11 August 2023
EMA/CHMP/362824/2023 Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for written procedure* on 14-17 August 2023

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

*** Written Procedure - comments on the draft documents should be forwarded to the Product Lead (PL) as identified in the CHMP agenda.**

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 vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CHMP 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).

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Scope: Letter by the applicant dated 28 July 2023 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in March 2023.

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7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

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Rapporteur: Kristina Dunder, Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: Withdrawal of marketing authorisation

Action: For information

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Information related to GMP inspections will not be published as it undermines the purpose of such inspections.

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Information related to GCP inspections will not be published as it undermines the purpose of such inspections.

12.3. Pharmacovigilance inspections

Information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections.

12.4. GLP inspections

Information related to GLP inspections will not be published as it undermines the purpose of such inspections.

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Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information.

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Action: For adoption

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B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA via written procedure on 1 August 2023:

EMEA/H/C/PSUSA/00002253/202207 (oxybutynin) CAPS: **Kentera** (EMEA/H/C/000532) (oxybutynin), Teva B.V., Rapporteur: Karin Janssen van Doorn NAPS: **NAPs** - EU PRAC Rapporteur: Jo Robays, "17/07/2017 To: 17/07/2022"	

B.4. EPARs / WPARs

Abrysvo - respiratory syncytial virus vaccines - EMEA/H/C/006027 Pfizer Europe MA EEIG, prevention of respiratory tract disease, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
APRETUDE - cabotegravir - EMEA/H/C/005756 ViiV Healthcare B.V., pre-exposure prophylaxis of HIV-1 infection, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Degarelix Accord - degarelix acetate - EMEA/H/C/006048 Accord Healthcare S.L.U., treatment of prostate cancer, Generic, Generic of Firmagon, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Enrylaze - crisantaspase - EMEA/H/C/005917 Jazz Pharmaceuticals Ireland Limited, indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL), Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Inaqovi - decitabine / cedazuridine - EMEA/H/C/005823 Otsuka Pharmaceutical Netherlands B.V., treatment of myeloid leukaemia, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Krazati - adagrasib - EMEA/H/C/006013	For information only. Comments can be sent to

Mirati Therapeutics B.V., treatment of patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation, New active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
Litfulo - ritlecitinib - EMEA/H/C/006025 Pfizer Europe MA EEIG, Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
LYFNUA - gefapixant - EMEA/H/C/005476 Merck Sharp & Dohme B.V., treatment of refractory or unexplained chronic cough, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Orserdu - elacestrant - EMEA/H/C/005898 Stemline Therapeutics B.V., treatment of postmenopausal woman and men with breast cancer, treatment of postmenopausal women and men, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Talvey - talquetamab - EMEA/H/C/005864, Orphan Janssen-Cilag International N.V., monotherapy treatment of adult patients with relapsed and refractory multiple myeloma, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tepkinly - epcoritamab - EMEA/H/C/005985, Orphan AbbVie Deutschland GmbH & Co. KG, treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tevimbra - tislelizumab - EMEA/H/C/005919, Orphan Novartis Europharm Limited, Tevimbra as monotherapy is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Tyenne - tocilizumab - EMEA/H/C/005781	For information only. Comments can be sent to

Fresenius Kabi Deutschland GmbH, treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), Giant Cell Arteritis (GCA), treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA), chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) and COVID-19, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	the PL in case necessary.
Tyruko - natalizumab - EMEA/H/C/005752 Sandoz GmbH, Therapy for active relapsing remitting multiple sclerosis (RRMS), Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Yesafili - aflibercept - EMEA/H/C/006022 Viatris Limited, treatment of age-related macular degeneration (AMD) and visual impairment, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time as these contain commercially confidential information.

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WS2545/G
Januvia-
EMEA/H/C/000722/WS2545/0083/G
Ristaben-
EMEA/H/C/001234/WS2545/0077/G
TESAVEL-
EMEA/H/C/000910/WS2545/0083/G
Xelevia-
EMEA/H/C/000762/WS2545/0091/G
Merck Sharp & Dohme B.V., Lead Rapporteur:
Patrick Vrijlandt

B.5.9. Information on withdrawn type II variation / WS procedure

B.5.10. Information on type II variation / WS procedure with revised timetable

LUMYKRAS - sotorasib - EMEA/H/C/005522/II/0010/G Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B. Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumours With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC." Request for Supplementary Information adopted on 25.05.2023.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in May 2023.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

B.6.1. Start of procedure for New Applications: timetables for information

in vitro diagnostic medical device - EMEA/H/D/006373
detection of PD-L1 protein

B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information

Edurant - rilpivirine - EMEA/H/C/002264/X/0042/G

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Gross-Martirosyan, Extension application

Eliquis - apixaban - EMEA/H/C/002148/X/0089/G
Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Menno van der Elst, Extension application

PHEBURANE - sodium phenylbutyrate - EMEA/H/C/002500/X/0037
Eurocept International B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information

B.6.4. Annual Re-assessments: timetables for adoption

Atriance - nelarabine - EMEA/H/C/000752/S/0062
Sandoz Pharmaceuticals d.d., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Mepsevii - vestronidase alfa - EMEA/H/C/004438/S/0036, Orphan
Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed

Hemgenix - etranacogene dezaparvovec - EMEA/H/C/004827/R/0007, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0058, Orphan, ATMP
Holostem Terapie Avanzate s.r.l., Rapporteur: Egbert Flory, Co-Rapporteur: Concetta

Quintarelli, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Rhea Fitzgerald
Palynziq - pegvaliase - EMEA/H/C/004744/R/0038, Orphan BioMarin International Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rhea Fitzgerald
Pazenir - paclitaxel - EMEA/H/C/004441/R/0015 ratiopharm GmbH, Generic, Generic of Abraxane, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Menno van der Elst
Retsevmo - selpercatinib - EMEA/H/C/005375/R/0026 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Menno van der Elst
SIRTURO - bedaquiline - EMEA/H/C/002614/R/0054, Orphan Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga
Trecondi - treosulfan - EMEA/H/C/004751/R/0019, Orphan medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Fátima Ventura, PRAC Rapporteur: Julia Pallos

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

Metalyse - tenecteplase - EMEA/H/C/000306/II/0070/G Boehringer Ingelheim International GmbH, Rapporteur: Martina Weise, "grouped application consisting of: C.I.6.a (Type II): To add the new therapeutic indication Acute Ischemic Stroke (AIS) for the new 25 mg presentation. Consequently, a separate SmPC and Package Leaflet are provided for the 25 mg presentation with the new indication. In addition, the MAH took the opportunity to implement editorial changes and minor updates to the PI of Metalyse 40 mg

(8,000 U) and 50 mg (10,000 U).”
Nilemdo - bempedoic acid - EMEA/H/C/004958/II/0031 Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola, “Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk: in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated, based on results from study 1002-043 (CLEAR). CLEAR Outcomes Study is a phase 3 multi-centre randomised, double-blind, placebo-controlled study to evaluate whether long-term treatment with bempedoic acid reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease who are statin intolerant. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)”
Nustendi - bempedoic acid / ezetimibe - EMEA/H/C/004959/II/0035 Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola, “Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for NUSTENDI, based on results from Study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are

statin intolerant; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)"	
Vabysmo - faricimab - EMEA/H/C/005642/II/0005 Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Inês Ribeiro-Vaz, "Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients with central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). These are global, multicenter, randomized, double-masked, active comparator-controlled, parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI."	
WS2552 Ongentys- EMEA/H/C/002790/WS2552/0060 Ontilyv-EMEA/H/C/005782/WS2552/0015 Bial Portela & Companhia S.A., Informed Consent of Ongentys, Lead Rapporteur: Martina Weise, Lead PRAC Rapporteur: Maria del Pilar Rayon, "Extension of indication to include treatment of signs and symptoms of Parkinson's Disease for Ongentys/Ontilyv, based on final results from study BIA-91067-303; this is a pivotal Phase III, multicentre, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of opicapone in patients with early idiopathic Parkinson's	

Disease receiving treatment with L-DOPA plus a DDCI, and who are without signs of any motor complication. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.0 of the RMP has also been submitted (only applicable to Ongentys) to reflect the changes made upon approval of the informed consent application, to keep consistency between the eCTD lifecycles of the two marketing authorisations (Ongentys and Ontilyv). Furthermore, the PI is brought in line with the latest QRD template version 10.3. In addition, as part of the application the MAH is requesting a 1-year extension of the market protection. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)”	

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Afstyla - lonoctocog alfa - EMEA/H/C/004075/II/0050 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
BIMERVAX - sars-cov-2 virus, variants b.1.351-b.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0005/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich	
BIMERVAX - sars-cov-2 virus, variants b.1.351-b.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0007/G Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich	
DaTSCAN - ioflupane (123i) - EMEA/H/C/000266/II/0066/G GE Healthcare B.V., Rapporteur: Alexandre Moreau	
Ebixa - memantine / memantine hydrochloride - EMEA/H/C/000463/II/0099 H. Lundbeck A/S, Duplicate, Duplicate of Axura,	

Rapporteur: Maria Concepcion Prieto Yerro

Hemangiol - propranolol - EMEA/H/C/002621/II/0025
Pierre Fabre Medicament, Rapporteur: Jean-Michel Race

Iasibon - ibandronic acid - EMEA/H/C/002025/II/0025
Pharmathen S.A., Generic, Generic of Bondronat, Rapporteur: Thalia Marie Estrup Blicher

IVF Media G5 Series - human albumin solution - EMEA/H/D/000003/II/0008
Vitrolife Sweden AB, Rapporteur: Filip Josephson

Kaftrio - ivacaftor / tezacaftor / elexacaftor - EMEA/H/C/005269/II/0042/G, Orphan
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol

Lacosamide Accord - lacosamide - EMEA/H/C/004443/II/0023/G
Accord Healthcare S.L.U., Generic, Generic of Vimpat, Rapporteur: John Joseph Borg

MINJUVI - tafasitamab - EMEA/H/C/005436/II/0012/G, Orphan
Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia

Orencia - abatacept - EMEA/H/C/000701/II/0158/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola

Ovitrelle - choriogonadotropin alfa - EMEA/H/C/000320/II/0089
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Pemetrexed Accord - pemetrexed - EMEA/H/C/004072/II/0025
Accord Healthcare S.L.U., Generic, Generic of Alimta, Rapporteur: John Joseph Borg

Perjeta - pertuzumab - EMEA/H/C/002547/II/0068/G
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia

PreHevbri - hepatitis b surface antigen (rdna) - EMEA/H/C/005466/II/0006

VBI Vaccines B.V., Rapporteur: Jan Mueller-Berghaus

Ryeqo - relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267/II/0019/G
Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt

Ryeqo - relugolix / estradiol / norethisterone acetate - EMEA/H/C/005267/II/0020/G
Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt

Skytrofa - lonapegsomatropin - EMEA/H/C/005367/II/0019/G, Orphan
Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt

Spikevax - covid-19 mrna vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0111/G
Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus

Vaxelis - diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0131
MCM Vaccine B.V., Rapporteur: Christophe Focke

Vyepti - eptinezumab - EMEA/H/C/005287/II/0012
H. Lundbeck A/S, Rapporteur: Jan Mueller-Berghaus

Zaltrap - aflibercept - EMEA/H/C/002532/II/0069/G
Sanofi Winthrop Industrie, Rapporteur: Filip Josephson

B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

BIMERVAX - SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer - EMEA/H/C/006058/II/0006
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Submission of the final report from study HAN-01 listed as a category 3

study in the RMP (MEA/006). This is a phase IIb, randomised, controlled, observer-blinded study to evaluate safety and immunogenicity of a recombinant protein RBD fusion dimer candidate vaccine against SARS-CoV-2 in adult healthy volunteers."

Braftovi - encorafenib - EMEA/H/C/004580/II/0031

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information on effect of encorafenib in combination with binimetinib on the single oral dose PK of specific CYP isozymes substrates, and effect of multiple doses of modafinil, a moderate CYP3A4 inducer, on the multiple oral dose PK of encorafenib administered with binimetinib based on final results from arm 1 and 3 of clinical study ARRAY-818-103/C4221003 (REC). ARRAY-818-103/ C4221003 study is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours."

Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0037

Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia, "Submission of the final clinical study report addendum for study DS8201-A-U303 (DESTINY-Breast04) in order to fulfil the recommendation to submit the final OS analysis. U303 is a phase 3, multicentre, randomised, open-label, active-controlled trial of trastuzumab deruxtecan (T-DXd), an anti-HER2-antibody drug conjugate (ADC), versus treatment of physician's choice for HER2-low, unresectable and/or metastatic breast cancer subjects."

Fetcroja - cefiderocol - EMEA/H/C/004829/II/0016

Shionogi B.V., Rapporteur: Filip Josephson, "Update of section 6.2 of the SmPC in order to update the incompatibility section in line with the PRAC recommendation following the PSUR for EMEA/H/C/PSUSA/00010849/202211."

JCOVDEN - covid-19 vaccine janssen

(ad26.cov2.s) - EMEA/H/C/005737/II/0074/G Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "Grouped application comprising two type II variations (C.I.13) as follows: - Submission of the final report from study TOX15258 - Ad26.COV2.S (Prophylactic COVID-19 Vaccine): A Transcriptomics Exploratory Study in Cambodian Cynomolgus Monkey. - Submission of the report from study TV-TEC-236300 - Biophysical studies on interactions between human platelet 4 and Ad26.COV2.S."
Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0028 Bayer AG, Rapporteur: Thalia Marie Estrup Blicher, "Submission of the final report from study 19764 (PMI) listed as a category 3 study in the RMP as well as pooled data from phase 3 studies 13024 (PROTECT VIII) and 15912 (PROTECT Kids). Study 19764 is a multicenter, single group, uncontrolled, open-label interventional post-marketing investigation (PMI) to assess safety and efficacy of Jivi treatment in patients with haemophilia A."
Mektovi - binimetinib - EMEA/H/C/004579/II/0027 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of the final report from study ARRAY 818-103 on Arms 1 and 3. This is a Phase 1, 3-arm, open-label DDI study in patients with BRAF V600-mutant unresectable or metastatic melanoma or other BRAF V600-E and/or K-mutant advanced solid tumours, to assess drug interactions between encorafenib + binimetinib combination and midazolam (CYP3A4 substrate), caffeine (CYP1A2 substrate), omeprazole (CYP2C19 substrate), losartan (CYP2C9 substrate), dextromethorphan (CYP2D6 substrate) and modafinil (moderate CYP3A4 inducer)."
Mozobil - plerixafor - EMEA/H/C/001030/II/0051 Sanofi B.V., Rapporteur: Peter Mol, "Update of section 4.6 of the SmPC in order to update information regarding duration of contraception after cessation of treatment; the Package Leaflet is updated accordingly. In addition, the

MAH took the opportunity to introduce a minor update to the Labelling section."	
Ozurdex - dexamethasone - EMEA/H/C/001140/II/0045 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section4.8 of the SmPC in order to add "Central serous chorioretinopathy" to the list of adverse drug reactions (ADRs) with frequency "uncommon" based on a safety signal and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and design changes to the Package Leaflet; and to bring the PI in line with the latest QRD template version 10.3."	
Remsima - infliximab - EMEA/H/C/002576/II/0133/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising three type II variations (C.I.4) as follows: - Update of section 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information based on Week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (Crohn's disease), listed as a category 3 study in the RMP; Study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease. - Update of section 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.	

- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study). The RMP version 16.1 has also been submitted. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI."	
Scemblix - asciminib - EMEA/H/C/005605/II/0008, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to add interaction information between asciminib and OATP1B and BCRP substrates, based on results from three PBPK simulation reports: DMPK-R2001088, DMPK-R2270328 and DMPK-R2300226. The Package Leaflet is updated accordingly."	
Scemblix - asciminib - EMEA/H/C/005605/II/0009, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, "Update of section 5.3 of the SmPC in order to update preclinical safety data based on final results from study R1570226: this is a 2-year rat carcinogenicity study. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."	
Veklury - remdesivir - EMEA/H/C/005622/II/0052 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update non-clinical information based on results from the non-clinical studies PC-540-2045 and PC-540-2046. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."	
Verzenios - abemaciclib - EMEA/H/C/004302/II/0028 Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Update of section 4.4 of the SmPC in order to add a new warning on "arterial thromboembolic events", based on a safety	

review. The Package Leaflet is updated accordingly."

Zaltrap - aflibercept - EMEA/H/C/002532/II/0070
Sanofi Winthrop Industrie, Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update information regarding the duration of contraceptive use after cessation of treatment. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

WS2544
Ebymect-
EMEA/H/C/004162/WS2544/0064
Komboglyze-
EMEA/H/C/002059/WS2544/0057
Xigduo-EMEA/H/C/002672/WS2544/0074
AstraZeneca AB, Lead Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Vitamin B12 decrease/deficiency' and to change the frequency of 'Vitamin B12 decrease/deficiency' in the list of adverse drug reactions (ADRs) from frequency 'very rare' to 'common'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

B.6.10. CHMP-PRAC assessed procedures

Amyvid - florbetapir (18F) - EMEA/H/C/002422/II/0044
Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.4 of the SmPC in order to remove the limitation regarding monitoring response to therapy based on available information in the scientific literature. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to update section 4.8 to the SmPC to align the clinical trial exposures with the RMP."

Kuvan - sapropterin - EMEA/H/C/000943/II/0078
BioMarin International Limited, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from

study KOGNITO, listed as a category 3 study in the RMP. This is a Phase IV Open-Label, Single-Cohort Study of the Long-Term Neurocognitive Outcomes in 4 to 5 Year-Old Children with Phenylketonuria Treated with Sapropterin Dihydrochloride (Kuvan) for 7 Years. The RMP version 16.0 has also been submitted."

Onpattro - patisiran - EMEA/H/C/004699/II/0034, Orphan

Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from study ALN-TTR02-006 (study 006), listed a category 3 study in the RMP. This is a multicenter, open-label, extension study to evaluate the long-term safety and efficacy of patisiran in patients with familial amyloidotic polyneuropathy who have completed a prior clinical study with patisiran. The RMP version 2.2 has also been submitted."

Tegsedi - inotersen - EMEA/H/C/004782/II/0038, Orphan

Akcea Therapeutics Ireland Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Rhea Fitzgerald, "Update of sections 4.4 and 4.8 of the SmPC in order to modify the warning on liver monitoring and drug-induced liver injury and to add 'drug-induced liver injury' to the list of adverse drug reactions (ADRs) with frequency not known, following the request in the Assessment Report for PAM procedure EMEA/H/C/004782/LEG/008. The Annex II and Package Leaflet are updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI."

Vaborem - meropenem / vaborbactam - EMEA/H/C/004669/II/0020

Menarini International Operations Luxembourg S.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Maria del Pilar Rayon, "Submission of the final reports from Global Microbiology Surveillance Study and Molecular Surveillance Report, listed as a category 3 study in the RMP. The RMP version 2.0 has also been submitted."

Vemlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0043/G

Gilead Sciences Ireland UC, Rapporteur: Janet

Koenig, PRAC Rapporteur: Valentina Di Giovanni, "Grouped application consisting of:

C.I.13: Submission of the final report from study GS-US-320-0108 listed as category 3 studies in the RMP. This is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Negative, Chronic Hepatitis B. The RMP version 10.1 has also been submitted.

C.I.13: Submission of the final report from study GS-US-320-0110 listed as category 3 studies in the RMP. This is a is a Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Tenofovir Alafenamide (TAF) 25 mg QD versus Tenofovir Disoproxil Fumarate (TDF) 300 mg QD for the Treatment of HBeAg-Positive, Chronic Hepatitis B. The RMP version 10.1 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led

Caelyx pegylated liposomal - doxorubicin - EMEA/H/C/000089/II/0107

Baxter Holding B.V., PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "Submission of an updated RMP version 6.1 in order to align to GVP Module V Revision 2 requirements, following a request received within the Assessment Report for procedure EMEA/H/C/PSUSA/00001172/202111."

PRAC Led

Enhertu - trastuzumab deruxtecan - EMEA/H/C/005124/II/0036

Daiichi Sankyo Europe GmbH, PRAC Rapporteur: Inês Ribeiro-Vaz, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the final report from study 'EU survey of relevant healthcare professionals on understanding of key risk minimisations measures pertaining to ILD/pneumonitis' listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS."

PRAC Led

Intuniv - guanfacine -
EMEA/H/C/003759/II/0033/G
Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of the final reports from the Drug Utilisation Study of Intuniv (guanfacine extended release) in European countries: a prescriber survey (EUPAS18739) and a retrospective database study (EUPAS18735), listed as category 3 studies in the RMP. The RMP version 4.0 has also been submitted."

PRAC Led
Plenadren - hydrocortisone -
EMEA/H/C/002185/II/0043
Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study SHP617-400 (EU AIR) listed as a category 3 PASS in the RMP; this is a European multi-centre, multi-country, post-authorization, observation study (registry) of patients with chronic adrenal insufficiency. The RMP version 4.0 has also been submitted."

PRAC Led
Reblozyl - luspatercept -
EMEA/H/C/004444/II/0023, Orphan
Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of the final report from study ACE-536-MDS-005 listed as a category 3 study in the RMP. This is a non-interventional post-authorisation safety study (PASS) to evaluate the effectiveness of the additional risk minimization measure (aRMM) for Reblozyl among Healthcare Providers (HCPs) in the EU/EEA. The RMP version 3.0 has been submitted in order to reflect the completion of the study and to remove the HCP checklist as routine aRMM. The Annex II is updated accordingly."

PRAC Led
REKAMBYS - rilpivirine -
EMEA/H/C/005060/II/0019
Janssen-Cilag International N.V., PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-

CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 4.1 in order to update the risk characterization information for the missing information "use in pregnancy" based on interim data of the Antiretroviral Pregnancy Register (APR), listed as a category 3 study in the RMP; and to align the milestones and due dates of this study following the outcome of procedure EMEA/H/C/PSUSA/00010901/202209. In addition, the MAH took the opportunity to update the status and the interim report milestones for the studies DUS and COMBINE-2."

PRAC Led

Stelara - ustekinumab -
EMEA/H/C/000958/II/0101/G

Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Update of section 4.4 of the SmPC in order to remove a warning on cardiovascular events based on final results from non-interventional PASS studies NDI-MACE (CNTO1275PSO4005) and Quantify MACE (PCSIMM004697), listed as category 3 studies in the RMP (MEA/053 and MEA/054). NDI-MACE is a Nordic Database Initiative for Exposure to Ustekinumab: A Review and Analysis of Major Adverse Cardiovascular Events from the Swedish and Danish National Registry Systems; Quantify MACE is an Observational Longitudinal Post-authorization Safety Study of STELARA in the Treatment of Psoriasis and Psoriatic Arthritis: Analysis of Major Adverse Cardiovascular Events (MACE) using Swedish National Health Registers. The Package Leaflet is updated accordingly. The RMP version 27.1 has also been submitted."

PRAC Led

WS2517
Edistride-
EMEA/H/C/004161/WS2517/0063
Forxiga-
EMEA/H/C/002322/WS2517/0084

AstraZeneca AB, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 30 in order to remove the potential important risk for Lower Limb Amputation."

B.6.12. CHMP-CAT assessed procedures

Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0028/G, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Armando Genazzani

CARVYKTI - ciltacabtagene autoleucel - EMEA/H/C/005095/II/0023, Orphan, ATMP

Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Yescarta - axicabtagene ciloleucel - EMEA/H/C/004480/II/0063, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to include new clinical data based on Overall Survival (OS) Primary Analysis from study KTE-C19-107 (ZUMA-7); this is a phase 3, randomized, open-label study evaluating the efficacy of axicabtagene ciloleucel versus standard of care therapy in subjects with relapsed/refractory diffuse large B cell lymphoma (DLBCL) in the 2nd line setting. In addition, the MAH took the opportunity to submit a consolidated Environmental Risk Assessment (ERA) document."

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS2408
Riarify-EMEA/H/C/004836/WS2408/0027
Trydonis-EMEA/H/C/004702/WS2408/0030

Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig

WS2503/G

Afstyla- **EMEA/H/C/004075/WS2503/0051/G** **IDELVION-** **EMEA/H/C/003955/WS2503/0067/G** **Respreeza-** **EMEA/H/C/002739/WS2503/0073/G** **Voncento-** **EMEA/H/C/002493/WS2503/0060/G** CSL Behring GmbH, Lead Rapporteur: Jan Mueller-Berghaus,	
WS2532/G **Hexacima-** **EMEA/H/C/002702/WS2532/0152/G** **Hexyon-** **EMEA/H/C/002796/WS2532/0156/G** Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus	
WS2540 **Biktarvy-** **EMEA/H/C/004449/WS2540/0057** **Descovy-** **EMEA/H/C/004094/WS2540/0064** **Genvoya-** **EMEA/H/C/004042/WS2540/0088** **Odefsey-** **EMEA/H/C/004156/WS2540/0062** **Vemlidy-** **EMEA/H/C/004169/WS2540/0044** Gilead Sciences Ireland UC, Lead Rapporteur: Bruno Sepodes	
WS2555/G **Kisplyx-** **EMEA/H/C/004224/WS2555/0057/G** **Lenvima-** **EMEA/H/C/003727/WS2555/0052/G** Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn	

B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY

B.7.1. Yearly Line listing for Type I and II variations

B.7.2. Monthly Line listing for Type I variations

B.7.3. Opinion on Marketing Authorisation transfer (MMD only)

B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)

B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)

B.7.6. Notifications of Type I Variations (MMD only)

C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

G. ANNEX G

H. ANNEX H - Product Shared Mailboxes – e-mail address

Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations *(section 2)*

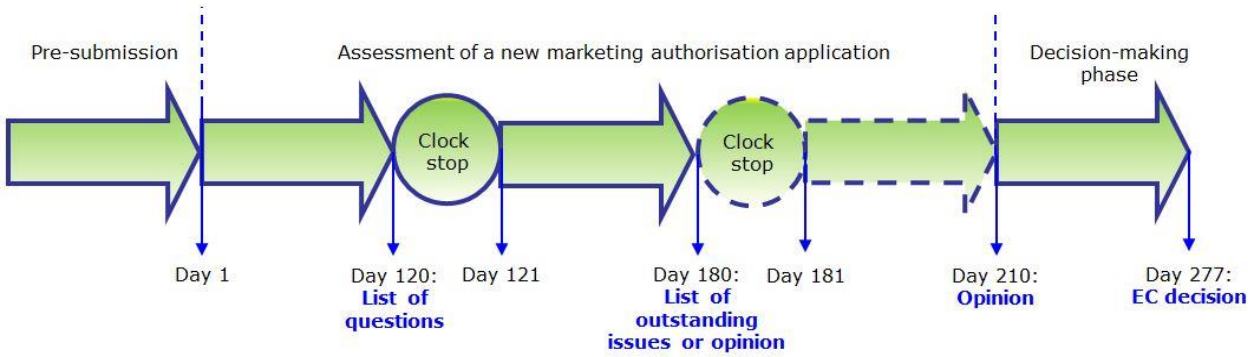
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications *(section 3)*

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 4)*

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 5)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 6)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. 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 EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

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