contraception to be used after trastuzumab emtansine treatment from 6 to 7 months in line with the trastuzumab product information; 2) due dates concerning the submission of the overall survival outcome data from the pivotal study BO21977 (EMILIA) in Annex II of the product information and the RMP; 3) due date in the RMP concerning the submission of data from the study BO25499; 4) due date in the RMP concerning the submission of data for study BO28407 (KAITLIN). A revised RMP version 4.0 has been provided as part of this application
MAH(s): Roche Registration Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.31. Ustekinumab – STELARA (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/000958/II/0041
Procedure scope: Update of SmPC section 4.8 to add the adverse reactions of skin exfoliation and erythrodermic psoriasis further to the request of the CHMP to implement the outcome of a PRAC signal recommendation. The Package Leaflet is updated accordingly
MAH(s): Janssen-Cilag International N.V.
Documents:

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

RMP evaluated in the context of a PSUR procedure

See also Certolizumab pegol – CIMZIA 6.1.6. , Eculizumab – SOLIRIS 6.1.12. , Fingolimod – GILENYA 6.1.17. , Ibritumomab tiuxetan – ZEVALIN 6.1.23. , Mifamurtide – MEPACT 6.1.32.

RMP evaluated in the context of PASS results

See also Human papillomavirus vaccine – GARDASIL, SILGARD 7.4.2. , Eltrombopag – REVOLADE 7.4.3. , Peginterferon alfa-2a – PEGASYS 7.4.4.

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

None

RMP evaluated in the context of a stand-alone RMP procedure

None

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[3]

6.1.1. Afatinib – GIOTRIF (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/002280/PSUV/0004
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Alemtuzumab – LEMTRADA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/003718/PSUV/0005
MAH(s): Genzyme Therapeutics Ltd

[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

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Aprepitant – EMEND (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/000527/PSUV/0044
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. 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/PSUV/0026
MAH(s): Glaxo Group 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/PSUV/0007
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Certolizumab pegol – CIMZIA (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/001037/PSUV/0041 (with RMP version 10.0)
MAH(s): UCB Pharma SA
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Cholic acid – ORPHACOL (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/001250/PSUV/0004
MAH(s): Laboratoires CTRS – Boulogne-Billancourt
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Dabigatran – PRADAXA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/PSUV/0069
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. 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/PSUV/0008
MAH(s): Orion Corporation
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Dexrazoxane – SAVENE (CAP), NAP

- Evaluation of a PSUSA[4] procedure

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

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001001/201402
MAH(s): Clinigen Healthcare Ltd, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Dimethyl fumarate – TECFIDERA (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/002601/PSUV/0005
MAH(s): Biogen Idec Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. 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/PSUV/0069 (with RMP version 11.0)
MAH(s): Alexion Europe SAS
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Emtricitabine – EMTRIVA (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/000533/PSUV/0096
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Enfuvirtide – FUZEON (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/000514/PSUV/0042
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Etravirine – INTELENCE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Patrick Maison (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000900/PSUV/0038
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Everolimus – AFINITOR (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/001038/PSUV/0039
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. 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/PSUV/0025
MAH(s): Novartis Europharm Ltd

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Fingolimod – GILENYA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002202/PSUV/0029 (with RMP version 8.0)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. 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/0009
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Fosaprepitant – IVEMEND (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/000743/PSUV/0025
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Hepatitis B vaccine (rDNA) – HBVAXPRO (CAP), NAP

- Evaluation of a PSUSA[5] 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

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001597/201402
MAH(s): Sanofi Pasteur MSD SNC, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Glycopyrronium bromide – ENUREV BREEZHALER (CAP), **SEEBRI BREEZHALER** (CAP), **TOVANOR BREEZHALER** (CAP)
Glycopyrronium bromide, indacaterol - **ULTIBRO BREEZHALER** (CAP), **ULUNAR BREEZHALER** (CAP), **XOTERNA BREEZHALER** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002691/PSUV/0006, EMEA/H/C/002430/PSUV/0006, EMEA/H/C/002690/PSUV/0007; EMEA/H/C/002679/PSUV/0003, EMEA/H/C/003875/PSUV/0002, EMEA/H/C/003755/PSUV/0005
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Human fibrinogen, human thrombin – EVARREST (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/002515/PSUV/0004
MAH(s): Omrix Biopharmaceuticals N. V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Ibritumomab tiuxetan – ZEVALIN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000547/PSUV/0040 (with RMP version 4.0)
MAH(s): Spectrum Pharmaceuticals B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Infliximab – **INFLECTRA** (CAP), **REMSIMA** (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/002778/PSUV/0012, EMEA/H/C/002576/PSUV/0010
MAH(s): Hospira UK Limited, Celltrion Healthcare Hungary Kft.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. 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/0010, EMEA/H/C/002499/PSUV/0011
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. 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/PSUV/0025
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. 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/PSUV/0035

MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Meningococcal group a, c, w135 and y conjugate vaccine – MENVEO (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/001095/PSUV/0045
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Methylnaltrexone – RELISTOR (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/000870/PSUV/0032
MAH(s): TMC Pharma Services Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Mifamurtide – MEPACT (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/000802/PSUV/0037 (with RMP version9.0)
MAH(s): Takeda France SAS
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Octocog alfa – ADVATE (CAP), NAP

- Evaluation of a PSUSA[6] procedure

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

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/PSUSA/00002200/201402
MAH(s): Baxter AG, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Pandemic influenza vaccine (H1N1v) (surface antigen, inactivated, adjuvanted) – FOCETRIA (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/000710/PSUV/0033
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Pandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture) – PANDEMIC INFLUENZA VACCINE H5N1 BAXTER (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/PSUV/0019
MAH(s): Baxter AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Pegloticase – KRYSTEXXA (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/002208/PSUV/0004
MAH(s): Savient Pharma Ireland Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. 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: Jean-Michel Dogné (BE)

Administrative details:
Procedure number(s): EMEA/H/C/002089/PSUV/0010
MAH(s): Baxter Innovations GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Raltegravir – ISENTRESS (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/000860/PSUV/0049
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Rasburicase – FASTURTEC (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/000331/PSUV/0041
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.39. 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/0004

MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.40. Retigabine – TROBALT (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/001245/PSUV/0029
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.41. Riociguat – ADEMPAS (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/002737/PSUV/0002
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.42. 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/PSUV/0032
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.43. Tacrolimus – PROTOPIC (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

Administrative details:
Procedure number(s): EMEA/H/C/000374/PSUV/0057
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.44. Teduglutide – REVESTIVE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002345/PSUV/0008
MAH(s): NPS Pharma Holdings Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.45. 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/PSUV/0017
MAH(s): Nordic Group B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.46. 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/PSUV/0028
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.47. 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/PSUV/0014
MAH(s): Clinigen Healthcare Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.48. 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/PSUV/0082
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.49. Travoprost – TRAVATAN (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/00003011/201402
MAH(s): Alcon Laboratories (UK) Ltd, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.50. Travoprost, timolol – DUOTRAV (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/000665/PSUV/0042
MAH(s): Alcon Laboratories (UK) Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

6.1.51. Voriconazole – VFEND (CAP), VORICONAZOLE ACCORD (CAP), NAP

- Evaluation of a PSUSA[8] 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/00003127/201402
MAH(s): Pfizer Limited, Accord Healthcare Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.52. Vortioxetine – BRINTELLIX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Veerle Verlinden (BE)

Administrative details:
Procedure number(s): EMEA/H/C/002717/PSUV/0003
MAH(s): H. Lundbeck A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.53. Zonisamide – ZONEGRAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

Administrative details:
Procedure number(s): EMEA/H/C/000577/PSUV/0073
MAH(s): Eisai Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[9]

6.2.1. Aliskiren – RASILEZ (CAP)
aliskiren, amlodopine – RASILAMLO (CAP)
aliskiren, hydrochlorothiazide – RASILECT HTC (CAP

- Evaluation of a follow-up to a PSUR procedure

[8] PSUR single assessment, referring to CAP, NAP
[9] Follow up as per the conclusions of the previous PSUR procedure, assessed outside of the next PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000780/LEG 038, EMEA/H/C/002073/LEG 014, EMEA/H/C/000964/LEG 033
Procedure scope: MAH's response to PSUV/0090 and PSUV/0060 as adopted in April 2014
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: Updated PRAC Rapp AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[10]

7.1.1. **Aprotinin** (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 number(s): EMEA/H/N/PSP/0004
Procedure scope: Evaluation of a protocol for a non-interventional post-authorisation safety study of pattern of use of Nordic aprotinin
MAH(s): Disphar International B.V (Nordic Group)
Documents:
For adoption: Procedure timetable

7.1.2. **Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony stimulating factor (sipuleucel-T) – PROVENGE** (CAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

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

Administrative details:
Procedure number(s): EMEA/H/C/002513/ANX 001
Procedure scope: PASS protocol P13-1 for an observational EU-based registry of men with mCRPC (therapy in men with metastatic castrate-resistant prostate cancer) to evaluate overall survival, the risk of ischemic stroke or myocardial infarction following treatment with Provenge and other identified and potential risks
MAH(s): Dendreon UK Ltd
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

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

7.1.3. Cyproterone, ethinylestradiol – DIANE 35 & other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms (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 number(s): NL/H/xxxx/WS/065
Procedure scope: Evaluation of a protocol for a drug utilisation study as per the conclusions of the Article 107i referral procedure
MAH(s): Bayer
Documents:
For adoption: Procedure timetable

7.1.4. Ethinylestradiol, gestodene transdermal patch (NAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure scope: Evaluation of a revised PASS protocol on the European active surveillance study comparing regimens of application in combined hormonal contraception (EURAS-CORA)
MAH(s): Bayer (Apleek)
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.1.5. Hydroxyethyl starch (HES) (NAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

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

Administrative details:
Procedure scope: Evaluation of a PASS protocol (drug utilisation study) to assess the effectiveness of the risk minimisation taken following the European Commission decision dated 19 December 2013 for the referral procedure EMEA/H/A-107I/1376
MAH(s): B. Braun Melsungen AG (Tetraspan, Venofundin), Fresenius Kabi Deutschland GmbH (Volulyte, Voluven Fresenius, Voluven, HyperHAES, HAES-steril), Serumwerk Bernburg AG (VitaHES, Vitafusal, Plasma Volume Redibag, PlasmaHES Redibag, Hesra, Hesra infuusioneste)
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[11]

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)

Administrative details:
Procedure number(s): EMEA/H/C/000780/MEA 036.1
Procedure scope: Revised PASS protocol for a non-interventional study CSPP100A2417: multi-database cohort study to assess the incidence rates of colorectal hyperplasia among hypertensive patients
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.2. Darunavir – **PREZISTA** (CAP)

- Evaluation of a PASS protocol

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/MEA 069.1
Procedure scope: Revised PASS protocol for a study to assess growth abnormalities (height) in children using Prezista in which data will be compared with data from the European pregnancy and paediatric HIV cohort collaboration (EPPICC) or other data in children on other antiretroviral(s) (ARV)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC advice

7.2.3. Dextromethorphan, quinidine – **NUEDEXTA** (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/002560/MEA 002.1
Procedure scope: MAH's response to the list of questions for an EU registry study to assess the safety, tolerability and effectiveness of dextromethorphan/quinidine in the treatment of pseudobulbar affect (PBA) (protocol: 13-AVR-402)
MAH(s): Jenson Pharmaceutical Services Ltd
Documents:
For adoption: PRAC advice

[11] 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

7.2.4. Etanercept – ENBREL (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/000262/MEA 156
Procedure scope: Evaluation of the proposed changes in the target number of recruited paediatric psoriasis patients for the PASS study (0081X1-4654): PURPOSE Study: long-Term, prospective, observational cohort study of the safety and effectiveness of etanercept in the treatment of paediatric psoriasis patients in a naturalistic setting
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

7.2.5. Fenofibrate, simvastatin – CHOLIB (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/002559/MEA 002.1
Procedure scope: Revised protocol for a drug utilisation research (DUR) study on the use of fenofibrate and simvastatin fixed combination: a European multinational study using secondary health records databases
MAH(s): Abbott Healthcare Products Ltd.
Documents:
For adoption: PRAC advice

7.2.6. Fingolimod – GILENYA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002202/MEA 031
Procedure scope: MAH's response to CHMP's request for the update of the long term safety study CFTY720D2406, as detailed in the final assessment report of variation II/21
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

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

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002422/MEA 002.2
Procedure scope: MAH's response to MEA-002.1 [European drug usage survey for Amyvid] as adopted in December 2013 including a revised PASS protocol (Study I6E-MC-AVBF)
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC advice

7.2.8. Ruxolitinib – JAKAVI (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/002464/MEA 012
Procedure scope: Final study protocol v1.0 for study CINC424A2408 - Jakavi utilisation in major EU markets
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.9. Telavancin – VIBATIV (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/001240/MEA 017.1
Procedure scope: Revised PASS protocol as MAH's response to MEA-017 [Audit of the effectiveness of educational materials for telavancin / Study CLIN_2014_TLV_003] RSI as adopted in June 2014
MAH(s): Clinigen Healthcare Ltd
Documents:
For adoption: PRAC advice

7.2.10. Telavancin – VIBATIV (CAP)

- Evaluation of a PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number: EMEA/H/C/001240/ANX 007.2

Procedure scope: MAH's response to MEA-007.1 (pregnancy exposure registry 9809-CL-1409) as adopted in June 2014, including updated PASS protocol (9809-CL-2404)
MAH(s): Clinigen Healthcare Ltd
Documents:
For adoption: PRAC advice

7.2.11. Tenofovir, disoproxil – VIREAD (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000419/MEA 256.3
Procedure scope: Revised PASS protocol as MAH's response to MEA 256.3 [HIV drug utilisation study protocol GS-EU-104-0433] following a request for supplementary information adopted at CHMP in January 2014
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[12]

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)[13]

7.4.1. Human papillomavirus vaccine types 6, 11, 16, 18 (recombinant, adsorbed) – GARDASIL (CAP), SILGARD (CAP)

- Evaluation of PASS results

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/000703/WS0643/0053 (with RMP version 8.0), EMEA/H/C/000732/WS0643/0049 (with RMP)
Procedure scope: Submission of the final pregnancy registry report in order to address PAMs MEA 65 (Gardasil) and MEA 64 (Silgard) on submission of annual pregnancy registry reports. The RMP is updated accordingly
MAH(s): Sanofi Pasteur MSD SNC (Gardasil), Merck Sharp & Dohme Limited (Silgard)
Documents:
For adoption: PRAC AR

7.4.2. Eltrombopag – REVOLADE (CAP)

- Evaluation of PASS results

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

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001110/II/0014/G (with RMP version 23.0)
Procedure scope: Submission of four final study reports for the fulfilment of RMP commitments and a proposal for changes in the RMP (replacement of a study and date extensions for RMP commitments listed in section III 4.3)
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC AR

7.4.3. Peginterferon alfa-2a – PEGASYS (CAP)

- Evaluation of PASS results

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/000395/II/0076 (with RMP version 7.0)
Procedure scope: Submission of the final clinical study report for study MV22255 (GUARD-C) (MEA 43.1) to add safety analysis of serious adverse events (SAEs) from an international observational cohort PASS on the prediction of unwanted adverse effects in individuals infected with chronic hepatits C receiving a long acting interferon plus ribavarin. The RMP is updated accordingly
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC AR

7.4.4. Ponatinib – ICLUSIG (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002695/II/0012 (without RMP)
Procedure scope: Submission of a study as part of the pharmacovigilance plan to evaluate whether ponatinib is an effective treatment in patients with newly diagnosed chronic myeloid leukaemia (CML) in chronic phase
MAH(s): Ariad Pharma Ltd
Documents:
For adoption: PRAC AR

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[14]

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

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000481/MEA/046.4
Procedure scope: Fifth year interim report from a registry in Juvenile Idiopathic Arthritis (JIA) patients
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC advice

7.5.2. **Adalimumab – HUMIRA** (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000481/MEA 080.2
Procedure scope: First annual registry report 2014 from a long-term non-interventional registry to assess safety and effectiveness of adalimumab in paediatric patients with moderately to severely active Crohn's disease (CD) (P11-292)
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC advice

7.5.3. **Canagliflozin – INVOKANA** (CAP)
canagliflozin, metformin - VOKANAMET (CAP)

- Evaluation of interim PASS results

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/MEA 005, EMEA/H/C/002656/MEA 004
Procedure scope: Independent data monitoring committee (IDMC) status report for the DIA3008 CANVAS study
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC advice

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

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

8.1.1. Galsulfase – NAGLAZYME (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000640/S/0053 (without RMP)
MAH(s): BioMarin Europe Ltd
Documents:
For adoption: PRAC advice

8.1.2. Lomitapide – LOJUXTA (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002578/S/0011 (without RMP)
MAH(s): Aegerion Pharmaceuticals Limited
Documents:
For adoption: PRAC advice

8.1.3. Modified vaccinia Ankara virus – IMVANEX (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002596/S/0010 (without RMP)
MAH(s): Bavarian Nordic A/S
Documents:
For adoption: PRAC advice

8.1.4. Vandetanib – CAPRELSA (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002315/R/0009 (without RMP)
MAH(s): AstraZeneca AB
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.

9.3. Others

None

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

None

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

11.3.1. **Cabergoline** (NAP)

- PRAC consultation on PASS study results, upon Italy's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Jelena Ivanovic (IT)

Administrative details:
Procedure scope: Final report for the study on utilisation of cabergoline for compliance with risk minimisation activities (SUCRE)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

11.3.2. **Isotretinoin** (NAP)

- PRAC consultation on risk minimisation measures, upon Netherland's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Sabine Straus (NL)

Administrative details:
Procedure scope: Evaluation of the results of a population-based study
MAH(s): various
Documents:
For adoption: PRAC advice

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

None

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 October 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

None

12.5.2. Additional Monitoring

None

12.5.3. List of Product under Additional Monitoring

- Consultation on the draft List, version October 2014

Status: *for information*

Documents:
For discussion: Revised additional monitoring List

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

- Update on collaboration with WHO regarding ICSR provision

Status: *for discussion*

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

- Non-imposed PASS protocols – proposal for a revised process

Status: *for discussion*

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Risk communication and Transparency

12.10.1. Public Participation in Pharmacovigilance

None

12.10.2. Safety Communication

None

12.11. Continuous pharmacovigilance

None

12.11.1. Incident Management

None

12.12. Interaction with EMA Committees and Working Parties

12.12.1. Committees

None

12.12.1. Blood Products Working Party

- Guideline on core SmPC for human plasma derived recombinant coagulation factor IX products

Status: *for discussion*

12.13. Interaction within the EU regulatory network

12.13.1. Policy on Scientific Publication and Representation

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

12.15. Others

None

13. Any other business

13.1. Marketing authorisation applications: planned submissions for the remainder of 2014

Status: *for discussion*

13.2. New organisational model: Review of the initial marketing authorisation applications (MAA) process

Status: *for discussion*

13.3. Update on EMA Medical Literature Monitoring Service project

Status: *for discussion*