06 April 2021
EMA/PRAC/197861/2021
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 06-09 April 2021

Chair: Sabine Straus – Vice-Chair: Martin Huber

06 April 2021, 10:30 – 19:30, via teleconference

07 April 2021, 08:30 – 19:30, via teleconference

08 April 2021, 08:30 – 19:30, via teleconference

09 April 2021, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

22 April 2021, 09:00 – 12:00, via teleconference

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.

Of note, this agenda is a working document primarily designed for PRAC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006, Rev. 1).

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PRAC Rapporteur: Eva Segovia

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Esketamine[11] - SPRAVATO (CAP) - PSUSA/00010825/202009

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Fremanezumab - AJOVY (CAP) - PSUSA/00010758/202009

Applicant: Teva GmbH

PRAC Rapporteur: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Gilteritinib - XOSPATA (CAP) - PSUSA/00010832/202009

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Ibalizumab - TROGARZO (CAP) - PSUSA/00010797/202009

Applicant: Theratechnologies Europe Limited

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Idebenone[12] - RAXONE (CAP) - PSUSA/00010412/202009

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[11] Centrally authorised product(s) only
[12] Centrally authorised product(s) only

6.1.22. Influenza vaccine (live attenuated, nasal) - FLUENZ TETRA (CAP) - PSUSA/00001742/202008

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Isatuximab - SARCLISA (CAP) - PSUSA/00010851/202009

Applicant: Sanofi-aventis groupe

PRAC Rapporteur: Eva Segovia

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Isavuconazole - CRESEMBA (CAP) - PSUSA/00010426/202009

Applicant: Basilea Pharmaceutica Deutschland GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Linaclotide - CONSTELLA (CAP) - PSUSA/00010025/202008

Applicant: Allergan Pharmaceuticals International Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Lorlatinib - LORVIQUA (CAP) - PSUSA/00010760/202009

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Mecasermin - INCRELEX (CAP) - PSUSA/00001942/202008

Applicant: Ipsen Pharma

PRAC Rapporteur: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Mepolizumab - NUCALA (CAP) - PSUSA/00010456/202009

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Meropenem, vaborbactam - VABOREM (CAP) - PSUSA/00010727/202008

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Moroctocog alfa - REFACTO AF (CAP) - PSUSA/00002089/202008

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Naldemedine - RIZMOIC (CAP) - PSUSA/00010753/202009

Applicant: Shionogi B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Naloxegol - MOVENTIG (CAP) - PSUSA/00010317/202009

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Naltrexone, bupropion - MYSIMBA (CAP) - PSUSA/00010366/202009

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated) - PANDEMIC INFLUENZA VACCINE H5N1 BAXTER (CAP) - PSUSA/00002282/202008

Applicant: Ology Bioservices Ireland Limited

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Pembrolizumab - KEYTRUDA (CAP) - PSUSA/00010403/202009

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Raltegravir - ISENTRESS (CAP) - PSUSA/00010373/202009

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adrien Inoubli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Risankizumab - SKYRIZI (CAP) - PSUSA/00010765/202009

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Rivaroxaban - XARELTO (CAP) - PSUSA/00002653/202009

Applicant: Bayer AG

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Sebelipase alfa - KANUMA (CAP) - PSUSA/00010422/202008

Applicant: Alexion Europe SAS

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Siponimod - MAYZENT (CAP) - PSUSA/00010818/202009

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Sodium zirconium cyclosilicate - LOKELMA (CAP) - PSUSA/00010675/202009

Applicant: AstraZeneca AB

PRAC Rapporteur: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Solriamfetol - SUNOSI (CAP) - PSUSA/00010831/202009

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Julia Pallos

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Tasonermin - BEROMUN (CAP) - PSUSA/00002850/202008

Applicant: Belpharma s.a.

PRAC Rapporteur: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Teduglutide - REVESTIVE (CAP) - PSUSA/00009305/202008

Applicant: Shire Pharmaceuticals Ireland Limited

PRAC Rapporteur: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Tildrakizumab - ILUMETRI (CAP) - PSUSA/00010720/202009

Applicant: Almirall S.A

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Tobramycin[13] [14] - VANTOBRA (CAP) - PSUSA/00010370/202009

Applicant: PARI Pharma GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Trabectedin - YONDELIS (CAP) - PSUSA/00003001/202009

Applicant: Pharma Mar, S.A.

PRAC Rapporteur: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Velmanase alfa - LAMZEDE (CAP) - PSUSA/00010677/202009

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs)

6.2.1. Anagrelide - ANAGRELIDE MYLAN (CAP); XAGRID (CAP); NAP - PSUSA/00000208/202009

Applicants: Mylan S.A.S (Anagrelide Mylan), Shire Pharmaceuticals Ireland Limited (Xagrid), various

[13] Nebuliser solution
[14] Centrally authorised product(s) only

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Glycopyrronium[15] - SIALANAR (CAP); NAP - PSUSA/00010529/202009

Applicants: Proveca Pharma Limited (Sialanar), various

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Trientine - CUFENCE (CAP); CUPRIOR (CAP); NAP - PSUSA/00010637/202009

Applicants: Orphalan (Cuprior), Univar Solutions BV (Cufence), various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Zoledronic acid[16] - ZOLEDRONIC ACID HOSPIRA (CAP); ZOLEDRONIC ACID MEDAC (CAP); ZOMETA (CAP); NAP - PSUSA/00003149/202008

Applicants: Medac Gesellschaft fur klinische Spezialpraparate mbH (Zoledronic acid medac), Novartis Europharm Limited (Zometa), Pfizer Europe MA EEIG (Zoledronic acid Hospira), various

PRAC Rapporteur: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.3. PSUR single assessment (PSUSA) procedures including nationally authorised products (NAPs) only

6.3.1. Bromazepam (NAP) - PSUSA/00000435/202008

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[15] Treatment of severe sialorrhea (chronic pathological drooling) indication(s) only
[16] Treatment of cancer and fractures indication(s)only

6.3.2. Dalteparin sodium (NAP) - PSUSA/00000922/202008

Applicant(s): various

PRAC Lead: Rugilė Pilvinienė

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Dermatophagoides pteronyssinus, dermatophagoides farina[17] [18] [19] (NAP) - PSUSA/00010582/202009

Applicant(s): various

PRAC Lead: Brigitte Keller-Stanislawski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Dexamfetamine (NAP) - PSUSA/00000986/202009

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Dexibuprofen (NAP) - PSUSA/00000996/202008

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Hexoprenaline sulfate (NAP) - PSUSA/00003170/202008

Applicant(s): various

PRAC Lead: Roxana Dondera

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Metronidazole, neomycin, nystatin (NAP) - PSUSA/00010508/202009

Applicant(s): various

[17] Allergen for therapy
[18] For oromucosal use only
[19] Medicinal product(s) authorised via mutually recognition procedure and decentralised procedure only

PRAC Lead: Roxana Dondera

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Modafinil (NAP) - PSUSA/00010242/202008

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Nifedipine (NAP) - PSUSA/00002156/202008

Applicant(s): various

PRAC Lead: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Oxcarbazepine (NAP) - PSUSA/00002235/202008

Applicant(s): various

PRAC Lead: Anette Kirstine Stark

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Pefloxacin (NAP) - PSUSA/00002322/202008

Applicant(s): various

PRAC Lead: Gabriela Jazbec

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Permethrin (NAP) - PSUSA/00002355/202008

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Phenytoin (NAP) - PSUSA/00002392/202008

Applicant(s): various

PRAC Lead: Ronan Grimes

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Poractant alfa (NAP) - PSUSA/00002478/202008

Applicant(s): various

PRAC Lead: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Suxamethonium (NAP) - PSUSA/00002834/202008

Applicant(s): various

PRAC Lead: Nikica Mirošević Skvrce

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Docetaxel - TAXOTERE (CAP) - EMEA/H/C/000073/LEG 039

Applicant: Sanofi Mature IP

PRAC Rapporteur: Tiphaine Vaillant

Scope: Detailed review on the potential risk for decreased efficacy of docetaxel when used along with any selective cyclooxygenase-2 (Cox-2) inhibitors as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00001152/201911) adopted in July 2020

Action: For adoption of advice to CHMP

6.4.2. Pregabalin - LYRICA (CAP) - EMEA/H/C/000546/LEG 054

Applicant: Upjohn EESV

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Detailed review of cases reporting suicidal action, behaviour or ideation as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00002511/202001) adopted in September 2020

Action: For adoption of advice to CHMP

6.4.3. Pregabalin - PREGABALIN PFIZER (CAP) - EMEA/H/C/003880/LEG 007

Applicant: Upjohn EESV

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Detailed review of cases reporting suicidal action, behaviour or ideation as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00002511/202001) adopted in September 2020

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. COVID-19 mRNA[20] vaccine (nucleoside-modified) - COMIRNATY (CAP) - EMEA/H/C/005735/II/0016/G

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Grouped variation consisting of: 1) update of section 4.8 SmPC to add 'diarrhea' and 'vomiting' as adverse drug reactions (ADRs) with frequencies and update the ADR 'pain in extremity' in order to fulfil MEA 002.1 concluded in February 2021; 2) update of section 4.8 SmPC to update the ADR 'hypersensitivity reactions' in more detail with the relevant frequency categories in order to fulfil LEG 022.1. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to perform editorial changes in section 6.6 of the SmPC

Action: For adoption of PRAC Assessment Report

6.5.2. Ocrelizumab - OCREVUS (CAP) - EMEA/H/C/004043/II/0024

Applicant: Roche Registration GmbH

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Update of section 4.4 of the SmPC to amend the wording on progressive multifocal leukoencephalopathy (PML) as requested in the conclusions of the latest periodic safety update report single assessment (PSUSA) procedure (PSUSA/00010662/202003) adopted in November 2020

Action: For adoption of PRAC Assessment Report

[20] Messenger ribonucleic acid

6.6. Expedited summary safety reviews[21]

6.6.1. Coronavirus (COVID-19) vaccine (ChAdOx1-S [recombinant]) - VAXZEVRIA (previously COVID-19 VACCINE ASTRAZENECA) (CAP) - EMEA/H/C/005675/LEG 036

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Cumulative review of cases of hypersensitivity as per the conclusions of the signal procedure (EPITT 19668) adopted in March 2021

Action: For adoption of advice to CHMP

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[22]

7.1.1. Cabotegravir - VOCABRIA (CAP); rilpivirine - REKAMBYS (CAP) - EMEA/H/C/PSP/J/0092

Applicant(s): Janssen-Cilag International N.V. (Rekambys), ViiV Healthcare B.V. (Vocabria)

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Protocol for a joint drug utilisation study (DUS) to assess adherence, effectiveness and resistance: a prospective observational cohort study in people living with human immunodeficiency virus (HIV) (PLWH) initiating antiretroviral (ARV) regimen of cabotegravir (CAB) + rilpivirine (RPV) long-acting (LA) in collaboration with EuroSIDA[23]

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.2. Direct acting antivirals (DAAV): Dasabuvir - EXVIERA (CAP); elbasvir, grazoprevir - ZEPATIER (CAP); glecaprevir, pibrentasvir - MAVIRET (CAP); ledipasvir, sofosbuvir - HARVONI (CAP); ombitasvir, paritaprevir, ritonavir - VIEKIRAX (CAP); sofosbuvir - SOVALDI (CAP); sofosbuvir, velpatasvir - EPCLUSA (CAP); sofosbuvir, velpatasvir, voxilaprevir - VOSEVI (CAP) - EMEA/H/C/PSA/J/0068

Applicant(s): Gilead Science International (on behalf of a consortium)

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Substantial amendment for a joint protocol previously agreed in June 2020 (PSA/J/0028.1) for a non-interventional imposed PASS on early recurrence of hepatocellular carcinoma (HCC) in hepatitis C virus (HCV)-infected patients after direct-acting antiviral (DAAV) therapy in order to estimate the risk of early HCC recurrence associated with DAAV

[21] Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC
[22] In accordance with Article 107n of Directive 2001/83/EC
[23] Prospective observational pan-European cohort study

therapy exposure relative to no DAAV therapy exposure during routine clinical care of HCV-infected patients with successfully treated HCC, as required in the outcome of the referral procedure under Article 20 of Regulation (EC) No 726/2004 on DAAV indicated for treatment of hepatitis C (interferon-free) completed in December 2016 (EMEA/H/A-20/1438)

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.3. Pitolisant - WAKIX (CAP) - EMEA/H/C/PSA/S/0060.1

Applicant: Bioprojet Pharma

PRAC Rapporteur: Kirsti Villikka

Scope: MAH's response to PSA/S/0060 [substantial amendment to a protocol previously agreed in September 2016 for a 5-year multicentre, observational PASS to document the utilisation of Wakix (pitolisant) in the treatment of narcolepsy with or without cataplexy and to collect information on its long-term safety when used in routine medical practice] as per the request for supplementary information (RSI) adopted in December 2020

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.4. Sotagliflozin – ZYNQUISTA (CAP) - EMEA/H/C/PSP/S/0084.4

Applicant: Guidehouse Germany GmbH

PRAC Rapporteur: Martin Huber

Scope: MAH's response to PSP/S/0084.3 [protocol for an observational retrospective cohort study using existing data sources on the incidence of diabetic ketoacidosis (DKA) in adult patients with type 1 diabetes mellitus (T1DM) treated with sotagliflozin as an adjunct to insulin versus insulin alone, as required in the outcome of the initial opinion/marketing authorisation (EMEA/H/C/004889) finalised in February 2019] as per the request for supplementary information (RSI) adopted in December 2020

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[24]

7.2.1. Cabotegravir - VOCABRIA (CAP) - EMEA/H/C/004976/MEA 004

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Protocol for study 215162 (listed as a category 3 study in the RMP): a prospective observational cohort study to monitor for hepatotoxicity and regimen discontinuation due to liver related adverse events among patients initiating cabotegravir-containing antiretroviral regimen. Summary objectives [final clinical study report (CSR): expected in March 2027]

Action: For adoption of advice to CHMP

[24] 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. Cabotegravir - VOCABRIA (CAP) - EMEA/H/C/004976/MEA 005

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Protocol for study 215163: a study on pregnancy and neonatal outcomes following prenatal exposure to cabotegravir long acting (CAB LA) – data from the European Pregnancy and Paediatric human immunodeficiency virus (HIV) Cohort Collaboration (EPPICC)

Action: For adoption of advice to CHMP

7.2.3. Cabotegravir - VOCABRIA (CAP) - EMEA/H/C/004976/MEA 006

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Protocol for study 215325: a study on pregnancy and neonatal outcomes following prenatal exposure to cabotegravir - data from the Antiretroviral Pregnancy Registry (APR)

Action: For adoption of advice to CHMP

7.2.4. Coronavirus (COVID-19) mRNA[25] vaccine (nucleoside-modified) - COMIRNATY (CAP) - EMEA/H/C/005735/MEA 017

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Protocol for study vACcine Covid-19 monitoring readinESS (ACCESS)/Vaccine monitoring Collaboration for Europe (VAC4EU): an assessment of occurrence of safety events of interest, including severe or atypical COVID-19 in real-world use of COVID-19 mRNA vaccine [final clinical study report (CSR): expected in January 2024] (from initial opinion/marketing authorisation)

Action: For adoption of advice to CHMP

7.2.5. Darbepoetin alfa - ARANESP (CAP) - EMEA/H/C/000332/MEA 092.2

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: MAH's response to MEA 092.1 [protocol for study 20190404: a retrospective cohort study to assess the use of erythropoiesis stimulating agents (ESAs) in subjects receiving myelosuppressive chemotherapy in Europe] as per the request for supplementary information (RSI) adopted in November 2020

Action: For adoption of advice to CHMP

[25] Messenger ribonucleic acid

7.2.6. Dimethyl fumarate - TECFIDERA (CAP) - EMEA/H/C/002601/MEA 007.2

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Amendment to a protocol previously agreed in October 2020 to study 109MS401 (ESTEEM): a multicentre, global, observational study to collect information on safety and to document the drug utilisation of Tecfidera (dimethyl fumarate) when used in routine medical practice in the treatment of relapsing multiple sclerosis

Action: For adoption of advice to CHMP

7.2.7. Fenofibrate, pravastatin sodium - PRAVAFENIX (CAP) - EMEA/H/C/001243/MEA 007.6

Applicant: Laboratoires SMB s.a.

PRAC Rapporteur: Adrien Inoubli

Scope: Amendment to a protocol previously agreed in 2014 for study POSE (Pravafenix Observational Study in Europe) (EUPAS13661): a European, observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice

Action: For adoption of advice to CHMP

7.2.8. Inotersen - TEGSEDI (CAP) - EMEA/H/C/004782/MEA 001.5

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Amendment to a protocol previously agreed in September 2020 for study TEG4001: a prospective, non-interventional, long-term, multinational cohort safety study of patients with hereditary transthyretin amyloidosis with polyneuropathy (hATTR-PN)

Action: For adoption of advice to CHMP

7.2.9. Sotagliflozin - ZYNQUISTA (CAP) - EMEA/H/C/004889/MEA 004.3

Applicant: Guidehouse Germany GmbH

PRAC Rapporteur: Martin Huber

Scope: MAH's response to MEA 004.2 [protocol for a nested, case-control study to evaluate the risk of malignancies (bladder, renal, breast, Leydig cell, pancreatic, thyroid and prostate cancers) in adult patients with type 1 diabetes mellitus (T1DM) using sotagliflozin in existing healthcare databases in Europe and in the United States [final clinical study report (CSR) expected in April 2030]] as per the request for supplementary information (RSI) adopted in October 2020

Action: For adoption of advice to CHMP

7.2.10. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/MEA 015.2

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Amendment to a protocol previously agreed in November 2020 for study A3921334 (listed as a category 3 study in the RMP): a non-interventional PASS to evaluate the effectiveness of additional risk minimisation measures (aRMM) materials for Xeljanz (tofacitinib) in Europe via a survey of healthcare professionals (HCPs), as requested in the conclusions of the referral procedure under Article 20 of Regulation (EC) No 726/2004 (EMEA/H/A-20/1485) finalised in November 2019

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[26]

7.3.1. Aprotinin (NAP) - EMEA/H/N/PSR/S/0030

Applicant: Nordic Group BV (Trasylol)

PRAC Rapporteur: Laurence de Fays

Scope: Results for a Nordic aprotinin patient registry to record utilisation information on patients at cardiac surgery centres

Action: For adoption of recommendation to CMDh (or request for supplementary information (RSI))

7.3.2. Dexamfetamine (NAP) - EMEA/H/N/PSR/S/0028

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Results of a PASS to evaluate the long-term safety of dexamfetamine to assess the incidence proportion and incidence rate for cardiovascular, psychiatric, growth and sexual maturity related adverse events in children with a diagnosis of attention deficit hyperactivity disorder (ADHD) who have been treated with dexamfetamine, methylphenidate or lisdexamfetamine as recorded in healthcare databases of three countries. The study also compares the risk of long-term cardiovascular, psychiatric, growth and sexual maturity-related adverse events of dexamfetamine versus methylphenidate or lisdexamfetamine in each database

Action: For adoption of recommendation to CMDh (or request for supplementary information (RSI))

7.3.3. Dexamfetamine (NAP) - EMEA/H/N/PSR/S/0029

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Ana Sofia Diniz Martins

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

Scope: Results of a drug utilisation study (DUS) to collect data on abuse, misuse, overdose, diversion and dependence related to dexamfetamine in five European countries

Action: For adoption of recommendation to CMDh (or request for supplementary information (RSI))

7.4. Results of PASS non-imposed in the marketing authorisation(s)[27]

7.4.1. Dapagliflozin - EDISTRIDE (CAP) - EMEA/H/C/004161/WS2009/0045/G; FORXIGA (CAP) - EMEA/H/C/002322/WS2009/0064/G

Applicant: AstraZeneca AB

PRAC Rapporteur: Annika Folin

Scope: Submission of the final report from studies MB102103, MB102104 and MB102110 listed as a category 3 study in the RMP. These are observational studies comparing the risk of severe complications of UTI, acute liver injury and acute kidney injury respectively, between patients with Type 2 Diabetes exposed to dapagliflozin and those exposed to other antidiabetic treatments. The RMP version 23.1 for Forxiga and Edistride has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.2. Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - GARDASIL (CAP) - EMEA/H/C/000703/II/0091

Applicant: MSD Vaccins

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of the final report from study V501-070 (listed as a category 3 study in the RMP): a post-licensure observational study of the safety of Gardasil (human papillomavirus vaccine) in males. The RMP (version 14.1) is updated accordingly. The MAH took the opportunity to update the RMP with the synopsis for the study protocol for an observational study combining health-registries in Sweden on the 2-dose effectiveness of Gardasil (human papillomavirus vaccine) as agreed in MEA 82.6 by the CHMP in June 2020

Action: For adoption of PRAC Assessment Report

7.4.3. Insulin detemir - LEVEMIR (CAP) - EMEA/H/C/000528/II/0101

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Anette Kirstine Stark

Scope: Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy, based on final results from non-interventional study NN304-4016 (listed as a category 3 study in the RMP): a diabetes pregnancy registry study conducted to assess the long-term safety of insulin use in pregnant women. The RMP (version 21.0) is updated accordingly

[27] 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

Action: For adoption of PRAC Assessment Report

7.4.4. Linaclotide - CONSTELLA (CAP) - EMEA/H/C/002490/II/0053

Applicant: Allergan Pharmaceuticals International Limited

PRAC Rapporteur: Martin Huber

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on intestinal perforation and to add gastrointestinal perforation to the list of adverse drug reactions (ADRs) with frequency rare based on the Truven MarketScan[28] study and as requested by the PRAC in the conclusions of LEG 15.1 adopted in December 2020 [as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00010025/201908) adopted in March 2020]. The MAH took the opportunity to update the list of local representatives in the package leaflet

Action: For adoption of PRAC Assessment Report

7.5. Interim results of imposed and non-imposed PASS submitted before the entry into force of the revised variation regulation

7.5.1. Adalimumab - AMGEVITA (CAP) - EMEA/H/C/004212/MEA 001.2

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: First interim report for study 20160264 (ABP 501) - British Society of Rheumatology Biologics Register for Rheumatoid Arthritis (BSRBR): an observational study to evaluate long term safety of Amgevita (adalimumab) in patients with rheumatoid arthritis [final report: expected in Q3 2027]

Action: For adoption of advice to CHMP

7.5.2. Deferasirox - EXJADE (CAP) - EMEA/H/C/000670/ANX 038.12

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Seventh annual interim report for study CICL670E2422: an observational, multicentre cohort study to evaluate the long-term exposure and safety of deferasirox in the treatment of paediatric non-transfusion dependent thalassaemia patients over 10 years old for whom deferoxamine is contraindicated or inadequate

Action: For adoption of advice to CHMP

[28] Truven MarketScan claims database used to assess the potential association between linaclotide and gastrointestinal (GI) perforation

7.5.3. Fenofibrate, pravastatin sodium - PRAVAFENIX (CAP) - EMEA/H/C/001243/MEA 007.7

Applicant: Laboratoires SMB s.a.

PRAC Rapporteur: Adrien Inoubli

Scope: Interim results for study POSE (Pravafenix Observational Study in Europe) (EUPAS13661): a European, observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/ fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice

Action: For adoption of advice to CHMP

7.5.4. Golimumab - SIMPONI (CAP) - EMEA/H/C/000992/MEA 033.5

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Third annual interim report for study MK-8259-050 (version 2.0) (listed as a category 3 study in the RMP): an observational PASS for golimumab in the treatment of poly-articular juvenile idiopathic arthritis (pJIA) using the German Biologics JIA registry (BiKeR)

Action: For adoption of advice to CHMP

7.5.5. Infliximab - REMICADE (CAP) - EMEA/H/C/000240/MEA 114.11

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Interim report for study C0168Z03 (PSOLAR: PSOriasis Longitudinal Assessment and Registry): a multicentre, open study of patients with plaque psoriasis who are candidates for systemic therapy including biologics [final clinical study report (CSR) for PSOLAR expected in June 2023]

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Acalabrutinib - CALQUENCE (CAP) - EMEA/H/C/005299/MEA 002

Applicant: AstraZeneca AB

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Protocol for study D8220C00008 (listed as a category 3 study in the RMP): a phase 3b, multicentre, open-label, single-arm study in subjects with chronic lymphocytic leukaemia (ASSURE) to address missing information around moderate to severe cardiac impaired patients in subjects treated with Calquence (acalabrutinib)

Action: For adoption of advice to CHMP

7.6.2. Melatonin - SLENYTO (CAP) - EMEA/H/C/004425/REC 002.1

Applicant: RAD Neurim Pharmaceuticals EEC SARL

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Second annual French 'recommendation temporaire d'utilisation (RTU)' report on special temporary recommendation of use for Circadin (melatonin) 2-6 mg in the autism spectrum disorder (ASD) and neurogenetic 6-18 year-old population for the period from October 2015 to July 2019

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

None

7.8. Ongoing Scientific Advice

None

7.9. Final Scientific Advice (Reports and Scientific Advice letters)

None

8. Renewals of the marketing authorisation, conditional renewal and annual reassessments

8.1. Annual reassessments of the marketing authorisation

None

8.2. Conditional renewals of the marketing authorisation

8.2.1. Ataluren - TRANSLARNA (CAP) - EMEA/H/C/002720/R/0061 (without RMP)

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Belantamab mafodotin - BLENREP (CAP) - EMEA/H/C/004935/R/0003 (without RMP)

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Annika Folin

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.3. Bulevirtide - HEPCLUDEX (CAP) - EMEA/H/C/004854/R/0003 (without RMP)

Applicant: MYR GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Entrectinib - ROZLYTREK (CAP) - EMEA/H/C/004936/R/0002 (without RMP)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Menno van der Elst

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.5. Imlifidase - IDEFIRIX (CAP) - EMEA/H/C/004849/R/0003 (without RMP)

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Menno van der Elst

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.6. Pretomanid - DOVPRELA (CAP) - EMEA/H/C/005167/R/0005 (without RMP)

Applicant: Mylan IRE Healthcare Limited

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Bortezomib - BORTEZOMIB SUN (CAP) - EMEA/H/C/004076/R/0015 (without RMP)

Applicant: Sun Pharmaceutical Industries Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Enoxaparin sodium - INHIXA (CAP) - EMEA/H/C/004264/R/0076 (with RMP)

Applicant: Techdow Pharma Netherlands B.V.

PRAC Rapporteur: Menno van der Elst

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Glycopyrronium - SIALANAR (CAP) - EMEA/H/C/003883/R/0018 (without RMP)

Applicant: Proveca Pharma Limited

PRAC Rapporteur: Zane Neikena

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Lenvatinib - KISPLYX (CAP) - EMEA/H/C/004224/R/0043 (without RMP)

Applicant: Eisai GmbH

PRAC Rapporteur: David Olsen

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Methotrexate - NORDIMET (CAP) - EMEA/H/C/003983/R/0018 (without RMP)

Applicant: Nordic Group B.V.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Sildenafil - MYSILDECARD (CAP) - EMEA/H/C/004186/R/0009 (without RMP)

Applicant: Mylan S.A.S

PRAC Rapporteur: Menno van der Elst

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. Vismodegib - ERIVEDGE (CAP) - EMEA/H/C/002602/R/0050 (without RMP)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Annika Folin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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.

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

None

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

None

10.3. Other requests

None

10.4. Scientific Advice

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Other requests

11.2.1. Dinoprostone (NAP) - SE/H/PSUFU/00001104/201909

Applicant(s): Ferring (Propess), Pfizer (Minoprostin, Prepidil, Prostaglandin E2 Pfizer, Prostin E2)

PRAC Lead: Annika Folin

Scope: Second PRAC consultation on a PSUR follow-up (PSU FU) procedure on risk minimisation measures to further minimise the risk of uterine hyperstimulation, including serious complications as uterine rupture, foetal and neonatal death and uterine haemorrhage, as discussed at PRAC and agreed by CMDh following the conclusion of the PSUSA procedure (PSUSA/00001104/201909) concluded in May 2020, and following advice on from PRAC adopted in December 2020, on request of Sweden

Action: For adoption of advice to Member States

11.2.2. Phenobarbital (NAP) - EE/H/PSUFU/00002370/202001

Applicant(s): Accord UK Limited (Phenobarbital Accord), Bausch Health Companies (Sevenaletta), Bayer (Phenobarbital), Bial (Bialminal), Desitin Arzneimittel GmbH (Luminal, Phenaemaletten, Phenaemal), Dompe Farmaceutici S.p.A. (Luminale), Kern Pharma S.L. (Luminal), Sanofi, Stada, Takeda (Fenemal), Teva

PRAC Lead: Maia Uusküla

Scope: PRAC consultation on a PSUR follow-up (PSU FU) procedure on a review of recent studies on major congenital malformations following exposure to phenobarbital in utero, on neurodevelopmental disorders, on the use of phenobarbital during pregnancy and on the need for additional risk minimisation measures, as discussed at PRAC and agreed by CMDh following the conclusion of the PSUSA procedure (PSUSA/00002370/202001) concluded in October 2020, on request of Estonia

Action: For adoption of advice to Member States

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively - update on the implementation of quantitative goals - Q1 2021

Action: For discussion

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

12.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

None

12.4. Cooperation within the EU regulatory network

12.4.1. Coronavirus (COVID-19) pandemic - update

Action: For discussion

12.4.2. Heads of Medicines Agencies (HMA)-EMA joint big data - Big data steering group: data standards strategy initiative - call for expressions of interest

Action: For discussion

12.4.3. Joint advisory board (JAB) for COVID-19 vaccines studies - call for expressions of interest

Action: For discussion

12.4.4. PRAC strategic review and learning meeting (SRLM) under the Portuguese presidency of the European Union (EU) Council - Remote meeting, 23 April 2021 - agenda

PRAC lead: Ana Sofia Diniz Martins, Marcia Sofia Sanches de Castro Lopes Silva

Action: For discussion

12.5. Cooperation with International Regulators

None

12.6. Contacts of the PRAC with external parties and interaction with the Interested Parties to the Committee

None

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2021 - planning update dated Q1 2021

Action: For discussion

12.8.2. PRAC workload statistics - Q1 2021

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

12.10. Periodic safety update reports (PSURs) & Union reference date (EURD) list

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC Lead: Menno van der Elst, Maia Uusküla

Action: For discussion

12.10.3. PSURs repository

None

12.10.4. Union reference date list - consultation on the draft list

Action: For adoption

12.11. Signal management

12.11.1. Signal management - feedback from Signal Management Review Technical (SMART) Working Group

PRAC Lead: Menno van der Elst

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

12.12.3. List of products under additional monitoring - consultation on the draft list

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

12.14.2. Tools, educational materials and effectiveness measurement of risk minimisations

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies - imposed PASS

None

12.15.2. Post-authorisation Safety Studies - non-imposed PASS

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Others

12.20.1. Real world data (RWE) use in marketing authorisation applications and extensions of indications - EMA study preliminary results

Action: For discussion

12.20.2. Video conferencing tool - WebEx rollout plan for PRAC

Action: For discussion

13. Any other business

14. Explanatory notes

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

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures

(Items 2 and 3 of the PRAC agenda)

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

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

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

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

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

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

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

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

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

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

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

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