3 February 2014
EMA/PRAC/66008/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

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Draft agenda for the meeting on 3-6 February 2014

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)

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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 8 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/

Chair: June Raine – Vice-Chair: Almath Spooner

3 February 2014, 13:00 – 19:00, room 3/A

4 February 2014, 08:30 – 19:00, room 3/A

5 February 2014, 08:30– 19:00, room 3/A

6 February 2014, 08:30 – 16:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

20 February 2014, 10:00-12:00, room 2/E, 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 scopes of procedures, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised and start of referrals will also be made available. For orphan medicinal products, the product name and the applicant are published as this information is already publicly available.

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 February 2014

Status: for adoption

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

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

Status: for adoption

Document: PRAC Final Minutes due for publication on 14 February 2014

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

None

2.3. Procedures for finalisation

None

2.4. Planned public hearings

None

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

3.1. Newly triggered Procedures

None

3.2. Ongoing Procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures

3.4.1. **Diacerein** (NAP)

- Re-examination procedure of the PRAC recommendation following the review of the benefit-risk balance following notification by France of a referral under Article 31 of Directive 2001/83/EC based on pharmacovigilance data

***Status**: for information*

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)
PRAC Co-Rapporteur: Harald Herkner (AT)

Administrative details:

Procedure number: EMEA/H/A-31/1349
EPITT 15994 – Follow-up Nov 2013
MAH(s): Negma-Wockhardt, TRB Chemedica
Triggered by: FR

3.5. 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. **Enzalutamide - XTANDI** (CAP)

- Signal of myalgia

***Status:** for discussion*

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

Administrative details:

EPITT 17795 – New signal
MAH(s): Astellas Pharma Europe B.V.
Leading MS: ES
Documents:
For adoption: PRAC recommendation

4.1.2. **Lansoprazole** (NAP)

- Signal of haemolytic anaemia

***Status:** for discussion*

Regulatory details:

PRAC Rapporteur: *to be appointed*

[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 17805 – New signal
MAH(s): various
Leading MS: FI
Documents:
For adoption: PRAC recommendation

4.1.3. Vildagliptin – **JALRA** (CAP), **GALVUS** (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 – New signal
MAH(s): Novartis Europharm Ltd
Leading MS: SE
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. Cetuximab – **ERBITUX** (CAP)

- Signal of increased fatal adverse events in patients with advanced solid tumours – publication from clinical trials

Status: *for discussion*

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

Administrative details:
EPITT 17795 – New signal
MAH(s): Merck KGaA
Leading MS: SE
Documents:
For adoption: PRAC recommendation

4.2.2. Mycophenolate mofetil - **CELLCEPT** (CAP)

- Signal of bronchiectasis and hypogammaglobulinaemia - publication from *Boddana et al*.; Clinical Transplantation 2011

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
EPITT 17760 – New signal
MAH(s): Roche Registration Ltd
Leading MS: UK
Documents:
For adoption: PRAC recommendation

4.2.3. Panitumumab - VECTIBIX (CAP)

- Signal of increased fatal adverse events in patients with advanced solid tumours – publication from clinical trials

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
EPITT 17795 – New signal
MAH(s): Amgen Europe B.V.
Leading MS: UK
Documents:
For adoption: PRAC recommendation

4.2.4. Paracetamol (NAP)

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

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 17796 – New signal
MAH(s): Bayer Pharma AG, various
Leading MS: BE
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. Amiodarone (NAP)

- Signal of carcinogenicity

Status: *for discussion*

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

Administrative details:
Procedure scope: Evaluation of the MAH's responses to PRAC recommendations as adopted at PRAC in October 2013
EPITT 17699 – Follow-up October 2013
MAH(s): Sanofi Aventis, various
Documents:
For adoption: PRAC recommendation

4.3.2. Basiliximab – SIMULECT (CAP)

- Signal of cardiovascular instability resulting in fatal outcome following off-label use in heart transplantation

***Status**: for discussion*

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000207/SDA/038
Procedure scope: Evaluation of the MAH's responses to PRAC recommendation as adopted at PRAC in February 2013
EPITT 17386 – Follow-up May 2013
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC recommendation

4.3.3. Etanercept – ENBREL (CAP)

- Signal of glioblastoma and other brain neoplasms

***Status**: for discussion*

Regulatory details:

PRAC Rapporteurs: Julia Dunne (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000262/SDA 158
Procedure scope: Evaluation of the MAH's responses to PRAC recommendation as adopted at PRAC in October 2013
EPITT 17425 – Follow-up October 2013
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC recommendation

4.3.4. Interferon beta 1a – AVONEX (CAP), REBIF (CAP) Interferon beta 1b - BETAFERON (CAP), EXTAVIA (CAP)

- Signal of thrombotic microangiopathy (TMA)

***Status**: for discussion*

Regulatory details:

Lead PRAC Rapporteur: Julie Williams (UK)
Product-specific MAH(s): Bayer Pharma AG (Betaferon), Biogen Idec (Avonex), Merck Serono Europe Limited (Rebif), Novartis Europharm Ltd (Extavia)
PRAC Rapporteurs: Dolores Montero Corominas (ES) (Avonex), Julie Williams (UK) (Betaferon, Extavia), Qun-Ying Yue (SE) (Rebif)

Administrative details:
Procedure number(s): EMEA/H/C000136/SDA 037, EMEA/H/C000933/SDA 017, EMEA/H/C000081/SDA 019 EMEA/H/C/000102/LEG 082.1
Procedure scope: Evaluation of the MAHs' responses to PRAC recommendation as adopted at PRAC in September 2013
EPITT 17653 – Follow-up September 2013
Documents:
For adoption: PRAC recommendation

4.3.5. Mefloquine (NAP)

- Signal of possibly permanent neurologic (vestibular) side effects

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure scope: Evaluation of the MAH's responses to PRAC recommendations as adopted at PRAC in October 2013
EPITT 10279 – Follow-up October 2013
MAH(s): Roche, various
Documents:
For adoption: PRAC recommendation

4.3.6. **Paracetamol** (NAP)

- Signal of drug-induced Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP)

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Veerle Verlinden (BE)

Administrative details:
Procedure scope: Assessment of available studies, scientific literature and data from RegiSCAR further to PRAC recommendation as adopted at PRAC in November 2013
EPITT 17744 – Follow-up November 2013
MAH(s): Bayer Pharma AG, various
Documents:
For adoption: PRAC recommendation

4.3.7. **Ustekinumab – STELARA** (CAP)

- Signal of dermatitis exfoliative

Status*: for discussion*

Regulatory details:

PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000958/SDA 040
Procedure scope: Evaluation of MAH's response to PRAC recommendation as adopted by PRAC in September 2013
EPITT 17661 – Signal follow-up September 2013
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Budesonide, 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/003890, EMEA/H/C/002348
Intended indication: Treatment of asthma and chronic obstructive pulmonary disease (COPD)

5.1.2. Bupropion, naltrexone

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

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

Administrative details:
Product number(s): EMEA/H/C/003687
Intended indication: Management of obesity

5.1.3. Canagliflozin, 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/002656
Intended indication: Treatment of type 2 diabetes mellitus

5.1.4. 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: Treatment of patients with human immunodeficiency virus (HIV-1)

5.1.5. 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: Treatment of adults with type 2 diabetes mellitus

5.1.6. 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
Intended indication: Treatment of Gaucher disease type 1

5.1.7. 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: Treatment of non-small cell lung cancer (NSCLC)

5.1.8. Oseltamivir

- 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/003717, *Generic*
Intended indication: Treatment and prevention of influenza

5.1.9. Propranolol

- 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/002621
Intended indication: Treatment of proliferating infantile haemangioma

5.1.10. Recombinant human n-acetylgalactosamine-6-sulfatase (rhgalns) – VIMIZM (CAP MAA)

- 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/002779, *Orphan*
Intended indication: Treatment of mucopolysaccharidosis
Applicant: BioMarin Europe Ltd

5.1.11. Umeclidinium bromide

- 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/002809
Intended indication: Treatment of symptoms in adult patients with chronic obstructive pulmonary disease (COPD)

5.1.12. Vedolizumab

- 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/002782
Intended indication: Treatment of ulcerative colitis and Crohn's disease

5.1.13. Vintafolide – VYNFINIT (CAP MAA)

- 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/002571, *Orphan*
Intended indication: Treatment of platinum resistant ovarian cancer (PROC)
Applicant: Endocyte Europe, B.V.

5.2. Medicines already authorised

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

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

- Evaluation of an RMP in the context of a variation

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

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: Evaluation of the updated RMP version 4.0
MAH(s): Almirall S.A
Documents:
For adoption: PRAC AR

5.2.2. Agomelatine – THYMANAX (CAP), VALDOXAN (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000916/II/0018, EMEA/H/C/000915/II/0020
Procedure scope: Evaluation of the updated RMP version 16.0
MAH(s): Servier (Ireland) Industries Ltd. (Thymanax), Les Laboratoires Servier (Valdoxan)
Documents:
For adoption: PRAC AR

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

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

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

Administrative details:
Procedure number(s): EMEA/H/C/002073/WS0500/0089, EMEA/H/C/000780/WS0500/0089, EMEA/H/C/000964/WS0500/0059
Procedure scope: Evaluation of the updated RMP to 1) reflect important pharmacovigilance milestones that were reached and to update accordingly timelines for completed and ongoing studies, 2) remove rash/SCARS, hypotension, cough, dizziness, peripheral oedema and hypokalaemia as identified risks
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

5.2.4. Colistimethate sodium – COLOBREATHE (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001225/II/0010
Procedure scope: Evaluation of the updated RMP version 4.0 in line with the revised variation regulation for any submission as of 4 August 2013
MAH(s): Forest Laboratories UK Limited
Documents:
For adoption: PRAC AR

5.2.5. Eltrombopag – REVOLADE (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/001110/II/0014/G
Procedure scope: Evaluation of 4 final study reports for the fulfilment of RMP commitments and a proposal for changes in the RMP (replacement of a study and date extensions for RMP commitments listed in section III 4.3)
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC AR

5.2.6. Everolimus – VOTUBIA (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/002311/II/0021
Procedure scope: Evaluation of the updated RMP version 8
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

5.2.7. Levetiracetam – KEPPRA (CAP)

- Evaluation of an RMP in the context of a variation

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/000277/II/0147
Procedure scope: Evaluation of the updated RMP to add information on the risks and related pharmacovigilance activities and risk minimisation measures for patients aged four years and older
MAH(s): UCB Pharma SA
Documents:
For adoption: PRAC AR

5.2.8. Panitumumab – VECTIBIX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000741/II/0056
Procedure scope: Evaluation of the updated RMP version 12 to amend important identified and potential risks, address PRAC recommendations, enhance the physicians education brochure (PEB), provide an update on the European Society of Pathologists (ESP) external quality assurance (EQA) programme and revise the timelines for category 1 and category 3 clinical studies
MAH(s): Amgen Europe B.V.
Documents:
For adoption: PRAC AR

5.2.9. Vemurafenib – ZELBORAF (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/002409/II/0013
Procedure scope: Evaluation of the updated RMP version 7 with proposal for revised study design to address MEA011, MEA012, MEA013
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC AR

5.2.10. Zoledronic acid – ACLASTA (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/000595/II/0044
Procedure scope: Evaluation of the updated RMP version 9.0
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

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

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: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002392/II/0009
Procedure scope: Extension of indication to include treatment of adult patients with diabetic macular oedema
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.12. Apixaban – ELIQUIS (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002148/II/014/G
Procedure scope: Grouping of 2 variations including an extension of indication to add the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults and a type IA variation to add a new pack size of 28 film coated tablets for Eliquis 5mg strength
MAH(s): Bristol-Myers Squibb / Pfizer EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.13. Bosutinib – BOSULIF (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

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

5.2.14. Crizotinib – XALKORI (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002489/II/0004
Procedure scope: Update of SmPC sections 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 to reflect the efficacy and safety data from study 1007 and the updated data from studies 1001 and 1005
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.15. Dabrafenib – TAFINLAR (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002604/II/0002/G
Procedure scope: Update of SmPC section 5.3 to add data from a 26-week toxicology study, G12071. The MAH has also revised the submission date for the final report for a drug-drug interaction study (MEA 006) and updated the RMP accordingly
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.16. Dexamethasone – OZURDEX (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001140/II/0015
Procedure scope: Extension of indication to include treatment of adult patients with diabetic macular oedema
MAH(s): Allergan Pharmaceuticals Ireland
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.17. Entecavir – BARACLUDE (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/000623/II/0041
Procedure scope: Extension of indication to include treatment of chronic hepatitis B virus (HBV) infection in paediatric patients from 2 to <18 years of age with compensated liver disease and evidence of active viral replication and persistently elevated serum ALT levels
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.18. Icatibant– FIRAZYR (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/000899/II/0024/G
Procedure scope: Extension of indication to include treatment of ACE-inhibitor induced angioedema: leading to update of SmPC sections 4.1, 4.2, 4.4, 4.5, 4.7, 4.8 and 5.1 and update of SmPC section 5.1 of the SmPC to include the results of the open-label extension phase of study FAST-3 (HGT-FIR-054)
MAH(s): Shire Orphan Therapies GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.19. Imatinib – IMATINIB ACTAVIS (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: Dolores Montero Corominas (ES)

Administrative details:
Product number(s): EMEA/H/C/002594/X/0003
Intended scope: Line extension to add a new strength 400mg hard capsule
MAH(S): Actavis Group PTC ehf
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.20. Infliximab – REMICADE (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/000240/II/0179
Procedure scope: Update of SmPC section 4.8 to add intestinal obstruction based on the data available from clinical trials, post-marketing experience and from registries in adult Crohn's Disease
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.21. Palivizumab – SYNAGIS (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: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000257/X/0095
Procedure scope: Introduction of a new pharmaceutical form: 100 mg/ml solution for injection presented in vials containing 0.5 ml and 1 ml
MAH(s): AbbVie Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.22. Peginterferon alfa-2a – PEGASYS (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/000395/II/0073
Procedure scope: Extension of indication to include the use of hepatitis C virus (HCV) NS3/4A protease inhibitors for the treatment of HCV genotype 1
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.23. Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) – PREVENAR 13 (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/001104/II/0098

Procedure scope: Update of SmPC sections 4.2, 4.4, 4.8 and 5.1 to add information on the use of Prevenar 13 in populations associated with high risk of pneumococcal infection
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.24. Telaprevir – INCIVO (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/002313/II/0023
Procedure scope: Update of SmPC sections 4.5 and 5.1 with study results of VX-950-HPC3008 darunavir substudy
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.25. Vismodegib – ERIVEDGE (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/002602/II/0005
Procedure scope: Evaluation of a non-clinical study (MEA) and revised version of the RMP (as a consequence of MEA fulfilment)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

RMP in the context of a stand-alone RMP procedure

5.2.26. Atosiban – TRACTOCILE (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000253/RMP 015.1
MAH(s): Ferring Pharmaceuticals A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.27. Bromfenac – YELLOX (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001198/RMP 009
MAH(s): Croma-Pharma GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.28. Filgrastim – BIOGRASTIM (CAP), RATIOGRASTIM (CAP), TEVAGRASTIM (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000826/MEA 019 (Biograstim), EMEA/H/C/000825/MEA 019 (Ratiograstim), EMEA/H/C/000827/MEA 019 (Tevagrastim)
MAH(s): AbZ Pharma GmbH (Biograstim), Ratiopharm GmbH (Ratiograstim), Teva GmbH (Tevagrastim)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.29. Imiglucerase – CEREZYME (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000157/RMP 046.1
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.30. Oseltamivir – TAMIFLU (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000402/RMP 096.1
MAH(s): Roche Registration Ltd
Documents:

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

RMP evaluated in the context of a PSUR procedure

See Corifollitropin alfa (ELONVA) under 6.1.4. ; Fampiridine (FAMPYRA) under 6.1.6. ; Gefitinib (IRESSA) under 6.1.7. ; Human rotavirus, live attenuated (ROTARIX) 6.1.8. ; Hydroxycarbamide (SIKLOS) under 6.1.9. ; Mirabegron (BETMIGA) under 6.1.16. ; Perampanel (FYCOMPA) under 6.1.21. ; Rufinamide (INOVELON) under 6.1.24.

RMP evaluated in the context of PASS results

See Epoetin zeta (RETACRIT) under 7.4.1. ; Epoetin zeta (SILAPO) under 7.4.2.

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

See Alipogene tiparvovec (GLYBERA) under 8.1.2. , Efavirenz – (STOCRIN, SUSTIVA) under 8.1.5. , Fentanyl (INSTANYL) under 8.1.6. , Liraglutide (VICTOZA) under 8.1.9.

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[3]

6.1.1. Aclidinium bromide – **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/002706/PSU 007, EMEA/H/C/002211/PSU 007 (without RMP)
MAH(s): Almirall S.A
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Agalsidase alfa – **REPLAGAL** (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/000369/PSU 080 (without RMP)
MAH(s): Shire Human Genetic Therapies AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

[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

6.1.3. Aripiprazole – ABILIFY (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/000471/PSU 069 (without RMP)
MAH(s): Otsuka Pharmaceutical Europe Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Corifollitropin alfa – ELONVA (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/001106/PSU 011 (with RMP version 6.0)
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Dasatinib – SPRYCEL (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000709/PSU 039 (without RMP)
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Fampridine – FAMPYRA (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/002097/PSU 005 (with RMP version 8.0)
MAH(s): Biogen Idec Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Gefitinib – IRESSA (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/001016/PSU 011 (with RMP version 8.0)
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Human rotavirus, live attenuated – ROTARIX (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/000639/PSU 078 (with RMP version 9.0)
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Hydroxycarbamide – SIKLOS (CAP)

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000689/PSU 031 (with RMP version 14)
MAH(s): Addmedica
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Idursulfase – ELAPRASE (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000700/PSU 034 (without RMP)
MAH(s): Shire Human Genetic Therapies AB
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. 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/PSU 005 (without RMP)
MAH(s): Leo Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. 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/PSU 013 (without RMP)
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Linagliptin, metformin – JENTADUETO (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/002279/PSU 006 (without RMP)
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. 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/PSU 010 (without RMP)
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. 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/PSU 009 (without RMP)
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.16. Methoxy polyethylene glycol-epoetin beta – MIRCERA (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/000739/PSU 018 (without RMP)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. 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/PSU 004 (with RMP version 2.0)
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Palonosetron – ALOXI (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/000563/PSU 021 (without RMP)
MAH(s): Helsinn Birex Pharmaceuticals Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

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

- Evaluation of a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000395/PSU 050 (without RMP)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Pegloticase – KRYSTEXXA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002208/PSU 011 (without RMP)
MAH(s): Savient Pharma Ireland Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. 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/PSU 008 (with RMP version 1.6)
MAH(s): Eisai Europe Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. 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/PSU 053 (without RMP)
MAH(s): Pfizer Limited
Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Ribavirin – **REBETOL** (CAP), **RIBAVIRIN MYLAN** (CAP), **RIBAVIRIN TEVA** (CAP), **RIBAVIRIN TEVA PHARMA BV** (CAP), NAP

- Evaluation of a PSUSA[4] procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00010007/201307
MAH(s): CT Arzneimittel GmbH (Ribavirin CT), Generics (UK) Limited (Ribavirin Mylan), JSC Olainfarm (Ribavirin 200mg capsules), Laboratorios Normon S.A. (Ribavirin Normon), Merck Sharp & Dohme Limited (Rebetol), Roche registration Limited (Copegus), Teva Pharma B.V. (Ribavirin Teva, Ribavirin Teva Pharma B.V.), Valeant (Ribavirin NL/H/2303/001/DC), Zentiva (Ribavirin Zentiva)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Rufinamide – **INOVELON** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000660/PSU 027 (with RMP version 8.0)
MAH(s): Eisai Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Saxagliptin – **ONGLYZA** (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/001039/PSU 030 (without RMP)
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. Telithromycin – **KETEK** (CAP)

- Evaluation of a PSUR procedure

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

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/000354/PSU 047 (without RMP)
MAH(s): Aventis Pharma S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[5]

6.2.1. Clofarabine – EVOLTRA (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000613/LEG 037.1
Procedure scope: MAH's response to PSU-037 (PSUR#9) as adopted in May 2013
MAH(s): Genzyme Europe BV
Documents:
For adoption: Updated PRAC Rap AR

6.2.2. Pregabalin – LYRICA (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/000546/LEG 040.1
Procedure scope: MAH's response to PSUR#14 as adopted at PRAC in September 2013
MAH(s): Pfizer Limited
Documents:
For adoption: Updated PRAC Rap AR

6.2.3. Oseltamivir – TAMIFLU (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000402/LEG 087.1
Procedure scope: MAH's response to PSUR#12 as adopted at PRAC in April 2013

[5] Follow up as per the conclusions of the previous PSUR procedure, assessed outside the following PSUR procedure

MAH(s): Roche Registration Ltd
Documents:
For adoption: Updated PRAC Rap AR

See also Interferon beta-1a (AVONEX) under 4.3.4.

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[6]

7.1.1. Lenalidomide - REVLIMID (CAP)

- Evaluation of an imposed PASS protocol

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000717/ANX/041.2
Procedure scope: Evaluation of a revised protocol for a retrospective drug utilisation study (CC-5013-MDS-012): a post-authorisation, non-interventional, retrospective, drug-utilisation study to describe the pattern of use of lenalidomide in patients with myelodysplastic syndromes (MDS)
MAH(s): Celgene Europe Limited
Documents:
For adoption: Letter of endorsement/objection/notification that study is a clinical trial, PRAC AR

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

- Evaluation of an imposed PASS protocol

Status: *for discussion and appointment of PRAC Rapporteur and adoption of timetable*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
Scope: Adoption of timetable and appointment of Rapporteur for the evaluation of a PASS protocol (following conclusion of 107i Referral) on a multicentre, non-interventional, uncontrolled, open-label, observational study in children to evaluate serum mg levels associated with the intake of Numeta G 16% E
MAH(s): Baxter
Documents:
For adoption: Timetable

7.1.3. Trimetazidine (NAP)

- Evaluation of an imposed PASS protocol

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

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

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

Administrative details:
Scope: Evaluation of a protocol for a drug utilisation study to verify the compliance of prescribers regarding the restriction of indications after marketing authorisation changes
MAH(s): Lupin Europe (on behalf of Actavis Group PTC ehf., Alvogen IPCo S.a.r.l., Apotex Europe B.V., Chemical Works of Gedeon Richter Plc., Generis Farmacêutica, S. A., Glenmark Pharmaceuticals s.r.o., Hexal AG (Sandoz / Novartis), Labesfal – Laboratorios Almiro S.A., Laboratorios Cinfa, S.A., Lupin (Europe) Limited, Mylan S.A.S., Pensa Pharma, S.A., Terapia S.A. (Ranbaxy group), Teva Pharmaceuticals Europe B.V.)
Documents:
For adoption: Letter of endorsement/objection/notification that study is a clinical trial, PRAC AR

7.1.4. **Trimetazidine** (NAP)

- Evaluation of an imposed PASS protocol

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

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

Administrative details:
Procedure scope: Evaluation of a protocol for a drug utilisation study to verify the compliance of prescribers regarding the restriction of indications after marketing authorisation changes
MAH(s): Servier
Documents:
For adoption: Letter of endorsement/objection/notification that study is a clinical trial, PRAC AR

7.1.5. **Trimetazidine** (NAP)

- Evaluation of an imposed PASS protocol

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

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

Administrative details:
Procedure scope: Evaluation of a protocol for a case-control study to assess and estimate the relationship between trimetazidine use and parkinsonism
MAH(s): Servier
Documents:
For adoption: Letter of endorsement/objection/notification that study is a clinical trial, PRAC AR

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[7]

7.2.1. **Aliskiren – RASILEZ** (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000780/MEA 034.1

[7] 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: Evaluation of a revised PASS protocol (CSPP100A2418): cohort study exploring the incidence of colorectal hyperplasia and gastrointestinal cancer in treated adult hypertensive patients in the United States
MAH(s): Novartis Europharm Ltd
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
Procedure scope: Evaluation of a PASS protocol (Study CACZ885G2401): non-interventional study collecting safety and efficacy data from systemic juvenile idiopathic arthritis (SJIA) patients enrolled in the Pharmachild registry who initiate treatment with canakinumab
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.3. Dapagliflozin – FORXIGA (CAP)

- Evaluation of a PASS protocol

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/002322/MEA 008.2
Procedure scope: MAH's response to MEA 008.1 [Updated Drug Utilisation SR protocol] as adopted at PRAC/CHMP in October 2013 and a revised study protocol for MB102134
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC advice

7.2.4. Fenofibrate, simvastatin – CHOLIB (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002559/MEA 002
Procedure scope: Evaluation of PASS protocol ABT285.E.001: drug utilisation research (DUR) study on the use of Cholib (fenofibrate and simvastatin fixed combination): a European multinational study using secondary health records databases
MAH(s): Abbott Healthcare Products Ltd.
Documents:
For adoption: PRAC advice

7.2.5. Hydrocortisone – PLENADREN (CAP)

- Evaluation of a PASS protocol

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/002185/MEA 005
Procedure scope: Evaluation of a PASS protocol for study SWE-DUS: a Swedish, retrospective, study progress reports to be provided on a yearly basis evaluating the pattern of Plenadren use from as part of the PSURs Swedish quality registries
MAH(s): ViroPharma SPRL
Documents:
For adoption: PRAC advice

7.2.6. Indacaterol, glycopyrronium bromide – ULTIBRO BREEZHALER (CAP), XOTERNA BREEZHALER (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002679/MEA 003, EMEA/H/C/003755/MEA 003
Procedure scope: Evaluation of a drug utilisation study protocol (QVA 149A2401): multinational, multi-database drug utilisation study of indacterol/glycopyrronium bromide in Europe
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.7. Lixisenatide – LYXUMIA (CAP)

- Evaluation of a PASS protocol

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/002445/MEA 007.1, EMEA/H/C/002445/MEA 008.1
Procedure scope: Evaluation of updated PASS protocols for retrospective database study and patient registry on GLP-1 receptor agonists and risk of acute pancreatitis, pancreatic cancer and thyroid cancer, in Particular medullary thyroid cancer. Also including response to MEA 007 and MEA 008 as adopted at PRAC/CHMP in July 2013
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC advice

7.2.8. Moroctocog alfa – REFACTO AF (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000232/MEA 115
Procedure scope: Evaluation of clinical study report for a post-authorisation safety surveillance registry or ReFacto AF in previously untreated patients (PUPs) in usual care settings - Study 443
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

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

- Evaluation of a PASS protocol

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

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/002094/MEA 020, EMEA/H/C/001208/MEA 024, EMEA/H/C/002269/MEA 019
Procedure scope: Evaluation of a PASS protocol synopsis V87_27 OB: post-marketing observational cohort safety study of the Novartis Vaccines and Diagnostics pandemic influenza A (H5N1) vaccine Foclivia in pregnant women in Great Britain using data from the clinical practice research datalink (CPRD)
MAH(s): Novartis Vaccines and Diagnostics S.r.l.
Documents:
For adoption: PRAC advice

7.2.10. Radium-223 – XOFIGO (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002653/MEA 004
Procedure scope: Evaluation of a PASS protocol (REASSURE study 16913): observational study to assess the long term safety profile and risks of developing second primary malignancies and their potential relationship to radium-223 in the routine clinical practice setting
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[8]

None

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

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

7.4.1. Epoetin zeta – RETACRIT (CAP)

- Evaluation of non-imposed 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/II/0053/G (with RMP)
Procedure scope: Evaluation of 1) MEA 44: clinical PASCO (PMS-830-07-0043) post-authorisation safety cohort observation of Silapo (epoetin zeta) administered for the treatment of renal anaemia; 2) MEA 45: clinical REG-830-10-0098 and REG-830-10-0097 (pilot study): epidemiological study based on healthcare 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

7.4.2. Epoetin zeta – SILAPO (CAP)

- Evaluation of non-imposed 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)
Procedure scope: Submission of the final reports for the following two studies in order to fulfil the post-authorisation measures MEA 036 and LEG 038: 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 transfusions versus cancer patients treated with transfusions 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

7.5. 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[10]

7.5.1. Bazedoxifene – CONBRIZA (CAP)

- Evaluation of interim PASS results

[9] 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
[10] 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/000913/MEA 012.5
Procedure scope: Evaluation of second progress report on PASS study B1781044: cohort study of venous thromboembolism and other clinical endpoints among osteoporotic women prescribed bazedoxifene, bisphosphonates or raloxifene in Europe
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

7.5.2. Boceprevir – VICTRELIS (CAP)

- Evaluation of interim PASS results

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002332/MEA 017.5
Procedure scope: Evaluation of second interim status report of postmarketing drug utilisation study: an observational PASS of Victrelis (boceprevir) among chronic hepatitis C patients (P08518)
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC advice

7.5.3. Caffeine – PEYONA (CAP)

- Evaluation of interim PASS results

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

Regulatory details:

PRAC Rapporteur: Harald Herkner (AT)

Administrative details:
Procedure number(s): EMEA/H/C/001014/MEA 001.8
Procedure scope: Evaluation of fourth interim report on Peyona PASS study to assess drug utilisation and safety of caffeine citrate (Nymusa) in treatment of premature infants
MAH(s): Chiesi Farmaceutici S.p.A.
Documents:
For adoption: PRAC advice

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

- Evaluation of interim PASS results

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/002691/MEA 002.2, EMEA/H/C/002430/MEA 002.2, EMEA/H/C/002690/MEA 002.2
Procedure scope: Evaluation of first interim results of a drug utilisation study: multinational, multi-database drug utilisation study of inhaled glycopyrronium in Europe
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.5.5. 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 002.2
Procedure scope: Evaluation of second interim analysis of the cystic fibrosis (CF) study
MAH(s): Pharmaxis Pharmaceuticals Limited
Documents:
For adoption: PRAC advice

7.5.6. Ticagrelor – BRILIQUE (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/001241/MEA 008.3
Procedure scope: Evaluation of the third annual progress report on drug utilisation study D5130N00010: pharmacoepidemiological study to examine patient characteristics, drug utilisation pattern and crude incidence rates of selected outcomes in new users of ticagrelor, clopidogrel and prasugrel in national Swedish registries
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC advice

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

8.1.1. Anagrelide – XAGRID (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000480/S/0057 (without RMP)

MAH(s): Shire Pharmaceutical Contracts Ltd.
Documents:
For adoption: PRAC advice

8.1.2. Alipogene tiparvovec – GLYBERA (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/002145/S/0027 (with RMP version 5.1)
MAH(s): uniQure biopharma B.V.
Documents:
For adoption: PRAC advice

8.1.3. Clopidogrel – GREPID (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
Procedure number(s): EMEA/H/C/001059/R/0029 (without RMP)
MAH(s): Pharmathen S.A.
Documents:
For adoption: PRAC advice

8.1.4. 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: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000613/S/0041 (without RMP)
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC advice

8.1.5. Efavirenz – STOCRIN (CAP), SUSTIVA (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

Administrative details:
Procedure number(s): EMEA/H/C/000250/R/0096 (with RMP), EMEA/H/C/000249/R/0120 (with RMP)
MAH(s): Merck Sharp & Dohme (Stocrin), Bristol-Myers Squibb Pharma EEIG (Sustiva)
Documents:
For adoption: PRAC advice

8.1.6. Fentanyl – INSTANYL (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000959/R/0022 (with RMP version 14)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC advice

8.1.7. Histamine dihydrochloride – CEPLENE (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

Administrative details:
Procedure number(s): EMEA/H/C/000796/S/0020 (without RMP)
MAH(s): Meda AB
Documents:
For adoption: PRAC advice

8.1.8. Lamivudine – ZEFFIX (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000242/R/0062 (without RMP)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

8.1.9. Liraglutide – VICTOZA (CAP)

- PRAC consultation on a renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001026/R/0025 (with RMP)
MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC advice

8.1.10. Pixantrone – PIXUVRI (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Julia Dunne (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002055/R/0014 (without RMP)
MAH(s): CTI Life Sciences Limited
Documents:
For adoption: PRAC advice

8.1.11. Plerixafor – MOZOBIL (CAP)

- PRAC consultation on a 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/001030/R/0019 (without RMP)
MAH(s): Genzyme Europe BV
Documents:
For adoption: PRAC advice

8.1.12. Tafamidis – VYNDAQEL (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002294/S/0012 (without RMP)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

8.1.13. Tocofersolan – VEDROP (CAP)

- PRAC consultation on a renewal 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/000920/R/0007 (with RMP)
MAH(s): Orphan Europe S.A.R.L.
Documents:
For adoption: PRAC advice

8.1.14. Tolvaptan – SAMSCA (CAP)

- PRAC consultation on a renewal 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/000980/R/0016 (without RMP)
MAH(s): Otsuka Pharmaceutical Europe Ltd
Documents:
For adoption: PRAC advice

8.1.15. Trabectedin – YONDELIS (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Line Michan (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000773/S/0037 (without RMP)
MAH(s): Pharma Mar, S.A.
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. Interferon beta 1a – **AVONEX** (CAP)**, REBIF** (CAP) **Interferon beta 1b - BETAFERON** (CAP), **EXTAVIA** (CAP)

- PRAC consultation on variation procedures, on CHMP's request

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

Regulatory details:

Lead PRAC Rapporteur: Julie Williams (UK)
PRAC Rapporteurs: Dolores Montero Corominas (ES) (Avonex), Julie Williams (UK) (Betaferon, Extavia), Qun-Ying Yue (SE) (Rebif)

Administrative details:

Procedure number(s): EMEA/H/C/000102/II/0141, EMEA/H/C/000136/II/0104, EMEA/H/C/000081/II/0091, EMEA/H/C/000933/II/0061
Procedure scope: Update of SmPC sections 4.4 and 4.8 to add safety information with regard to focal segmental glomerulosclerosis
Product-specific MAH(s): Bayer Pharma AG (Betaferon), Biogen Idec (Avonex), Merck Serono Europe Limited (Rebif), Novartis Europharm Ltd (Extavia)
Documents:
For adoption: PRAC advice

10.2. Timing and message content in relation to Member States safety announcements

None

10.3. Other requests

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

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

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

Regulatory details:

PRAC Rapporteur: Miguel Angel-Macia (ES)

Administrative details:

Procedure number(s): EMEA/H/C/002673/ANX 002
Procedure scope: CHMP request for PRAC advice on clinical trial protocol for study HZC115151: interventional post-authorisation safety study to further investigate the risk of pneumonia with Relvar Ellipta compared with other inhaled corticosteroid (ICS)/ long-acting beta2 agonists (LABA) FDC in the treatment of chronic obstructive pulmonary disease (COPD)
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

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

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

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

Regulatory details:

PRAC Rapporteur: Miguel Angel-Macia (ES)

Administrative details:
Procedure number(s): EMEA/H/C/002673/ANX 004
Procedure scope: CHMP request for PRAC advice on clinical trial protocol for study HZA115150: interventional post-authorisation safety study to further investigate the risk of pneumonia with Relvar Ellipta compared with other inhaled corticosteroid (ICS)/ long-acting beta2 agonists (LABA) FDC in the treatment of asthma
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC advice

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

11.1. Safety related variations of the marketing authorisation

11.1.1. **Flucloxacillin** (NAP)

- PRAC consultation on a variation procedure, on Member State's request

Status: *for discussion and agreement of advice to Member States*

Regulatory details:

Lead PRAC member: Sabine Straus (NL)

Administrative details:
Procedure scope: PRAC consultation on a variation to add a warning in SmPC section 4.4 of Flucloxacillin and Floxapen to exercise special caution regarding drug induced liver injury in subjects with HLA-B*5701 haplotype
MAH(s): Actavis Group PTC
Documents:
For adoption: PRAC advice

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. **Gadolinium containing contrast agents** (NAP, CAP)

- PRAC consultation on harmonised traceability of gadolinium-containing contrast agents, on Member State's request

Status: *for discussion and agreement of advice to Member States*

Regulatory details:

Lead PRAC member: Qun-Ying Yue (SE)

Administrative details:
Procedure scope: PRAC consultation on EU harmonised traceability method for effective monitoring of the use of Gadolinium containing contrast agents (GdCAs)
MAH(s): Mallinckrodt Deutschland GmbH (Optimark), various

Documents:
For adoption: PRAC advice

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

None

12.2. Pharmacovigilance audits and inspections

12.2.1. Pharmacovigilance Systems and their Quality Systems

None

12.2.2. Pharmacovigilance Inspections

12.2.2.1. Union Procedure on Follow-up to Pharmacovigilance Inspections

- Union procedure on the management of pharmacovigilance inspection findings with potential significant impact on the benefit-risk profile of the concerned medicinal products

Status*: for discussion*

Documents:
For adoption: Draft Union procedure guideline

12.2.3. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

None

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

12.3.3.1. Consultation on the draft List, version February 2014

12.3.3.1.1. 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

12.5.3.1. Consultation on the draft List, version February 2014

***Status**: for information*

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

None

12.6.2. Changes to EudraVigilance Database and functional specifications

None

12.6.3. EudraVigilance annual report

- 2013 EudraVigilance (human) annual report

***Status**: for information*

12.6.1. Practical implementation of Article 20 pharmacovigilance referral procedures

***Status:** for discussion*

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

None

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.9.2. Practical implementation of Article 20 pharmacovigilance referral procedures

- Questions and answers documents on practical implementation

Status: *for discussion*

12.10. Renewals, conditional renewals, annual reassessments

12.10.1. 5-year renewal procedures

- Proposal for refining the handling of 5-year renewal PRAC advice

Status: *for discussion*

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. Biologics Working Party (BWP), Blood Products Working Party (BPWP)

- Review of intravenous and subcutaneous immunoglobulins for thromboembolic events, procoagulant activity

Status: *for discussion*

12.13.3. Paediatric committee (PDCO)

- Strengthening interaction between PDCO and PRAC

Status: *for discussion*

12.13.4. Vaccine Working Party (VWP)

- Explanatory note on the withdrawal of the 'Note for Guidance on Harmonisation of Requirements for Influenza Vaccines' (CPMP/BWP/214/96) and of the Core SmPC/PIL for inactivated seasonal influenza vaccines (CMDh/128/2003/Rev5 and CMDh/129/2008/Rev3)

Status: *for discussion*

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. Others

13. Any other business

13.1.1. Cutaneous severe adverse drug reactions

Status*: for information*

13.1.2. EMA move in 2014 to new building

Status*: for information*

13.1.3. EMA reorganisation

- Member States' consultation on the implementation

Status: *for discussion*

13.1.4. EMA's proposal for a framework to incorporate patients' views during evaluation of benefit-risk by the EMA Scientific Committees

Status*: for discussion*