3 November 2014
EMA/PRAC/677871/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 3-6 November 2014

Chair: June Raine – Vice-Chair: Almath Spooner

03 November 2014, 13:00 – 19:00, room 3/A

04 November 2014, 08:30 – 19:00, room 3/A

05 November 2014, 08:30 – 19:00, room 3/A

06 November 2014, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

20 November 2014, 10:00-12:00, room 5/B, via teleconference

Health and Safety Information

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

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised. The start of referrals will also be announced in the meeting highlights. For orphan medicinal products, the applicant name is published as this information is already publicly available.

Note on access to documents

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

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Explanatory notes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table of contents

1. Introduction

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

1.2. Adoption of agenda of the meeting of 3-6 November 2014

Status: *for adoption*

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

1.3. Minutes of the previous PRAC meeting on 6-9 October 2014

Status: *for adoption*

Document: PRAC final Minutes due for publication by 14 November 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. **Codeine** (NAP)

- Review of the benefit-risk balance of codeine indicated for the treatment of cough in paediatric patients following notification by Germany of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Status: *for discussion and agreement of a list of outstanding issues*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)
PRAC Co-Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number: EMEA/H/A-31/1394
MAH(s): various
Documents:
For adoption: List of outstanding issues (LoOI), revised timetable

3.2.2. **Hydroxyzine** (NAP)

- Review of the benefit-risk balance of hydroxyzine following the notification by Hungary 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: Arnaud Batz (FR)
PRAC Co-Rapporteur: Julia Pallos (HU)

Administrative details:
Procedure number: EMEA/H/A-31/1400
MAH(s): UCB, various
Documents:
For adoption: List of outstanding issues (LoOI), revised timetable
For discussion: PDCO report

3.3. Procedures for finalisation

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

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

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

Regulatory details:
PRAC Rapporteur: Menno van der Elst (NL)
PRAC Co-Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000598/A20/0031, EMEA/H/C/000597/A20/0032
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC AR, PRAC recommendation

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

None

3.5. Others

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Infliximab – **INFLECTRA** (CAP), **REMICADE** (CAP), **REMSIMA** (CAP)

- Signal of rhabdomyolysis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *To be appointed*

Administrative details:
EPITT 18129 – New signal
MAH(s): Hospira UK Limited (Inflectra), Janssen Biologics B.V. (Remicade), Celltrion Healthcare Hungary Kft. (Remsima)
Lead MS: SE
Documents:
For adoption: PRAC recommendation

4.1.2. **Methylprednisolone** (NAP)

- Signal of hepatotoxicity after high dose intravenous use

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18121 – New signal
MAH(s): various
Lead MS: AT
Documents:
For adoption: PRAC recommendation

4.1.3. **Vemurafenib – ZELBORAF** (CAP)

- Signal of Dupuytren's contracture

Status: *for discussion*

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

[1] Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

Administrative details:
EPITT 18111 – New signal
MAH(s): Roche Registration Ltd
Lead MS: SE
Documents:
For adoption: PRAC recommendation

4.1.4. Vildagliptin – **GALVUS** (CAP), **JALRA** (CAP), **XILIARX** (CAP)
Vildagliptin, metformin – EUCREAS (CAP), **ICANDRA** (CAP), **ZOMARIST** (CAP)

- Signal of renal failure

Status: *for discussion*

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

Administrative details:
EPITT 18106 – New signal
MAH(s): Novartis Europharm Ltd
Lead MS: SE
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

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

- Signal of aggression and related events

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
EPITT 18127 – New signal
MAH(s): Otsuka Pharmaceutical Europe Ltd
Lead MS: PT
Documents:
For adoption: PRAC recommendation

4.2.2. Dimethyl fumarate – **TECFIDERA** (CAP)

- Signal of progressive multifocal leukoencephalopathy (PML)

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
EPITT 18136 – New signal
MAH(s): Biogen Idec Ltd
Lead MS: DE
Documents:
For adoption: PRAC recommendation

4.2.3. Gadoversetamide – OPTIMARK (CAP)
Gadodiamide, gadopentetic acid, gadolinium (NAP)

- Signal of nephrogenic systemic fibrosis

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18141 – New signal
MAH(s): Mallinckrodt Deutschland (Optimark), various
Lead MS: UK
Documents:
For adoption: PRAC recommendation

4.2.4. HMG-CoA reductase inhibitors: atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, simvastatin (NAP)

- Signal of immune-mediated necrotizing myopathy (IMNM)

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18140 – New signal
MAH(s): various
Lead MS: FR
Documents:
For adoption: PRAC recommendation

4.2.5. Octocog alfa – HELIXATE NEXGEN (CAP), KOGENATE (CAP)

- Signal of inhibitor development in previously untreated patients

Status: *for discussion*

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

Administrative details:
EPITT 18134 – New signal
MAH(s): Bayer Pharma AG
Lead MS: DE
Documents:
For adoption: PRAC recommendation

4.2.6. Paliperidone – INVEGA (CAP), XEPLION (CAP)

- Signal of acute renal failure

Status: *for discussion*

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

Administrative details:
EPITT 18102 – New signal
MAH(s): Janssen-Cilag International N.V.
Lead MS: SE
Documents:
For adoption: PRAC recommendation

4.2.7. Pantoprazole – CONTROLOC CONTROL (CAP), **PANTECTA CONTROL** (CAP), **PANTOLOC CONTROL** (CAP), **PANTOZOL CONTROL** (CAP), **SOMAC CONTROL** (CAP)

- Signal of subacute cutaneous lupus erythematosus (SCLE)

- ***Status:*** *for discussion*

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
EPITT 18119 – New signal
MAH(s): Takeda GmbH
Lead MS: UK
Documents:
For adoption: PRAC recommendation

4.2.8. Radium Ra^{223} dichloride – XOFIGO (CAP)

- Signal of cerebral haemorrhage

- ***Status:*** *for discussion*

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
EPITT 18142 – New signal
MAH(s): Bayer Pharma AG
Lead MS: UK
Documents:
For adoption: PRAC recommendation

4.2.9. Sorafenib – NEXAVAR (CAP)

- Signal of acute generalised exemanthous pustulosis (AGEP)

Status: *for discussion*

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

Administrative details:
EPITT 18109 – New signal
MAH(s): Bayer Pharma AG
Lead MS: SE

Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

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

- Signal of heart valves disorders

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 13832 – Follow-up July 2014
MAH(s): Merck Sharp & Dohme Limited (Adrovance, Fosavance, Vantavo), Les Laboratoires Servier (Osseor, Protelos), various
Documents:
For adoption: PRAC recommendation

4.3.2. 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 September 2014
MAH(s): Astellas (Eligard)
Documents:
For adoption: PRAC recommendation

4.3.3. Sildenafil – REVATIO (CAP), **VIAGRA** (CAP)

- Signal of increased risk of incident melanoma

Status: *for discussion*

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

Administrative details:
EPITT 17997 – Follow-up July 2014
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC recommendation

4.3.4. Vildagliptin – GALVUS (CAP), **JALRA** (CAP), **XILIARX** (CAP)
Vildagliptin, metformin – EUCREAS (CAP), **ICANDRA** (CAP), **ZOMARIST** (CAP)

- Signal of interstitial lung disease

Status: *for discussion*

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

Administrative details:
EPITT 17793 – Follow-up June 2014
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. 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

5.1.2. Aripiprazole

- 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/003926, *Generic*
Intended indication(s): Treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.3. Aripiprazole

- 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/003803, *Generic*
Intended indication(s): Treatment of schizophrenia in adults and in adolescents aged 15 years and older
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.4. Aripiprazole

- 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/004008, *Generic*
Intended indication(s): Treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.5. Aripiprazole

- 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/003899, *Generic*
Intended indication(s): Treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.6. Asfotase alfa

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

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

Administrative details:
Product number(s): EMEA/H/C/003794, *Orphan*
Intended indication(s): Treatment for long-term enzyme replacement therapy in patients with paediatric-onset hypophosphatasia
Applicant: Alexion Europe SAS
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.7. Atazanavir, 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/003904
Intended indication(s): Treatment of human immunodeficiency virus (HIV-1) infected adults aged 18 years and older in combination with other antiretroviral medicinal products
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.8. 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

5.1.9. Edoxaban

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

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

Administrative details:
Product number(s): EMEA/H/C/002629
Intended indication(s): Prevention of stroke and systemic embolism and treatment of venous thromboembolism
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.10. 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

5.1.11. Empagliflozin, metformin

- 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/003770
Intended indication(s): Treatment of type II diabetes
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.12. Human alpha1-proteinase inhibitor

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

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

Administrative details:
Product number(s): EMEA/H/C/002739
Intended indication(s): Treatment to slow the underlying destruction of lung tissue
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.13. Human fibrinogen, human thrombin

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

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

Administrative details:
Product number(s): EMEA/H/C/002807
Intended indication(s): Adjunct to haemostasis
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.14. Lamivudine, raltegravir

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

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

Administrative details:
Product number(s): EMEA/H/C/003823
Intended indication(s): Treatment of human immunodeficiency virus (HIV-1)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.15. 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

5.1.16. Mifepristone

- 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/002830*, Orphan*
Intended indication(s): Treatment of signs and symptoms of endogenous Cushing's syndrome in adults
Applicant: FGK Representative Service GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.17. 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

5.1.18. 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

5.1.19. Oritavancin

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

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

Administrative details:
Product number(s): EMEA/H/C/003785
Intended indication(s): Treatment of complicated skin and soft tissue infections (cSSTI)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.20. Ospemifene

- 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/002780
Intended indication(s): Treatment of vulvar and vaginal atrophy (VVA)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.21. Pegaspargase

- 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/003789
Intended indication(s): Therapy in acute lymphoblastic leukaemia (ALL) in children, adolescents and adult patients
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.22. Pegfilgrastim

- 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/003910, *informed consent*
Intended indication(s): Treatment of neutropenia

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

5.1.23. Plasmodium falciparum circumsporozoite protein fused with hepatitis B surface antigen (rts), and combined with hepatitis B surface antigen (s) in the form of non-infectious virus-like particles (vlps) produced in yeast cells (saccharomyces cerevisiae) by recombinant DNA technology

- 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/W/002300
Intended indication(s): Active immunisation against malaria
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.24. Rasagiline

- 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/003957, *informed consent*
Intended indication(s): Treatment of Parkinson's disease
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.25. 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

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

5.1.27. Sufentanil

- 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/002784, *Hybrid*
Intended indication(s): Management of moderate to severe acute pain
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.28. Susoctocog alfa

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

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

Administrative details:
Product number(s): EMEA/H/C/002792
Intended indication(s): Treatment of haemophilia A
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and advice

5.1.29. Tedizolid

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

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

Administrative details:
Product number(s): EMEA/H/C/002846
Intended indication(s): Treatment of tissue infections (cSSTI)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.30. Tolvaptan

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

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

Administrative details:
Product number(s): EMEA/H/C/002788, *Orphan*
Intended indication(s): Treatment of kidney disease (ADPKD)
Applicant: Otsuka Pharmaceutical Europe Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.31. Voriconazole

- 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/003737, *Generic*
Intended indication(s): Treatment of fungal infections
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and advice

5.1.32. 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. Alglucosidase alfa – MYOZYME (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000636/II/0052
Procedure scope: Update to the RMP (version 7.2)
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC AR

5.2.2. Filgrastim – GRASTOFIL (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/002150/II/0007
Procedure scope: Update of the RMP (version 5.3) to reflect class-specific safety updates made in the Grastofil product information in line with the Neupogen product information
MAH(s): Apotex Europe BV
Documents:
For adoption: PRAC AR

5.2.3. Insulin human – INSUMAN (CAP)

- Evaluation of an RMP in the context of a variation

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

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

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

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

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

5.2.5. Romiplostim – NPLATE (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000942/II/0045
Procedure scope: Type II variation to remove the existing education programme (physician education booklet and dosing calculator) as a condition. The RMP (version 14) is updated accordingly
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC AR

5.2.6. Tocilizumab – ROACTEMRA (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000955/II/0043

Procedure scope: Update to the currently approved RMP (version 16.2) with information from the final clinical study report (CSR) of study NA25220
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC AR

5.2.7. Tenofovir disoproxil – VIREAD (CAP)
Emtricitabine, tenofovir disoproxil – EVIPLERA(CAP), TRUVADA (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/000419/WS0598/0141/G, EMEA/H/C/002312/WS0598/0048/G, EMEA/H/C/000594/WS0598/0107/G
Procedure scope: Worksharing variation to: 1) update the RMP to remove study 174-0127 on renal safety; add references to studies previously submitted, add intermediate results for APR and MITOC studies and 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

5.2.8. Bedaquiline – SIRTURO (CAP)

- Evaluation of an RMP in the context of variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002614/II/0004/G
Procedure scope: Update of SmPC sections 4.4, 4.8 and 5.1 to reflect the final results of study TMC207-C208 stage 2 and study TMC207-C209. The MAH also took the opportunity to clarify the statement in SmPC section 4.5 related to the interaction of bedaquiline and lopinavir/ritonavir
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.9. Bosentan – TRACLEER (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/000401/II/0066

Procedure scope: Extension of indication to include treatment of symptomatic pulmonary arterial hypertension in paediatric patients aged from 3 months to 18 years. The SmPC has been updated in order to include the data generated in studies conducted according to the agreed paediatric investigation plan for bosentan (EMEA-000425-PIP02-10-M04). As a consequence, SmPC sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, 5.3 and 6.6 have been updated. The package leaflet has been updated accordingly. In addition, taking into account the new data in the paediatric population, .the RMP (version 5) is updated accordingly
MAH(s): Actelion Registration Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.10. Colestilan – BINDREN (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002377/II/0006/G
Procedure scope Group of variations to update SmPC section 4.5 to include the results of a completed drug-drug interaction study with colestilan and candesartan. In addition, update of section 5.1 in order to include the ATC code and pharmacotherapeutic classification. The RMP has been updated to include the results of the mentioned drug-drug interaction study. The package leaflet is updated accordingly
MAH(s): Mitsubishi Tanabe Pharma Europe Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.11. Dabigatran – PRADAXA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Torbjorn Callreus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/II/0066
Procedure scope: Final clinical study report (CSR) for study 1160.86 (open label, non-comparative pharmacokinetic and pharmacodynamic study to evaluate the effect of Pradaxa on coagulation parameters including a calibrated thrombin time test in patients with moderate renal impairment undergoing primary unilateral elective total knee or hip replacement surgery). The RMP (version 28.6) is updated accordingly
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.12. Darbapoetin alfa – ARANESP (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000332/II/0130
Procedure scope: Update of SmPC sections 4.2, 4.8, 5.1 and 5.2 to incorporate dosing recommendations for paediatric patients from 1 to < 11 years and to reflect the available data in the paediatric population, following the submission of the clinical study report of the paediatric study 20050256. The package leaflet and RMP are updated accordingly. Additionally, the MAH took the opportunity to implement the latest QRD template and to correct typographical errors in the product information
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.13. Deferiprone – FERRIPROX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000236/II/0089/G
Procedure scope: Update of SmPC section 4.5 regarding the combination of deferiprone with other iron chelators further to a request of the PRAC in the assessment of the PSUR (PSUV/083). Update of SmPC section 5.1 and the RMP with the results of study LA37-111 conducted to evaluate the effect of deferiprone on cardiac QT and QTC interval duration
MAH(s): Apotex Europe BV
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.14. Dibotermin alfa – INDUCTOS (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: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000408/II/0071
Procedure scope: Extension of indication to broaden the use of Inductos in interbody lumbar spine fusion
MAH(s): Medtronic BioPharma B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.15. Febuxostat – ADENURIC (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: Jan Neuhauser (AT)

Administrative details:
Procedure number(s): EMEA/H/C/000777/II/0037
Procedure scope: Update of SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 for the 120 mg strength further to the introduction of a new indication for prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of tumour lysis syndrome (TLS)
MAH(s): Menarini International Operations Luxembourg S.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.16. Ferumoxytol – RIENSO (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002215/II/0008
Procedure scope: Extension of indication to add all cause iron deficiency anaemia when oral therapy is ineffective or inappropriate or where there is a need for rapid iron repletion As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 were proposed to be updated
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.17. Ibandronic acid – IBANDRONIC ACID ACCORD (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

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

5.2.18. Ivacaftor – KALYDECO (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/002494/II/0031
Procedure scope: Update of SmPC sections 4.8 and 5.1 to reflect the results of part 2 of study VX12-770-111 as a fulfilment of the post-authorisation measure (PAM) MEA 007

MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.19. 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 in order to include information regarding capillary leakage syndrome (CLS); a class effect of G-CSFs. The package leaflet is updated accordingly. The RMP (version 7.1) is also updated accordingly
MAH(s): Sicor Biotech UAB
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.20. Methylnaltrexone – RELISTOR (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: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000870/II/0030
Procedure scope: Extension of indication for the treatment of opioid induced constipation in adult non cancer pain patients. Consequently, the MAH proposed the update of SmPC sections 4.1, 4.2, 4.4 and 5.1. The package leaflet is updated accordingly
MAH(s): TMC Pharma Services Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.21. Ocriplasmin – JETREA (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002381/X/0013
Procedure scope: Introduction of a ready-to-use (RTU) formulation with adjusted fill volume for Jetrea 0.375 mg/0.3 mL
MAH(s): ThromboGenics NV
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.22. Paliperidone – INVEGA (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/000746/II/0043
Procedure scope: Update of SmPC sections 4.1 in order to extend the indication to include depressive symptom domain of schizoaffective disorder. Additionally SmPC section 5.1 has been updated to reflect the data from study SCA-3004 on paliperidone palmitate effects in the maintenance of symptom control
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.23. 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: Grouped 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 RMP (version 3.1) is updated accordingly
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.24. 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

5.2.25. Ulipristal – ELLAONE (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/001027/II/0021
Procedure scope: Change in the classification for supply from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' in the EU. Update of the product information in line with a non-prescription setting. Updates of SmPC sections 4.2, 4.4 and 5.1 based on repeated use study (protocol 091015-001) and on interim data from the STEella study in post-menarcheal girls and adult women (protocol 2914-010)
MAH(s): Laboratoire HRA Pharma, SA
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.26. Ulipristal – ESMYA (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/002041/II/0028
Procedure scope: Update of SmPC section 4.1 with subsequent updates to sections 4.2, 4.4, 4.8 and 5.1 in order to extend the current indication to long term (repeated intermittent) treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
MAH(s): Gedeon Richter Plc.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.27. Tobramycin – TOBI PODHALER (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/002155/II/0027/G
Procedure scope: Update of SmPC sections 4.2, 4.4 and 4.8 of in order to reflect data from study CTBM100C2401 (in fulfilment of MEA 10)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.28. Trastuzumab – HERCEPTIN (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/000278/II/0084/G
Procedure scope: Update of SmPC sections 4.2 and 4.8 with information on switching between intravenous (IV) and subcutaneous (SC) formulations further to safety data from study MO22982. The package leaflet is updated accordingly. Update of SmPC section 4.2 with a statement regarding switching between Herceptin and biosimilars
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.29. 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 therapeutic 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

RMP evaluated in the context of a PSUR procedure

See also Colestilan – BINDREN 6.1.8. ; Histamine dihydrochloride – CEPLENE 6.1.19. ; Olanzapine – ZYPADHERA 6.1.30. ; Parecoxib – DYNASTAT 6.1.32. ; Regadenoson – RAPISCAN 6.1.34.

RMP evaluated in the context of PASS results

See also Pioglitazone – ACTOS, GLUSTIN, pioglitazone, glimepiride – TANDEMACT, pioglitazone, metformin – COMPETACT, GLUBRAVA 7.4.1. and 7.4.2. ; Regorafenib – STIVARGA 7.4.3.

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

5.2.30. Eltrombopag – REVOLADE (CAP)

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

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

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

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

5.2.31. Zoledronic acid – ACLASTA (CAP)

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

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

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

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

See also: Denosumab - PROLIA 8.1.6.

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

None

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[3]

6.1.1. Abiraterone – ZYTIGA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002321/PSUV/0024
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Alipogene tiparvovec – GLYBERA (CAP)

- Evaluation of a PSUR 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 the PRAC recommends the maintenance of the terms of the marketing authorisation(s), the procedure finishes at the PRAC level

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002145/PSUV/0036
MAH(s): uniQure biopharma B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Alogliptin – VIPIDIA (CAP)
alogliptin, metformin – VIPDOMET (CAP)
alogliptin, pioglitazone – **INCRESYNC** (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002182/PSUV/0007, EMEA/H/C/002178/PSUV/0008
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Bortezomib – VELCADE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000539/PSUV/0073
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Catumaxomab – REMOVAB (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/000972/PSUV/0021
MAH(s): Neovii Biotech GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Ceftaroline fosamil – ZINFORO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002252/PSUV/0019
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Cidofovir – VISTIDE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
Procedure number(s): EMEA/H/C/000121/PSUV/0044
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Colestilan – BINDREN (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002377/PSUV/0005 (with RMP version 4.0)
MAH(s): Mitsubishi Tanabe Pharma Europe Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Dapagliflozin – FORXIGA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002322/PSUV/0014
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Defibrotide – DEFITELIO (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/002393/PSUV/0003
MAH(s): Gentium S.p.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and haemophilus influenzae type b (Hib) conjugate vaccine (adsorbed) – HEXACIMA (CAP), HEXAXIM (Art 58), HEXYON (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002702/PSUV/0011, EMEA/H/W/002495/PSUV/0019, EMEA/H/C/002796/PSUV/0013
MAH(s)/Scientific Opinion Holder(s): Sanofi Pasteur
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. Ertapenem – INVANZ (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/000389/PSUV/0051
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002020/PSUV/0024, EMEA/H/C/000698/PSUV/0045
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Febuxostat – ADENURIC (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Jan Neuhauser (AT)

Administrative details:
Procedure number(s): EMEA/H/C/000777/PSUV/0035
MAH(s): Menarini International Operations Luxembourg S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Fenofibrate, pravastatin – PRAVAFENIX (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/001243/PSUV/0012
MAH(s): Laboratoires SMB S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Fesoterodine – TOVIAZ (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/000723/PSUV/0042
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. Golimumab – SIMPONI (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/000992/PSUV/0058
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Granisetron – SANCUSO (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Jolanta Gulbinovic (LT)

Administrative details:
Procedure number(s): EMEA/H/C/002296/PSUV/0034
MAH(s): ProStrakan Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Histamine dihydrochloride – CEPLENE (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/000796/PSUV/0021 (with RMP version 7.0)
MAH(s): Meda AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (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/000758/PSUV/0070

MAH(s): Novartis Vaccines and Diagnostics GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Insulin glulisine – APIDRA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000557/PSUV/0060
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Ivabradine – CORLENTOR (CAP), PROCORALAN (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000598/PSUV/0032, EMEA/H/C/000597/PSUV/0033
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Japanese encephalitis vaccine (inactivated, adsorbed) – IXIARO (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/000963/PSUV/0062
MAH(s): Valneva Austria GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Lurasidone – LATUDA (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/002713/PSUV/0002
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Macitentan – OPSUMIT (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002697/PSUV/0003
MAH(s): Actelion Registration Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. Mannitol – BRONCHITOL (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001252/PSUV/0014
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002226/PSUV/0027
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Ocriplasmin – JETREA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002381/PSUV/0014
MAH(s): ThromboGenics NV
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Ofatumumab – ARZERRA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001131/PSUV/0030
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Olanzapine – ZYPADHERA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Terhi Lehtinen (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000890/PSUV/0024 (with RMP version 11.0)
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Panitumumab – VECTIBIX (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/000741/PSUV/0062
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Parecoxib – DYNASTAT (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/000381/PSUV/0062 (with RMP version 4.0)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Pasireotide – SIGNIFOR (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002052/PSUV/0015
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Regadenoson – RAPISCAN (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001176/PSUV/0015 (with RMP version 6.0)
MAH(s): Rapidscan Pharma Solutions EU Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Somatropin – NUTROPINAQ (CAP), OMNITROPE (CAP), SOMATROPIN BIOPARTERS (CAP), NAP

- Evaluation of a PSUSA[4] procedure

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

Regulatory details:
PRAC Rapporteur: Torbjorn Callreus (DK)

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

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00002772/201403
MAH(s): Ipsen Pharma, Sandoz GmbH, BioPartners GmbH, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. Tadalafil – **ADCIRCA** (CAP), **CIALIS** (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001021/PSUV/0019, EMEA/H/C/000436/PSUV/0076
MAH(s): Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Telmisartan, amlodipine – **TWYNSTA** (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/001224/PSUV/0021
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Telmisartan, hydrochorothiazide – **KINZALKOMB** (CAP), **KINZALMONO** (CAP), **MICARDIS** (CAP), **MICARDISPLUS** (CAP), **PRITOR** (CAP), **PRITORPLUS** (CAP), NAP

- Evaluation of a PSUSA[5] 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/PSUSA/00002882/201404
MAH(s): Bayer Pharma AG (Kinzalkomb, Kinzalmono, Pritor, PritorPlus), Boehringer Ingelheim International GmbH (Micardis, MicardisPlus), various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.39. Tenofovir – **VIREAD** (CAP), NAP

- Evaluation of a PSUSA[6] procedure

[5] 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/00002892/201403
MAH(s): Gilead Sciences International Ltd, various
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.40. Tocilizumab – ROACTEMRA (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000955/PSUV/0041
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.41. Vandetanib – CAPRELSA (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/002315/PSUV/0010
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[7]

6.2.1. Plerixafor – MOZOBIL (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/001030/LEG 024

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

Procedure scope: Evaluation of the MAH's response to request for supplementary information to PSU 017 (PSUR#7) previously adopted at PRAC
MAH(s): Genzyme Europe BV
Documents:
For adoption: Updated PRAC Rapp AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[8]

7.1.1. **Domperidone** (NAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: *to be appointed*

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

7.1.2. **Domperidone** (NAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: *to be appointed*

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

7.1.3. **Umeclidinium bromide – INCRUSE** (CAP)
umeclidinium bromide, vilanterol – ANORO (CAP), **LAVENTAIR** (CAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

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

Administrative details:
Procedure number(s): EMEA/H/C/PSP/J/0003
Procedure scope: Evaluation of an imposed PASS protocol (study 201038): non-interventional observational cohort study to quantify the incidence and comparative safety of selected cardiovascular and cerebrovascular events in chronic obstructive pulmonary disease (COPD) patients with umeclidinium/vilanterol compared with tiotropium as a condition of the licence
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC AR, Letter of endorsement/objection/notification that study is a clinical trial

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[9]

7.2.1. **Albiglutide – EPERZAN** (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/002735/MEA 002
Procedure scope: Evaluation of a PASS protocol for an observational database study (non-interventional cohort) (protocol PRJ2335) to assess the risk of acute pancreatitis in subjects exposed to albiglutide, other GLP-1 agonists or DPP-4 inhibitors compared to other antidiabetic agents
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC advice

7.2.2. **Albiglutide – EPERZAN** (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/002735/MEA 003
Procedure scope: Evaluation of a PASS protocol for a phase IV observational database study (non-interventional cohort,) (Protocol PRJ2331) to assess the risk of thyroid and pancreatic cancers, and malignancy when used in combination with insulins in observational databases of sufficient size that provides long term longitudinal follow up of patients
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC advice

7.2.3. **Albiglutide – EPERZAN** (CAP)

- Evaluation of a PASS protocol

[9] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002735/MEA 004
Procedure scope: Evaluation of a PASS protocol for a phase IV observational drug utilisation and foetal outcome study (non-interventional cohort) (protocol PRJ2376) to assess the proportion and characteristic of type2 diabetic women of childbearing potential who are prescribed albiglutide
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC advice

7.2.4. Albiglutide – EPERZAN (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/002735/MEA 005
Procedure scope: Evaluation of a PASS protocol for a phase IV observational drug utilisation and foetal outcome study (non-interventional cohort) (protocol PRJ2379) to assess the proportion and characteristics of type 2 diabetic women who are exposed to albiglutide during pregnancy
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC advice

7.2.5. Catridecacog – NOVOTHIRTEEN (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/002284/MEA 003.3
Procedure scope: Evaluation of a revised PASS protocol for a prospective multi-centre observational study on treatment of congenital FXIII deficiency (NN1841-3868)
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC advice

7.2.6. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000758/MEA 041.3
Procedure scope: Evaluation of the MAH's response to MEA-041.2 (study V58_30OB protocol replacing study V58P14) following the request for supplementary information adopted at PRAC in January 2014
MAH(s): Novartis Vaccines and Diagnostics GmbH
Documents:
For adoption: PRAC advice

7.2.7. **Voriconazole – VFEND** (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000387/MEA 087.1
Procedure scope: Evaluation of a revised PASS protocol (study A1501020): effectiveness of risk minimisation measures aiming at reducing the risks of phototoxicity, squamous cell carcinoma (SCC) of the skin and hepatic toxicity in patients receiving voriconazole in EU
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[10]

None

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

7.4.1. **Pioglitazone – ACTOS** (CAP), **GLUSTIN** (CAP)
pioglitazone, glimepiride – **TANDEMACT** (CAP)
pioglitazone, metformin – **COMPETACT** (CAP), **GLUBRAVA** (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/WS0646/0065, EMEA/H/C/000286/WS0646/0063, EMEA/H/C/000680/WS0646/0040, EMEA/H/C/000655/WS0646/0050, EMEA/H/C/000893/WS0646/0036 (with RMP)
Procedure scope: Evaluation of the results of study AD-4833-411: drug utilisation study on the use of pioglitazone in clinical practice in the UK after the labelling change dated July 2011. The RMP is updated accordingly to reflect the finalisation of the study
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC AR

[10] In accordance with Article 107p-q of Directive 2001/83/EC
[11] 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. Pioglitazone – ACTOS (CAP), GLUSTIN (CAP)
pioglitazone, glimepiride – TANDEMACT (CAP)
pioglitazone, metformin – COMPETACT (CAP), GLUBRAVA (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/WS0647, EMEA/H/C/000286/WS0647, EMEA/H/C/000680/WS0647, EMEA/H/C/000655/WS0647, EMEA/H/C/000893/WS0647 (with RMP)
Procedure scope: Evaluation of study 01-03-TL-OPI-524: cohort study of pioglitazone and bladder cancer in patients with diabetes, and updated RMP in order to reflect the finalisation of the study
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC AR

7.4.3. Regorafenib – STIVARGA (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002573/II/0005 (with RMP)
Procedure scope: Evaluation of the final results of study 14814 (cardiovascular safety study, category 3): evaluation of the effect of regorafenib on cardiovascular safety parameters, specifically QT/QTc intervals and left ventricular ejection fraction (LVEF)
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC AR

7.5. Interim results of imposed and non-imposed PASS and results of non-imposed PASS submitted before the entry into force of the revised variations regulation[12]

7.5.1. Adalimumab – HUMIRA (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000481/MEA 075.3
Procedure scope: Second annual progress report for a long-term non-interventional registry to assess safety and effectiveness of adalimumab in patients with moderately to severely active ulcerative colitis (UC)

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

MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC advice

7.5.2. Certolizumab pegol – CIMZIA (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/00103/MEA 005.1
Procedure scope: Evaluation of interim reports from ARTIS (RA0021), RABBIT (RA0020), US National Databank for Rheumatic Diseases (RA0005) and BSRBR (RA0022)
MAH(s): UCB Pharma SA
Documents:
For adoption: PRAC advice

7.5.3. Cobicistat – TYBOST (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/2572/MEA 013.1
Procedure scope: Interim report on the antiretroviral pregnancy registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.4. Elvitegravir – VITEKTA (CAP)
elvitegravir, cobicistat, emtricitabine, tenofovir - STRIBILD (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002577/MEA 009.1, EMEA/H/C/002574/MEA 013.1
Procedure scope: Interim report on the antiretroviral pregnancy registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.5. Emtricitabine – EMTRIVA (CAP)
emtricitabine, tenofovir – TRUVADA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000533/MEA 047.1, EMEA/H/C/000594/MEA 040.1
Procedure scope: Interim report on the antiretroviral pregnancy registry (APR)
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.5.6. Golimumab – SIMPONI (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000992/MEA 005.3
Procedure scope: Fourth annual report on a German registry study RABBIT to study the long term safety of biologics
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.5.7. Golimumab – SIMPONI (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000992/MEA 006.2
Procedure scope: Third annual report of a registry study of the Swedish database initiative for exposure to golimumab: review and analysis of adverse events from the Swedish National registry system (CNTOART4003)
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.5.8. Golimumab – SIMPONI (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000992/MEA 007

Procedure scope: First annual report on a pregnancy research initiative to study the exposure to golimumab during pregnancy in patients with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis: review and analysis of birth outcomes from the Swedish, Danish, and Finnish medical birth registers (CNTO148ART4001)
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

7.5.9. Golimumab – SIMPONI (CAP)

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000992/MEA 008.1
Procedure scope: First annual report on i3 drug safety epidemiology study (CNTO148ART4002), prospective observational study using a large US health insurance claims database to estimate the long term safety profile in patients with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis initiating golimumab and other types of biological and non-biological treatments after the launch of golimumab
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC advice

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

- Evaluation of interim PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000898/MEA 008.3
Procedure scope: Progress report on a post-authorisation safety surveillance (PASS): observational, non-interventional study in vascular surgery
MAH(s): Omrix Biopharmaceuticals N. V.
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. Bedaquiline – SIRTURO (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002614/R/0003 (without RMP)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC advice

8.1.3. Bosutinib – BOSULIF (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002373/R/0010 (without RMP)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

8.1.4. Cabozantinib – COMETRIQ (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002640/R/0009 (without RMP)
MAH(s): TMC Pharma Services Ltd
Documents:
For adoption: PRAC advice

8.1.5. Canakinumab – ILARIS (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

***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/S/0035 (without RMP)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

8.1.6. **Denosumab – PROLIA** (CAP)

- PRAC consultation on a five-year renewal of the marketing authorisation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001120/R/0043 (with RMP)
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC advice

See also under 5.2

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

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

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

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

10.1.1. **Mycophenolate mofetil – CELLCEPT** (CAP)

- PRAC consultation on a safety-related variation, upon CHMP request

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000082/II/0119
Procedure scope: Update of SmPC sections 4.4 and 4.8 of the SmPC following assessment of SDA036 in order to add a warning and update the safety information on bronchiectasis and hypogammaglobulineamia. The package leaflet is updated accordingly. The MAH also provided with a DHPC as requested by the PRAC
MAH(s): Roche Registration Ltd
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. **Flupirtine** (NAP)

- PRAC consultation on variation, upon Germany's request

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Martin Huber (DE)

Administrative details:
Procedure number(s): AB/H/XXX/II/XXX
Procedure scope: PRAC involvement in the evaluation of an RMP (version 1.0) following the implementation of the Commission Decision dated 5 September 2013 of the article 107i referral procedure on flupirtine
MAH(s): Teva Pharma B.V. (Katadolon retard)
Documents:
For adoption: PRAC advice

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. **Clarithromycin** (NAP)

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

Status: *for discussion and agreement of PRAC advice*

Regulatory details:
Lead member: Almath Spooner (IE)

Administrative details:
Procedure number(s): IE/H/PSUR/0020/003
Procedure scope: PRAC involvement in the evaluation of a PSUR worksharing procedure regarding the cardiovascular safety of clarithromycin
MAH(s): Abbott (Klacid), various
Documents:
For adoption: PRAC advice

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC meeting under the Italian presidency of the council of the EU

Status*: for information*

Documents:
For information: report from the PRAC meeting in Rome 30 September-1 October 2014

12.2. Pharmacovigilance audits and inspections

12.2.1. Pharmacovigilance Systems and their Quality Systems

None

12.2.2. Pharmacovigilance Inspections

None

12.2.3. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

- Consultation on the handling of PSUR single assessment for Nationally Approved Products only

Status: *for agreement*

Documents:
For adoption: Draft CMDh standard operating procedure

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

- Consultation on the draft list, version November 2014

Status: *for discussion and agreement of the list*

Documents:
For adoption: Revised EURD List

12.4. Signal Management

12.4.1. Signal Management

- Feedback from Signal Management Review Technical (SMART) Working Group

***Status**: for information*

12.5. Adverse Drug Reactions reporting and additional reporting

12.5.1. Management and Reporting of Adverse Reactions to Medicinal Products

None

12.5.2. Additional Monitoring

None

12.5.3. List of Product under Additional Monitoring

- Consultation on the draft list, version November 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

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

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

Status: *for discussion*

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Renewals, conditional renewals, annual reassessments

None

12.11. Risk communication and Transparency

12.11.1. Public Participation in Pharmacovigilance

None

12.11.2. Safety Communication

None

12.12. Continuous pharmacovigilance

12.12.1. Incident Management

None

12.13. Interaction with EMA Committees and Working Parties

12.13.1. Committees

None

12.13.2. Blood Products Working Party (BPWP)

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

Status: *for discussion*

12.13.3. Blood Products Working Party (BPWP)

- Guideline on core SmPC for plasma-derived fibrin sealant/haemostatic products

Status: *for discussion*

12.13.4. Healthcare Professionals' Working Party (HCPWP)

- Work plan 2015

Status: *for agreement*

Documents:
For adoption: Draft workplan

12.13.5. Patients' and Consumers' Working Party (PCWP)

- Work plan 2015

Status: *for agreement*

Documents:
For adoption: Draft workplan

12.14. Interaction within the EU regulatory network

12.14.1. EU Regulatory Network Strategy for Best Evidence

- Reflection paper on a strategy for best evidence

Status*: for discussion*

12.14.2. Post-Authorisation Safety Studies

- EU collaborative framework for patient registries

Status: *for discussion*

Documents:
For discussion: Draft strategy paper on registries

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

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

None

12.16. Others

None

13. Any other business

None