8 September 2014
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Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 8-11 September 2014

Chair: June Raine – Vice-Chair: Almath Spooner

8 September 2014, 13:00 – 19:00, room 3/A

9 September 2014, 08:30 – 19:00, room 3/A

10 September 2014, 08:30– 19:00, room 3/A

11 September 2014, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

17 September 2014, 10:00-12:00, room 5/D, 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

Adoption of agenda of the meeting of 8-11 September 2014

Status: *for adoption*

Document: PRAC Agenda Rev.3 due for publication on 8 September 2014

1.2. Minutes of the previous PRAC meeting on 7-10 July 2014

Status: *for adoption*

Document: PRAC final Minutes due for publication by 19 September 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

3.2.1. 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 list of outstanding issues*

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: List of outstanding issues (LoOI), revised timetable (or PRAC AR, PRAC recommendation)

3.3. Procedures for finalisation

None

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

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. **Latanoprost** (NAP)

- Signal of increased number of eye disorders after change of formulation

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 18068 – New signal
MAH(s): Pfizer (Xalatan), various
Leading MS: UK
Documents:
For adoption: PRAC recommendation

4.1.2. **Natalizumab – TYSABRI** (CAP)

- Signal of neonatal haematological abnormalities (thrombocytopenia/anaemia)

Status: *for discussion*

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

Administrative details:
EPITT 18067 – New signal
MAH(s): Biogen Idec Ltd
Leading MS: DE

[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

Documents:
For adoption: PRAC recommendation

4.1.3. Paliperidone – INVEGA (CAP)

- Signal of accidental exposure of children to oral formulations

Status: *for discussion*

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

Administrative details:
EPITT 18069 – New signal
MAH(s): Janssen-Cilag International N.V.
Leading MS: SE
Documents:
For adoption: PRAC recommendation

4.1.4. Paroxetine (NAP)

- Signal of aggression

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18089 – New signal
MAH(s): GlaxoSmithKline, various
Leading MS: NL
Documents:
For adoption: PRAC recommendation

4.1.5. Temozolomide – TEMODAL (CAP)

- Signal of dehydration leading to renal failure

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
EPITT 18064 – New signal
MAH(s): Merck Sharp & Dohme Limited
Leading MS: DE
Documents:
For adoption: PRAC recommendation

4.1.6. Teriparatide – FORSTEO (CAP)

- Signal of non-uraemic calciphylaxis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 18056 – New signal
MAH(s): Eli Lilly Nederland B.V.
Leading MS: UK
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. Interferon alfa-2b – INTRONA (CAP)
Interferon beta-1a – AVONEX (CAP), **REBIF** (CAP)
Interferon beta-1b - BETAFERON (CAP), **EXTAVIA** (CAP**)**
Peginterferon alfa-2a - **PEGASYS** (CAP)
Peginterferon alfa-2b - **PEGINTRON** (CAP)

- Signal of pulmonary arterial hypertension

Status: *for discussion*

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

Administrative details:
EPITT 18059 – New signal
MAH(s): Biogen Idec (Avonex), Merck Serono Europe Limited (Rebif), Bayer Pharma AG (Betaferon), Novartis Europharm Ltd (Extavia), Merck Sharp & Dohme Limited (IntronA, PegIntron), Roche Registration Ltd (Pegasys)
Leading MS: SE
Documents:
For adoption: PRAC recommendation

4.2.2. Lithium carbonate, citrate, sulfate and acetate (NAP)

- Signal of solid renal tumours

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18090 – New signal
MAH(s): various
Leading MS: DE
Documents:
For adoption: PRAC recommendation

4.2.3. Thiotepa – TEPADINA (CAP)

- Signal of pulmonary arterial hypertension

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
EPITT 18046 – New signal
MAH(s): Adienne S.r.l. S.U.

Leading MS: FR
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. Androgen Deprivation Therapy (ADT) (NAP)
Abiraterone – ZYTIGA (CAP); **degarelix – FIRMAGON** (CAP)

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

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
EPITT 13886 – Follow-up May 2014
MAH(s): Janssen-Cilag International N.V., Ferring Pharmaceuticals A/S, various
Leading MS: DE
Documents:
For adoption: PRAC recommendation

4.3.2. Cefepime (NAP)

- Signal of convulsions

Status: for discussion

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
EPITT 17859 – Follow-up March 2014
MAH(s): various
Lead MS: PT
Documents:
For adoption: PRAC recommendation

4.3.3. Chlorhexidine (NAP)

- Signal of risk of chemical injury including burns when used in skin disinfection in premature infants

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 18000 – Follow-up June 2014
Leading MS: UK
MAH(s): various
Documents:
For adoption: PRAC recommendation

4.3.4. Imatinib – GLIVEC (CAP), NAP

- Signal of decreased estimated glomerular filtration rate (eGFR)

Status: *for discussion*

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

Administrative details:
EPITT 17946 – Follow-up April 2014
MAH: Novartis Europharm Ltd
Documents:
For adoption: PRAC recommendation

4.3.5. Leuprorelin, suspension for injection (NAP)

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

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
EPITT 17753 – Follow-up May 2014
MAH(s): Astellas (Eligard)
Documents:
For adoption: PRAC recommendation

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

- Signal of cardiovascular events

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 17931 – Follow-up April 2014
MAH: various
Leading MS: UK
Documents:
For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Aclidinium, formoterol

- 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/003969, EMEA/H/C/003745
Intended indication(s): Maintenance bronchodilator treatment for airflow obstruction and relief of symptoms in adult patients with chronic obstructive pulmonary disease (COPD)
Documents:

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

5.1.2. 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(s): Treatment of phototoxicity in adult patients with erythropoietic protoporphyria (EPP)
Applicant: Clinuvel (UK) Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.3. Apremilast

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

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

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

5.1.4. Balugrastim

- 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/002637
Intended indication(s): Treatment of chemotherapy-induced neutropenia
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.5. Bazedoxifene, estrogens conjugated

- 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/002314
Intended indication(s): Treatment of oestrogen deficiency and osteoporosis
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.6. 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): Percutaneous coronary intervention (PCI)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.7. Ciclosporin

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

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

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

5.1.8. Clopidogrel

- 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/004006, *Generic*
Intended indication(s): Prevention of myocardial infarction and acute coronary syndrome, ischaemic stroke, peripheral arterial disease, acute coronary syndrome, prevention of atherothrombotic and thromboembolic events in atrial fibrillation
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.9. Dalbavancin

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

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

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

5.1.10. Darunavir, cobicistat

- 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/002819
Intended indication(s): Treatment of patients with human immunodeficiency virus (HIV-1)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.11. Dasabuvir

- 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/003837
Intended indication(s): Treatment of chronic hepatitis C
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.12. Dulaglutide

- 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/002825
Intended indication(s): Treatment of adults with type 2 diabetes mellitus
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.13. Eliglustat

- 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/003724, *Orphan*
Intended indication(s): Treatment of Gaucher disease type 1
Applicant: Genzyme Europe BV
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.14. Idebenone

- 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/003834, *Orphan, Hybrid*
Intended indication(s): Treatment of Leber hereditary optic neuropathy (LHON)
Applicant: Santhera Pharmaceuticals (Deutschland) GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.15. Ketoconazole

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

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

Administrative details:
Product number(s): EMEA/H/C/003906, *Orphan*
Intended indication(s): Treatment of Cushing's syndrome
Applicant: Laboratoire HRA Pharma

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

5.1.16. Levofloxacin

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

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

Administrative details:
Product number(s): EMEA/H/C/002789, *Orphan*
Intended indication(s): Treatment of chronic pulmonary infections
Applicant: Aptalis Pharma SAS
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.17. Naloxegol

- 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/002810
Intended indication(s): Treatment of adult patients 18 years and older with opioid-induced constipation (OIC) including patients with inadequate response to laxatives
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.18. Nintedanib

- 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/003821, *Orphan*
Intended indication(s): Treatment of idiopathic pulmonary fibrosis (IPF)
Applicant: Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.19. Nintedanib

- 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/002569
Intended indication(s): Treatment of non-small cell lung cancer (NSCLC)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.20. Nonacog gamma

- 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/003771
Intended indication(s): Treatment of haemophilia B
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.21. 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, *Orphan*
Intended indication(s): Treatment of ovarian cancer
Applicant: AstraZeneca AB
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.22. Ombitasvir, paritaprevir, ritonavir

- 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/003839
Intended indication(s): Treatment of chronic hepatitis C
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.23. Panobinostat

- 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/003725*, Orphan*
Intended indication(s): Treatment of patients with multiple myeloma
Applicant: Novartis Pharmaceuticals UK Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.24. Phenylephrine, ketorolac trometamol

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

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

Administrative details:
Product number(s): EMEA/H/C/003702
Intended indication(s): Maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement (ILR) in adults
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.25. Pitolisant

- 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/002616, *Orphan*
Intended indication(s): Treatment of narcolepsy treatment of narcolepsy
Applicant: Bioprojet Pharma
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.26. Ramucirumab

- 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/002829, *Orphan*
Intended indication(s): Treatment of gastric cancer
Applicant: Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.27. Safinamide

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

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

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

5.1.28. Secukinumab

- 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/003729
Intended indication(s): Treatment of plaque of psoriasis
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.29. Sofosbuvir, ledipasvir

- 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/003850
Intended indication: Treatment of chronic hepatitis C
Documents:

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

5.1.30. Sonidegib

- 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/002839
Intended indication(s): Treatment of advanced basal cell carcinoma (BCC)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.31. Tadalafil

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

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

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

5.1.32. Tasimelteon

- 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/003870*, Orphan*
Intended indication(s): Treatment of non-24-hour sleep-wake disorder (non-24) in the totally blind
Applicant: Vanda Pharmaceuticals Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.33. Vorapaxar

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

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

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

5.2. Medicines already authorised

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

5.2.1. Aclidinium bromide – **BRETARIS GENUAIR** (CAP), **EKLIRA GENUAIR** (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002706/II/0012, EMEA/H/C/002211/II/0012
Procedure scope: Update of the RMP to version 4.0
MAH(s): Almirall S.A
Documents:
For adoption: PRAC AR

5.2.2. Adalimumab – **HUMIRA** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000481/II/0130
Procedure scope: Update of RMP to version 11.1
MAH(s): AbbVie Ltd
Documents:
For adoption: PRAC AR

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

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000780/WS0588/0094, EMEA/H/C/002073/WS0588/0095, EMEA/H/C/000964/WS0588/0064
Procedure scope: Update of the RMP to amend the timelines for initiation, completion and submission of study reports of ongoing or planned studies together with update to some of objectives of the planned long-term safety and efficacy study
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

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

5.2.4. Capecitabine – XELODA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000316/II/0060
Procedure scope: Update of RMP to version 7 further to a request of PRAC/CHMP in assessment of variations, including an update on dihydropyrimidine dehydrogenase deficiency (MEA 029)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC AR

5.2.5. Dabigatran – PRADAXA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/II/0058
Procedure scope: Changes in the agreed study protocol for 1160.136 (SPAF MEA 025), a global registry program GLORIA-AF investigating patients with newly diagnosed non-valvular AF at risk for stroke receiving dabigatran. The consequent changes were done to the RMP that was also submitted within this variation
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC AR

5.2.6. Pioglitazone – ACTOS (CAP), GLUSTIN (CAP)
Pioglitazone, glimepiride – TANDEMACT (CAP)
Pioglitazone, metformin – COMPETACT (CAP), GLUBRAVA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

Administrative details:
Procedure number(s): EMEA/H/C/000285/WS0609/0063, EMEA/H/C/000286/WS0609/0061, EMEA/H/C/000680/WS0609/0038, EMEA/H/C/000655/WS0609/0048, EMEA/H/C/000893/WS0609/0034
Procedure scope: Update of the RMP to version 19 (for Actos, Glustin, Competact and Glubrava) and version 17 (for Tandemact) in order to change the due date for reporting of the Pan-European multiple database bladder cancer risk characterisation study ER 12-9433 (previously listed as AD4833-410) from 30 September 2014 to 30 December 2014
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC AR

5.2.7. **Riociguat - ADEMPAS** (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002737/II/0001 (with RMP version 3.0)
Procedure scope: Submission 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 AR

5.2.8. **Sildenafil – REVATIO** (CAP)

- Evaluation of an RMP in the context of a variation

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/000638/II/0061
Procedure scope: Update of the RMP and consequential update of the annex II
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC AR

5.2.9. **Tenofovir disoproxil, emtricitabine, rilpivirine, – EVIPLERA** (CAP)
Tenofovir disoproxil, emtricitabine – TRUVADA (CAP)
Tenofovir disoproxil – VIREAD (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002312/WS0598/0048/G, EMEA/H/C/000594/WS0598/0107/G, EMEA/H/C/000419/WS0598/0141/G
Procedure scope: Worksharing variations to: 1) update of the RMP to remove FUM 234 (study 174-0127 on renal safety); to add references to studies previously submitted, to add intermediate results for APR and MITOC studies and to correct the classification from category 3 to 4 of the 7 studies (in the RMP for Eviplera and Truvada); 2) update the deadline for the final submission of study 104-0423 in the RMP
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC AR

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

5.2.10. Abatacept – ORENCIA (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/000701/II/0081/G
Procedure scope: Grouped variations to: 1) update of SmPC sections 4.4 and 4.8 regarding systemic injection reactions with the use of subcutaneous abatacept to harmonize the SmPC for SC abatacept with the SmPC for intravenous (IV) abatacept. The RMP is updated accordingly; 2) change to the milestones for the core subcutaneous study protocols IM101063, IM101167, IM101173, IM101174 and IM101185 study timelines
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.11. 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 for the treatment of macular oedema following branch retinal vein occlusion (BRVO). New clinical and nonclinical data is introduced to the SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2. The PL is being updated accordingly
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.12. Bevacizumab – AVASTIN (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000582/II/0072
Procedure scope: Extension of indication for the use of Avastin 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 5.1 and the Package Leaflet are updated
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.13. Bortezomib – VELCADE (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: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000539/II/0072
Procedure scope: Extension of indication for the use of Velcade in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma. Consequently, SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 and the Package Leaflet are updated
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.14. Cabozantinib – COMETRIQ (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/002640/II/0006
Procedure scope: Update of SmPC section 4.4 to delete the warning on concomitant use with proton pump inhibitors further to the results of a drug-drug Interaction Study XL184-018 with medicinal products affecting gastric pH (esomeprazole and Famotidine) (MEA 004). The Package leaflet is updated accordingly. The MAH also took the opportunity to make a correction in section 4.5 and the PL
MAH(s): TMC Pharma Services Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.15. Caffeine – PEYONA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Jan Neuhauser (AT)

Administrative details:
Procedure number(s): EMEA/H/C/001014/II/0013
Procedure scope: Update of SmPC section 4.8 to reflect the results of an European Non-Interventional Post-Authorisation Study to assess drug utilisation and safety of caffeine citrate in the treatment of premature infants affected by apnoea. This study addresses a post-authorisation measure in the RMP. Section 4 of the package leaflet is updated accordingly
MAH(s): Chiesi Farmaceutici S.p.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

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

- Evaluation of an RMP in the context of a variation

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/000721/II/0061
Procedure scope: Update of SmPC section 4.6 on pregnancy outcomes in women exposed to the vaccine during pregnancy to reflect the outcome of study EPI-HPV-018 (an observational cohort) and other available data on safety during pregnancy. The Package Leaflet is amended accordingly
MAH(s): GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.17. Collagenase clostridium histolyticum – XIAPEX (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/002048/II/0044
Procedure scope: Extension of indication for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity. The PL is updated accordingly
MAH(s): Swedish Orphan Biovitrum AB (publ)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.18. Darunavir – PREZISTA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

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

5.2.19. Darunavir – PREZISTA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000707/II/0064
Procedure scope: Update of the SmPC with an extension of indication in treatment naïve children aged 3 to 12 years and changes in the posology of the treatment experienced children aged 3 to 12 years with no DRV RAMs based on the data from a 2 week qd substudy of the Phase 2 study TMC114 C228 and results from model-based pharmacokinetic simulations. The PL has been updated accordingly
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.20. Darunavir – PREZISTA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000707/II/0067/G
Procedure scope: Grouped variations to: 1) update SmPC sections 4.3 and 4.5 with information of CYP3A mechanism based interactions, 2) update SmPC sections 4.3 and 4.5 with information of CYP2D6 mechanism based interactions. The PL is updated accordingly. In addition editorial changes are implemented in SmPC sections 4.3, 4.4, 4.5 and 9 and list of local representatives in PL is revised
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.21. Dolutegravir –TIVICAY (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/002753/II/0005/G
Procedure scope: Grouped variations: 1) update of SmPC section 4.5 to revise information concerning the interaction between dolutegravir and boceprevir based on a drug-drug interaction study; 2) inclusion of information concerning the hepatic uptake transporters OATP1B1 and OATP1B3 based on an in vitro study requested to address a post-authorisation measure
MAH(s): ViiV Healthcare
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

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

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002574/II/0022
Procedure scope: Update of SmPC sections 4.2, 4.4 and 4.8 to revise recommendations to initiate/discontinue treatment based on creatinine levels and to update safety data as a result of the interim 48 weeks data from the GS-US-236-0118 study. Consequently Annex II.D 'conditions or restrictions with regard to the safe and effective use of the medicinal product' is updated. The MAH included additional analyses using the pooled Week 144 safety analysis set from theGS-US-236-0102 and GS-US-236-0103 studies to support this variation. The RMP has been updated accordingly and is provided in this submission
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.23. Eslicarbazepine – ZEBINIX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000988/II/0044
Procedure scope: Update of SmPC sections 4.2 and 5.1 with the information from concluded safety and efficacy study in the elderly
MAH(s): Bial - Portela & Cª, S.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.24. Fluticasone furoate, vilanterol – RELVAR ELLIPTA (CAP)
Fluticasone furoate, vilanterol trifenatate – REVINTY ELLIPTA (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/002673/WS0602/0005/G, EMEA/H/C/002745/WS0602/0001/G
Procedure scope: Grouped variations: 1) addition of hypersensitivity to SmPC section 4.8. The Package Leaflet has been updated accordingly; 2) amendment of the due date in Annex II and the RMP for the provision of the clinical study report (CSR) for study HZC115151. The application included a revised RMP version 7.0
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.25. Insulin degludec – TRESIBA (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/002498/II/0011
Procedure scope: Extension of indication in children aged from 1 to 18 years. Update to SmPC sections 4.1, 4.2, 4.8 and 5.1. The PL is updated accordingly. In addition, update of the Section 2 of the PL in line with the existing information in SmPC section 4.2
MAH(s): Novo Nordisk A/S
Documents
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.26. 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: Addition of new strength 300 U/ml, grouped with 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

5.2.27. Ipilimumab – YERVOY (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002213/II/0026/G
Procedure scope: Update of SmPC sections 4.8 and 5.1 further to the one-year interim results of two observational studies CA184332 and CA184338 (MEA 029 and MEA 030) and survival data from the chemotherapy-naive patients pooled across Phase 2 and 3 clinical trials. The RMP is updated accordingly to change also the timelines of two category 3 studies CA184143 (MEA 017) and CA184242 (MEA 027)
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.28. Leflunomide – ARAVA (CAP), LEFLUNOMIDE WINTHROP (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000235/WS0560/0062/G, EMEA/H/C/001129/WS0560/0019/G
Procedure scope: Worksharing variations: 1) update of SmPC sections 4.3 and 4.4 of contraindicating and adding a warning on teriflunamide (active metabolite of leflunomide); 2) update of SmPC section 4.5 for leflunomide related to the study reports HWA486/1032/001 (interaction cimetidine) and - HWA486/2F0.1 (interaction with methotrexate); 3) update of SmPC section 4.5 for teriflunomide related to the following Study reports INT11697-INT11720-INT12503-INT12500-INT10564-INT6040. Furthermore the MAH took the opportunity of this worksharing to include drug reaction with eosinophilia and systemic symptoms (DRESS) in the RMP as requested by PRAC
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.29. Linagliptin – TRAJENTA (CAP)
Linagliptin, metformin – JENTADUETO (CAP)

- Evaluation of an RMP in the context of a variation, worksharing procedure

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

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

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

5.2.30. Lipegfilgrastim – LONQUEX (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/002556/II/0004
Procedure scope: Update of SmPC sections 4.4 and 4.8 upon PRAC's request to include information regarding capillary leakage syndrome (CLS); a class effect of G-CSFs. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the SmPC, Annex II and the Package Leaflet, and to update the contact details for the local representative in Malta in the Package Leaflet. An updated RMP version 7.1 is included in this submission
MAH(s): Sicor Biotech UAB
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.31. Liraglutide – VICTOZA (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001026/II/0027
Procedure scope: Implementation of the conclusions of the Art 5(3) referral procedure on GLP-1 based products and pancreatic issues. The MAH proposes an update to SmPC section 4.4 with the PL updated accordingly. The submission includes an update of the RMP
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.32. Loxapine – ADASUVE (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002400/II/0010/G
Procedure scope: Update of Section 4.5 of the SmPC with the results of the Lorazepam Drug-Drug Interaction Study (m5.3.5.4, CSR 204-402) and the CYP Induction study (DM-103).
MAH(s): Alexza UK Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.33. Nitric oxide – INOMAX (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/000337/II/0039
Procedure scope: Submission of an updated RMP for INOmax. Consequently, the Annex II conditions are updated. The MAH takes the opportunity to introduce minor changes to the SmPC section 4.8 and PIL in line with the QRD template
MAH(s): Linde Healthcare AB
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.34. 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: Addition of a new indication for Abraxane 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 the MAH proposes to update SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 and to update the Package Leaflet accordingly. An updated RMP version 14.0 has been provided accordingly

MAH(s): Celgene Europe Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.35. Palonosetron – ALOXI (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: Almath Spooner (IE)

Administrative details:
Procedure number(s): EMEA/H/C/000563/II/0038
Procedure scope: Extension of the indication for paediatric patients 1 month of age and older for the prevention of nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy for the IV formulation, based on the paediatric studies PALO-10-14 and PALO-10-20 and update of sections 5.1 and 5.2 of the Aloxi Oral formulation to reflect those studies
MAH(s): Helsinn Birex Pharmaceuticals Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.36. Pegvisomant – SOMAVERT (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: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000409/X/0072
Procedure scope: Addition of 25 mg and 30 mg powder and solvent for solution for injection
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.37. Pneumococcal polysaccharide conjugate vaccine (adsorbed) – SYNFLORIX (CAP)

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

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/000973/II/0083
Procedure scope: Re-analysis of the convulsions reported in Synflorix clinical studies and those reported during post marketing surveillance as a result of a commitment made in the context of variations II/0069 & II/0070. An updated version of the Synflorix RMP (version 11.0) including the convulsion re-analyses is submitted within this application as well as the amended clinical study report of study 10PN-PD-DIT-028
MAH(s): GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.38. Pramipexole – OPRYMEA (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000941/X/0017
Procedure scope: Addition of new strengths 2.62 mg and 3.15 mg prolonged-release tablets
MAH(s): Krka d.d. Novo mesto
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.39. Propanolol – HEMANGIOL (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/002621/II/0002
Procedure scope: Update of SmPC section 4.8 to reflect the number of studies and the number of patients included in the safety database analysed, following completion of 2 safety studies one of which to investigate long term effects including effect on growth
MAH(s): Pierre Fabre Dermatologie
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.40. Ruxolitinib – JAKAVI (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/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, the MAH proposes to update SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2. The Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC. An updated RMP version 4.0 has been provided as part of the application
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.41. 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/0017/G
Procedure scope: Grouping of two type II variations to update SmPC sections 4.5 and 5.2 based on the drug-drug interaction studies CINC424A2102, undertaken to evaluate the effects of ruxolitinib on the pharmacokinetics of a monophasic oral contraceptive, and CINC424A2103, undertaken to evaluate the intestinal CYP3A4 inhibitory effect of ruxolitinib on the pharmacokinetics of orally administered midazolam. The application addresses MEA 003 and MEA 004. A revised RMP version 3.1 has been included as part of the application
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.42. Shingles (herpes zoster) vaccine (live) – ZOSTAVAX (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/000674/II/0077
Procedure scope: Update of SmPC sections 4.3, 4.4, 4.8 and 5.1 to reflect the results of a double blind placebo controlled study to investigate the immunogenicity, and safety of Zostavax in subjects with HIV infection to address a post-authorisation measure in the RMP. The MAH took the opportunity to perform other updates of the RMP: to classify Herpes zoster/herpes zoster like rash and varicella/varicella-like rash as an Important Identified Risk and to reflect in the RMP the results of 2 other clinical studies with Implications for Safety Concerns (Protocol 029 a booster dose study and Protocol 016)
MAH(s): Sanofi Pasteur MSD SNC
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.43. Sitagliptin – JANUVIA (CAP), RISTABEN (CAP), TESAVEL (CAP), XELEVIA (CAP)

- Evaluation of an RMP in the context of a variation, worksharing procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000722/WS0534/0039, EMEA/H/C/001234/WS0534/0029, EMEA/H/C/000910/WS0534/0039, EMEA/H/C/000762/WS0534/0043
Procedure scope: Update to SmPC section 4.4 and submission of an updated RMP to implement the CHMP recommendations of the Art 5(3) referral procedure on GLP-1-based therapies and pancreatic safety. The PL is proposed to be updated accordingly. The RMP is also updated to include rhabdomyolysis as a potential risk as outcome of post-authorisation measure LEG 006.2
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.44. Sitagliptin, metformin – **EFFICIB** (CAP), **JANUMET** (CAP), **RISTFOL** (CAP), **VELMETIA** (CAP)

- Evaluation of an RMP in the context of a variation, worksharing procedure

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

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

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

5.2.45. Temsirolimus – **TORISEL** (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000799/II/0058
Procedure scope: Update of SmPC sections 4.5 and 5.2 following the pharmacokinetic (PK) analysis from an in vivo drug-drug interaction (DDI) study between temsirolimus 175mg or 75mg and desipramine
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.46. Trastuzumab emtansine – **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: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002389/II/0006/G
Procedure scope: Grouped variations: 1) Update of SmPC section 4.6 and section 2 of the Package Leaflet in order to change the duration of contraception to be used after Kadcyla (trastuzumab emtansine) treatment from 6 to 7 months in line with the Herceptin (trastuzumab) product information. Furthermore the MAH took the opportunity to make minor editorial changes in the Package Leaflet; 2) Update of the 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) Update the due date in the RMP concerning the submission of data from the study BO25499; 4) Update of the due date in the RMP concerning the submission of data for the 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

5.2.47. Travoprost – TRAVATAN (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/000390/II/0046
Procedure scope: Extension of the indication for decrease of elevated intraocular pressure in paediatric patients with ocular hypertension or paediatric glaucoma
MAH(s): Alcon Laboratories (UK) Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.48. Vinflunine – JAVLOR (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

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

RMP evaluated in the context of a PSUR procedure

See Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony stimulating factor (sipuleucel-T) – PROVENGE 6.1.7. , Betaine anhydrous – CYSTADANE 6.1.9. , Brentuximab vedotin – ADCETRIS 6.1.11. , Dexamethasone – OZURDEX 6.1.20. , Emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA 6.1.22. , Fampridine – FAMPYRA 6.1.27. Nalmefene – SELINCRO 6.1.45. , Pirfenidone – ESBRIET 6.1.51. , Prasugrel – EFIENT 6.1.54. , Pregabalin – LYRICA 6.1.55. , Tipranavir – APTIVUS 6.1.66. , Velaglucerase alfa – VPRIV 6.1.69.

RMP evaluated in the context of PASS results

Bevacizumab – AVASTIN 7.4.3. , Epoetin zeta – RETACRIT 7.4.5. , Epoetin zeta – SILAPO 7.4.6. and 7.4.7. , Golimumab – SIMPONI 7.4.8. , Infliximab – REMICADE 7.4.9. , Mannitol – BRONCHITOL 7.4.10. , Teriparatide – FORSTEO 7.4.15.

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

5.2.49. Eltrombopag – REVOLADE (CAP)

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

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001110/R/0018 (with RMP)
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC advice

5.2.50. Leflunomide – LEFLUNOMIDE WITHTROP (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001129/R/0018 (with RMP)
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC advice

5.2.51. Meningococcal group a, c, w135 and y conjugate vaccine – MENVEO (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001095/R/0046 (with RMP)
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC advice

5.2.52. Sevelamer – RENAGEL (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Terhi Lehtinen (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000254/R/0100 (with RMP)
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC advice

5.2.53. Thiotepa – **TEPADINA** (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/001046/R/0017 (with RMP)
MAH(s): Adienne S.r.l. S.U.
Documents:
For adoption: PRAC advice

5.2.54. Zoledronic acid – **ACLASTA** (CAP)

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

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000595/R/0051 (with RMP)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

Others

Bisphosphonates, denosumab and risk of osteonecrosis of the jaw (ONJ): consultation with Scientific Advisory Group (SAG) Oncology, see under 12.12.2.2.

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[3]

6.1.1. Abacavir, lamivudine, zidovudine – **KIVEXA** (CAP), **TRIZIVIR** (CAP), **ZIAGEN** (CAP), NAP

- Evaluation of a PSUSA[4] procedure

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

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00003144/201312
MAH(s): ViiV Healthcare UK Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Aclidinium – **BRETARIS GENUAIR** (CAP), **EKLIRA GENUAIR** (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/002211/PSUV/0015, EMEA/H/C/002706/PSUV/0014
MAH(s): Almirall S.A
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Adalimumab – **HUMIRA** (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/000481/PSUV/0131
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Aflibercept – **ZALTRAP** (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/002532/PSUV/0009
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Ingebjørg Buajordet (NO)

Administrative details:
Procedure number(s): EMEA/H/C/000916/PSUV/0021, EMEA/H/C/000915/PSUV/0023
MAH(s): Servier (Ireland) Industries Ltd., Les Laboratoires Servier
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Anidulafungin – ECALTA (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/000788/PSUV/0027
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony stimulating factor (sipuleucel-T) – PROVENGE (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/002513/PSUV/0001 (with RMP version 7.0)
MAH(s): Dendreon UK LTD
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Axitinib – INLYTA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Ingebjørg Buajordet (NO)

Administrative details:
Procedure number(s): EMEA/H/C/002406/PSUV/0009
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Betaine anhydrous – CYSTADANE (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/000678/PSUV/0015 (with RMP version 5.0)
MAH(s): Orphan Europe S.A.R.L.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Bevacizumab – AVASTIN (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/000582/PSUV/0070
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Brentuximab vedotin – ADCETRIS (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/002455/PSUV/0019 (with RMP version 4.0)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. Catridecacog – NOVOTHIRTEEN (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/002284/PSUV/0004
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Clofarabine – EVOLTRA (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/000613/PSUV/0044
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Cobicistat – TYBOST (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/002572/PSUV/0007
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Colistimethate sodium – COLOBREATHE (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/001225/PSUV/0014
MAH(s): Forest Laboratories UK Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Copper (^{64}Cu) chloride – CUPRYMINA (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/002136/PSUV/0002
MAH(s): Sparkle Srl
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. Crizotinib – XALKORI (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/002489/PSUV/0017
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Dabrafenib – TAFINLAR (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/002604/PSUV/0005
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Degarelix – FIRMAGON (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/000986/PSUV/0023
MAH(s): Ferring Pharmaceuticals A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Dexamethasone – OZURDEX (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/001140/PSUV/0017 (with RMP version 4.0)
MAH(s): Allergan Pharmaceuticals Ireland
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Docetaxel – **DOCETAXEL ACCORD** (CAP), **DOCETAXEL KABI** (CAP), **DOCETAXEL MYLAN** (CAP), **DOCETAXEL TEVA** (CAP), **DOCETAXEL WINTHROP** (CAP), **TAXOTERE** (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/00001152/201311
MAH(s): Accord Healthcare Limited (Docetaxel Accord), Fresenius Kabi Oncology Plc (Docetaxel Kabi), Mylan S.A.S. (Docetaxel Mylan), Teva Pharma B.V. (Docetaxel Teva), Aventis Pharma S.A. (Docetaxel Withrop, Taxotere), various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Elvitegravir – **VITEKTA** (CAP)
Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil – STRIBILD (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002577/PSUV/0006, EMEA/H/C/002574/PSUV/0029
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Emtricitabine, rilpivirine, tenofovir disoproxil – **EVIPLERA** (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/002312/PSUV/0041 (with RMP version 7.0)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Epoetin beta – **NEORECORMON** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

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

Administrative details:
Procedure number(s): EMEA/H/C/000116/PSUV/0084
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Eptifibatide – **INTEGRILIN** (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/000230/PSUV/0070
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. Estradiol, nomegestrol acetate – **IOA** (CAP), **ZOELY** (CAP), NAP

- Evaluation of a PSUSA[6] 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/00002182/201401
MAH(s): Merck Sharp & Dohme Limited (Ioa), Theramex S.r.l. (Zoely) various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. Etanercept – **ENBREL** (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/000262/PSUV/0172
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Fampridine – **FAMPYRA** (CAP)

- Evaluation of a PSUR procedure

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002097/PSUV/0017 (with RMP version 9.0)
MAH(s): Biogen Idec Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Fenofibrate, simvastatin – CHOLIB (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/002559/PSUV/0005
MAH(s): Abbott Healthcare Products Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Fondaparinux– ARIXTRA (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/000403/PSUV/0062
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Gadoversetamide – OPTIMARK (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/000745/PSUV/0022
MAH(s): Mallinckrodt Deutschland GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Hepatitis B (rDNA) vaccine (adjuvanted, adsorbed) – FENDRIX (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/000550/PSUV/0037
MAH(s): GlaxoSmithKline Biologicals
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Human coagulation factor VIII, human von Willebrand factor – VONCENTO (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/002493/PSUV/0007
MAH(s): CSL Behring GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Imiquimod – ALDARA (CAP), ZYCLARA (CAP), NAP

- Evaluation of a PSUSA[7] 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/PSUSA/00001729/201401
MAH(s): Meda AB, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Ingenol mebutate – PICATO (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/002275/PSUV/0005
MAH(s): Leo Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

6.1.36. Ivacaftor – KALYDECO (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/002494/PSUV/0021
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Linaclotide – CONSTELLA (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/002490/PSUV/0016
MAH(s): Almirall S.A
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Lipegfilgrastim – LONQUEX (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/002556/PSUV/0002
MAH(s): Sicor Biotech UAB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.39. Lixisenatide – LYXUMIA (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/002445/PSUV/0005
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.40. Lomitapide – LOJUXTA (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/002578/PSUV/0008
MAH(s): Aegerion Pharmaceuticals Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.41. Loxapine – ADASUVE (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/002400/PSUV/0007
MAH(s): Alexza UK Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.42. 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/0002
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.43. Meningococcal group b vaccine (rDNA, component, adsorbed) – BEXSERO (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/002333/PSUV/0019
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.44. Mercaptopurine – XALUPRINE (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/002022/PSUV/0008
MAH(s): Nova Laboratories Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.45. 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/0013
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.46. Nalmefene – SELINCRO (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/002583/PSUV/0009 (with RMP version 3.0)
MAH(s): H. Lundbeck A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.47. Nilotinib – TASIGNA (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/000798/PSUV/0069
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.48. Nitisinone – **ORFADIN** (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/000555/PSUV/0044
MAH(s): Swedish Orphan Biovitrum International AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUSA[8] 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/00002220/201402
MAH(s): Glaxo Group Ltd (Alli), Roche Registration Ltd (Xenical), various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.50. Paclitaxel – **ABRAXANE** (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/000778/PSUV/0066
MAH(s): Celgene Europe Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.51. Perampanel – **FYCOMPA** (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/002434/PSUV/0014
MAH(s): Eisai Europe Ltd.

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

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.52. Pirfenidone – ESBRIET (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002154/PSUV/0020 (with RMP version 6.0)
MAH(s): InterMune UK Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.53. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) – PREVENAR 13 (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/001104/PSUV/0107
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.54. Pomalidomide – IMNOVID (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/002682/PSUV/0006
MAH(s): Celgene Europe Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.55. Prasugrel – EFIENT (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/000984/PSUV/0016 (with RMP version 10.0)
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.56. Pregabalin – LYRICA (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/000546/PSUV/0069 (with RMP version 11.0)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.57. Raloxifene – EVISTA (CAP), OPTRUMA (CAP), RALOXIFENE TEVA (CAP), NAP

- Evaluation of a PSUSA[9] procedure

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00002603/201312
MAH(s): Daiichi Sankyo Europe GmbH (Evista), Eli Lilly Nederland B.V. (Optruma), Teva Pharma B.V. (Raloxifene Teva), various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.58. Riluzole – RILUTEK (CAP), RILUZOLE ZENTIVA (CAP), NAP

- Evaluation of a PSUSA[10] 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/PSUSA/00002645/201312
MAH(s): Aventis Pharma S.A., various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.59. Rivastigmine – EXELON (CAP), PROMETAX (CAP), RIVASTIGMINE 1A PHARMA (CAP), RIVASTIGMINE HEXAL (CAP), RIVASTIGMINE SANDOZ (CAP), NAP

- Evaluation of a PSUSA[11] procedure

[9] PSUR single assessment, referring to CAP, NAP
[10] PSUR single assessment, referring to CAP, NAP
[11] 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/00002654/201401
MAH(s): 1 A Pharma GmbH (Rivastigmine 1A Pharma), Hexal AG (Rivastigmine Hexal), Novartis Europharm Ltd (Exelon, Prometax), Sandoz Pharmaceuticals GmbH (Rivastigmine Sandoz), various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.60. Rotigotine – **LEGANTO** (CAP), **NEUPRO** (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002380/PSUV/0013, EMEA/H/C/000626/PSUV/0063
MAH(s): UCB Manufacturing Ireland Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.61. Rufinamide – **INOVELON** (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/000660/PSUV/0030
MAH(s): Eisai Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.62. Ruxolitinib – **JAKAVI** (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/002464/PSUV/0015
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.63. Sildenafil – VIAGRA (CAP), NAP

- Evaluation of a PSUSA[12] 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/PSUSA/00002699/201312
MAH(s): Pfizer Limited, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.64. Silodosin – SILODYX (CAP), UROREC (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/001209/PSUV/0017, EMEA/H/C/001092/PSUV/0017
MAH(s): Recordati Ireland Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.65. Sorafenib – NEXAVAR (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/000690/PSUV/0037
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.66. Teriflunomide – AUBAGIO (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/002514/PSUV/0005
MAH(s): Sanofi-Aventis Groupe

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

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.67. Tipranavir – APTIVUS (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/000631/PSUV/0067 (with RMP version 5.0)
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.68. Trastuzumab emtansine – KADCYLA (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/002389/PSUV/0004
MAH(s): Roche Registration Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.69. Ulipristal – ESMYA (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/002041/PSUV/0025
MAH(s): Gedeon Richter Plc.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.70. Velaglucerase alfa – VPRIV (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/001249/PSUV/0018 (with RMP version 8.1)

MAH(s): Shire Pharmaceuticals Ireland Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.71. Vemurafenib – ZELBORAF (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/002409/PSUV/0016
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.72. Vismodegib – ERIVEDGE (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/002602/PSUV/0007
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[13]

6.2.1. Aclidinium bromide – BRETARIS GENUAIR (CAP), EKLIRA GENUAIR (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002706/LEG 006.2, EMEA/H/C/002211/LEG 006.2
Procedure scope: MAH's response to LEG 006.1 (LEG006/PSU-004/PSUR#1) as adopted in June 2014
MAH(s): Almirall S.A
Documents:
For adoption: Updated PRAC Rapp AR

6.2.2. Buprenorphine, naloxone – SUBOXONE (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000697/LEG 027
Procedure scope: MAH's response to the request for additional information as concluded in the evaluation of PSUR#7 [PSUV/0023] as adopted in May 2014
MAH(s): RB Pharmaceuticals Ltd.
Documents:
For adoption: Updated PRAC Rapp AR

6.2.3. Vernakalant – BRINAVESS (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001215/LEG 021
Procedure scope: MAH's response to the request for additional information as concluded in the evaluation of PSUV/0019 (PSUR #5 [PSU-008]) as adopted in April 2014
MAH(s): Cardiome UK Limited
Documents:
For adoption: Updated PRAC Rapp AR

6.2.4. Voriconazole – VFEND (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000387/LEG 085.2
Procedure scope: MAH's response to the request for additional information as concluded in the evaluation of PSUR#13 as adopted at PRAC in October 2013
MAH(s): Pfizer Limited
Documents:
For adoption: Updated PRAC Rapp AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[14]

7.1.1. Cyproterone, ethinylestradiol – DIANE 35 & other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms (NAP)

- Evaluation of an imposed PASS protocol

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

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

Administrative details:
Procedure number(s): NL/H/xxxx/WS/073
Procedure scope: Evaluation of a protocol for a PASS to evaluate physician knowledge of safety and safe use information for Diane-35 and its generics in Europe, as per the conclusions of the Article 107i concluded in May 2013
MAH(s): Bayer
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.1.2. Cyproterone, ethinylestradiol – DIANE 35 & other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms (NAP)

- Evaluation of an imposed PASS protocol

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

Administrative details:
Procedure number(s): NL/H/xxxx/WS/073
Procedure scope: Evaluation of a protocol for a drug utilisation study on the prescribing indications for cyproterone, ethinylestradiol (CPA/EE) in five European countries, as per the conclusions of the Article 107i concluded in May 2013
MAH(s): Bayer
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.1.3. Glycopyrronium bromide, indacaterol – ULTIBRO BREEZHALER (CAP), ULUNAR BREEZHALER (CAP), XOTERNA BREEZHALER (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002679/ANX 002.1, EMEA/H/C/003875/ANX 003, EMEA/H/C/003755/ANX 002.1
Procedure scope: Evaluation of the updated PASS protocol for a multinational database cohort study to assess RMP specified safety outcomes in association with indacaterol/glycopyrronium bromide in Europe
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.1.4. Modified vaccinia Ankara virus – IMVANEX (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002596/SOB 002

Procedure scope: PASS protocol for 1) POX-MVA-038: observational, non-interventional post-authorisation safety study for the prophylactic vaccination with IMVANEX in adults; 2) POX-MVA-039: An observational, non-interventional post-authorisation safety and efficacy study for the prophylactic vaccination with IMVANEX following re-emergence of circulating smallpox infections
MAH(s): Bavarian Nordic A/S
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

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

- Evaluation of an imposed PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/00560/ANX 034, EMEA/H/C/00561/ANX 034
Procedure scope: 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

7.1.6. **Teicoplanin** (NAP)

- 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): DE/H/3916/001-003/MR ; DE/H/3918/001-003/MR ; DK/H/2336/001-003/MR
Procedure scope: Evaluation of a revised protocol for a prospective, observational cohort, non-comparative study describing the safety profile of the higher recommended teicoplanin loading dose of 12 mg/kg twice a day
MAH(s): Sanofi-Aventis (Targocid)
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)[15]

7.2.1. **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

[15] 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

Procedure scope: PASS protocol for a non-interventional study to assess the effectiveness of the additional risk minimisation measures for Eliquis (apixaban) for PRAC assessment (No. CV185365). The draft study protocol includes the evaluation of the effectiveness of the HCP educational materials and patient alert card for the indication on prevention of stroke in patients with non-valvular atrial fibrillation
MAH(s): Bristol-Myers Squibb / Pfizer EEIG
Documents:
For adoption: PRAC advice

7.2.2. Canakinumab - ILARIS (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/001109/MEA/037.1
Procedure scope: Revised PASS protocol for a non-interventional study collecting safety and efficacy data from SJIA patients enrolled in Pharmachild registry (Study CACZ885G2401)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.3. Dabigatran – PRADAXA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/MEA 041.1
Procedure scope: MAH's response to MEA-041 including a revised PASS protocol of Study No. 1160.149, as adopted at PRAC in May 2014
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC advice

7.2.4. Delamanid - DELTYBA (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/002552/MEA 002
Procedure scope: PASS protocol for study 242-120402: multicentre EU-wide observational non-interventional post-authorisation study to assess the safety and drug usage of delamanid (OPC-67683) in routine medical practice in multidrug-resistant tuberculosis patients (Delamanid registry)
MAH(s): Otsuka Novel Products GmbH
Documents:
For adoption: PRAC advice

7.2.5. 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 001.1, EMEA/H/C/002560/MEA 001.2
Procedure scope: Evaluation of the MAH's responses to the list of questions on a revised PASS protocol for an observational study to collect information on utilisation patterns of Nuedexta when used in routine medical practice (protocol number: 13-AVR-403), as adopted in December 2013
MAH(s): Jenson Pharmaceutical Services Ltd
Documents:
For adoption: PRAC advice

7.2.6. Fenofibrate, pravastatin - PRAVAFENIX (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/001243/MEA 007.4
Procedure scope: Evaluation of the MAH's responses to the list of questions for a revised PASS protocol: European, observational, three-year cohort study on the safety of the fixed-dose combination pravastatin 40 mg/fenofibrate 160 mg in real clinical practice (FENOPRA-IV-14-1), as adopted by PRAC in April 2014
MAH(s): Laboratoires SMB S.A.
Documents:
For adoption: PRAC advice

7.2.7. Follitropin alfa - OVALEAP (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/002608/MEA 002
Procedure scope: PASS protocol of a prospective observational study to assess the safety of Ovaleap compared to Gonal-f in one treatment cycle with respect to the incidence rates of OHSS in infertile women undergoing superovulation for assisted reproductive technologies (ART)
MAH(s): Teva Pharma B.V.
Documents:
For adoption: PRAC advice

7.2.8. Glycopyrronium bromide, indacaterol – ULTIBRO BREEZHALER (CAP), ULUNAR BREEZHALER (CAP), XOTERNA BREEZHALER (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002679/MEA 003.1, EMEA/H/C/003875/MEA 004, EMEA/H/C/003755/MEA 003.1
Procedure scope: Evaluation of the updated protocol for a drug utilisation study (DUS) (QVA 149A2401) to determine the proportion of patients who do not meet the criteria specified in the product information and the proportion of patients who have missing information as per RMP or pre-defined high risk treatment conditions
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

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

- Evaluation of a PASS protocol

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
Procedure scope: PASS protocol of a non-interventional cohort study of the safety of live attenuated influenza vaccine (LAIV) in subjects 2-17 years of age (D2560C00008)
MAH(s): MedImmune LLC
Documents:
For adoption: PRAC advice

7.2.10. 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 265.2
Procedure scope: Evaluation of the MAH's responses to the list of questions for a revised PASS protocol to explore the long term safety profile of tenofovir disoproxil fumarate and describe the management of tenofovir-associated renal and bone toxicity in chronic hepatitis B-infected adolescents in Europe (GS-EU-174-1403), as adopted by PRAC in June 2014
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.2.11. 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 045.1
Procedure scope: Revised PASS protocol for BSR register of tocilizumab treated patients and prospective surveillance study for adverse events
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC advice

7.2.12. 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 041.2
Procedure scope: Revised registry protocol collecting long term efficacy and safety data in polyarticular juvenile idiopathic arthritis (pJIA) treatment
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[16]

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)[17]

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

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000780/WS0561/0092, EMEA/H/C/002073/WS0561/0093, EMEA/H/C/000964/WS0561/0062
Procedure scope: Submission of the final study report for the non-interventional study CSPP100A2415 – a cohort study including a nested case-control analysis using data from the United States IMS PharMetrics Plus health plan claims database – assessing the prevalence and incidence of angioedema among patients with hypertension treated with aliskiren or other antihypertensive medications in the US
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

[16] In accordance with Article 107p-q of Directive 2001/83/EC
[17] In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

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

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000780/WS/0581, EMEA/H/C/002073/WS/0581, EMEA/H/C/000964/WS/0581
Procedure scope: Submission of the final study report for the non- interventional study CSPP100A2414 – A cohort study to assess various safety outcomes in aliskiren initiators using US claims data.
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

7.4.3. Bevacizumab – AVASTIN (CAP)

- Evaluation of PASS results

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/0073/G (with RMP 17.0)
Procedure scope: Submission of two final clinical study reports (CSR) (MO18725 and ML21823), both listed in Section III.4 details of outstanding additional pharmacovigilance activities of the RMP. Consequentially the RMP has been updated to version 17.0
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC AR

7.4.4. Data Collection on Adverse Events of Anti-HIV Drugs (D:A:D) study

- PRAC evaluation of D:A:D data merger results

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

Regulatory details:
PRAC Representatives: Filip Josephson (SE), Deborah Ashby (UK)

Administrative details:
Procedure number(s): N/A
Procedure scope: Evaluation of the 14th data merger
MAH(s): various
Documents:
For adoption: PRAC AR

7.4.5. Epoetin zeta – RETACRIT (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000872/0053/G (with RMP version 13.0)
Procedure scope: Final reports for the following two studies in order to fulfil post-authorisation measures: 1) MEA 044: PASCO (PMS-830-07-0043): post-authorisation safety cohort observation of Silapo (epoetin zeta) administered for the treatment of renal anaemia 2) MEA 045: REG-830-10-0098 and REG-830-10-0097 (Pilot Study): epidemiological study based on health care insurance data to determine the risk of venous thromboembolism and all-cause mortality in cancer patients treated with epoetins either with or without transfusions versus cancer patients treated with transfusions alone
MAH(s): Hospira UK Limited
Documents:
For adoption: PRAC AR

7.4.6. Epoetin zeta – SILAPO (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000760/II/0031/G (with RMP version 10.0)
Procedure scope: Final reports for the following two studies in order to fulfil post-authorisation measures: 1) MEA 036: post-authorisation safety cohort observation of Silapo (epoetin zeta) administered intravenously for the treatment of renal anaemia (PASCO); 2) LEG 038: risk of venous thromboembolism and all-cause mortality in cancer patients treated with epoetins either with or without transfusion versus cancer patients treated with transfusion alone. This submission includes an updated RMP to reflect the outcome of the two studies
MAH(s): Stada Arzneimittel AG
Documents:
For adoption: PRAC AR

7.4.7. Golimumab – SIMPONI (CAP)

- Evaluation of PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000992/II/0060 (with RMP version 10.1)
Procedure scope: Submission of the final report of educational programme on the risk of serious infection, congestive heart failure, maladministration and the potential for hypersensitivity reactions (as requested in MEA 010.1). A revised RMP is included to reflect the final report of the educational programme survey and to include the latest version of mock-up of proposed additional risk minimization measures, to add synopses of the completed studies C0524T08 and C0524T09 (related to procedure II/55), and to update the unknowns related to treatment benefits section of the public summary (related to procedure X/47)
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC AR

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

- Evaluation of PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000240/II/0182/G (with RMP version 9.1)
Procedure scope: Submission of the final reports from the rheumatoid arthritis (RA) registries BIOBADASER, BSRBR, and RABBIT cohort 1. An updated RMP is submitted in order to delete lack of efficacy and hypersensitivity from the missing information and add acute hypersensitivity reaction (including anaphylactic shock) as important identified risk
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC AR

7.4.9. Mannitol – **BRONCHITOL** (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001252/II/0011 (with RMP version 5)
Procedure scope: Provision of further qualitative sputum microbiology data from study DPM-B-305 in relation to the safety concern of microbial infection via a contaminated inhaler device (MEA 003)
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC AR

7.4.10. Palivizumab – **SYNAGIS** (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000257/II/0098 (without RMP)
Procedure scope: Submission of the final study report for study A11-632, an observational study carried out to assess the risk of autoimmune and allergic diseases in high risk children exposed to palivizumab, in fulfilment of the Post Authorisation Measure (REC) FU2 032
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC AR

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

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Almath Spooner (IE)

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

7.4.12. Teriparatide – FORSTEO (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000425/II/0039/G (with RMP version 3.0)
Procedure scope: Submission of the concluding report of the European Union component of the post-authorisation safety study (PASS), Study B3D-MC-GHBX(1) and the update to the RMP of Forsteo. Proposal to remove 'limited clinical trial experience in pre-menopausal women' as important missing information
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC advice

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[18]

7.5.1. Abatacept - ORENCIA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000701/MEA/048.2
Procedure scope: Annual updates of the juvenile idiopathic arthritis (JIA) registry
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC advice

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

- Evaluation of interim PASS results

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

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000797/MEA/039
Procedure scope: Annual periodic update report for malignant events [ATR-14-022]
MAH(s): Bristol-Myers Squibb and Gilead Sciences Ltd
Documents:
For adoption: PRAC advice

7.5.3. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (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/000758/MEA 041.2
Procedure scope: Yearly interim clinical study report (V58_30OB*) for a post-marketing observational cohort study to replace study V58P14 (prematurely terminated)
MAH(s): Novartis Vaccines and Diagnostics GmbH
Documents:
For adoption: PRAC advice

7.5.4. Mannitol - BRONCHITOL (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001252/ANX 002.3
Procedure scope: MAH's response to MEA-002.2 (second interim report) questions, as adopted in February 2014
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC advice

7.5.5. Vernakalant - BRINAVESS (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001215/LEG 022
Procedure scope: Evaluation of a serious case of hypotension together with causality assessment
MAH(s): Cardiome UK Limited

Documents:
For adoption: PRAC advice

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

8.1.1. Amifampridine – FIRDAPSE (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001032/S/0027 (without RMP)
MAH(s): BioMarin Europe Ltd
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. Nelarabine – ATRIANCE (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000752/S/0025 (without RMP)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

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

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

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

10.1.1. **Colistimethate sodium - COLOBREATHE** (CAP)

- PRAC consultation on a variation procedure, upon CHMP request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number: EMEA/H/C/001225/II/0015
Procedure scope: Consultation of the PRAC on a DHPC in the framework of a variation of SmPC sections 4.2 and 6.6 to update the information on the administration of the product. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template
MAH(s): Forest Laboratories UK Limited
Documents:
For adoption: PRAC advice

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

11.1.1. **Ethinylestradiol, dienogest** (NAP)

- PRAC consultation on a variation procedure, upon Germany's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Valerie Strassmann (DE)

Administrative details:
Procedure scope: Consultation on the evaluation of a variation relating to a meta-analysis of 4 studies LASS, INAS-OC, TASC and INAS-SCORE (interim results)

MAH(s): Bayer Schering Pharma Oy (Celimona)
Documents:
For adoption: PRAC advice

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. **Acetylsalicylic acid** (NAP)

- PRAC consultation on a review of safety in pregnancy, upon France's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Arnaud Batz (FR)

Administrative details:
Procedure scope: Safety in pregnancy
MAH(s): Bayer (Asproflash)
Documents:
For adoption: PRAC advice

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

- PRAC consultation on risk of accidental exposure, upon Netherlands' request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Sabine Straus (NL)

Administrative details:
Procedure scope: Consultation on MAH's proposal to improve patch visibility and timelines for implementation
MAH(s): Janssen-Cilag (Durogesic)
Documents:
For adoption: PRAC advice

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. European Pharmacovigilance legislation

- Measuring the impact of the new pharmacovigilance legislation

Status: *for discussion*

12.1.2. PRAC Plenary activities

- Figures over 2 years

***Status**: for information*

12.1.3. PRAC Work Programme

- Draft PRAC Work Programme 2014-2015

***Status**: for agreement*

12.2. Pharmacovigilance audits and inspections

12.2.1.1. Pharmacovigilance Audit Facilitation Group (PAFG)

- Risk ratings of pharmacovigilance process areas

***Status:** for discussion*

Documents:
For adoption: draft guidance on network risk ratings of pharmacovigilance process areas

12.2.2. Pharmacovigilance Systems and their Quality Systems

None

12.2.3. Pharmacovigilance Inspections

None

12.2.4. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

12.3.1.1. PSUR single Assessment for Nationally Approved Products only

***Status:** for discussion*

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

12.3.3.1. Consultation on the draft List, version September 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

- Measuring the impact of additional monitoring elements – proposal for EMA procured ENCePP study on qualitative aspects

Status: *for information and nomination of PRAC Sponsor(s)*

12.5.3. List of Product under Additional Monitoring

12.5.3.1. Consultation on the draft List, version September 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

None

12.6.2. Changes to EudraVigilance Database and functional specifications

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

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

None

12.12.2. Incident Management

None

12.13. Interaction with EMA Committees and Working Parties

12.13.1. Committees

None

12.13.2. Working Parties

12.13.2.1. Feedback from EMA/EDQM Joint Workshop on Characterisation of new clotting factor concentrates (FVIII, FIX)

***Status**: for discussion*

12.13.2.2. Scientific Advisory Group (SAG) Oncology

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

***Status**: for agreement*

Documents:
For discussion: SAG package, list of experts

12.14. Interaction within the EU regulatory network

None

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

12.15.2. PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium)

- VISUALizE study (VISualizing Uncertainty Among Laypersons and Experts): proposal for pharmacovigilance assessors involvement

***Status**: for information*

12.15.3. Others

None

13. Any other business

13.1. New organisational model: Harmonisation of timetables for post-authorisation measures

***Status:** for discussion*

13.2. Procedural Advice on CAT-CHMP-PRAC Rapporteur Appointments

***Status:** for agreement*

Documents:
For adoption: Draft Procedural advice