10 June 2014
EMA/PRAC/345401/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 10-13 June 2014

Chair: June Raine – Vice-Chair: Almath Spooner

10 June 2014, 13:00 – 19:00, room 3/A

11 June 2014, 08:30 – 19:00, room 3/A

12 June 2014, 08:30 – 19:00, room 3/A

13 June 2014, 08:30 – 13:00, room 3/A

Organisational, regulatory and methodological matters (ORGAM)

26 June 2014, 10:00-12:00, room 6/A, 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 therapeutic indications listed against products, 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 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 are subject 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 on 10-13 June 2014

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 10 June 2014

1.3. Minutes of the previous PRAC meeting on 5-8 May 2014

Status: for adoption

Document: PRAC final Minutes due for publication by 20 June 2014

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

2.2.1. **Methadone medicinal products for oral use containing povidone** (NAP)

- Review of the benefit-risk balance following notification by Norway of a referral under Article 107i of Directive 2001/83/EC, based on pharmacovigilance data

Status*: for discussion*

Regulatory details:
PRAC Rapporteur: Qun-Ying Yue (SE)
PRAC Co-Rapporteur: Karen Pernille Harg (NO)

Administrative details:
Procedure number: EMEA/H/A-107i/1395
MAH(s): Martindale Pharma, various
Documents:
For discussion: PRAC (co-)Rapporteurs' assessment reports

2.3. Procedures for finalisation

None

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

3.1. Newly triggered Procedures

3.1.1. **Ibuprofen** (NAP)

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

Status: *for discussion and agreement of a list of questions and procedure timetable*

Regulatory details:
PRAC Rapporteur: *to be appointed*
PRAC Co-Rapporteur: *to be appointed*

Administrative details:
MAH(s): various
Triggering MS: UK
Documents:
For adoption: List of Questions (LoQ), procedure timetable

3.2. Ongoing Procedures

3.2.1. **Bromocriptine** (NAP)

- 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 discussion and agreement of a list of outstanding issues*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)
PRAC Co-Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number: EMEA/H/A-31/1379
MAH(s): Sanofi-aventis, Meda Pharma, various
Documents:
For adoption: List of outstanding issues (LoOI), revised procedure timetable (or PRAC AR, PRAC recommendation)

3.2.2. **Hydroxyzine** (NAP)

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

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Isabelle Robine (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 Questions (LoQ) to the Paediatric Committee (PDCO)

3.3. Procedures for finalisation

None

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

None

4. Signals assessment and prioritisation[1]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Vildagliptin – GALVUS (CAP), JALRA (CAP), XILIARX (CAP) Vildagliptin, metformin - EUCREAS (CAP), ICANDRA (CAP), ZOMARIST (CAP)

- Signal of rhabdomyolysis

Status: *for discussion*

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

Administrative details:
EPITT 17959 – New signal
Leading MS: SE
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC recommendation

4.2. New signals detected from other sources

4.2.1. Chlorhexidine (NAP)

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

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
EPITT 18000 – New signal
Leading MS: UK
MAH(s): various
Documents:
For adoption: PRAC recommendation

4.2.2. Ipilimumab – YERVOY (CAP)

- Signal of posterior reversible encephalopathy syndrome (PRES)

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

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
EPITT 17955 – New signal
Leading MS: NL
MAH(s): Bristol-Myers Squibb Pharma EEIG
Documents:
For adoption: PRAC recommendation

4.3. Signals follow-up and prioritisation

4.3.1. Dexmedetomidine – DEXDOR (CAP)

- Signal of infantile apnoeic attack

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
EPITT 17657 – Follow-up January 2014
MAH(s): Orion Corporation
Documents:
For adoption: PRAC recommendation

4.3.2. Enzalutamide - XTANDI (CAP)

- Signal of myalgia

Status: *for discussion*

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

Administrative details:
EPITT 17792 – Follow-up February 2014
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC recommendation

4.3.3. Fluoroquinolones:
ciprofloxacin (NAP), **enoxacin** (NAP), **flumequine** (NAP), **lomefloxacin** (NAP), **levofloxacin** (NAP), **moxifloxacin** (NAP), **norfloxacin** (NAP), **ofloxacin** (NAP), **pefloxacin** (NAP), **prulifloxacin** (NAP), **rufloxacin** (NAP)

- Signal of retinal detachment

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:
EPITT 15914 – Follow-up April 2013
MAH(s): Bayer, Sanofi, various
Documents:

For adoption: PRAC recommendation

4.3.4. **Lansoprazole** (NAP)

- Signal of haemolytic anaemia

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

Administrative details:
EPITT 17805 – Follow-up February 2014
MAH(s): various
Documents:
For adoption: PRAC recommendation

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

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

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
EPITT 17760 – Follow-up February 2014
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC recommendation

4.3.6. **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 February 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. Bazedoxifene, estrogens conjugated

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

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

Administrative details:
Product number(s): EMEA/H/C/002314
Intended indication: Treatment of oestrogen deficiency and osteoporosis
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.2. Clopidogrel, acetylsalicylic acid

- 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/002272
Intended indication: Prevention of atherothrombotic events
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.3. Daclatasvir

- 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/003768
Intended indication: Treatment of chronic hepatitis C virus (HCV)
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

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) in: 1) antiretroviral therapy (ART) naïve adults; 2) Antiretroviral therapy (ART)-experienced adults with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+ cell count ≥ 100 cells x 106/l
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.5. Dolutegravir, abacavir, lamivudine

- 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/002754
Intended indication: Treatment of human immunodeficiency virus (HIV) infection in adults and adolescents from 12 years of age who are antiretroviral treatment-naïve or are infected with HIV without documented or clinically suspected resistance to any of the three antiretroviral agents in Triumeq
Documents:

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

5.1.6. 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
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.7. Edoxaban

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

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

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

5.1.8. Flutemetamol F-18

- 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/002557
Intended indication: Visual detection of amyloid-beta neuritic plaques in the brains
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.9. Ibrutinib

- 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/003791, *Orphan*
Intended indication: Treatment of mantle cell lymphoma, chronic lymphocytic leukaemia, small lymphocytic lymphoma
Applicant: Janssen-Cilag International N.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.10. Idelalisib

- 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/003843
Intended indication: Treatment of patients with relapsed chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma (iNHL)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.11. Insulin degludec, liraglutide

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

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

Administrative details:
Product number(s): EMEA/H/C/002647
Intended indication: Treatment of type 2 diabetes mellitus
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.12. Insulin glargine

- 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/002835*, Biosimilar*
Intended indication: Treatment of diabetes mellitus
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.13. Ketoconazole

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

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

Administrative details:
Product number(s): EMEA/H/C/003906, *Orphan*
Intended indication: Treatment of Cushing's syndrome
Applicant: Laboratoire HRA Pharma
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.14. Lutetium, isotope of mass 177

- 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/002749
Intended indication: Radiolabelling of carrier molecules
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.1.15. Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches

- 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/002705
Intended indication: Control of serum phosphorus levels in patients with end-stage renal disease (ESRD)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.16. Naloxegol

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

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

Administrative details:
Product number(s): EMEA/H/C/002810
Intended indication: Treatment of adult patients 18 years and older with opioid-induced constipation (OIC) including patients with inadequate response to laxatives
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.17. Olaparib

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

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

Administrative details:
Product number(s): EMEA/H/C/003726, *Orphan*
Intended indication: Treatment of ovarian cancer
Applicant: AstraZeneca AB
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.18. 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: Treatment of complicated skin and soft tissue infections (cSSTI)
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.19. Ramucirumab

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

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

Administrative details:
Product number(s): EMEA/H/C/002829, *Orphan*
Intended indication: Treatment of gastric cancer

Applicant: Eli Lilly Nederland B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.1.20. 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: Treatment of complicated skin and soft tissue infections (cSSTI) in adults
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2. Medicines already authorised

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

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

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

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

5.2.2. Adalimumab – **HUMIRA** (CAP)

- Evaluation of an RMP in the context of a variation

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

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

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

5.2.3. Dabigatran – **PRADAXA** (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: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/II/0058
Procedure scope: Changes in the agreed study protocol for 1160.136 (SPAF MEA 025), a global Registry Program GLORIA-AF investigating patients with newly diagnosed non-valvular atrial fibrillation at risk for stroke receiving dabigatran. Consequent changes were done to the RMP (version 28.3)
MAH(s): Boehringer Ingelheim International GmbH
Documents:
For adoption: PRAC AR

5.2.4. 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: Update of the RMP (version 8.0)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC AR

5.2.5. Fondaparinux – ARIXTRA (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/000403/II/0061
Procedure scope: Update of the RMP (version 1.9) including an update of the current timeline for completion of the superficial vein thrombosis post-marketing observational study from December 2013 to December 2014
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC AR

5.2.6. Human fibrinogen, human thrombin – EVICEL (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/000898/II/0026

Procedure scope: Update of the RMP (version 11.0)
MAH(s): Omrix Biopharmaceuticals N. V.
Documents:
For adoption: PRAC AR

5.2.7. Insulin glulisine – APIDRA (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/000557/II/0054
Procedure scope: Update of RMP (version 6.0)
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC AR

5.2.8. Prucalopride – RESOLOR (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/001012/II/0030
Procedure scope: Revised RMP (version 11.0) and updated study protocol of a study specified in the pharmacovigilance plan, following a request from the PRAC based on the review of the PRAC on PSUR 006 (EMEA/H/C/001012/PSU/012) and RMP vs. 10 (EMEA/H/C/1012 RMP 020) as adopted by CHMP in May 2013. This includes an update of the safety concerns and of the study due dates in section III. 4.3 of the RMP
MAH(s): Shire Pharmaceuticals Ireland
Documents:
For adoption: PRAC AR

5.2.9. Sildenafil – REVATIO (CAP)

- Evaluation of an RMP in the context of a variation

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000638/II/0061
Procedure scope: Update of the RMP (version 6) and consequential update to Annex II
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC AR

5.2.10. Strontium ranelate – OSSEOR (CAP), PROTELOS (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/000561/II/0038, EMEA/H/C/000560/II/0043
Procedure scope: Update of the RMP (version 14) to include all the measures agreed during the recent Article 20 procedure
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC AR

5.2.11. Telmisartan – KINZALMONO (CAP), **MICARDIS** (CAP), **PRITOR** (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000211/WS0570/0099, EMEA/H/C/000209/WS0570/0103, EMEA/H/C/000210/WS0570/0112
Procedure scope: Submission of updated RMPs (version 6.0)
MAH(s): Bayer Pharma AG (Kinzalmono, Pritor), Boehringer Ingelheim (Micardis)
Documents:
For adoption: PRAC AR

5.2.12. Telmisartan, hydrochlorothiazide – KINZALKOMB (CAP), **MICARDISPLUS** (CAP), **PRITORPLUS** (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:
Procedure number(s): EMEA/H/C/000415/WS0569, EMEA/H/C/000413/WS0569, EMEA/H/C/000414/WS0569
Procedure scope: Submission of updated RMPs (version 9.0)
MAH(s): Bayer Pharma AG (Kinzalkomb, PritorPlus), Boehringer Ingelheim (MicardisPlus)
Documents:
For adoption: PRAC AR

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

5.2.13. Abatacept – ORENCIA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Kirsti Villikka (FI)

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

5.2.14. Aflibercept – EYLEA (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/002392/II/0009
Procedure scope: Update of SmPC section 4.1 to add a new indication for treatment of adult patients with diabetic macular oedema. Consequential updates were proposed for SmPC sections 4.2, 4.4, 4.8, 5.1 and 5.2. SmPC section 4.8 was furthermore updated to introduce a single table of adverse drug reactions
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.15. Apixaban – ELIQUIS (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/002148/II/0014/G
Procedure scope: Grouping of 2 variations including a type II extension of indication to include 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

5.2.16. Bevacizumab – AVASTIN (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000582/II/0063

Procedure scope: Extension of indication to include the use of Avastin in combination with chemotherapy (paclitaxel, topotecan or pegylated liposomal doxorubicin) in patients with recurrent, platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube carcinoma based on the results of study MO22224 (AURELIA)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.17. Cetuximab – ERBITUX (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/000558/II/0066
Procedure scope: Update of SmPC section 5.1 with efficacy data by RAS (KRAS and NRAS) tumour status from the CRYSTAL (EMR 62 202-013) and FIRE3 studies
MAH(s): Merck KGaA
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.18. Darunavir – PREZISTA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

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

5.2.19. 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: Update of SmPC section 4.1 to add a new indication for treatment of adult patients with diabetic macular oedema. Consequential updates were proposed for SmPC sections 4.2, 4.4, 4.8, 5.1 and 5.2. In addition, the MAH proposed to reduce and consolidate the current HCP leaflet, which is provided as tear off section after the package leaflet
MAH(s): Allergan Pharmaceuticals Ireland
Documents:

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

5.2.20. Eslicarbazepine – ZEBINIX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

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

5.2.21. Etanercept – ENBREL (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000262/II/0167
Procedure scope: Extension of indication to treatment of adults with severe non-radiographic axial spondyloarthritis (nr-AxSpA)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.22. Fidaxomicin – DIFICLIR (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/002087/II/0016
Procedure scope: Update of SmPC sections 4.5 and 5.2 with results from study 2819-CL-2003, assessing the effect of multiple doses of fidaxomicin on the pharmacokinetics of a single dose of rosuvastatin in healthy male subjects. With respect to missing information on the impact of fidaxomicin on intestinal efflux transporters (BCRP, MRP2, OAP2B1), a corresponding deletion from the RMP is proposed
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.23. 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 include 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

5.2.24. Ibandronic acid – IBANDRONIC ACID ACCORD (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

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

5.2.25. Influenza vaccine (split virion, inactivated) – IDFLU (CAP), INTANZA (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/000966/II/0026, EMEA/H/C/000957/II/0029
Procedure scope: Update of the product information to reflect that the strains are in accordance with the WHO recommendation and the EU decision for the 2014/2015 season. There is no change in the strains selected for the composition of the influenza vaccines compared to the previous season and the variation is therefore limited to an administrative update of the product information and a stability data update. In addition an update of the RMP to include an enhanced safety surveillance plan is provided
MAH(s): Sanofi Pasteur, Sanofi Pasteur MSD SNC
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.26. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – OPTAFLU (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/000758/II/0069
Procedure scope: Update of the product information to reflect that the strains are in accordance with the WHO recommendation and the EU decision for the 2014/2015 season. There is no change in the strains selected for the composition of the influenza vaccines compared to the previous season and the variation is therefore limited to an administrative update of the product information and a stability data update. In line with the adopted interim guidance on safety surveillance for seasonal influenza vaccines in the EU, an updated RMP including an enhanced safety surveillance plan is submitted
MAH(s): Novartis Vaccines and Diagnostics GmbH
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.27. 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/0009
Procedure scope: Update of SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 to extend the indication of Kalydeco in the treatment of cystic fibrosis to patients aged 6 years and older who have other gating (class III) mutation in the CFTR gene than G551D
MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

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

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

5.2.29. Lixisenatide – LYXUMIA (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/002445/II/0003
Procedure scope: Update of SmPC section 4.4 in order to implement the recommendations of the recent Article 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Sanofi-Aventis Groupe
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.30. Nitric oxide – INOMAX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000337/II/0039
Procedure scope: Update of SmPC section 4.8 and Annex IID and RMP with respect to details of training and education methods to be used for INOmax and the approved nitric oxide delivery systems (NODS)
MAH(s): Linde Healthcare AB
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.31. 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
MAH(s): TMC Pharma Services Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.32. Nilotinib – TASIGNA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000798/II/0067
Procedure scope: Update of SmPC sections 4.2, 4.4, 4.8 and 5.1 further to 60 month data analysis from the phase III multicentre, open-label, randomised study CAMN107A2303 of imatinib versus nilotinib in adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in chronic phase (CML-CP) (ANX 40.3)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.33. Ofatumumab – ARZERRA (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Doris Stenver (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001131/II/0027
Procedure scope: Update of SmPC sections 4.4 and 4.8 with regard to infusion reactions
MAH(s): Glaxo Group Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.34. 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: Torbjörn Callréus (DK)

Administrative details:
Product 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

5.2.35. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – ADJUPANRIX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001206/II/0034
Procedure scope: Update of SmPC section 4.4 to include a statement regarding the observed increased risk of narcolepsy following vaccination with Pandemrix, the MAH's ASO3 adjuvanted H1N1 influenza vaccine, based on a review of epidemiologic or post-marketing surveillance
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:

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

5.2.36. Pneumococcal polysaccharide conjugate vaccine (adsorbed) – SYNFLORIX (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/000973/II/0079
Procedure scope: Update of SmPC section 5.1 to reflect the results of the phase III/IV clinical trial (Finnish Invasive Pneumococcal disease vaccine) to evaluate the effectiveness of Synflorix (against reduction of hospital-diagnosed pneumonia, and impact on tympanostomy tube placements and outpatient antimicrobial prescriptions) to address a post-authorisation measure
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.37. Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – PREPANDRIX (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000822/II/0051
Procedure scope: Update of SmPC to include a statement regarding the observed increased risk of narcolepsy following vaccination with Pandemrix, the MAH's ASO3 adjuvanted H1N1 influenza vaccine, based on a review of epidemiologic or post-marketing surveillance
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.38. Pyronaridine, artesunate – PYRAMAX (Art 58)

- 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/W/002319/II/0002
Procedure scope: Changes to SmPC section 4.1 to remove restrictions on repeated course of treatment in any individual and use only in areas of low transmission with evidence of artesmisinin resistance, based on further clinical experience. Consequent changes in SmPC sections 4.2, 4.4, 4.8. Change is also made to SmPC Section 4.2 in relation to dosing in mild to moderate renal impairment. A minor editorial adjustment is proposed to SmPC section 5.1
Scientific Opinion Holder(s): Shin Poong Pharmaceutical Co., Ltd.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.39. Regorafenib – STIVARGA (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/002573/II/0001
Procedure scope: Extension of indication to include treatment of patients with gastrointestinal stromal tumours (GIST) who have been previously treated with 2 tyrosine kinase inhibitors. As a consequence, SmPC sections 4.1, 4.2, 4.8 and 5.1 were proposed to be updated
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.40. Saxagliptin – ONGLYZA (CAP)
saxagliptin, metformin – KOMBOGLYZE (CAP)

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

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001039/WS0528/0025, EMEA/H/C/002059/WS0528/0015
Procedure scope: Update of SmPC section 4.4 in order to implement the recommendations of an Article 5(3) procedure on GLP-1-based therapies and pancreatic safety
MAH(s): Bristol-Myers Squibb / AstraZeneca EEIG
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.41. Temsirolimus – TORISEL (CAP)

- Evaluation of an RMP in the context of a variation

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

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

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

RMP evaluated in the context of a PSUR procedure

See also Deferasirox – EXJADE under 6.1.12. , Eribulin – HALAVEN under 6.1.13. , Erlotinib – TARCEVA under 6.1.14. , Pixantrone dimaleate – PIXUVRI under 6.1.28. , Rotavirus vaccine, live, oral – ROTATEQ under 6.1.32. , Sapropterin – KUVAN under 6.1.33. , Tafamidis – VYNDAQEL under 6.1.37.

RMP evaluated in the context of PASS results

See also Ceftaroline fosamil – ZINFORO under 7.4.1. , Eltrombopag – REVOLADE under 7.4.2.

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

5.2.42. Corifollitropin alfa – ELONVA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:
Procedure number(s): EMEA/H/C/001106/R/0018 (with RMP version 7.1)
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC advice

5.2.43. Lamivudine, abacavir – KIVEXA (CAP)

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

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

Regulatory details:

PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000581/R/0051 (with RMP version 2.0)
MAH(s): ViiV Healthcare
Documents:
For adoption: PRAC advice

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

5.2.44. 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 015.2
MAH(s): Ferring Pharmaceuticals A/S
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.45. 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 (FI)

Administrative details:
Procedure number(s): EMEA/H/C/000253/RMP 096.2
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

5.2.46. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – **ADJUPANRIX** (CAP), **PUMARIX** (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: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001206/RMP 035.1, EMEA/H/C/001212/RMP 030.1
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP assessment overview and advice

5.2.47. Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – **PREPANDRIX** (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: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000822/RMP 057.1
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC RMP AR, PRAC RMP Assessment overview and Advice

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures[3]

6.1.1. Aflibercept – **EYLEA** (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 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: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002392/PSUV/0011 (without RMP)
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. Alogliptin – VIPIDIA (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/0004 (without RMP)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Alogliptin, metformin – VIPDOMET (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/002654/PSUV/0005 (without RMP)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. 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/002178/PSUV/0005 (without RMP)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Anagrelide – XAGRID (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/00000208/201309 (without RMP)
MAH(s): Shire Pharmaceutical Contracts Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Apixaban – ELIQUIS (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/002148/PSUV/0018 (without RMP)
MAH(s): Bristol-Myers Squibb / Pfizer EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Boceprevir – VICTRELIS (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/002332/PSUV/0028 (without RMP)
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Bosentan – STAYVEER (CAP), TRACLEER (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/002644/PSUV/0006 (without RMP), EMEA/H/C/000401/PSUV/0065 (without RMP)

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

MAH(s): Marklas Nederlands BV (Stayveer), Actelion Registration Ltd. (Tracleer)
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Bromfenac – YELLOX (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001198/PSUV/0007 (without RMP)
MAH(s): Croma-Pharma GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Conestat alfa – RUCONEST (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/001223/PSUV/0014 (without RMP)
MAH(s): Pharming Group N.V
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Copper (^{64}Cu) chloride – CUPRYMINA (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002136/PSUV/0001 (without RMP)
MAH(s): Sparkle Srl
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. Deferasirox – EXJADE (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/000670/PSUV/0037 (with RMP version 9.0)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Eribulin – HALAVEN (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/002084/PSUV/0018 (with RMP version 3.0)
MAH(s): Eisai Europe Ltd.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Erlotinib – TARCEVA (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/000618/PSUV/0036 (with RMP version 4.0)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Ferumoxytol – RIENSO (CAP)

- Evaluation of a PSUR procedure

Status: *for discussion*

Regulatory details:
PRAC Rapporteur: Martin Huber (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002215/PSUV/0014 (without RMP)
MAH(s): Takeda Pharma A/S

6.1.16. Fidaxomicin – DIFICLIR (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/002087/PSUV/0017 (without RMP)
MAH(s): Astellas Pharma Europe B.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.17. Human normal immunoglobulin – HYQVIA (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/002491/PSUV/0004 (without RMP)
MAH(s): Baxter Innovations GmbH
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (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/000721/PSUV/0055 (without RMP)
MAH(s): GlaxoSmithKline Biologicals S.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Hydroxocobalamin – CYANOKIT (CAP), NAP

- Evaluation of a PSUSA[5] 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/00001690/201311 (without RMP)
MAH(s): Merck Santé S.A.S.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Indacaterol – HIROBRIZ BREEZHALER (CAP), ONBREZ BREEZHALER (CAP), OSLIF BREEZHALER (CAP)

- Evaluation of a PSUR procedure

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

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

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/001211/PSUV/0031 (without RMP), EMEA/H/C/001114/PSUV/0030 (without RMP), EMEA/H/C/001210/PSUV/0030 (without RMP)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Irbesartan, hydrochlorothiazide – **COAPROVEL** (CAP), **KARVEZIDE** (CAP), **IRBESARTAN HYDROCHLOROTHIAZIDE ZENTIVA** (CAP), NAP

- Evaluation of a PSUSA[6] procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/PSUSA/00001653/201309 (without RMP)
MAH(s): Sanofi Clir SNC (CoAprovel), Sanofi-Aventis Groupe (Karvizide, Irbesartan hydrochlorothiazide Zentiva), various
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/0030 (without RMP), EMEA/H/C/000597/PSUV/0031 (without RMP)
MAH(s): Les Laboratoires Servier
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Linaclotide – **CONSTELLA** (CAP)

- Evaluation of a PSUR procedure

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/002490/PSUV/0010 (without RMP)
MAH(s): Almirall S.A.

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

Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Modified vaccinia ankara virus – IMVANEX (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/002596/PSUV/0007 (without RMP)
MAH(s): Bavarian Nordic A/S
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Pandemic influenza vaccine (H1N1) (whole virion, inactivated, prepared in cell culture) – CELVAPAN (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/000982/PSUV/0027 (without RMP)
MAH(s): Baxter AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.26. Pegvisomant – SOMAVERT (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/000409/PSUV/0070 (without RMP)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. Piperaquine, dihydroartemisinin – EURARTESIM (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/001199/PSUV/0011 (without RMP)
MAH(s): Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Pixantrone – PIXUVRI (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/002055/PSUV/0015 (with RMP version 6.0)
MAH(s): CTI Life Sciences Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Radium-223 – XOFIGO (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/002653/PSUV/0002 (without RMP)
MAH(s): Bayer Pharma AG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.30. Rilpivirine – EDURANT (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/002264/PSUV/0012 (without RMP)
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Rituximab – MABTHERA (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/000165/PSUV/0093 (without RMP)
MAH(s): Roche Registration Ltd
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. Rotavirus vaccine, live, oral – ROTATEQ (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/000669/PSUV/0050 (with RMP version 6.0)
MAH(s): Sanofi Pasteur MSD, SNC
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. Sapropterin – KUVAN (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/000943/PSUV/0029 (with RMP version 8.0)
MAH(s): Merck Serono Europe Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. Saxagliptin, metformin – KOMBOGLYZE (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/002059/PSUV/0016 (without RMP)
MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. Shingles (herpes zoster) vaccine (live) – ZOSTAVAX (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/000674/PSUV/0069 (without RMP)
MAH(s): Sanofi Pasteur MSD, SNC
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. Stiripentol – DIACOMIT (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/000664/PSUV/0015 (without RMP)
MAH(s): Biocodex
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. Tafamidis – VYNDAQEL (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/002294/PSUV/0015 (with RMP version 7.0)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Toremifene – FARESTON (CAP), NAP

- Evaluation of a PSUSA[7] 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/00002999/201309 (without RMP)
MAH(s): Orion Corporation
Documents:
For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures[8]

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

- Evaluation of a follow-up to a PSUR procedure

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

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002211/LEG 006.1, EMEA/H/C/002706/LEG 006.1
Procedure scope: MAH's response to LEG 006 adopted in January 2014
MAH(s): Almirall S.A.
Documents:
For adoption: Updated PRAC PSUR AR

6.2.2. Infliximab – REMICADE (CAP)

- Evaluation of a follow-up to a PSUR procedure

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000240/LEG 135.6
Procedure scope: MAH's response to LEG-135.5 following the CHMP conclusions adopted in January 2014
MAH(s): Janssen Biologics B.V.
Documents:
For adoption: Updated PRAC PSUR AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[9]

7.1.1. Ethinylestradiol, gestodene transdermal patch (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 scope: PASS protocol of EURAS-CORA
MAH(s): Bayer (Apleek)
Documents:
For adoption: Procedure timetable

7.1.2. Flupirtine (NAP)

- Evaluation of an imposed PASS protocol

Status: *for decision*

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

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

Administrative details:
Procedure scope: Protocol for a non-interventional post-authorisation safety study to evaluate the effectiveness of the risk minimisation measures for the use of flupirtine 100 mg immediate-release capsules in daily practice
MAH(s): Meda Pharma (Flupigil, Metanor)
Documents:
For adoption: PRAC AR
For adoption: Letter of endorsement/objection/notification that study is a clinical trial

7.1.3. **Sodium, magnesium, potassium sulphates** for bowel preparation (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 scope: Protocol for a multi-centre European observational drug utilisation study (DUS) of post-commitment BLI800 to assess drug utilisation in the real life setting in a representative sample of the European target population
MAH(s): Ipsen Pharma (Eziclen, Izinova)
Documents:
For adoption: Procedure timetable

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[10]

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 034.2
Procedure scope: MAH's response to MEA 034.1 (PASS CSPP100A2418 - colorectal cancer) as adopted in February 2014
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.2. **Catridecacog – NOVOTHIRTEEN** (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/002284/MEA 003.2
Procedure scope: MAH's response to MEA 3.1 containing amendment to PASS NN1841-3868 4

[10] 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

MAH(s): Novo Nordisk A/S
Documents:
For adoption: PRAC advice

7.2.3. Darunavir – PREZISTA (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Sabine Straus (NL)

Administrative details:
Procedure number(s): EMEA/H/C/000707/MEA 069
Procedure scope: PASS protocol to assess growth abnormalities (height) in children using Prezista in which data will be compared with data from the European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) or other data in children on other antiretroviral (ARV). (Category 3) - PENTA study
MAH(s): Janssen-Cilag International N.V.
Documents:
For adoption: PRAC advice

7.2.4. Eltrombopag – REVOLADE (CAP)

- Evaluation of a PASS protocol

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/MEA 020.1, MEA 025.1 & MEA 026.1
Procedure scope: MAH's responses to PRAC assessment of MEA-020 as adopted in January 2014, containing an updated PASS protocol WEUSKOP7136 (study of HCV patients treated with eltrombopag: multicentre, prospective observational cohort study of thrombocytopenic HCV patients receiving eltrombopag)
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC advice

7.2.5. Florbetaben (^{18}F) – NEURACEQ (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/002553/MEA 001.1
Procedure scope: MAH's response to list of questions adopted by the PRAC (PASS Study 1 - Revision of Protocol FBB-01_02_13), dated 5 December 2013
MAH(s): Piramal Imaging Limited
Documents:
For adoption: PRAC advice

7.2.6. Human coagulation factor VIII, human von Willibrand factor – VONCENTO (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/002493/MEA 001.1
Procedure scope: Evaluation of two PASS protocols on 1) open-label, multi-centre PASS to assess the efficacy and safety of Voncento in male subjects with haemophilia A (CSLCT-BIO-12-78); 2) open-label, multi-centre PASS to assess the efficacy and safety of Voncento in subjects with von Willebrand disease (CSLCT-BIO-12-83)
MAH(s): CSL Behring GmbH
Documents:
For adoption: PRAC advice

7.2.7. Insulin glargine – LANTUS (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000284/MEA 051
Procedure scope: PASS protocol related to a packaging differentiation study UK SoloStar differentiation study: test in patients with Type 1 or Type 2 diabetes in the UK, to evaluate the ease of differentiating between SoloStar pens containing different types of insulin
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC advice

7.2.8. Insulin glulisine – APIDRA (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/000557/MEA 037
Procedure scope: PASS protocol related to a packaging differentiation study UK SoloStar differentiation study: test in patients with Type 1 or Type 2 diabetes in the UK, to evaluate the ease of differentiating between SoloStar pens containing different types of insulin
MAH(s): Sanofi-aventis Deutschland GmbH
Documents:
For adoption: PRAC advice

7.2.9. Ranibizumab – LUCENTIS (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000557/REC 0067
Procedure scope: Submission of a 3-year observation study protocol (F2401) to evaluate the long-term efficacy and safety in subjects with choroidal neovascularisation (CNV) secondary to pathologic myopia (PM)
MAH(s): Novartis Europharm Ltd
Documents:
For adoption: PRAC advice

7.2.10. Sodium oxybate – XYREM (CAP)

- Evaluation of a PASS protocol

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

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

Administrative details:
Procedure number(s): EMEA/H/C/000593/MEA 002.4
Procedure scope: MAH's response to FUM-002.3 relating to an amendment to protocol C00302 on the reformulation of the sample size from 1,000 to 750 patients
MAH(s): UCB Pharma Ltd.
Documents:
For adoption: PRAC advice

7.2.11. Telavancin – VIBATIV (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/001240/MEA 006.3, EMEA/H/C/001240/MEA 017
Procedure scope: MEA 006.3: Revised protocol of the study of the use of intravenous telavancin in the clinical setting. MEA 017: Audit of the effectiveness of educational materials for telavancin, study no. CLIN_2014_TLV_003
MAH(s): Clinigen Healthcare Ltd
Documents:
For adoption: PRAC advice

7.2.12. Tenofovir disoproxil – VIREAD (CAP)

- Evaluation of a PASS protocol

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

Regulatory details:
PRAC Rapporteur: Isabelle Robine (FR)

Administrative details:
Procedure number(s): EMEA/H/C/000419/MEA 265.1

Procedure scope: MAH's response to request for information (RSI) to MEA265 (final protocol for Viread HBV PASS study GS-EU-174-1403) as adopted in October 2013
MAH(s): Gilead Sciences International Ltd
Documents:
For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)[11]

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)[12]

7.4.1. Ceftaroline fosamil – ZINFORO (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Julie Williams (UK)

Administrative details:
Procedure number(s): EMEA/H/C/002252/II/0011 (with RMP version 11.0)
Procedure scope: Submission of the final clinical study report for study D3720C00002 (phase III, multicentre, randomised, double-blind, comparative study to evaluate the efficacy and safety of intravenous ceftaroline fosamil versus intravenous ceftriaxone in the treatment of adult hospitalised patients with community-acquired bacterial pneumonia in Asia) as requested in the RMP
MAH(s): AstraZeneca AB
Documents:
For adoption: PRAC AR

7.4.2. Eltrombopag – REVOLADE (CAP)

- Evaluation of PASS results

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

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

Administrative details:
Procedure number(s): EMEA/H/C/001110/II/0014/G (with RMP version 23)
Procedure scope: Submission of four final study reports for the fulfilment of RMP commitments and a proposal for changes in the RMP (replacement of a study and date extensions for RMP commitments listed in section III 4.3)
MAH(s): GlaxoSmithKline Trading Services
Documents:
For adoption: PRAC AR

7.4.3. Etanercept – ENBREL (CAP)

- Evaluation of PASS results

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

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000262/II/0170 (without RMP)
Procedure scope: Submission of the final report for observational surveillance registry study 20040210 as listed in Part III of the RMP
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC AR

7.4.4. Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) – **PANDEMRIX** (CAP)

- Evaluation of PASS results

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

Regulatory details:
PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000832/II/0068 (without RMP)
Procedure scope: Review of the data from the test-negative case-control analysis of a retrospective epidemiological study conducted in Quebec, Canada to evaluate the risk of narcolepsy associated with vaccination with Arepanrix and to follow-up cases to assess any atypical or differential clinical course and prognosis in any vaccinated vs. non-vaccinated subjects. This submission fulfils post authorisation measure ANX 115, therefore it is proposed to remove this condition from Annex II
MAH(s): GlaxoSmithKline Biologicals S.A.
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[13]

7.5.1. **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 017.7
Procedure scope: MAH's response to MEA 017.5 (interim data on the observational PASS of Victrelis (boceprevir) among chronic hepatitis C patients (P08518) as adopted in February 2014
MAH(s): Merck Sharp & Dohme Limited
Documents:
For adoption: PRAC advice

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

7.5.2. Rufinamide – INOVELON (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/000660/MEA 011.9
Procedure scope: Submission of the fifth annual interim report for Inovelon registry study
MAH(s): Eisai Ltd
Documents:
For adoption: PRAC advice

8. Annual Reassessments and Conditional Renewals of the Marketing Authorisation

8.1.1. Brentuximab vedotin – ADCETRIS (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/002455/R/0017 (without RMP)
MAH(s): Takeda Pharma A/S
Documents:
For adoption: PRAC advice

8.1.2. Crizotinib – XALKORI (CAP)

- PRAC consultation on a conditional 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/002489/R/0015 (without RMP)
MAH(s): Pfizer Limited
Documents:
For adoption: PRAC advice

8.1.3. Idursulfase – ELAPRASE (CAP)

- PRAC consultation on an annual reassessment of the marketing authorisation

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

Regulatory details:

PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:
Procedure number(s): EMEA/H/C/000700/S/0050 (without RMP)
MAH(s): Shire Human Genetic Therapies AB
Documents:
For adoption: PRAC advice

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. On-going or concluded pharmacovigilance inspection

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

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. Epoetin beta – NEORECORMON (CAP)

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

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

Regulatory details:
PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): EMEA/H/C/000116/II/083
Procedure scope: Submission of measures to minimise the potential risk of retinopathy of prematurity (RoP) as requested in the PSUR procedure covering the period 2007-2010
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

10.3.1. Antiretroviral medicinal products:

Abacavir – ZIAGEN (CAP); **abacavir, lamivudine – KIVEXA** (CAP); **abacavir, lamivudine, zidovudine – TRIZIVIR** (CAP); **atazanavir– REYATAZ** (CAP); **cobicistat – TYBOST** (CAP); **darunavir – PREZISTA** (CAP); **efavirenz – STOCRIN** (CAP), **SUSTIVA** (CAP); **efavirenz, emtricitabine, tenofovir disoproxil – ATRIPLA** (CAP); **elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil – STRIBILD** (CAP); **emtricitabine – EMTRIVA** (CAP); **emtricitabine, tenofovir disoproxil – TRUVADA** (CAP); **emtricitabine, rilpivirine, tenofovir disoproxil – EVIPLERA** (CAP); **enfuvirtide – FUZEON** (CAP); **etravirine – INTELENCE** (CAP); **fosamprenavir – TELZIR** (CAP); **indinavir – CRIXIVAN** (CAP); **lamivudine – EPIVIR** (CAP); **lamivudine, zidovudine – COMBIVIR** (CAP); **lopinavir, ritonavir – KALETRA** (CAP); **maraviroc – CELSENTRI**

(CAP); **nevirapine – VIRAMUNE** (CAP); **raltegravir – ISENTRESS** (CAP); **rilpivirine – EDURANT** (CAP); **ritonavir – NORVIR** (CAP); **saquinavir – INVIRASE** (CAP); **stavudine – ZERIT** (CAP); **tenofovir disoproxil – VIREAD** (CAP); **tipranavir - APTIVUS** (CAP)

- PRAC consultation on post-authorisation measures, upon CHMP request

Status: *for discussion and agreement of a lead PRAC Rapporteur*

Regulatory details:
PRAC Rapporteur: *to be appointed*

Administrative details:
Procedure number(s): N/A
Procedure scope: Review of class labelling on mitochondrial dysfunction, lactic acidosis and lipodystrophy
MAH(s): AbbVie Ltd (Kaletra, Norvir), Boehringer Ingelheim International GmbH (Aptivus, Viramune), Bristol-Myers Squibb Pharma EEIG (Reyataz, Sustiva, Zerit), Bristol-Myers Squibb and Gilead Sciences Ltd.(Atripla), Gilead Sciences International Ltd.(Emtriva, Eviplera, Stribild, Truvada, Tybost, Viread), Janssen-Cilag International N.V.(Edurant, Intelence, Prezista), Merck Sharp & Dohme Ltd (Crixivan, Isentress, Stocrin), Roche Registration Ltd. (Fuzeon, Invirase), ViiV Healthcare UK Limited (Celsentri, Combivir, Epivir, Kivexa, Telzir, Trizivir, Ziagen)

10.3.2. **Dabigatran - PRADAXA** (CAP)

- PRAC consultation on post-authorisation measures, upon CHMP request

Status: *for discussion and adoption of PRAC advice to CHMP*

Regulatory details:
PRAC Rapporteur: Torbjörn Callréus (DK)

Administrative details:
Procedure number(s): EMEA/H/C/000829/LEG 0042.1
Procedure scope: Assessment of MAH's response to request for supplementary information (RSI) adopted by the CHMP in April 2014
MAH(s): Boehringer Ingelheim International GmbH
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. **Aceclofenac** (NAP)

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

Status: *for discussion and agreement of advice*

Regulatory details:
Lead member: Dolores Montero Corominas (ES)

Administrative details:
Procedure number(s): ES/H/XXXX/WS/001
Procedure scope: Update the product information of systemic aceclofenac-containing medicinal products in accordance with the outcome of the referral procedure for diclofenac, DHPC
MAH(s): Almirall, S.A., Temis Farma, S.L., Ivowen Ltd. (Airtal and associated names)

Documents:
For adoption: PRAC advice

11.1.2. Olmesartan (NAP)
Olmesartan, hydrochlorothiazide (NAP)

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

Status*: for discussion and agreement of advice*

Regulatory details:
Lead member: Valerie Strassmann (DE)

Administrative details:
Procedure number(s): DE/H/xxxx/WS/068/G
Procedure scope: Work sharing variation assessing the implementation in the product information the PRAC recommendation regarding the risk of cardiovascular mortality in patients with type II diabetes as well as the PRAC/FDA recommendation to include a warning about sprue-like enteropathy in association with the use of olmesartan
MAH(s): Daiichi Sankyo Europe GmbH (Olmetec and associated names)
Documents:
For adoption: PRAC advice

11.1.3. Solutions for parenteral nutrition combination, emulsion for infusion (NAP)

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

Status: *for discussion and agreement of advice*

Regulatory details:
Lead member: Ulla Wändel Liminga (SE)

Administrative details:
Procedure number(s): SE/H/948/2-3/II/1i
Procedure scope: Evaluation of RMP within a type II variation: evaluation of the effectiveness of risk minimisation measures: survey and acceptable success threshold to indicate whether the survey participants demonstrate understanding of the DHPC and SmPC recommendations regarding the risk of hypermagnesemia and the recommendations for monitoring serum magnesium levels during product use
MAH(s): Baxter (Numeta G19%E, G16%E and associated names)
Documents:
For adoption: PRAC advice

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC Work Programme

- Draft PRAC Work Programme 2014-2015

***Status**: for discussion*

12.2. Pharmacovigilance audits and inspections

12.2.1. Pharmacovigilance Systems and their Quality Systems

None

12.2.2. Pharmacovigilance Inspections

None

12.2.3. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

None

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

- Consultation on the draft list, version June 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

- Guidance on EudraVigilance analysis to support community procedures

***Status:** for discussion*

12.5.2. Additional Monitoring

None

12.5.3. List of Product under Additional Monitoring

- Consultation on the draft list, version June 2014

Status: *for information*

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

12.6.2. Changes to EudraVigilance Database and functional specifications

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

12.7.1.1. Progressive multifocal leukoencephalopathy (PML): possibilities for monitoring and labelling

- Possibilities for monitoring and labelling: development of an evidence-based strategy

Status: *for discussion*

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

- Imposed PASS protocol workflow

Status: *for discussion*

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Risk communication and Transparency

12.10.1. Public Participation in Pharmacovigilance

None

12.10.2. Safety Communication

None

12.11. Continuous pharmacovigilance

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

None

12.11.2. Marketing cessation, marketing suspension and withdrawals of medicinal products from the market

- Update on the list of withdrawn products

Status: *for discussion*

12.11.3. Incident Management

None

12.12. Interaction with EMA Committees and Working Parties

12.12.1. Paediatric Committee (PDCO)

- EMA Extrapolation Group: call for expert nominations

Status: *for discussion*

12.12.2. Working Parties

None

12.12.3. Pharmacovigilance Inspectors Working Group (PhV IWG)

- Organisation of training course

Status*: for information*

12.13. Interaction within the EU regulatory network

None

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

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

None

12.14.2. International Organisation for Standardisation (ISO) - Identification of Medicinal Products (IDMP) standards

- EU Task Force

Status: *for discussion*

12.14.3. Others

None

13. Any other business

13.1. EMA move in 2014 to new building

Status: *for information*

13.2. EMA reorganisation

- New organisational model: changes in the operation of processing Type II variations

Status: *for discussion*