6 January 2015
EMA/PRAC/9223/2015
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 6-9 January 2015

Chair: June Raine – Vice-Chair: Almath Spooner

06 January 2015, 13:00 – 19:00, room 3/A

07 January 2015, 08:30 – 19:00, room 3/A

08 January 2015, 08:30 – 19:00, room 3/A

09 January 2015, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

22 January 2015, 10:00-12:00, room 6/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 January 2015

Status: *for adoption*

Document: PRAC Agenda Rev.3 due for publication 6 January 2015

1.3. Minutes of the previous PRAC meeting on 1-4 December 2014

Status: *for adoption*

Document: PRAC final Minutes due for publication by 16 January 2015

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

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

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

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

- Signal of deafness

Status: *for discussion*

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

Administrative details:
EPITT 18175 – New signal
MAH(s): Amgen Europe B.V.
Lead MS: SE
Documents:
For adoption: PRAC recommendation

4.1.2. **Olanzapine – ZYPADHERA** (CAP), **ZYPREXA** (CAP), **ZYPREXA VELOTAB** (CAP)

- Signal of angle closure glaucoma

[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: Terhi Lehtinen (FI)

Administrative details:
EPITT 18159 – New signal
MAH(s): Eli Lilly Nederland B.V.
Lead MS: FI
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. Amiodarone (NAP)
Daclatasvir - DAKLINZA (CAP)
Sofosbuvir - SOVALDI (CAP)

- Signal of arrhythmia

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
EPITT 18177 – New signal
MAH(s): Gilead Sciences International Ltd (Sovaldi), Bristol-Myers Squibb Pharma EEIG (Daklinza), various
Lead MS: PT
Documents:
For adoption: PRAC recommendation

4.2.2. Benzodiazepines (NAP)

- Signal of Alzheimer's disease

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18195 – New signal
MAH(s): various
Lead MS: DK
Documents:
For adoption: PRAC recommendation

4.2.3. Clopidogrel – PLAVIX (CAP)
Prasugrel – EFIENT (CAP)

- Safety of dual antiplatelet therapy

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
EPITT 18184 – New signal
MAH(s): Eli Lilly Nederland B.V. (Efient), Sanofi Clir SNC (Plavix)
Lead MS: PT
Documents:
For adoption: PRAC recommendation

4.2.4. Leflunomide – ARAVA (CAP)

- Signal of colitis

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
EPITT 18189 – New signal
MAH(s): Sanofi-aventis Deutschland GmbH (Arava, Leflunomide Winthrop), Teva B.V.(Repso), Teva Pharma B.V. (Leflunomide Teva), Medac Gesellschaft fur klinische Spezialpraparate GmbH (Leflunomide medac), Ratiopharm GmbH (Leflunomide ratiopharm)
Lead MS: NL
Documents:
For adoption: PRAC recommendation

4.2.5. Sildenafil – REVATIO (CAP), VIAGRA (CAP)

- Signal of pulmonary haemorrhage in off label paediatric use

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:
EPITT 18183 – New signal
MAH(s): Pfizer Limited (Revatio, Viagra), Actavis Group PTC ehf (Sildenafil Actavis), Ratiopharm GmbH (Silendafil Ratiopharm), Teva Pharma B.V. (Sildenafil Teva)
Lead MS: NL
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. Gadoversetamide – OPTIMARK (CAP)
gadodiamide (NAP), **gadopentetic acid** (NAP)

- Signal of nephrogenic systemic fibrosis in patients with acute kidney injury

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
EPITT 18141 – Follow-up November 2014
MAH(s): Mallinckrodt Deutschland (Optimark), various
Documents:
For adoption: PRAC recommendation

4.3.2. Latanoprost (NAP)

- Signal of increased reporting of eye disorders, in particular eye irritation, after change of formulation

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 18068 – Follow-up September 2014
MAH(s): Pfizer (Xalatan), various
Documents:
For adoption: PRAC recommendation

4.3.3. Lithium (NAP)

- Signal of solid renal tumours

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
EPITT 18090 – Follow-up September 2014
MAH(s): various
Documents:
For adoption: PRAC recommendation

4.3.4. Paroxetine (NAP)

- Signal of aggression

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
EPITT 18089 – Follow-up September 2014
MAH(s): GlaxoSmithKline, various
Documents:
For adoption: PRAC recommendation

4.3.5. Pravastatin – PRAVAFENIX (CAP)
Atorvastatin, fluvastatin, lovastatin, pitavastatin, rosuvastatin, simvastatin (NAP)

- Signal of immune-mediated necrotizing myopathy (IMNM)

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
EPITT 18140 – Follow-up November 2014
MAH(s): various
Documents:
For adoption: PRAC recommendation

4.3.6. Recombinant Factor VIII:
Antihemophilic factor (recombinant) (NAP)
Moroctocog alfa – REFACTO AF (CAP)
Octocog alfa – ADVATE (CAP), **HELIXATE NEXGEN** (CAP), **KOGENATE** (CAP)

- Signal of inhibitor development in previously untreated patients

Status: *for discussion*

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

Administrative details:
EPITT 18134 – Follow-up December 2014
MAH(s): Baxter AG (Advate, Recombinate), Bayer Pharma AG (Kogenate, Helixate NexGen), Pfizer Limited (ReFacto AF), various
Documents:
For adoption: PRAC recommendation

4.3.7. Teriparatide – FORSTEO (CAP)

- Signal of non-uraemic calciphylaxis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 18056 – Follow-up September 2014
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC recommendation

4.3.8. 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 October 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. Cangrelor

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

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

Administrative details:
Product number(s): EMEA/H/C/003773
Intended indication(s): Reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention (PCI)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.2. Cobimetinib

- 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/003960
Intended indication(s): Treatment of metastatic melanoma
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.3. Dinutuximab

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

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

Administrative details:
Product number(s): EMEA/H/C/002800*, Orphan*
Intended indication(s): Treatment of neuroblastoma
Applicant: United Therapeutics Europe Ltd
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/003981, *Generic*
Intended indication(s): Treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.5. 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/004009, *Generic*
Intended indication(s): Treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.6. 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/003935, *Generic*
Intended indication(s): Treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.7. Edoxaban

- 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/002629
Intended indication(s): Prevention of stroke, embolism and treatment of venous thromboembolism
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.8. Evolocumab

- 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/003766
Intended indication(s): Treatment of hypercholesterolaemia, mixed dyslipidaemia and homozygous familial hypercholesterolaemia
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.9. Fentanyl

- 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/002715
Intended indication(s): Treatment of acute moderate to severe post-operative pain
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.10. Human fibrinogen, human thrombin

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

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

Administrative details:
Product number(s): EMEA/H/C/002807
Intended indication(s): Supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.11. Lamivudine, raltegravir

- 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/003823
Intended indication(s): Treatment of human immunodeficiency virus (HIV-1)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.12. Lenvatinib

- 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/003727, *Orphan*
Intended indication(s): Treatment of papillary thyroid cancer and follicular thyroid cancer
Applicant: Eisai Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.13. Mercaptamine

- 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/003769, *Orphan*
Intended indication(s): Treatment of cystinosis
Applicant: Orphan Europe S.A.R.L.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.14. 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(s): Prevention of chemotherapy-induced nausea and vomiting (CINV)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.15. Nivolumab

- 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/003840
Intended indication(s): Treatment of cancer after prior chemotherapy
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.16. Nivolumab

- 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/003985
Intended indication(s): Treatment of advanced (unresectable or metastatic) melanoma in adults
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.17. Oritavancin

- 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/003785
Intended indication(s): Treatment of complicated skin and soft tissue infections (cSSTI)

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

5.1.18. Talimogene laherparepvec

- 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/002771
Intended indication: Treatment of adults with melanoma that is regionally or distantly metastatic
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.19. Tedizolid

- 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/002846
Intended indication(s): Treatment of tissue infections (cSSTI)
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

5.2.1. Dapagliflozin – FORXIGA (CAP)
Dapagliflozin, metformin – XIGDUO (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): EMA/H/C/002322/WS0601/0016/G, EMA/H/C/002672/WS0601/0006/G
Procedure scope: Revised RMP with 4 revised due dates relating to pharmacoepidemiology programmes MB102103 study, MB102104 study, MB102110 study and MB102118 study
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC AR

5.2.2. Dasatinib – SPRYCEL (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): MEA/H/C/000709/II/0045/G
Procedure scope: Revised RMP (version 13) to change pulmonary arterial hypertension (PAH), pregnancy-related malformative and foeto-neonatal toxicity from important potential risks to important identified risks. Addition of an important potential risk of CYP3A4 drug interactions, toxic skin reactions. Removal from important missing information of use in patients with severe renal impairment and use in patients with severe hepatic impairment
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC AR

5.2.3. Micafungin – MYCAMINE (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/000734/II/0026
Procedure scope: Revised RMP to update the important identified risk of drug interaction; include a second survey to be conducted in Q1 2015 to further assess the effectiveness of risk minimisation measures as requested by the PRAC in May 2014
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC AR

5.2.4. Oseltamivir – TAMIFLU (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000402/II/0114
Procedure scope: Proposal for a new and alternative study BV29684 assessing the 'safety of prenatal exposure to oseltamivir' as a category 3 study (MEA 099) to replace the agreed 2-year extension of the Danish-Swedish registry (NV25577)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC AR

5.2.5. Pregabalin – LYRICA (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/000546/II/0073/G
Procedure scope: Revised RMP to update the targeted report form/follow-up questionnaire for abuse, misuse, dependence and change risk of misuse, abuse and dependence from potential to identified as requested by the PRAC in the recommendation of PSUV/0069 procedure. Change of the due date of PASS A0081096
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC AR

5.2.6. Rivaroxiban – 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: Amendment to Annex II of the marketing authorisation to extend and expand the ongoing epidemiological rivaroxaban PASS programme to fulfil the CHMP objective on the post-approval programme for the acute coronary syndrome (ACS) indication
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC AR

5.2.7. Temozolomide – TEMODAL (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/000229/II/0072
Procedure scope: Revised RMP (version 5.0) to reclassify hepatobiliary disorders from important potential to important identified risk following the request from PRAC/CHMP in the assessment of variation II/63
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC AR

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

5.2.8. Abacavir – ZIAGEN (CAP)
Lamivudine – EPIVIR (CAP), LAMIVUDINE VIIV (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, lamivudine (ABC, 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 WHO treatment guidelines for dosing of ABC scored tablet and 3TC scored tablet in subjects ≥ 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

5.2.9. 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: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002392/II/0013
Procedure scope: Extension of indication to the treatment of macular oedema following branch retinal vein occlusion (BRVO). SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated with new clinical and nonclinical data. The package leaflet is updated accordingly
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.10. 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/0072
Procedure scope: Extension of indication to the use of bevacizumab in combination with paclitaxel and cisplatin or paclitaxel and topotecan in patient with persistent, recurrent, or metastatic carcinoma of the cervix. Consequently, SmPC sections 4.1, 4.2, 4.4, 4.8 and 5 and the package leaflet are updated
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.11. Ferumoxytol – RIENSO (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002215/II/0008
Procedure scope: Extension of indication to all cause iron deficiency anaemia when oral therapy is ineffective or inappropriate or where there is a need for rapid iron repletion. As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 are updated. The package leaflet is updated accordingly. The MAH took the opportunity to propose minor editorial changes to the SmPC and to propose the update of the product information in line with the latest version of the QRD template (9.0)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.12. Human thrombin, human fibrinogen – TACHOSIL (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/000505/II/0057
Procedure scope: Extension of indication for the use of Tachosil as suture line sealing in dura mater closure. As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8, and 5.1 of and the package leaflet are updated
MAH(s): Takeda Austria GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.13. Ibandronic acid – IBANDRONIC ACID ACCORD (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002638/X/0006
Procedure scope: Addition of a new strength/potency and a new pharmaceutical form 3 mg solution for injection
MAH(s): Accord Healthcare Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.14. Insulin glargine – OPTISULIN (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: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000309/X/0079/G
Procedure scope: Extension of the marketing authorisation to register additional strength 300 U/ml, grouped with a type IA variation to vary the invented name from Optisulin to Toujeo
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.15. Interferon alfa-2b – INTRONA (CAP) peginterferon alfa-2b – PEGINTRON (CAP), VIRAFERONPEG (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/000281/WS0611/0099, EMEA/H/C/000280/WS0611/0119, EMEA/H/C/000329/WS0611/0112
Procedure scope: Update of SmPC section 4.4 with updated information on homicidal ideation and for patients with decompensated liver disease, and update of SmPC section 4.8 with pulmonary fibrosis added as post-marketing adverse experience. The package leaflet is updated accordingly. For Intron A only, the MAH takes the opportunity to implement minor linguistic revisions in various languages arising from an internal quality check
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.16. Japanese encephalitis vaccine (inactivated, adsorbed) – IXIARO (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/000963/II/0065/G
Procedure scope: Update of SmPC sections 4.2, 4.4, 4.5, 4.8 and 5.1 to include data of clinical trial sponsored by Novartis Vaccines V49_23, testing concomitant use in conventional and accelerated schedules of Ixiaro with Rabipur. Update of SmPC as recommended during the renewal procedure R/0055 with inclusion of relevant data on elderly population
MAH(s): Valneva Austria GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.17. Paclitaxel – ABRAXANE (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/000778/II/0067
Procedure scope: Extension of indication for the use of paclitaxel in combination with carboplatin for the first-line treatment of non-small cell lung cancer (NSCLC) in adult patients who are not candidates for potentially curative surgery and/or radiation therapy. Consequently SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of and the package leaflet are updated
MAH(s): Celgene Europe Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.18. Ruxolitinib – JAKAVI (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/002464/II/0016
Procedure scope: Extension of indication to add treatment of adult patients with polycythaemia very resistant to or intolerant of hydroxyurea. As a result, SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 and the package leaflet are updated
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.19. Silodosin – SILODYX (CAP), UROREC (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/001209/WS0672/0018/G, EMEA/H/C/001092/WS0672/0019/G
Procedure scope: Grouped variation to 1) update SmPC sections 4.8 and 5.1 to add efficacy and safety information from a European phase IV open label clinical study undertaken in patients with benign prostate hyperplasia. The RMP is updated accordingly; 2) update of the RMP with changes requested by the PRAC in the recent renewal procedure and PSUR procedures
MAH(s): Recordati Ireland Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.20. 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: Extension of indication including an update of SmPC sections 4.1, 4.2 and 5.1 to add the combination therapy of Teysuno with oxaliplatin (with or without epirubicin) with consequential updates to SmPC sections 4.3, 4.4, 4.5, 4.6, 4.8 and the package leaflet
MAH(s): Nordic Group B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.21. Thiotepa – TEPADINA (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/001046/II/0018
Procedure scope: Update of SmPC section 4.8 of to update the safety information on pulmonary arterial hypertension with uncommon frequency. The package leaflet is updated accordingly
MAH(s): Adienne S.r.l. S.U.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.22. Ustekinumab – STELARA (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: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000958/II/0042
Procedure scope: Extension of indication to add the treatment of moderate to severe plaque psoriasis in paediatric patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. As a consequence, SmPC sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 and the package leaflet are updated. A revised RMP (version 12) is assessed as part of the application
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.23. Vismodegib – ERIVEDGE (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/002602/II/0015/G
Procedure scope: Grouped variations: 1) Following the review of GP28465 study report, update of SmPC section 4.3 to delete the contraindication with St John's wort; section 4.4 to delete the warning relating to the concomitant treatment with strong CYP inducers and section 4.5 to update the effects of concomitant medicinal products. The package leaflet is updated accordingly. 2) Following the review of GP27839 study report as well as new clinical pharmacokinetic (PK) and PK modelling data, update of SmPC section 4.2 regarding the posology information for patients with hepatic and renal impairment; section 5.2 to reflect the new PK data generated in patients with hepatic and renal impairment. 3) Finally, submission of a summary document outlining new non-clinical, clinical PK data generated since the initial marketing authorisation to complement the existing oral contraceptive drug-drug interaction data
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

RMP evaluated in the context of a PSUR procedure

See also Ferumoxytol – RIENSO 6.1.12. , Hydroxycarbamide – SIKLOS 6.1.16. , Liraglutide – VICTOZA 6.1.19.

RMP evaluated in the context of PASS results

See also Paliperidone – XEPLION 7.4.2.

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

5.2.24. Filgrastim – NIVESTIM (CAP)

- Evaluation of an RMP on the context of a five year-renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/001142/R/0025
MAH(s): Hospira UK Limited
Documents:
For adoption: PRAC advice

5.2.25. Leflunomide – LEFLUNOMIDE MEDAC (CAP)

- Evaluation of an RMP on the context of a five year-renewal 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/001227/R/0019
MAH(s): Medac Gesellschaft fur klinische Spezialpraparate mbH
Documents:
For adoption: PRAC advice

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. Ambrisentan – VOLIBRIS (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/000839/PSUV/0040
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Aminolevulinic acid hydrochloride – AMELUZ (CAP), NAP

- Evaluation of a PSUSA[4] 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/PSUSA/00010006/201406
MAH(s): Biofrontera Bioscience GmbH, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Avanafil – SPEDRA (CAP)

- Evaluation of a PSUR procedure

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

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002581/PSUV/0010
MAH(s): Menarini International Operations Luxembourg S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Belatacept – **NULOJIX** (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/002098/PSUV/0023
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Bromelain enriched proteolytic enzyme preparation from ananas comosus – **NEXOBRID** (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/002246/PSUV/0018
MAH(s): MediWound Germany GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. C1 inhibitor, human – **CINRYZE** (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/001207/PSUV/0027
MAH(s): ViroPharma SPRL
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Cabazitaxel – **JEVTANA** (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/002018/PSUV/0025
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Canakinumab – ILARIS (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/001109/PSUV/0034
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Dasatinib – SPRYCEL (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/000709/PSUV/0041
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Dextromethorphan, quinidine – NUEDEXTA (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/002560/PSUV/0004
MAH(s): Jenson Pharmaceutical Services Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Emedastine – EMADINE (CAP), NAP

- Evaluation of a PSUSA[5] 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/PSUSA/00001207/201405
MAH(s): Alcon Laboratories (UK) Ltd, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. Ferumoxytol – RIENSO (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/002215/PSUV/0015 (with RMP version 3.3)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Galsulfase – NAGLAZYME (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/000640/PSUV/0054
MAH(s): BioMarin Europe Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Human fibrinogen, human thrombin – TACHOSIL (CAP)

- Evaluation of a PSUSA[6] procedure

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

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

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

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001627/201406
MAH(s): Takeda Austria GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Human normal immunoglobulin – FLEBOGAMMA DIF (CAP), **HIZENTRA** (CAP), **HYQVIA** (CAP), **KIOVIG** (CAP), **PRIVIGEN** (CAP), NAP

- Evaluation of a PSUSA[7] 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/PSUSA/00001633/201405
MAH(s): Instituto Grifols S.A., various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Hydroxycarbamide – SIKLOS (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/000689/PSUV/0025 (with RMP v 15.0)
MAH(s): Addmedica
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. Icatibant – FIRAZYR (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/000899/PSUV/0027
MAH(s): Shire Orphan Therapies GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Influenza vaccine (live attenuated, nasal) – FLUENZ (CAP), **FLUENZ TETRA** (CAP)

- Evaluation of a PSUR procedure

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

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/001101/PSUV/0061, EMEA/H/C/002617/PSUV/0023
MAH(s): MedImmune LLC
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Liraglutide – VICTOZA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001026/PSUV/0029 (with RMP version 4.0)
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Matrix applied characterised autologous cultured chondrocytes – MACI (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/002522/PSUV/0005
MAH(s): Aastrom Biosciences DK ApS
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Mirabegron – BETMIGA (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/002388/PSUV/0015
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Misoprostol – HEMOPROSTOL (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/W/002652/PSUV/0002
MAH(s): Linepharma France
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Nateglinide – STARLIX (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/000335/PSUV/0028
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Nepafenac – NEVANAC (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/000818/PSUV/0029
MAH(s): Alcon Laboratories (UK) Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Omalizumab – XOLAIR (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/000606/PSUV/0061
MAH(s): Novartis Europharm Ltd

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. Paliperidone – **INVEGA** (CAP), **XEPLION** (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/000746/PSUV/0044, EMEA/H/C/002105/PSUV/0016
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. Pegaptanib – **MACUGEN** (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/000620/PSUV/0061
MAH(s): PharmaSwiss Ceska Republika s.r.o
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Peginterferon alfa-2a – **PEGASYS** (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/000395/PSUV/0077
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Pertuzumab – **PERJETA** (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/002547/PSUV/0011
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Ponatinib – **ICLUSIG** (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/002695/PSUV/0014
MAH(s): Ariad Pharma Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Pyronaridine, artesunate – **PYRAMAX** (Art 58)

- 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/W/002319/PSUV/0007
MAH(s): Shin Poong Pharmaceutical Co., Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Ranibizumab – **LUCENTIS** (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/000715/PSUV/0049
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Roflumilast – **DALIRESP** (CAP), **DAXAS** (CAP), **LIBERTEK** (CAP)

- Evaluation of a PSUSA[8] procedure

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

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/PSUSA/00002658/201407
MAH(s): Takeda GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Sofosbuvir – SOVALDI (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/002798/PSUV/0009
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Tigecycline – TYGACIL (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/000644/PSUV/0088
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. Tobramycin – TOBI PODHALER (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/002155/PSUV/0026
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Umeclidinium, vilanterol – **ANORO** (CAP), **LAVENTAIR** (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/002751/PSUV/0001, EMEA/H/C/003754/PSUV/0001
MAH(s): Glaxo Group Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[9]

6.2.1. Nilotinib – **TASIGNA** (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000798/LEG 047
Procedure scope: MAH's response to PRAC recommendation on PSUV/0069 as adopted in September 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. Deferasirox – **EXJADE** (CAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number: EMEA/H/C/000670/ANX/038.5
Procedure scope: Evaluation of MAH's responses to ANX 038.4 as adopted by PRAC in July 2014 including a revised PASS protocol for study CICL670E2422: observational cohort study in paediatric non transfusion dependant-thalassaemia (NTDT) patients over 10 years
MAH(s): Novartis Europharm Ltd
Documents:

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

For adoption: PRAC AR, letter of endorsement/objection/notification that study is a clinical trial

7.1.2. **Domperidone** (NAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Patrick Maison (FR)

Administrative details:
Procedure number(s): EMEA/H/N/PSP/0008
Procedure scope: Evaluation of a protocol for a non-interventional post-authorisation safety study (drug utilisation study) in routine clinical practice to assess the effectiveness of the risk minimisation measures and to monitor off-label use of domperidone as per the conclusions of the Article 31 referral
MAH(s): Pierre Fabre Medicament (Domperidone Pierre Fabre, Oroperidys, Peridys)
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.1.3. **Domperidone** (NAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Patrick Maison (FR)

Administrative details:
Procedure number(s): EMEA/H/N/PSP/0009
Procedure scope: Evaluation of a protocol for a non-interventional post-authorisation safety study (drug utilisation study) in routine clinical practice to assess the effectiveness of the risk minimisation measures and to monitor off-label use of domperidone as per the conclusions of the Article 31 referral
MAH(s): Rottapharm (Domperidona Gamir)
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

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

- Evaluation of an imposed PASS protocol

Status: *for decision*

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

Administrative details:
Procedure number: EMEA/H/C/000561/ANX 034, EMEA/H/C/000560/ANX 034
Procedure scope: Evaluation of a PASS protocol for a non-interventional safety study to evaluate the effectiveness of the applied risk minimisation measures, including a description of the treated patient population in everyday clinical practice
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

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

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Torbjorn Callreus (DK)

Administrative details:
Procedure number: EMEA/H/C/002691/ANX 001.5, EMEA/H/C/002430/ANX 001.4, EMEA/H/C/002690/ANX 001.5
Procedure scope: Evaluation of a revised PASS protocol on cardio- and cerebrovascular outcomes (multinational database cohort study to assess adverse cardiovascular outcomes in association with inhaled glycopyrronium in Europe)
MAH(s): Novartis Europharm Ltd
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. Abatacept – **ORENCIA** (CAP)

- Evaluation of a PASS protocol

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 054
Procedure scope: Evaluation of a PASS protocol for a non-interventional, non-imposed protocol IM101-537 aimed at assessing the effectiveness of risk minimisation measure (patient alert card)
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC advice

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

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Ingebjørg Buajordet (NO)

Administrative details:
Procedure number(s): EMEA/H/C/000916/MEA 023, EMEA/H/C/000915/MEA 023
Procedure scope: Evaluation of a PASS protocol for a study using databases in four European countries to assess the incidence of hospitalisation for liver injury in current medical practice in comparison with other antidepressant drugs
MAH(s): Servier (Ireland) Industries Ltd., Les Laboratoires Servier
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

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

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Ingebjørg Buajordet (NO)

Administrative details:
Procedure number(s): EMEA/H/C/000916/MEA 024, EMEA/H/C/000915/MEA 024
Procedure scope: Evaluation of a PASS protocol for a non-interventional post-authorisation safety study/pharmacogenomic study to explore the potential liver injury and potential associated risk factors, risk of hepatotoxic reactions associated with agomelatine in reasonable timelines. Pharmacogenomic study: further explore the potential liver injury and potential associated risk factors, specific investigations are implemented for patients who exhibit abnormal liver enzymes (ALAT, ASAT or ALP value > 3 x ULN or total bilirubin > 2 ULN) in the ongoing and planned clinical trials with agomelatine, with close follow-up of abnormalities until resolution, and determination of key variables in liver function assessment and appropriate etiological investigations. DNA should be taken allowing for search of the influence of different genetic polymorphisms
MAH(s): Servier (Ireland) Industries Ltd., Les Laboratoires Servier
Documents:
For adoption: PRAC advice

7.2.4. Apixaban – **ELIQUIS** (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002148/MEA 021.1
Procedure scope: Evaluation of the MAH's response to the request for supplementary information in the PRAC assessment report on the draft protocol for a non-interventional study to assess the effectiveness of the additional minimisation measures for the prevention of bleeding (as adopted in September 2014)
MAH(s): Bristol-Myers Squibb / Pfizer EEIG
Documents:
For adoption: PRAC advice

7.2.5. Bromelain enriched proteolytic enzyme preparation from ananas comosus – **NEXOBRID** (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/002246/MEA 003.1
Procedure scope: Evaluation of a revised PASS protocol (MW2013-06-01) for a drug utilisation study to further evaluate the effectiveness of the risk minimisation activities (including evaluation of educational and training materials)
MAH(s): MediWound Germany GmbH

Documents:
For adoption: PRAC advice

7.2.6. Insulin lispro – **HUMALOG** (CAP), **LIPROLOG** (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/000088/MEA 025, EMEA/H/C/000393/MEA 018
Procedure scope: Evaluation of a PASS protocol for a study examining the effectiveness of risk minimisation
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC advice

7.2.7. 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 041.3
Procedure scope: Evaluation of the MAH's response to MEA-041.2 request for supplementary of information as adopted in September 2014: revised registry protocol collecting long term efficacy and safety data in polyarticular juvenile idiopathic arthritis (pJIA) treatment (EU BSRBR registry (study WA22479))
MAH(s): Roche Registration Limited
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. Emtricitabine, rilpivirine, tenofovir disoproxil – **EVIPLERA** (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

[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

Administrative details:
Procedure number(s): EMEA/H/C/002312/II/0053 (without RMP)
Procedure scope: Submission of the clinical study report of the Eviplera/Edurant healthcare professional survey undertaken to gain an understanding of the effectiveness of the current prescribing conditions in minimising the risk associated with taking the products without food/a meal, potentially associated with the risk of development of drug resistance
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC AR

7.4.2. Paliperidone – XEPLION (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/002105/II/0017 (with RMP)
Procedure scope: Submission of the final study report for a drug utilisation study conducted in Europe to fulfil an additional pharmacovigilance activity in the current combined paliperidone/paliperidone palmitate risk-management plan (version 5.1). The RMP has been updated accordingly (version 5.3)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC AR

7.4.3. Ulipristal – ELLAONE (CAP)

- Evaluation of PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001027/II/0033 (without RMP)
Procedure scope: Submission of the final clinical study report to address the CHMP request from MEA007.5 (study HRA 2914-012): prospective multicentre observational study to assess clinical follow-up and outcomes of pregnancies exposed to ella/ellaOne. No changes to the product information are proposed
MAH(s): Laboratoire HRA Pharma
Documents:
For adoption: PRAC AR

7.4.4. Rilpivirine – EDURANT (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002264/II/0015 (without RMP)

Procedure scope: Submission of the clinical study report of the Eviplera/Edurant healthcare professional survey undertaken to gain an understanding of the effectiveness of the current prescribing conditions in minimising the risk associated with taking the products without food/a meal, potentially associated with the risk of development of drug resistance
MAH(s): Janssen-Cilag International N.V.
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. Darunavir – PREZISTA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000707/MEA 069.2
Procedure scope: Interim results of the observational study to assess growth abnormalities (height) in HIV-infected children and adolescents on antiretroviral therapy in Europe (PENTA study)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC advice

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

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000797/MEA 038.1
Procedure scope: Interim report on the antiretroviral pregnancy registry (APR)
MAH(s): Bristol-Myers Squibb and Gilead Sciences Ltd.
Documents:
For adoption: PRAC advice

7.5.3. Exenatide – BYDUREON (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/002020/MEA 010.2

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

Procedure scope: Annual report on a study H8O-MC-B016, a modified prescription event monitoring (Modified PEM) to identify possible cases of pancreatitis, enrolling primary care patients with type 2 diabetes who receive prescription for exenatide once weekly
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC advice

7.5.4. Exenatide – BYDUREON (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/002020/MEA 011.3
Procedure scope: Annual report on an epidemiologic study using one or more European databases to identify possible cases of thyroid neoplasms among type 2 diabetes mellitus patients who initiate exenatide once weekly
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC advice

7.5.5. Human normal immunoglobulin – PRIVIGEN (CAP)

- Evaluation of interim PASS results

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/000831/MEA 022.2
Procedure scope: First interim report on the study entitled Privigen use and haemolytic anaemia in adults and children and the Privigen safety profile in children with chronic inflammatory demyelinating polyneuropathy (CIDP): observational hospital-based cohort study in the US
MAH(s): CSL Behring GmbH
Documents:
For adoption: PRAC advice

7.5.6. 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 121.7
Procedure scope: Annual report on the adults ulcerative colitis (UC) patient registry (OPUS), including the investigation of episodic/re-treatment
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.5.7. Influenza vaccine (live attenuated, nasal) – FLUENZ TETRA (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002617/MEA 004.1
Procedure scope: Evaluation of the first interim results of PASS D2560C00008: non-interventional cohort study of the safety of live attenuated influenza vaccine (LAIV) in subjects 2-17 years of age
MAH(s): MedImmune LLC
Documents:
For adoption: PRAC advice

7.5.8. Influenza vaccine (live attenuated, nasal) – FLUENZ TETRA (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002617/MEA 006
Procedure scope: First annual report on a post-marketing observational evaluation of the safety of live attenuated influenza vaccine (LAIV) in children and adolescents with high-risk conditions
MAH(s): MedImmune LLC
Documents:
For adoption: PRAC advice

7.5.9. Interferon beta-1a – REBIF (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/000136/LEG 040
Procedure scope: Feasibility assessment of the case control study comparing the risk of thrombotic microangiopathy (TMA) with different Rebif formulations
MAH(s): Merck Serono Europe Limited
Documents:
For adoption: PRAC advice

7.5.10. Rivastigmine – EXELON (CAP), PROMETAX (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000169/MEA 0036, EMEA/H/C/000255/MEA 037
Procedure scope: Interim report on the trends of multiple patch use and with CIOMS reports of medication errors and misuse
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

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

8.1.1. Agalsidase alfa – REPLAGAL (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/000369/S/0086 (without RMP)
MAH(s): Shire Human Genetic Therapies AB
Documents:
For adoption: PRAC advice

8.1.2. Clofarabine – EVOLTRA (CAP)

- PRAC consultation on an annual reassessment 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/000613/S/0045 (without RMP)
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC advice

8.1.3. Lapatinib – TYVERB (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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/000795/R/0039 (without RMP)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

8.1.4. Mecasermin – INCRELEX (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000704/S/0032 (without RMP)
MAH(s): Ipsen Pharma
Documents:
For adoption: PRAC advice

8.1.5. Pixantrone – PIXUVRI (CAP)

- PRAC consultation on a conditional renewal 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/002055/R/0020 (with RMP)
MAH(s): CTI Life Sciences Limited
Documents:
For adoption: PRAC advice

8.1.6. Tafamidis – VYNDAQEL (CAP)

- PRAC consultation on an annual reassessment 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/002294/S/0022 (without RMP)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

See also under 5.2

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

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

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

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

None

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

None

10.3. Other requests

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Azithromycin oral and intravenous formulations (NAP)

- PRAC consultation on a safety-related variations upon Finland's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Terhi Lehtinen (FI)

Administrative details:
Procedure number: FI/H/XXXX/WS/23
Procedure scope: PRAC consultation on a variation procedure evaluating the draft PASS protocol (A0661209) for a non-imposed non-interventional study in the Kaiser Permanente databases to examine the effects of azithromycin use on cardiovascular outcome
MAH(s): Pfizer (Zithromax)
Documents:
For adoption: PRAC advice

11.1.2. Domperidone (NAP)

- PRAC consultation on a safety-related variations upon Belgium's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:

Lead member: Jean-Michel Dogné (BE)

Administrative details:
Procedure number: BE/H/0106/01-04,08-09/II/044
Procedure scope: PRAC consultation on a variation procedure evaluating a RMP as required in the Annex IV conditions to the marketing authorisation(s) following Article 31 referral for domperidone containing products (Commission Decision dated 14 July 2014)
MAH(s): Zentiva (Motilium)
Documents:
For adoption: PRAC advice

11.1.3. **Ibuprofen** (NAP)

- PRAC consultation on a safety-related variations upon Malta's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:

Lead member: Amy Tanti (MT)

Administrative details:
Procedure number: MT/H/0101/001-004/II/007
Procedure scope: PRAC consultation on a variation procedure evaluating the MAH's request to add Kounis syndrome to the product information
MAH(s): Actavis (Ibuprofen Actavis)
Documents:
For adoption: PRAC advice

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. **Cilastatin** (NAP)
imipenem (NAP)

- PRAC consultation on a PSUR worksharing procedure upon Norway's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:

Lead member: Ingebjorg Buajordet (NO)

Administrative details:
Procedure number: NO/H/PSUR/0003/002
Procedure scope: PRAC consultation on a PSUR worksharing procedure on the addition of drug reaction with eosinophilia and systemic symptoms (DRESS) to the product information
MAH(s): various
Documents:
For adoption: PRAC advice

11.3.2. **Apomorphine** (NAP)

- PRAC consultation on concomitant use of apomorphine with domperidone following the completion of Article 31 referral for domperidone, upon Germany's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Martin Huber (DE)

Administrative details:
Procedure number: *Not applicable*
Procedure scope: PRAC consultation on the concomitant use of apomorphine with domperidone contraindicated with QT-prolonging drugs following the completion of Article 31 referral for domperidone containing products (Commission Decision dated 14 July 2014)
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. PSUR Repository

- PSUR repository implementation plan

Status*: for discussion*

12.3.3. Union Reference Date (EURD) List

- Consultation on the draft list, version January 2015

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

- Additional monitoring: optional scope

Status: *for discussion*

12.5.3. List of Product under Additional Monitoring

- Consultation on the draft list, version January 2015

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

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

None

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Renewals, conditional renewals, annual reassessments

None

12.11. Risk communication and Transparency

12.11.1. Public Participation in Pharmacovigilance

None

12.11.2. Safety Communication

None

12.12. Continuous pharmacovigilance

12.12.1. Incident Management

None

12.13. Interaction with EMA Committees and Working Parties

12.13.1. Committees

None

12.13.2. Working Parties

None

12.14. Interaction within the EU regulatory network

12.14.1. European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

- Feedback from the ENCePP plenary meeting, November 2014

Status: *for discussion*

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

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

None

12.16. Others

None

13. Any other business

13.1. Guidance to applicants on responses to questions received from EMA Scientific Committees during the evaluation within the centralised procedure

Status: *for agreement*

Documents:
For agreement: Draft guidance document

13.2. Pharmacovigilance programme and revised implementation governance

Status: *for discussion*