



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2014
EMA/PRAC/745328/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 1-4 December 2014

Chair: June Raine – Vice-Chair: Almath Spooner

1 December 2014, 13:00 – 19:00, room 2/A

2 December 2014, 08:30 – 19:00, room 2/A

3 December 2014, 08:30 – 19:00, room 2/A

4 December 2014, 08:30 – 16:00, room 2/A

Organisational, regulatory and methodological matters (ORGAM)

18 December 2014, 10:00-12:00, room 8/B, via teleconference

Health and Safety Information

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

Disclaimers

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

Note on access to documents

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



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=W00b01ac05800240d0

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	9
1.1. Welcome and declarations of interest of members, alternates and experts.....	9
1.2. Adoption of agenda of the meeting of 1-4 December 2014	9
1.3. Minutes of the previous PRAC meeting on 3-6 November 2014.....	9
2. EU Referral Procedures for Safety Reasons: Urgent EU Procedures	9
2.1. Newly triggered procedures	9
2.2. Ongoing Procedures.....	9
2.3. Procedures for finalisation	9
2.4. Planned public hearings.....	9
3. EU Referral Procedures for Safety Reasons: Other EU Referral Procedures	9
3.1. Newly triggered Procedures	9
3.2. Ongoing Procedures.....	9
3.2.1. Ambroxol (NAP); bromhexine (NAP)	9
3.2.2. Dexibuprofen (NAP); ibuprofen (NAP)	10
3.3. Procedures for finalisation	10
3.4. Article 5(3) of Regulation (EC) No 726/2004 as amended: PRAC advice on CHMP request.....	10
3.5. Others	10
4. Signals assessment and prioritisation	10
4.1. New signals detected from EU spontaneous reporting systems.....	10
4.1.1. Lenalidomide – REVLIMID (CAP)	10
4.1.2. Natalizumab – TYSABRI (CAP).....	11
4.1.3. Trabectedin – YONDELIS (CAP)	11
4.2. New signals detected from other sources.....	11
4.3. Signals follow-up and prioritisation	12
4.3.1. Interferon alfa-2a (NAP) Interferon alfa-2b – INTRONA (CAP) Interferon beta-1a – AVONEX (CAP), REBIF (CAP) Interferon beta-1b - BETAFERON (CAP), EXTAVIA (CAP) Peginterferon alfa-2a - PEGASYS (CAP) Peginterferon alfa-2b - PEGINTRON (CAP), VIRAFERONPEG (CAP)	12
4.3.2. Vildagliptin – GALVUS (CAP), JALRA (CAP), XILARX (CAP) Vildagliptin, metformin - EUCREAS (CAP), ICANDRA (CAP), ZOMARIST (CAP)	12
5. Risk Management Plans	12
5.1. Medicines in the pre-authorisation phase.....	12
5.1.1. Allogenic human heterologous liver cells.....	12
5.1.2. Aripiprazole	13
5.1.3. Ceftolozane, tazobactam	13
5.1.4. Ceritinib	13
5.1.5. Ciclosporin.....	13
5.1.6. Dalbavancin.....	13
5.1.7. Dasiprotimut-T.....	14
5.1.8. Ex vivo autologous corneal epithelial cells including stem cells	14

5.1.9. Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)	14
5.1.10. Isavuconazole	14
5.1.11. Levofloxacin	14
5.1.12. Liraglutide	15
5.1.13. Naltrexone, bupropion	15
5.1.14. Phenylephrine, ketorolac trometamol	15
5.1.15. Pregabalin	15
5.1.16. Pregabalin	16
5.1.17. Pregabalin	16
5.1.18. Pregabalin	16
5.1.19. Pregabalin	16
5.1.20. Pregabalin	16
5.1.21. Safinamide	17
5.1.22. Sevelamer	17
5.2. Medicines already authorised	17
<i>RMP in the context of a variation – PRAC-led procedure</i>	17
5.2.1. Aliskiren – RASILEZ (CAP) aliskiren, amlodipine – RASILAMLO (CAP) aliskiren, hydrochlorothiazide – RASILEZ HCT (CAP)	17
5.2.2. Elvitegravir, cobicistat, emtricitabine, tenofovir – STRIBILD (CAP)	17
5.2.3. Fentanyl – INSTANYL (CAP)	18
5.2.4. Ibritumomab tiuxetan – ZEVALIN (CAP)	18
5.2.5. Influenza vaccine (split virion, inactivated) – IDFLU (CAP), INTANZA (CAP)	18
5.2.6. Nilotinib – TASIGNA (CAP)	19
5.2.7. Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) – PANDEMRIX (CAP)	19
5.2.8. Pegfilgrastim – NEULASTA (CAP)	19
5.2.9. Teduglutide – REVESTIVE (CAP)	20
5.2.10. Telaprevir – INCIVO (CAP)	20
<i>RMP in the context of a variation – CHMP-led procedure</i>	20
5.2.11. Bortezomib – VELCADE (CAP)	20
5.2.12. Caffeine – PEYONA (CAP)	20
5.2.13. Collagenase clostridium histolyticum – XIAPEX (CAP)	21
5.2.14. Empagliflozin – JARDIANCE (CAP)	21
5.2.15. Epoetin beta – NEORECORMON (CAP)	21
5.2.16. Human coagulation factor VIII, human von Willebrand factor – VONCENTO (CAP)	22
5.2.17. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (CAP)	22
5.2.18. Insulin degludec – TRESIBA (CAP)	22
5.2.19. Insulin degludec, liraglutide – XULTOPHY (CAP)	23
5.2.20. Ipilimumab – YERVOY (CAP)	23
5.2.21. Lapatinib – TYVERB (CAP)	23
5.2.22. Lenalidomide – REVLIMID (CAP)	24
5.2.23. Palonosetron – ALOXI (CAP)	24
5.2.24. Perampanel – FYCOMPA (CAP)	24
5.2.25. Pertuzumab – PERJETA (CAP)	25

5.2.26. Pramipexole – OPRYMEA (CAP)	25
5.2.27. Prucalopride – RESOLOR (CAP)	25
<i>RMP evaluated in the context of a PSUR procedure</i>	26
<i>RMP evaluated in the context of PASS results</i>	26
<i>RMP evaluated in the context of a renewal of the marketing authorisation, conditional renewal or annual reassessment</i>	26
5.2.28. Insulin glargine – LANTUS (CAP)	26
<i>RMP evaluated in the context of a stand-alone RMP procedure</i>	26
<i>Others</i>	26
6. Periodic Safety Update Reports (PSURs)	26
6.1. Evaluation of PSUR procedures	26
6.1.1. Aflibercept – EYLEA (CAP)	26
6.1.2. Apixaban – ELIQUIS (CAP)	27
6.1.3. Azacitidine – VIDAZA (CAP)	27
6.1.4. Boceprevir – VICTRELIS (CAP)	27
6.1.5. Bromfenac – YELLOX (CAP)	28
6.1.6. Caffeine – PEYONA (CAP)	28
6.1.7. Canagliflozin – INVOKANA (CAP)	28
6.1.8. Capecitabine – CAPECITABINE MEDAC (CAP), ECANSYA (CAP), XELODA (CAP), NAP	28
6.1.9. Capsaicin – QUTENZA (CAP), NAP	29
6.1.10. Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins – CHONDROCELECT (CAP)	29
6.1.11. Cholera vaccine (inactivated, oral) – DUKORAL (CAP)	29
6.1.12. Conestat alfa – RUCONEST (CAP)	29
6.1.13. Decitabine – DACOGEN (CAP)	30
6.1.14. Emtricitabine, tenofovir disoproxil – TRUVADA (CAP)	30
6.1.15. Fentanyl – EFFENTORA (CAP), INSTANYL (CAP), PECFENT (CAP), NAP	30
6.1.16. Ferumoxytol – RIENSO (CAP)	31
6.1.17. Fidaxomicin – DIFICLIR (CAP)	31
6.1.18. Fluticasone furoate, vilanterol – RELVAR ELLIPTA (CAP), REVINTY ELLIPTA (CAP) ..	31
6.1.19. Follitropin beta – FERTAVID (CAP), PUREGON (CAP)	31
6.1.20. Fulvestrant – FASLODEX (CAP)	32
6.1.21. Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – GARDASIL (CAP), SILGARD (CAP)	32
6.1.22. Influenza vaccine (split virion, inactivated) – IDFLU (CAP), INTANZA (CAP)	32
6.1.23. Insulin lispro – HUMALOG (CAP), LIPROLOG (CAP)	32
6.1.24. Laronidase – ALDURAZYME (CAP)	33
6.1.25. Lidocaine, prilocaine – FORTACIN (CAP)	33
6.1.26. Linagliptin – TRAJENTA (CAP) linagliptin, metformin – JENTADUETO (CAP)	33
6.1.27. Methylthioninium chloride – METHYLTHIONINIUM CHLORIDE PROVEBLUE (CAP), NAP	33
6.1.28. Mitotane – LYSODREN (CAP)	34
6.1.29. Mycophenolate – CELLCEPT (CAP), NAP	34
6.1.30. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – ADJUPANRIX (CAP), PUMARIX (CAP) Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – PREPANDRIX (CAP)	34

6.1.31. Piperazine, arteminol, dihydroartemisinin – EURARTESIM (CAP)	35
6.1.32. Pixantrone – PIXUVRI (CAP).....	35
6.1.33. Radium-223 – XOFIGO (CAP)	35
6.1.34. Rilpivirine – EDURANT (CAP)	35
6.1.35. Saxagliptin, metformin – KOMBOGLYZE (CAP).....	36
6.1.36. Sevelamer – RENAGEL (CAP), RENVELA (CAP).....	36
6.1.37. Shingles (herpes zoster) vaccine (live) – ZOSTAVAX (CAP)	36
6.1.38. Sildenafil – REVATIO (CAP)	36
6.1.39. Sunitinib – SUTENT (CAP)	37
6.1.40. Tafamidis – VYNDAQEL (CAP).....	37
6.1.41. Temoporfin – FOSCAN (CAP)	37
6.1.42. Tolvaptan – SAMSCA (CAP)	38
6.1.43. Turoctocog alfa – NOVOEIGHT (CAP).....	38
6.1.44. Ulipristal – ELLAONE (CAP)	38
6.1.45. Varenicline – CHAMPIX (CAP)	38
6.2. Follow-up to PSUR procedures	39
6.2.1. Paclitaxel – ABRAXANE (CAP).....	39
6.2.2. Pregabalin – LYRICA (CAP)	39
7. Post-authorisation Safety Studies (PASS)	39
7.1. Protocols of PASS imposed in the marketing authorisation(s)	39
7.1.1. Aprotinin (NAP)	39
7.1.2. Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor (sipuleucel-T) – PROVENGE (CAP)	40
7.1.3. Cyproterone, ethinylestradiol (NAP)	40
7.1.4. Deferasirox – EXJADE (CAP)	40
7.1.5. Flupirtine (NAP).....	41
7.1.6. Sodium, magnesium, potassium sulphates for bowel preparation (NAP)	41
7.2. Protocols of PASS non-imposed in the marketing authorisation(s)	41
7.2.1. Cobicistat – TYBOST (CAP)	41
7.2.2. Fidaxomicin – DIFICLIR (CAP)	42
7.2.3. Florbetaben (¹⁸ F) – NEURACEQ (CAP).....	42
7.2.4. Insulin glargine – LANTUS (CAP) Insulin glulisine – APIDRA (CAP)	42
7.2.5. Lipegfilgrastim – LONQUEX (CAP)	42
7.2.6. Tenofovir – VIREAD (CAP)	43
7.3. Results of PASS imposed in the marketing authorisation(s)	43
7.4. Results of PASS non-imposed in the marketing authorisation(s)	43
7.4.1. Aliskiren – RASILEZ (CAP) aliskiren, amlodipine – RASILAMLO (CAP) aliskiren, hydrochlorothiazide – RASILEZ HCT (CAP)	43
7.4.2. Human papillomavirus vaccine [types 6, 11, 18] (recombinant, adsorbed)– GARDASIL (CAP), SILGARD (CAP)	44
7.4.3. Insulin degludec – TRESIBA (CAP)	44
7.4.4. Ivacaftor – KALYDECO (CAP).....	44
7.4.5. Palivizumab – SYNAGIS (CAP)	45
7.4.6. Telaprevir – INCIVO (CAP)	45
7.4.7. Tigecycline – TYGACIL (CAP).....	45

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	46
7.5.1. Adefovir dipivoxil –HEPSERA (CAP)	46
7.5.2. Aripiprazole – ABILIFY MAINTENA (CAP)	46
7.5.3. Etravirine – INTELENCE (CAP)	46
7.5.4. Infliximab – INFLECTRA (CAP), REMSIMA (CAP)	47
7.5.5. Rotigotine – LEGANTO (CAP), NEUPRO (CAP)	47
8. Renewals of the Marketing Authorisation, Conditional Renewals and Annual Reassessments	47
8.1.1. Alipogene tiparvovec – GLYBERA (CAP)	47
8.1.2. Cholic acid – ORPHACOL (CAP)	47
8.1.3. Delamanid – DELTYBA (CAP)	48
8.1.4. Ofatumumab – ARZERRA (CAP)	48
8.1.5. Tocofersolan – VEDROP (CAP)	48
9. Product related pharmacovigilance inspections	49
9.1. List of planned pharmacovigilance inspections	49
9.1.1. Risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders connected with human centrally authorised products	49
9.2. On-going or concluded pharmacovigilance inspection	49
10. Other Safety issues for discussion requested by the CHMP or the EMA	49
10.1. Safety related variations of the marketing authorisation (MA)	49
10.1.1. Human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) – CERVARIX (CAP)	49
10.2. Timing and message content in relation to MS safety announcements	49
10.3. Other requests	49
11. Other Safety issues for discussion requested by the Member States .	50
11.1. Safety related variations of the marketing authorisation	50
11.2. Renewals of the Marketing Authorisation	50
11.3. Other requests	50
11.3.1. Ciprofloxacin for systemic use (NAP)	50
11.3.2. Influenza vaccine (surface antigen, inactivated, adjuvanted) – FLUAD (NAP)	50
12. Organisational, regulatory and methodological matters	50
12.1. Mandate and organisation of the PRAC	50
12.2. Pharmacovigilance audits and inspections	51
12.2.1. Pharmacovigilance Systems and their Quality Systems	51
12.2.2. Pharmacovigilance Inspections	51
12.2.3. Pharmacovigilance Audits	51
12.3. Periodic Safety Update Reports & Union Reference Date (EURD) List	51
12.3.1. Periodic Safety Update Reports	51
12.3.2. PSURs Repository	51
12.3.3. Union Reference Date List	51
12.4. Signal Management	51
12.4.1. Signal Management	51

12.5. Adverse Drug Reactions reporting and additional reporting	51
12.5.1. Management and Reporting of Adverse Reactions to Medicinal Products.....	51
12.5.2. Additional Monitoring.....	52
12.5.3. List of Product under Additional Monitoring	52
12.6. EudraVigilance Database	52
12.6.1. Activities related to the confirmation of full functionality	52
12.7. Risk Management Plans and Effectiveness of risk Minimisations	52
12.7.1. Risk Management Systems	52
12.7.2. Tools, Educational Materials and Effectiveness Measurement for Risk Minimisation .	52
12.8. Post-authorisation Safety Studies	52
12.8.1. Post-Authorisation Safety Studies	52
12.9. Community Procedures	52
12.9.1. Referral Procedures for Safety Reasons	52
12.10. Renewals, conditional renewals, annual reassessments.....	52
12.10.1. Five-year renewal procedure process.....	52
12.11. Risk communication and Transparency	53
12.11.1. Public Participation in Pharmacovigilance	53
12.11.2. Safety Communication.....	53
12.12. Continuous pharmacovigilance	53
12.12.1. Incident Management	53
12.13. Interaction with EMA Committees and Working Parties	53
12.13.1. Committees.....	53
12.13.2. Working Parties	53
12.13.3. Scientific Advisory Group (SAG) Oncology	53
12.14. Interaction within the EU regulatory network.....	54
12.14.1. Policy on scientific publication and representation	54
12.15. Contacts of the PRAC with external parties and interaction of the EMA with interested parties.....	54
12.15.1. Guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)	54
12.16. Others.....	54
13. Any other business	54
13.1. Marketing authorisation application (MAA) process	54
13.2. Medication error	54
13.2.1. Communication on prevention of medication errors.....	54
13.2.2. Update on EMA medication error action plan	54
13.3. Guidance to applicants on responses to questions received from EMA Scientific Committees during the evaluation within the centralised procedure.....	54

1. Introduction

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

1.2. Adoption of agenda of the meeting of 1-4 December 2014

Status: for adoption

Document: PRAC Agenda Rev.3 due for publication on 1 December 2014

1.3. Minutes of the previous PRAC meeting on 3-6 November 2014

Status: for adoption

Document: PRAC final Minutes due for publication by 12 December 2014

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

2.1. Newly triggered procedures

None

2.2. Ongoing Procedures

None

2.3. Procedures for finalisation

None

2.4. Planned public hearings

None

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

3.1. Newly triggered Procedures

None

3.2. Ongoing Procedures

3.2.1. Ambroxol (NAP); bromhexine (NAP)

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

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

Regulatory details:

PRAC Rapporteur: Margarida Guimarães (PT)

PRAC Co-Rapporteurs: Jean-Michel Dogné (BE), Harald Herkner (AT)

Administrative details:

MAH(s): Boehringer Ingelheim, various

Documents:

For adoption: List of outstanding issues (LoOI), revised timetable

3.2.2. Dexibuprofen (NAP); ibuprofen (NAP)

- Review of the benefit-risk balance following the 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 outstanding issues

Regulatory details:

PRAC Rapporteur: Dolores Montero Corominas (ES)

PRAC Co-Rapporteur: Julie Williams (UK)

Administrative details:

MAH(s): various

Documents:

For adoption: List of outstanding issues (LoOI), revised timetable

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

3.5. Others

None

4. Signals assessment and prioritisation¹

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Lenalidomide – REVLIMID (CAP)

- Signal of Parkinson's disease

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: Arnaud Batz (FR)

Administrative details:

EPITT 18135 – New signal

MAH(s): Celgene Europe Limited

Lead MS: FR

Documents:

For adoption: PRAC recommendation

4.1.2. Natalizumab – TYSABRI (CAP)

- Signal of anaemia

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

Administrative details:

EPITT 18137 – New signal

MAH(s): Biogen Idec Ltd

Lead MS: DE

Documents:

For adoption: PRAC recommendation

4.1.3. Trabectedin – YONDELIS (CAP)

- Signal of capillary leak syndrome

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Torbjorn Callreus (DK)

Administrative details:

EPITT 18115 – New signal

MAH(s): Pharma Mar, S.A.

Lead MS: DK

Documents:

For adoption: PRAC recommendation

4.2. New signals detected from other sources

None

4.3. Signals follow-up and prioritisation

4.3.1. Interferon alfa-2a (NAP)

Interferon alfa-2b – INTRONA (CAP)

Interferon beta-1a – AVONEX (CAP), REBIF (CAP)

Interferon beta-1b - BETAFERON (CAP), EXTAVIA (CAP)

Peginterferon alfa-2a - PEGASYS (CAP)

Peginterferon alfa-2b - PEGINTRON (CAP), VIRAFERONPEG (CAP)

- Signal of pulmonary arterial hypertension

Status: *for discussion*

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:

EPITT 18059 – Follow-up September 2014

MAH(s): Biogen Idec (Avonex), Merck Serono Europe Limited (Rebif), Bayer Pharma AG (Betaferon), Novartis Europharm Ltd (Extavia), Merck Sharp & Dohme Limited (IntronA, PegIntron, ViraferonPeg), Roche Registration Ltd (Pegasys, Roferon-A)

Documents:

For adoption: PRAC recommendation

4.3.2. 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 – Follow-up June 2014

MAH(s): Novartis Europharm Ltd

Documents:

For adoption: PRAC recommendation

5. Risk Management Plans

5.1. Medicines in the pre-authorisation phase

5.1.1. Allogenic human heterologous liver cells

- 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/003750, ATMP, Orphan

Intended indication(s): Treatment of urea cycle disorders (UCD)

Applicant: Cytonet GmbH & Co KG

Documents:

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

5.1.2. Aripiprazole

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

Status: for discussion and agreement of advice to CHMP

Administrative details:

Product number(s): EMEA/H/C/004021, *Generic*

Intended indication(s): Treatment of schizophrenia

Documents:

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

5.1.3. Ceftolozane, tazobactam

- 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/003772

Intended indication(s): Treatment of complicated intra-abdominal infections and complicated urinary tract infections in adults

Documents:

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

5.1.4. Ceritinib

- 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/003819

Intended indication(s): Treatment of non-small cell lung cancer (NSCLC)

Documents:

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

5.1.5. Ciclosporin

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

Status: for discussion and agreement of advice to CHMP

Administrative details:

Product number(s): EMEA/H/C/002066

Intended indication(s): Treatment of keratitis

Documents:

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

5.1.6. Dalbavancin

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

Status: for discussion and agreement of advice to CHMP

Administrative details:

Product number(s): EMEA/H/C/002840

Intended indication(s): Treatment of tissue infections (cSSTI)

Documents:

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

5.1.7. Dasiprotimut-T

- 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/002772, *Orphan*

Intended indication(s): Treatment of non-Hodgkin's lymphoma (FL)

Applicant: Biovest Europe Ltd

Documents:

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

5.1.8. Ex vivo autologous corneal epithelial cells including stem cells

- 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/002450, *ATMP, Orphan*

Intended indication(s): Treatment of limbal stem cell deficiency

Applicant: Chiesi Farmaceutici S.p.A.

Documents:

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

5.1.9. Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)

- 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/003852

Intended indication(s): Treatment of human papillomavirus (HPV) diseases

Documents:

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

5.1.10. Isavuconazole

- 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/002734

Intended indication(s): Treatment of invasive aspergillosis and for the treatment of mucormycosis

Documents:

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

5.1.11. Levofloxacin

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

Status: for discussion and agreement of advice to CHMP

Administrative details:

Product number(s): EMEA/H/C/002789

Intended indication(s): Treatment of chronic pulmonary infections

Documents:

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

5.1.12. 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/003780

Intended indication(s): Treatment of obesity

Documents:

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

5.1.13. Naltrexone, bupropion

- 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(s): Management of obesity

Documents:

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

5.1.14. Phenylephrine, ketorolac trometamol

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

Status: for discussion and agreement of advice to CHMP

Administrative details:

Product number(s): EMEA/H/C/003702

Intended indication(s): Maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement (ILR) in adults

Documents:

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

5.1.15. Pregabalin

- 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/004024, *Generic*

Intended indication(s): Treatment of neuropathic pain, epilepsy and generalised anxiety disorder (GAD)

Documents:

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

5.1.16. Pregabalin

- 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/003962, *Generic*

Intended indication(s): Treatment of peripheral and central neuropathic pain in adults

Documents:

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

5.1.17. Pregabalin

- 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/004078, *Generic*

Intended indication(s): Treatment of epilepsy and generalised anxiety disorder (GAD)

Documents:

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

5.1.18. Pregabalin

- 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/004010, *Generic*

Intended indication(s): Treatment of neuropathic pain, epilepsy, generalised anxiety disorder (GAD)

Documents:

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

5.1.19. Pregabalin

- 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/004070, *Generic*

Intended indication(s): Treatment of epilepsy and generalised anxiety disorder (GAD)

Documents:

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

5.1.20. Pregabalin

- 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/003900, *Generic*

Intended indication(s): Treatment of epilepsy and generalised anxiety disorder (GAD)

Documents:

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

5.1.21. Safinamide

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

Status: for discussion and agreement of advice to CHMP

Administrative details:

Product number(s): EMEA/H/C/002396

Intended indication(s): Treatment of Parkinson's disease (PD)

Documents:

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

5.1.22. Sevelamer

- 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/003968

Intended indication(s): Control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis

Documents:

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

5.2. Medicines already authorised

RMP in the context of a variation² – PRAC-led procedure

5.2.1. Aliskiren – RASILEZ (CAP)

aliskiren, amlodipine – RASILAMLO (CAP)

aliskiren, hydrochlorothiazide – RASILEZ HCT (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:

Procedure number(s): EMEA/H/C/000780/WS0588/0094, EMEA/H/C/002073/WS0588/0095,

EMEA/H/C/000964/WS0588/0064

Procedure scope: Revised RMP in order to update the timelines for initiation, completion and submission of study reports of ongoing or planned studies together with update to some of objectives of the planned long-term safety and efficacy study

MAH(s): Novartis Europharm Ltd

Documents:

For adoption: PRAC AR

5.2.2. Elvitegravir, cobicistat, emtricitabine, tenofovir – STRIBILD (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: Rafe Suvarna (UK)

Administrative details:

Procedure number(s): EMEA/H/C/002574/II/0036/G

Procedure scope: Grouped variations to update the RMP with 1) information on applications recently finalised and studies recently concluded, 2) due date for a category 3 study (GS-US-236-0140), 3) agreed change in due date for a category 3 study (GS-US-236-0141)

MAH(s): Gilead Sciences International Ltd

Documents:

For adoption: PRAC AR

5.2.3. Fentanyl – INSTANYL (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/000959/II/0028

Procedure scope: Revised RMP to add a planned study to evaluate the effectiveness of the educational material approved in July 2013 as requested by PRAC and addition of new potential risks as requested by PRAC following the assessment of the latest PSUR and RMP

MAH(s): Takeda Pharma A/S

Documents:

For adoption: PRAC AR

5.2.4. Ibritumomab tiuxetan – ZEVALIN (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Torbjorn Callreus (DK)

Administrative details:

Procedure number(s): EMEA/H/C/000547/II/0043

Procedure scope: Update of the RMP to reflect the completion and analysis of study SAG 307722

MAH(s): Spectrum Pharmaceuticals B.V.

Documents:

For adoption: PRAC AR

5.2.5. Influenza vaccine (split virion, inactivated) – IDFLU (CAP), INTANZA (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)

Administrative details:

Procedure number(s): EMEA/H/C/000966/WS0638/0028, EMEA/H/C/000957/WS0638/0031

Procedure scope: Update of the RMP (version 8)

MAH(s): Sanofi Pasteur MSD SNC

Documents:

For adoption: PRAC AR

5.2.6. Nilotinib – TASIGNA (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:

Procedure number(s): EMEA/H/C/000798/II/0071

Procedure scope: Update of the RMP (version 13)

MAH(s): Novartis Europharm Ltd.

Documents:

For adoption: PRAC AR

5.2.7. Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) – PANDEMRIX (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/000832/II/0074

Procedure scope: Update of obligations to conduct post-authorisation non-clinical studies including timings for key data planned to further elucidate the potential role of Pandemrix in the onset of narcolepsy

MAH(s): GlaxoSmithKline Biologicals

Documents:

For adoption: PRAC AR

5.2.8. Pegfilgrastim – NEULASTA (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/000420/II/0082

Procedure scope: Updated RMP (version 3) to address the PRAC recommendation concerning capillary leak syndrome and cytokine release syndrome

MAH(s): Amgen Europe B.V.

Documents:

For adoption: PRAC AR

5.2.9. Teduglutide – REVESTIVE (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Torbjorn Callreus (SE)

Administrative details:

Procedure number(s): EMEA/H/C/002345/II/0009

Procedure scope: Updated RMP to reflect the use of nursing services as a risk minimisation effort to decrease adverse events of fluid overload

MAH(s): NPS Pharma Holdings Limited

Documents:

For adoption: PRAC AR

5.2.10. Telaprevir – INCIVO (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/002313/II/0033

Procedure scope: Revised RMP (version 7.0) to include the MAH's request for a waiver for doing the second-wave survey of the effectiveness of the rash educational programme in 2015

MAH(s): Janssen-Cilag International N.V.

Documents:

For adoption: PRAC AR

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

5.2.11. Bortezomib – VELCADE (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:

Procedure number(s): EMEA/H/C/000539/II/0072

Procedure scope: Extension of indication for the use of bortezomib in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma. Consequently, the MAH proposed updates of SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 and the package leaflet

MAH(s): Janssen-Cilag International N.V.

Documents:

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

5.2.12. Caffeine – PEYONA (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Jan Neuhauser (AT)

Administrative details:

Procedure number(s): MEA/H/C/001014/II/0013

Procedure scope: Update of SmPC section 4.8 to reflect the results of a European non-interventional post-authorisation study to assess drug utilisation and safety of caffeine citrate in the treatment of premature infants affected by apnoea. This study addresses a post-authorisation measure in the RMP. Section 4 of the package leaflet is updated accordingly

MAH(s): Chiesi Farmaceutici S.p.A.

Documents:

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

5.2.13. Collagenase clostridium histolyticum – XIAPEX (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:

Procedure number(s): EMEA/H/C/002048/II/0044

Procedure scope: Update of the SmPC with a new indication in the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity. The package leaflet is updated accordingly

MAH(s): Swedish Orphan Biovitrum AB (publ)

Documents:

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

5.2.14. Empagliflozin – JARDIANCE (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/002677/II/0002

Procedure scope: Update of SmPC section 4.5 in order to reflect the results of an in vitro study investigating the inhibition of UGT2B7, UGT1A3, UGT1A8, and UGT1A9. The RMP is updated to reflect the finalisation of the study and the results

MAH(s): Boehringer Ingelheim International GmbH

Documents:

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

5.2.15. Epoetin beta – NEORECORMON (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:

Procedure number(s): EMEA/H/C/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 RMP AR, PRAC RMP assessment overview and advice

5.2.16. Human coagulation factor VIII, human von Willebrand factor – VONCENTO (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/002493/II/0008/G

Procedure scope: Extension of indication to include prophylactic treatment of patients with von Willebrand disease (VWD). In addition the MAH is providing data to support treatment of paediatric patients with VWD

MAH(s): CSL Behring GmbH

Documents:

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

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

- Evaluation of an RMP in the context of a variation

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogné (BE)

Administrative details:

Procedure number(s): EMEA/H/C/000721/II/0061

Procedure scope: Update of SmPC section 4.6 on pregnancy outcomes in women exposed to the vaccine during pregnancy to reflect the outcome of study EPI-HPV-018 (an observational cohort) and other available data on safety during pregnancy. The package leaflet is amended accordingly

MAH(s): GlaxoSmithKline Biologicals

Documents:

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

See also 10.1.1.

5.2.18. Insulin degludec – TRESIBA (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:

Procedure number(s): EMEA/H/C/002498/II/0011

Procedure scope: Extension of indication in children aged from 1 to 18 years. Update to SmPC sections 4.1, 4.2, 4.8 and 5.1. The package leaflet is updated accordingly. In addition, update of the Section 2 of the package leaflet in line with the existing information in SmPC section 4.2

MAH(s): Novo Nordisk A/S

Documents:

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

5.2.19. Insulin degludec, liraglutide – XULTOPHY (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:

Procedure number(s): EMEA/H/C/002647/II/0001/G

MAH(s): Novo Nordisk A/S

Documents:

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

5.2.20. Ipilimumab – YERVOY (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Sabine Straus (NL)

Administrative details:

Procedure number(s): EMEA/H/C/002213/II/0028/G

MAH(s): Bristol-Myers Squibb Pharma EEIG

Documents:

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

5.2.21. Lapatinib – TYVERB (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/000795/II/0037

Procedure scope: Update of SmPC section 5.1 with information on lapatinib effect on central nervous system (CNS) metastasis further to comparative data on the incidence of CNS metastases from studies

EGF108919 (COMPLETE), EGF105485 (TEACH) and EGF106708 (ALTTO) (SOB 002.4). Annex II is also updated further to the fulfilment of the specific obligation

MAH(s): Glaxo Group Ltd

Documents:

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

5.2.22. Lenalidomide – REVLIMID (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/000717/X/0073/G

Procedure scope: Extension of indication for the continuous treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant A line extension application to add the following strength: 20 mg (21 capsules pack)

MAH(s): Celgene Europe Limited

Documents:

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

5.2.23. Palonosetron – ALOXI (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Almath Spooner (IE)

Administrative details:

Procedure number(s): EMEA/H/C/000563/II/0038

Procedure scope: Extension of indication to paediatric patients of 1 month of age and older for the prevention of nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy for the intravenous (IV) formulation, based on the paediatric studies PALO-10-14 and PALO-10-20 and update of SmPC sections 5.1 and 5.2 of the oral formulation to reflect those studies

MAH(s): Helsinn Birex Pharmaceuticals Ltd.

Documents:

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

5.2.24. Perampanel – FYCOMPA (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/002434/II/0016

Procedure scope: Extension of indication as adjunctive treatment of Primary Generalised Tonic-Clonic seizures in patients with epilepsy aged 12 years and older. SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 and the package leaflet are updated accordingly

MAH(s): Eisai Europe Ltd.

Documents:

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

5.2.25. Pertuzumab – PERJETA (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/002547/II/0010

Procedure scope: Extension of indication of the use of pertuzumab in combination with trastuzumab and docetaxel as part of a neoadjuvant treatment for patients with locally advanced, inflammatory or early stage HER2-positive breast cancer suitable for neo-adjuvant therapy

MAH(s): Roche Registration Ltd

Documents:

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

5.2.26. Pramipexole – OPRYMEA (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:

Procedure number(s): EMEA/H/C/000941/X/0017

Procedure scope: Addition of new strengths 2.62 mg and 3.15 mg prolonged-release tablets

MAH(s): Krka d.d. Novo mesto

Documents:

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

5.2.27. Prucalopride – RESOLOR (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/001012/II/0034

Procedure scope: Extension of indication to the male population for the treatment of symptomatic treatment of chronic constipation in whom laxatives fail to provide adequate relief

MAH(s): Shire Pharmaceuticals Ireland Ltd.

Documents:

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

RMP evaluated in the context of a PSUR procedure

See also Bromfenac – YELLOX 6.1.5. , Piperazine tetraphosphate, arteminol , dihydroartemisinin – EURARTESIM 6.1.31. , Tafamidis – VYNDAQEL 6.1.40. , Turoctocog alfa – NOVOEIGHT 6.1.43. , Ulipristal acetate – ELLAONE 6.1.44.

RMP evaluated in the context of PASS results

See also Human papillomavirus vaccine [types 6, 11, 18] (recombinant, adsorbed) – GARDASIL, SILGARD 7.4.2. , Insulin degludec – TRESIBA 7.4.3. , Ivacaftor – KALYDECO 7.4.4. , Telaprevir – INCIVO 7.4.6.

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

5.2.28. Insulin glargine – LANTUS (CAP)

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Menno van der Elst (NL)

Administrative details:

Procedure number(s): EMEA/H/C/000284/R/0096

MAH(s): Sanofi-aventis Deutschland GmbH

Documents:

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

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

None

Others

Bisphosphonates, denosumab and risk of osteonecrosis of the jaw (ONJ): consultation with Scientific Advisory Group (SAG) Oncology, see under 12.13.3.

6. Periodic Safety Update Reports (PSURs)

6.1. Evaluation of PSUR procedures³

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: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/002392/PSUV 016

MAH(s): Bayer Pharma AG

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.2. 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 022

MAH(s): Bristol-Myers Squibb / Pfizer EEIG

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.3. Azacitidine – VIDAZA (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/000978/PSUV 029

MAH(s): Celgene Europe Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.4. Boceprevir – VICTRELIS (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/002332/PSUV 031

MAH(s): Merck Sharp & Dohme Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.5. Bromfenac – YELLOX (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Torbjorn Callreus (DK)

Administrative details:

Procedure number(s): EMEA/H/C/001198/PSUV 010 (with RMP version 8.0)

MAH(s): Cromapharma GmbH

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.6. Caffeine – PEYONA (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Jan Neuhauser (AT)

Administrative details:

Procedure number(s): EMEA/H/C/001014/PSUV 014

MAH(s): Chiesi Farmaceutici S.p.A.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.7. Canagliflozin – INVOKANA (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/002649/PSUV 007

MAH(s): Janssen-Cilag International N.V.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.8. Capecitabine – CAPECITABINE MEDAC (CAP), ECANSYA (CAP), XELODA (CAP), NAP

- Evaluation of a PSUSA⁴ procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:

Procedure number(s): EMEA/H/C/PSUSA/00000531/201404

⁴ PSUR single assessment, referring to CAP, NAP

MAH(s): Medac Gesellschaft fuer klinische Spezialpraeparate m.b.H (Capecitabine Medac), Krka d.d. Novo mesto (Ecansya), Roche Registration Ltd (Xeloda)

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.9. Capsaicin – QUTENZA (CAP), NAP

- Evaluation of a PSUSA⁵ procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Magda Pedro (PT)

Administrative details:

Procedure number(s): EMEA/H/C/PSUSA/00000533/201405

MAH(s): Astellas Pharma Europe B.V., various

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.10. Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins – CHONDROCELECT (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/000878/PSUV 011

MAH(s): TiGenix NV

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.11. Cholera vaccine (inactivated, oral) – DUKORAL (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/000476/PSUV 046

MAH(s): Crucell Sweden AB

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.12. Conestat alfa – RUCONEST (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: Rafe Suvarna (UK)

Administrative details:

Procedure number(s): EMEA/H/C/001223/PSUV 020

MAH(s): Pharming Group N.V

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.13. Decitabine – DACOGEN (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Patrick Maison (FR)

Administrative details:

Procedure number(s): EMEA/H/C/002221/PSUV 014

MAH(s): Janssen-Cilag International N.V.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.14. Emtricitabine, tenofovir disoproxil – TRUVADA (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/000594/PSUV 108

MAH(s): Gilead Sciences International Ltd

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.15. Fentanyl – EFFENTORA (CAP), INSTANYL (CAP), PECFENT (CAP), NAP

- Evaluation of a PSUSA⁶ procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/PSUSA/00001369/201404

MAH(s): Teva Pharma B.V. (Effentora), Takeda Pharma A/S (Instanyl), Archimedes Development Limited (PecFent), various

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

⁶ PSUR single assessment, referring to CAP, NAP

6.1.16. Ferumoxytol – RIENSO (CAP)

- Evaluation of a PSUR procedure

Status: for preliminary discussion

Regulatory details:

PRAC Rapporteur: Martin Huber (DE)

Administrative details:

Procedure number(s): EMEA/H/C/002215/PSUV 015

MAH(s): Takeda Pharma A/S

Documents:

For discussion: Preliminary PRAC Rapporteur AR

6.1.17. 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 020

MAH(s): Astellas Pharma Europe B.V.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.18. Fluticasone furoate, vilanterol – RELVAR ELLIPTA (CAP), REVINTY ELLIPTA (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/002673/PSUV 006, EMEA/H/C/002745/PSUV 002

MAH(s): Glaxo Group Ltd

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.19. Follitropin beta – FERTAVID (CAP), PUREGON (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/001042/PSUV 024, EMEA/H/C/000086/PSUV 082

MAH(s): Merck Sharp & Dohme Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.20. Fulvestrant – FASLODEX (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/000540/PSUV 044

MAH(s): AstraZeneca UK Ltd.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.21. Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – GARDASIL (CAP), SILGARD (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/000703/PSUV 052, EMEA/H/C/000732/PSUV 048

MAH(s): Sanofi Pasteur MSD SNC, Merck Sharp & Dohme Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.22. Influenza vaccine (split virion, inactivated) – IDFLU (CAP), INTANZA (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/000966/PSUV 027, EMEA/H/C/000957/PSUV 030

MAH(s): Sanofi Pasteur, Sanofi Pasteur MSD SNC

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.23. Insulin lispro – HUMALOG (CAP), LIPROLOG (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/000088/PSUV 128, EMEA/H/C/000393/PSUV 095
MAH(s): Eli Lilly Nederland B.V.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.24. Laronidase – ALDURAZYME (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/000477/PSUV 052
MAH(s): Genzyme Europe BV

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.25. Lidocaine, prilocaine – FORTACIN (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/002693/PSUV 001
MAH(s): Plethora Solutions Ltd.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

**6.1.26. Linagliptin – TRAJENTA (CAP)
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/002110/PSUV 016, EMEA/H/C/002279/PSUV 022
MAH(s): Boehringer Ingelheim International GmbH

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.27. Methylthioninium chloride – METHYLTHIONINIUM CHLORIDE PROVEBLUE (CAP), NAP

- Evaluation of a PSUSA⁷ procedure

⁷ 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/PSUSA/00002029/201405

MAH(s): Provepharm SAS

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.28. Mitotane – LYSODREN (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/000521/PSUV 016

MAH(s): Laboratoire HRA Pharma, SA

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.29. Mycophenolate – CELLCEPT (CAP), NAP

- Evaluation of a PSUSA⁸ procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:

Procedure number(s): EMEA/H/C/PSUSA/00002099/201405

MAH(s): Roche Registration Ltd

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

**6.1.30. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – ADJUPANRIX (CAP), PUMARIX (CAP)
Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) – PREPANDRIX (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/001206/PSUV 040, EMEA/H/C/001212/PSUV 010,

EMEA/H/C/000822/PSUV 056

⁸ PSUR single assessment, referring to CAP, NAP

MAH(s): GlaxoSmithKline Biologicals

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.31. Piperazine, arteminol, 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 014 (with RMP version 12.0)

MAH(s): Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.32. 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 018

MAH(s): CTI Life Sciences Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.33. 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 005

MAH(s): Bayer Pharma AG

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.34. 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 0014

MAH(s): Janssen-Cilag International N.V.

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.35. 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 017

MAH(s): Bristol-Myers Squibb/AstraZeneca EEIG

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.36. Sevelamer – RENAGEL (CAP), RENVELA (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Veerle Verlinden (BE)

Administrative details:

Procedure number(s): EMEA/H/C/000254/PSUV 101, EMEA/H/C/000993/PSUV 029

MAH(s): Genzyme Europe BV

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.37. 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 078

MAH(s): Sanofi Pasteur MSD SNC

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.38. Sildenafil – REVATIO (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/000638/PSUV 063

MAH(s): Pfizer Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.39. Sunitinib – SUTENT (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:

Procedure number(s): EMEA/H/C/000687/PSUV 052

MAH(s): Pfizer Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.40. Tafamidis – VYNDAQEL (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/002294/PSUV 018 (with RMP version 8.0)

MAH(s): Pfizer Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.41. Temoporfin – FOSCAN (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/000318/PSUV 037

MAH(s): Biolitec pharma Ltd

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.42. Tolvaptan – SAMSCA (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/000980/PSUV 019

MAH(s): Otsuka Pharmaceutical Europe Ltd

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.43. Turoctocog alfa – NOVOEIGHT (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/002719/PSUV 001 (with RMP version 3.0)

MAH(s): Novo Nordisk A/S

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.44. Ulipristal – ELLAONE (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/001027/PSUV 032 (with RMP version 14.0)

MAH(s): Laboratoire HRA Pharma, SA

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.1.45. Varenicline – CHAMPIX (CAP)

- Evaluation of a PSUR procedure

Status: for discussion and agreement of recommendation to CHMP

Regulatory details:

PRAC Rapporteur: Doris Stenver (DK)

Administrative details:

MAH(s): Pfizer Limited

Documents:

For adoption: PRAC PSUR AR, PRAC recommendation

6.2. Follow-up to PSUR procedures⁹

6.2.1. Paclitaxel – ABRAXANE (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/000778/LEG 029

Procedure scope: MAH's response to PRAC recommendation on PSUV/0066, as adopted in September 2014

MAH(s): Celgene Europe Limited

Documents:

For adoption: Updated PRAC Rapp 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 046

Procedure scope: MAH's response to PRAC recommendation on PSUV/0069 as adopted in September 2014

MAH(s): Pfizer Limited

Documents:

For adoption: Updated PRAC Rapp AR

7. Post-authorisation Safety Studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)¹⁰

7.1.1. Aprotinin (NAP)

- Evaluation of an imposed PASS protocol

Status: for appointment of Rapporteur and agreement of timetable

Regulatory details:

PRAC Rapporteur: Veerle Verlinden (BE)

Administrative details:

Procedure number(s): EMEA/H/N/PSP/0004

⁹ Follow up as per the conclusions of the previous PSUR procedure, assessed outside of the next PSUR procedure

¹⁰ In accordance with Article 107n of Directive 2001/83/EC

Procedure scope: Evaluation of a protocol for a non-interventional post-authorisation safety study of pattern of use of Nordic aprotinin

MAH(s): Disphar International B.V (Nordic Group)

Documents:

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

7.1.2. Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor (sipuleucel-T) – PROVENGE (CAP)

- Evaluation of an imposed PASS protocol

Status: for decision

Regulatory details:

PRAC Rapporteur: Brigitte Keller-Stanislawski (DE)

Administrative details:

Procedure number: EMEA/H/C/002513/ANX 001

Procedure scope: Evaluation of a PASS protocol to establish and keep an observational EU-based registry therapy in men with metastatic castrate-resistant prostate cancer (mCRPC) to evaluate overall survival, the risk of ischemic stroke or myocardial infarction following treatment with Provenge and other identified and potential risks (observational study P13-1)

MAH(s): Dendreon UK Ltd

Documents:

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

7.1.3. Cyproterone, ethinylestradiol (NAP)

- Evaluation of an imposed PASS protocol

Status: for decision

Regulatory details:

PRAC Rapporteur Menno van der Elst (NL)

Administrative details:

Procedure number(s): EMEA/H/N/PSP/0006

Procedure scope: Evaluation of a protocol for a drug utilisation study (database DUS) following EC decision dated 25 July 2013 on a referral procedure (EMEA/H/107i/1357)

MAH(s): Bayer (Diane 35)

Documents:

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

7.1.4. Deferasirox – EXJADE (CAP)

- Evaluation of an imposed PASS protocol

Status: for decision

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number: EMEA/H/C/000670/ANX 038.5

Procedure scope: Evaluation of MAH's responses to ANX 038.4 as adopted by PRAC in July 2014 including a revised PASS protocol for study C1CL670E2422: observational cohort study in paediatric non transfusion dependant-thalassaemia (NTDT) patients over 10 years

MAH(s): Novartis Europharm Ltd

Documents:

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

7.1.5. Flupirtine (NAP)

- Evaluation of an imposed PASS protocol

Status: for decision

Regulatory details:

PRAC Rapporteur: Valerie Strassmann (DE)

Administrative details:

Procedure number: EMEA/H/N/PSP/0005.2

Procedure scope: Evaluation of a revised 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)

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

7.1.6. Sodium, magnesium, potassium sulphates for bowel preparation (NAP)

- Evaluation of an imposed PASS protocol

Status: for decision

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number: EMEA/H/N/PSP/0007.1

Procedure scope: Evaluation of a revised 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)

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

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)¹¹**7.2.1. Cobicistat – TYBOST (CAP)**

- Evaluation of a PASS protocol

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:

Procedure number(s): EMEA/H/C/002572/MEA 012.1

Procedure scope: Evaluation of the MAH's response to MEA-012 (draft procedure protocol and a feasibility assessment for a drug utilisation study) as adopted in April 2014

MAH(s): Gilead Sciences International Ltd

Documents:

For adoption: PRAC advice

¹¹ In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

7.2.2. Fidaxomicin – DIFICLIR (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/002087/MEA 004

Procedure scope: Evaluation of a revised PASS protocol for a Drug Utilisation Study (DUS) of the use of oral fidaxomicin (clinical study 2819-CL-2002)

MAH(s): Astellas Pharma Europe B.V.

Documents:

For adoption: PRAC advice

7.2.3. Florbetaben (¹⁸F) – 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: Evaluation of a revised PASS protocol for a non-interventional prospective observational multicentre, multi-country registry to observe usage pattern, safety and tolerability of florbetaben (¹⁸F) in clinical practice (study FBB-01_03_13)

MAH(s): Piramal Imaging Limited

Documents:

For adoption: PRAC advice

7.2.4. Insulin glargine – LANTUS (CAP)

Insulin glulisine – APIDRA (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 051.1, EMEA/H/C/000557/MEA 037.1

Procedure scope: Revised 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, following list of questions adopted at PRAC in June 2014

MAH(s): Sanofi-aventis Deutschland GmbH

Documents:

For adoption: PRAC advice

7.2.5. Lipegfilgrastim – LONQUEX (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/002556/MEA 004.1

Procedure scope: Evaluation of the MAH's responses to MEA-004 (PASS Study XM22-ONC-50002, drug utilisation study) request for supplementary information (RSI) as adopted in May 2014

MAH(s): Sicom Biotech UAB

Documents:

For adoption: PRAC advice

7.2.6. Tenofovir – VIREAD (CAP)

- Evaluation of a PASS protocol

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/000419/MEA 265.3

Procedure scope: Evaluation of an updated PASS protocol for the HIV post-authorisation safety study: GS-EU-104-1402

MAH(s): Gilead Sciences International Ltd

Documents:

For adoption: PRAC advice

7.3. Results of PASS imposed in the marketing authorisation(s)¹²

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)¹³

7.4.1. Aliskiren – RASILEZ (CAP)

aliskiren, amlodipine – RASILAMLO (CAP)

aliskiren, hydrochlorothiazide – RASILEZ HCT (CAP)

- Evaluation of an RMP in the context of a variation

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Carmela Macchiarulo (IT)

Administrative details:

Procedure number(s): EMEA/H/C/000780/WS0581/0093, EMEA/H/C/002073/WS0581/0094,

EMEA/H/C/000964/WS0581/0063 (without RMP)

Procedure scope: Submission of the final study report for the non-interventional study CSPP100A2414: cohort study to assess various safety outcomes in aliskiren initiators using US claims data

MAH(s): Novartis Europharm Ltd

Documents:

¹² In accordance with Article 107p-q of Directive 2001/83/EC

¹³ In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

For adoption: PRAC AR

7.4.2. Human papillomavirus vaccine [types 6, 11, 18] (recombinant, adsorbed)– GARDASIL (CAP), SILGARD (CAP)

- Evaluation of PASS results

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:

Procedure number(s): EMEA/H/C/000703/WS0643/0053 (with RMP), EMEA/H/C/000732/WS0643/0049 (with RMP)

Procedure scope: Submission of the final pregnancy registry report in order to address MEA 65 (Gardasil) and MEA 64 (Silgard) on submission of annual pregnancy registry reports and a consequential update of the RMP (version 8)

MAH(s): Sanofi Pasteur MSD SNC

Documents:

For adoption: PRAC AR

7.4.3. Insulin degludec – TRESIBA (CAP)

- Evaluation of PASS results

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:

Procedure number(s): EMEA/H/C/002498/II/0012 (with RMP)

Procedure scope: Final study report for a study/survey with the objective of investigating the impact of red-green colour blindness on the ability to discriminate between the packages and the prefilled pen devices of the two different strengths as well as bolus insulin products marketed in colour schemes relevant in red-green colour blindness

MAH(s): Novo Nordisk A/S

Documents:

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

7.4.4. Ivacaftor – KALYDECO (CAP)

- Evaluation of PASS results

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)

Administrative details:

Procedure number(s): EMEA/H/C/002494/II/0032 (with RMP)

Procedure scope: Submission of the final PopPK report (including data from all completed studies that had enrolled patients aged 6-11 years [including Study 110 and Study 111]) to fulfil post-authorisation measure MEA 010

MAH(s): Vertex Pharmaceuticals (U.K.) Ltd.

Documents:

For adoption: PRAC AR

7.4.5. Palivizumab – SYNAGIS (CAP)

- Evaluation of PASS results

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Torbjorn Callreus (DK)

Administrative details:

Procedure number(s): EMEA/H/C/000257/II/0098 (without RMP)

Procedure scope: Submission of the final study report for study A11-632, an observational study carried out to assess the risk of autoimmune and allergic diseases in high risk children exposed to palivizumab, in fulfilment of the Post Authorisation Measure (REC) FU2 032.4

MAH(s): AbbVie Ltd.

Documents:

For adoption: PRAC AR

7.4.6. Telaprevir – INCIVO (CAP)

- Evaluation of PASS results

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:

Procedure number(s): EMEA/H/C/002313/II/0034 (with RMP)

Procedure scope: Submission of a study report (HIV/HCV co-infection study, VX-950HPC3008) and a revised RMP in order to update the information on the mentioned study. Update of SmPC sections 4.2, 4.4, 4.8 and 5.1 in accordance with the results of study VX-950HPC3008. In addition, the MAH took the opportunity to change in the SmPC the word 'subjects' into 'patients' in the description of the C211 study description (section 5.1). The package leaflet is updated accordingly

MAH(s): Janssen-Cilag International N.V.

Documents:

For adoption: PRAC AR

7.4.7. Tigecycline – TYGACIL (CAP)

- Evaluation of PASS results

Status: for discussion and adoption of PRAC Assessment Report

Regulatory details:

PRAC Rapporteur: Miguel-Angel Macia (ES)

Administrative details:

Procedure number(s): EMEA/H/C/000644/II/0089 (without RMP)

Procedure scope: Submission of the final PASS study report. This also incorporates the response to the assessment by the PRAC re ANX 58.4 - the outcome of the previously submitted progress report to delete the obligation to conduct a PASS study, as currently stated in Annex II. Editorial updates are made to the SmPC and package leaflet

MAH(s): Pfizer Limited

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 regulation¹⁴

7.5.1. Adefovir dipivoxil –HEPSERA (CAP)

- Evaluation of interim PASS results

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Arnaud Batz (FR)

Administrative details:

Procedure number(s): EMEA/H/C/000485/MEA 070

Procedure scope: Interim report on the antiretroviral pregnancy registry

MAH(s): Gilead Sciences International Ltd

Documents:

For adoption: PRAC advice

7.5.2. Aripiprazole – ABILIFY MAINTENA (CAP)

- Evaluation of interim PASS results

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Qun-Ying Yue (SE)

Administrative details:

Procedure number(s): EMEA/H/C/002755/MEA 005

Procedure scope: PASS study report on the results of the analysis of EPS-related events to be presented in the RMP

MAH(s): Otsuka Pharmaceutical Europe Ltd

Documents:

For adoption: PRAC advice

7.5.3. Etravirine – INTELENCE (CAP)

- Evaluation of interim PASS results

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Patrick Maison (FR)

Administrative details:

Procedure number(s): EMEA/H/C/000900/MEA 049

Procedure scope: First annual report on study TMC125-EPPICC (pharmacovigilance study to define the long-term safety profile of etravirine in HIV-1-infected children and adolescents in Europe)

MAH(s): Janssen-Cilag International N.V.

Documents:

For adoption: PRAC advice

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

7.5.4. Infliximab – INFLECTRA (CAP), REMSIMA (CAP)

- Evaluation of interim PASS results

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:

Procedure number(s): EMEA/H/C/002778/MEA 008, EMEA/H/C/002576/MEA 008

Procedure scope: Annual safety report on post-marketing surveillance to evaluate safety and efficacy in Korea

MAH(s): Hospira UK Limited, Celltrion Healthcare Hungary Kft

Documents:

For adoption: PRAC advice

7.5.5. Rotigotine – LEGANTO (CAP), NEUPRO (CAP)

- Evaluation of interim PASS results

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Magda Pedro

Administrative details:

Procedure number(s): EMEA/H/C/002380/MEA/003.5, EMEA/H/C/000626/MEA/003.11

Procedure scope: Annual status report for PASS SP854 (TRUST)

MAH(s): UCB Manufacturing Ireland Ltd.

Documents:

For adoption: PRAC advice

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

8.1.1. 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/0039 (without RMP)

MAH(s): UniQure Biopharma B.V.

Documents:

For adoption: PRAC advice

8.1.2. Cholic acid – ORPHACOL (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/001250/S/0008 (without RMP)

MAH(s): Laboratoires CTRS – Boulogne Billancourt

Documents:

For adoption: PRAC advice

8.1.3. Delamanid – DELTYBA (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Rafe Suvarna (UK)

Administrative details:

Procedure number(s): EMEA/H/C/002552/R/0004 (without RMP)

MAH(s): Otsuka Novel Products GmbH

Documents:

For adoption: PRAC advice

8.1.4. Ofatumumab – ARZERRA (CAP)

- PRAC consultation on a conditional renewal of the marketing authorisation

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/R/0033 (without RMP)

MAH(s): Glaxo Group Ltd

Documents:

For adoption: PRAC advice

8.1.5. Tocofersolan – VEDROP (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/000920/S/0012 (without RMP)

MAH(s): Orphan Europe S.A.R.L.

Documents:

For adoption: PRAC advice

See also under 5.2

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

9.1.1. Risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders connected with human centrally authorised products

Status: for discussion and agreement of the programme

Documents:

For adoption: Confidential Human-pharmacovigilance inspection programme 2014-2017 (second revision for 2014) for final adoption at CHMP

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

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

Status: for discussion and agreement of advice to CHMP

Regulatory details:

PRAC Rapporteur: Jean-Michel Dogné (BE)

Administrative details:

Procedure number(s): EMEA/H/C/000721/II/0061

Procedure scope: Update of SmPC section 4.6 on pregnancy outcomes in women exposed to the vaccine during pregnancy to reflect the outcome of study EPI-HPV-018 (an observational cohort) and other available data on safety during pregnancy. The package leaflet is amended accordingly
MAH(s): GlaxoSmithKline Biologicals

Documents:

For adoption: PRAC advice

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

None

10.3. Other requests

None

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Renewals of the Marketing Authorisation

None

11.3. Other requests

11.3.1. Ciprofloxacin for systemic use (NAP)

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

Status: for discussion and agreement of PRAC advice

Regulatory details:

Lead member: Ingebjorg Buajordet (NO)

Administrative details:

Procedure number: NO/H/PSUR/0010/002

Procedure scope: PSUR worksharing procedure and request for PRAC advice on the need for contraindicating the concomitant use of ciprofloxacin and agomelatine and confirmation of potential signals

MAH(s): Bayer HealthCare (Ciprobay, Ciproxin)

Documents:

For adoption: PRAC advice

11.3.2. Influenza vaccine (surface antigen, inactivated, adjuvanted) – FLUAD (NAP)

- PRAC consultation on a batch suspension of use upon Italy's request

Status: for discussion and agreement of PRAC advice

Regulatory details:

Lead member: Carmela Macchiarulo (IT)

Administrative details:

Procedure number: *Not applicable*

Procedure scope: Suspension of use of two batches of Flud following reports of serious adverse events after flu vaccination

MAH(s): Novartis Vaccines and Diagnostics (Flud)

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

- Risk Management plans-related issues identified as part of pharmacovigilance inspections

Status: *for discussion*

12.2.3. Pharmacovigilance Audits

None

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

12.3.1. Periodic Safety Update Reports

- PSUR Single Assessment (PSUSA) procedures for nationally approved products (NAP) only

Status: *for discussion*

Documents:

For discussion: Assessment Report template for PSUSA procedures for NAPs only

12.3.2. PSURs Repository

None

12.3.3. Union Reference Date List

- Consultation on the draft list, version December 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

- EU individual case safety report (ICSR) implementation guide

Status: *for agreement*

Documents:

For adoption: Draft implementation guide

12.5.2. Additional Monitoring

None

12.5.3. List of Product under Additional Monitoring

- Consultation on the draft list, version December 2014

Status: *for information*

Documents:

For discussion: Revised additional monitoring List

12.6. EudraVigilance Database

12.6.1. Activities related to the confirmation of full functionality

None

12.7. Risk Management Plans and Effectiveness of risk Minimisations

12.7.1. Risk Management Systems

None

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

None

12.8. Post-authorisation Safety Studies

12.8.1. Post-Authorisation Safety Studies

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

Status: *for discussion*

12.9. Community Procedures

12.9.1. Referral Procedures for Safety Reasons

None

12.10. Renewals, conditional renewals, annual reassessments

12.10.1. Five-year renewal procedure process

- Update to Committees on the changes to the renewal procedure process

Status: for discussion

12.11. Risk communication and Transparency

12.11.1. Public Participation in Pharmacovigilance

None

12.11.2. Safety Communication

- Benefit-risk communication to users of medicines - how can regulators best meet the information needs of patients and healthcare professionals

Status: for discussion

Documents:

For discussion: Workshop report

12.12. Continuous pharmacovigilance

- Effects tables as part of the procedures evaluated by the PRAC

Status: for discussion

12.12.1. Incident Management

None

12.13. Interaction with EMA Committees and Working Parties

12.13.1. Committees

None

12.13.2. Working Parties

None

12.13.3. Scientific Advisory Group (SAG) Oncology

- Bisphosphonates, denosumab: effectiveness of risk minimisation measures: consultation of the SAG oncology on the risk of osteonecrosis of the jaw (ONJ)

Status: for discussion

12.14. Interaction within the EU regulatory network

12.14.1. Policy on scientific publication and representation

Status: for discussion

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

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

None

12.16. Others

None

13. Any other business

13.1. Marketing authorisation application (MAA) process

- Update to Committees about changes to the MAA process

Status: for discussion

13.2. Medication error

13.2.1. Communication on prevention of medication errors

Status: for discussion and agreement

13.2.2. Update on EMA medication error action plan

Status: for discussion

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

Status: for agreement

Documents:

For agreement: Draft guidance document