21 August 2020
EMA/CHMP/430123/2020 Rev.1[1]
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda of CHMP written procedure* 17-20 August 2020

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.

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).

[1] Overall update of agenda

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1. Introduction

1.1. Adoption of agenda

CHMP agenda for 17 - 20 August 2020

1.2. Adoption of the minutes

The CHMP minutes from the 20 - 23 July 2020 meeting will be adopted at the September CHMP plenary on 14–17 September 2020.

2. Oral Explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

No items

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)

No items

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)

No items

3.4. Update on on-going initial applications for Centralised procedure

3.4.1. doxorubicin - EMEA/H/C/005320

Treatment of breast cancer, ovarian cancer, progressive multiple myeloma and AIDS-related Kaposi's sarcoma.

Scope: Letter from the applicant dated 12 August 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in March 2020.

Action: For adoption

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List of Outstanding Issues adopted on 26.03.2020. List of Questions adopted on 17.10.2019.

3.4.2. ponesimod - EMEA/H/C/005163

Treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Scope: Letter from the applicant dated 6 August 2020 requesting an extension to the clock-stop to respond to the list of questions adopted in July 2020.

Action: For adoption

List of Questions adopted on 23.07.2020.

3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004

3.5.1. Elzonris - tagraxofusp - Orphan - EMEA/H/C/005031

Stemline Therapeutics B.V.; treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Scope: Re-examination notification, appointment of rapporteurs

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 23.07.2020. List of Outstanding Issues adopted on 26.03.2020, 25.06.2019. List of Questions adopted on 24.04.2019.

3.5.2. Gamifant - emapalumab - Orphan - EMEA/H/C/004386

Swedish Orphan Biovitrum AB (publ); treatment of paediatric patients with primary haemophagocytic lymphohistiocytosis (HLH).

Scope: Re-examination notification, appointment of rapporteurs

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 23.07.2020. List of Outstanding Issues adopted on 25.06.2020, 27.06.2019. List of Questions adopted on 13.12.2018.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion

No items

4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues

No items

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

No items

4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008

No items

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

No items

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

No items

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

6. Ancillary medicinal substances in medical devices

6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

No items

8.2. Priority Medicines (PRIME)

Disclosure of information related to priority medicines cannot be released at present time as these contain commercially confidential information

9. No items Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Qtrilmet – metformin hydrochloride/saxagliptin/dapagliflozin - EMEA/H/C/004910

AstraZeneca AB

Rapporteur: Kristina Dunder, Co-Rapporteur: Alar Irs

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

10.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004

No items

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

10.2.1. Presence of nitrosamine impurities in human medicinal products containing chemically synthesised active pharmaceutical ingredients EMEA/H/A-5(3)/1490

MAHs: various

Referral Rapporteur: Martina Weise, Referral Co-Rapporteurs: Kristina Dunder

Scope: Question and Answer document for stakeholders, adopted via written procedure on 3 August 2020.

Action: For information

10.3. Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004

No items

10.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

No items

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

10.6.1. Gadolinium-containing contrast agents (GdCA): gadobenic acid (NAP), gadoteridol (NAP) - EMEA/H/A-31/1097

Applicant: Bracco Imaging SpA

Lead Rapporteur: Johann Lodewijk Hillege (NL)

Scope: Annual cumulative reviews on NSF cases submission as a post-authorisation measure resulting from the 2010 Article 31 referral procedure for gadolinium-containing contrast agents

Timetable

Action: For adoption

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

10.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

10.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) of Commission Regulation (EC) No 1084/2003

No items

10.10. Procedure under Article 29 of Regulation (EC) 1901/2006

No items

10.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) of Commission Regulation No 1234/2008

No items

11. Pharmacovigilance issue

11.1. Early Notification System

No items

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

13. Innovation Task Force

No items

14. Organisational, regulatory and methodological matters

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

14.1.1. Safety Working Party (SWP)

Chair(s): Jan Willem Van der Laan/Susanne Brendler-Schwaab

SWP position on N-nitrosomethylphenylamine (NMPA) acceptable intake adopted via written procedure on 3 August 2020

Action: For information

14.1.2. Biostatistics Working Party (BSWP)

Chair(s): Kit Roes/Jörg Zinserling

CMDh questions to BSWP on Cabazaxitel

Action: For adoption

15. Any other business

15.1. AOB topic

No items

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for August 2020: **For information**

A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for August 2020: **For information**

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Information related to pre-submission of initial applications cannot be released at the present time as these contain commercially confidential information.

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal

B.2.2. Renewals of Marketing Authorisations for unlimited validity

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

B.4. EPARs / WPARs

Adakveo - crizanlizumab - EMEA/H/C/004874, Orphan Novartis Europharm Limited, treatment of sickle cell 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.
Arsenic trioxide medac - arsenic trioxide - EMEA/H/C/005218 medac Gesellschaft fur klinische Spezialpraparate	For information only. Comments can be sent to the PL in case necessary.

mbH, treatment of relapsed acute promyelocytic leukaemia (APL), Generic, Generic of TRISENOX, Generic application (Article 10(1) of Directive No 2001/83/EC)	
AYVAKYT - avapritinib - EMEA/H/C/005208, Orphan Blueprint Medicines (Netherlands) B.V., treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) harbouring the platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation, 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.
Blenrep - belantamab mafodotin - EMEA/H/C/004935, Orphan GlaxoSmithKline (Ireland) Limited, treatment of patients with relapsed or 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.
Calquence - acalabrutinib - EMEA/H/C/005299, Orphan AstraZeneca AB, treatment of adult patients with chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL), 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.
Dapivirine Vaginal Ring 25 mg - dapivirine - EMEA/H/W/002168, Article 58 International Partnership for Microbicides Belgium AISBL, Reducing the risk of HIV-1 infection via vaginal intercourse in sexually active HIV-uninfected women, 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.
Equidacent - bevacizumab - EMEA/H/C/005181 Centus Biotherapeutics Europe Limited, treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.	For information only. Comments can be sent to the PL in case necessary.

First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer. First line treatment of patients with advanced and/or metastatic renal cell cancer., Similar biological application (Article 10(4) of Directive No 2001/83/EC)	
Fampridine Accord - fampridine - EMEA/H/C/005359 Accord Healthcare S.L.U., treatment of Multiple Sclerosis, Generic, Generic of Fampyra, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Jyseleca - filgotinib - EMEA/H/C/005113 Gilead Sciences Ireland UC, treatment of adult patients with moderately to severely active rheumatoid arthritis, 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.
UPKANZ - deferiprone - EMEA/H/C/005004, Orphan Apotex B.V., treatment of neurodegeneration with brain iron accumulation, Hybrid application (Article 10(3) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the EPL in case necessary.
ZYNRELEF - bupivacaine / meloxicam - EMEA/H/C/005205 Heron Therapeutics, B.V., for application into the surgical site to reduce postoperative pain, Fixed combination application (Article 10b 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.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

B.5.3. CHMP-PRAC assessed procedures

B.5.4. PRAC assessed procedures

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

B.5.8. Unclassified procedures and worksharing procedures of type I variations

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

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

PRAC Led **Betmiga - mirabegron - EMEA/H/C/002388/II/0033** Astellas Pharma Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro "Final study report of the PASS Study 178-CL-114; an evaluation of cardiovascular events in users of mirabegron and other treatments for overactive bladder." Request for Supplementary Information adopted on 11.06.2020, 13.02.2020.	Request for an extension to the clock-stop to respond to the RSI adopted in June 2020.

PRAC Led **WS1653** **Enbrel-EMEA/H/C/000262/WS1653/0230** **LIFMIOR-EMEA/H/C/004167/WS1653/0024** Pfizer Europe MA EEIG, Lead Rapporteur: Maria Concepcion Prieto Yerro, Lead PRAC Rapporteur: Eva A. Segovia, PRAC-CHMP liaison: Maria Concepcion Prieto Yerro, "Submission of the second 5-year report from the British Society for Rheumatology Biologics Register (BSRBR, also referred as study B1801309) listed as a category 3 study in the RMP. This is a prospective observational cohort study which investigates the long-term outcomes of patients with rheumatoid arthritis treated with etanercept with particular reference to safety." Request for Supplementary Information adopted on 17.04.2020, 16.01.2020.	Request by the applicant for an extension to the clock-stop to respond to the RSI adopted in April 2020.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

autologous human chondrocytes in vitro expanded - EMEA/H/C/004598, ATMP,
repair of cartilage defects of the knee joint

bimekizumab - EMEA/H/C/005316,
treatment of plaque psoriasis

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

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

abiraterone acetate - EMEA/H/C/005408,
treatment of metastatic prostate cancer
List of Questions adopted on 30.01.2020.

bevacizumab - EMEA/H/C/005286,
treatment of metastatic carcinoma of the colon or

rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.
List of Questions adopted on 28.05.2020.

remimazolam - EMEA/H/C/005246,
indicated for procedural sedation
List of Questions adopted on 30.04.2020.

salmeterol xinafoate / fluticasone propionate - EMEA/H/C/005591,
treatment of asthma
List of Questions adopted on 27.02.2020.

ioflupane (123I) - EMEA/H/C/005135,
indicated for detecting loss of functional dopaminergic neuron terminals in the striatum
List of Questions adopted on 14.11.2019.

risperidone - EMEA/H/C/005406,
treatment of schizophrenia
List of Questions adopted on 28.05.2020.

hepatitis B surface antigen - EMEA/H/C/005063,
prevention of hepatitis B virus infection
List of Questions adopted on 25.07.2019.

Hulio - adalimumab - EMEA/H/C/004429/X/0016,
"Extension application to add a new strength of 20 mg solution for injection. The RMP (version 3.1) is updated in accordance."
List of Questions adopted on 23.07.2020.

insulin aspart - EMEA/H/C/004965,
treatment of diabetes mellitus
List of Questions adopted on 27.02.2020.

autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing

anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - EMEA/H/C/005102, Orphan, ATMP
Kite Pharma EU B.V., treatment of adult patients with relapsed or refractory Mantle cell lymphoma (MCL). Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). Treatment of mantle cell lymphoma (MCL)
List of Questions adopted on 20.05.2020.

lenalidomide - EMEA/H/C/005348,
treatment of multiple myeloma,
List of Questions adopted on 28.05.2020.

autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene - EMEA/H/C/005321, Orphan, ATMP
Orchard Therapeutics (Netherlands) BV, treatment of metachromatic leukodystrophy (MLD)
List of Questions adopted on 20.03.2020.

moxetumomab pasudotox - EMEA/H/C/005322, Orphan
AstraZeneca AB, relapsed or refractory hairy cell leukaemia (HCL) after receiving at least two prior systemic therapies
List of Questions adopted on 30.04.2020.

Nuceiva - botulinum toxin type A - EMEA/H/C/004587/X/0005
Evolus Pharma Limited, "Extension application to add a new strength of 50 U for botulinum toxin type A for powder for solution for injection in vial (glass), for intramuscular administration."
List of Questions adopted on 28.05.2020.

ofatumumab - EMEA/H/C/005410,
treatment of relapsing forms of multiple sclerosis
List of Questions adopted on 28.05.2020.

lumasiran - EMEA/H/C/005040, Orphan
Alnylam Netherlands B.V., primary hyperoxaluria

type 1 (PH1)
List of Questions adopted on 21.07.2020.

bevacizumab - EMEA/H/C/005556,
treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer.
First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer.
First line treatment of patients with advanced and/or metastatic renal cell cancer.,
List of Questions adopted on 28.05.2020.

pertuzumab / trastuzumab - EMEA/H/C/005386,
treatment of early breast cancer, metastatic breast cancer
List of Questions adopted on 28.05.2020.

valoctocogene roxaparvovec - EMEA/H/C/004749, Orphan, ATMP
BioMarin International Limited, treatment of haemophilia A
List of Questions adopted on 24.04.2020.

fostemsavir - EMEA/H/C/005011,
indicated, in combination with other antiretrovirals, for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen due to resistance, intolerance or safety considerations.
List of Questions adopted on 28.04.2020.

salmeterol xinafoate / fluticasone propionate - EMEA/H/C/004881,
treatment of asthma
List of Questions adopted on 27.02.2020.

selpercatinib - EMEA/H/C/005375,
treatment of adults with: advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy; advanced RET fusion-positive thyroid cancer who require systemic

therapy and who have progressed following prior treatment. As monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
List of Questions adopted on 28.05.2020.

potassium - EMEA/H/C/005407, Orphan
Advicenne S.A., treatment of distal renal tubular acidosis (dRTA) in patients aged 6 months and older.
List of Questions adopted on 26.03.2020.

sunitinib - EMEA/H/C/005419,
treatment of gastrointestinal stromal tumour (GIST) and metastatic renal cell carcinoma (MRCC) and pancreatic neuroendocrine tumours (pNET),
List of Questions adopted on 27.02.2020.

Tivicay - dolutegravir - EMEA/H/C/002753/X/0058/G
ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Extension application to add a new pharmaceutical form associated with new strength (5mg dispersible tablet). The new presentation is indicated for the treatment of HIV infected children from 4 weeks of life and weighing at least 3 kilograms.
Type II variation (C.I.4) to update the currently approved Product Information, Labelling and Package Leaflet for the existing film -coated tablets (10mg, 25mg and 50mg) for children 6 years and older and weighing at least 15 kg. The application comprises PK, safety, and efficacy data from the Phase I/II study (P1093) and PK and safety data from relevant sub-studies nested within the Phase II/III Study ODYSSEY (PENTA 20).
In addition, the applicant took the opportunity to amend section 4.1 of SmPc, the indication for the approved Tivicay film-coated tablets to clarify

that children should be "aged at least 6 years" as the current approved indication is inclusive of those aged 6 years.
The RMP (version 16) is updated in accordance."
List of Questions adopted on 28.05.2020.

tucatinib - EMEA/H/C/005263,
treatment of metastatic breast cancer or brain metastases
List of Questions adopted on 28.05.2020.

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

Atriance - nelarabine - EMEA/H/C/000752/S/0051
Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Hans Christian Siersted,

IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/S/0054
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Brigitte Keller-Stanislawski

Mepsevii - vestronidase alfa - EMEA/H/C/004438/S/0017, Orphan
Ultragenyx Germany GmbH, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Eva A. Segovia

Naglazyme - galsulfase - EMEA/H/C/000640/S/0083
BioMarin International Limited, Rapporteur: Fátima Ventura, PRAC Rapporteur: Ana Sofia Diniz Martins

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

Caprelsa - vandetanib - EMEA/H/C/002315/R/0046
Genzyme Europe BV, Rapporteur: Alexandre Moreau, Co-Rapporteur: Paula Boudewina van

Hennik, PRAC Rapporteur: Tiphaine Vaillant

Eliquis - apixaban - EMEA/H/C/002148/R/0077

Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Menno van der Elst

Flixabi - infliximab - EMEA/H/C/004020/R/0064

Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Ulla Wändel Liminga

Galafold - migalastat - EMEA/H/C/004059/R/0027, Orphan

Amicus Therapeutics Europe Limited, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Ulla Wändel Liminga

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/R/0032, Orphan, ATMP

Chiesi Farmaceutici S.p.A., Rapporteur: Egbert Flory, Co-Rapporteur: Paolo Gasparini, CHMP Coordinators: Jan Mueller-Berghaus and Daniela Melchiorri, PRAC Rapporteur: Rhea Fitzgerald

IDELVION - albutrepenonacog alfa - EMEA/H/C/003955/R/0047, Orphan

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Menno van der Elst

Odefsey - emtricitabine / rilpivirine / tenofovir alafenamide - EMEA/H/C/004156/R/0049

Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Ana Sofia Diniz Martins

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

Lonquex - lipegfilgrastim - EMEA/H/C/002556/II/0058/G

Teva B.V., Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kirsti Villikka

"Extension of indication to include treatment of the paediatric population for Lonquex and introduction of an age appropriate presentation in vials; as a consequence, sections 4.1, 4.2, 4.8, Committee for medicinal products for human use (CHMP) EMA/CHMP/430123/2020 Page 22/48 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 12.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.1."

Nulojix - belatacept - EMEA/H/C/002098/II/0070

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Ulla Wändel Liminga, "Extension of indication to include the use of belatacept in conversion from a calcinerin inhibitor -based regimen to a belatacept-based regimen post transplantation; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 18.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1 and requirement on sodium excipients is added."

WS1840
OPDIVO-EMEA/H/C/003985/WS1840/0089
Yervoy-EMEA/H/C/002213/WS1840/0084

Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Blanca Garcia-Ochoa, Lead PRAC Rapporteur: Brigitte Keller-Stanislawski, "Extension of indication to include treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability_high (MSI-H) metastatic colorectal cancer (CRC) for combination treatment with Opdivo and Yervoy; as a consequence, sections 4.1, 4.2 ,4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version18.0 for Opdivo and version 29.0 for Yervoy of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Bexsero - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/002333/II/0094
GSK Vaccines S.r.l, Rapporteur: Kristina Dunder,

Desloratadine ratiopharm - desloratadine - EMEA/H/C/002404/II/0025/G
ratiopharm GmbH, Rapporteur: Koenraad Norga

Entyvio - vedolizumab - EMEA/H/C/002782/II/0053
Takeda Pharma A/S, Rapporteur: Daniela Melchiorri

Evenity - romosozumab - EMEA/H/C/004465/II/0005
UCB Pharma S.A., Rapporteur: Kristina Dunder

Flixabi - infliximab - EMEA/H/C/004020/II/0062
Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus

Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0004/G
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Flucelvax Tetra - influenza vaccine surface antigen inactivated prepared in cell cultures - EMEA/H/C/004814/II/0017
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Herzuma - trastuzumab - EMEA/H/C/002575/II/0032/G
Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus

Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0119/G
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

IMVANEX - smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0055
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

Jivi - damoctocog alfa pegol - EMEA/H/C/004054/II/0014
Bayer AG, Rapporteur: Kirstine Moll Harboe

Kovaltry - octocog alfa - EMEA/H/C/003825/II/0031
Bayer AG, Rapporteur: Kristina Dunder

Lucentis - ranibizumab - EMEA/H/C/000715/II/0088
Novartis Europharm Limited, Rapporteur: Kristina Dunder

Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0047
GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus

NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0050/G, Orphan
MediWound Germany GmbH, Rapporteur: Janet Koenig

Nulojix - belatacept -

EMEA/H/C/002098/II/0069
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson

Nulojix - belatacept - EMEA/H/C/002098/II/0071
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson

Pemetrexed Hospira - pemetrexed - EMEA/H/C/003970/II/0024
Pfizer Europe MA EEIG, Generic, Generic of Alimta, Rapporteur: Alar Irs

Praluent - alirocumab - EMEA/H/C/003882/II/0058/G
sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege

Reblozyl - luspatercept - EMEA/H/C/004444/II/0001/G, Orphan
Celgene Europe BV, Rapporteur: Milena Stain

Rilutek - riluzole - EMEA/H/C/000109/II/0065
Sanofi Mature IP, Rapporteur: Kirstine Moll Harboe

Rixubis - nonacog gamma - EMEA/H/C/003771/II/0035/G
Baxalta Innovations GmbH, Rapporteur: Andrea Laslop

Ruconest - conestat alfa - EMEA/H/C/001223/II/0056
Pharming Group N.V, Rapporteur: Andrea Laslop

Sancuso - granisetron - EMEA/H/C/002296/II/0058
Kyowa Kirin Holdings B.V., Rapporteur: Simona Stankeviciute

Simulect - basiliximab - EMEA/H/C/000207/II/0107
Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus

Verzenios - abemaciclib -
EMEA/H/C/004302/II/0012/G
Eli Lilly Nederland B.V., Rapporteur: Filip Josephson

VITRAKVI - larotrectinib -
EMEA/H/C/004919/II/0010/G
Bayer AG, Rapporteur: Filip Josephson

Xenical - orlistat -
EMEA/H/C/000154/II/0083
CHEPLAPHARM Arzneimittel GmbH, Rapporteur: Jean-Michel Race

Yervoy - ipilimumab -
EMEA/H/C/002213/II/0083/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik

Zavicefta - ceftazidime / avibactam -
EMEA/H/C/004027/II/0023/G
Pfizer Ireland Pharmaceuticals, Rapporteur: Bjorg Bolstad

WS1863/G
Incruse Ellipta-EMEA/H/C/002809/
WS1863/0030/G
Rolufta Ellipta-EMEA/H/C/004654/
WS1863/0015/G
GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro

WS1904/G
Hexacima-
EMEA/H/C/002702/WS1904/0105/G
Hexaxim-
EMEA/H/W/002495/WS1904/0110/G
Hexyon-
EMEA/H/C/002796/WS1904/0109/G
Sanofi Pasteur Europe, Lead Rapporteur: Jan Mueller-Berghaus

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

AUBAGIO - teriflunomide -
EMEA/H/C/002514/II/0032

sanofi-aventis groupe, Rapporteur: Martina Weise, "C.I.4. Update of section 4.4 of the SmPC in order to update information on the liver monitoring schedule and the use of concomitant potentially hepatotoxic drugs based on evidence from diverse clinical and postmarketing sources including results from three studies, namely TENERE/EFC10891 (Phase 3 multi-center, randomized, double-blind, open-label (for IFN β - 1a), parallel-group study), Teri-PRO/LPS13567 study (Phase 4, multicenter, prospective, single-arm, open-label study) and TERIKIDS/EFC11759 (Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with 10 to 17 years of age) together with postmarketing data including real-world data from two European National Disease registries (The Danish Multiple Sclerosis Registry and Belgian Treatment in Multiple Sclerosis, or BELTRIMS registry) and one US-based database of electronic health records (Optum Humedica Database) and postmarketing experience included in the Sanofi Global pharmacovigilance database."

Cresemba - isavuconazole - EMEA/H/C/002734/II/0031, Orphan

Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.2 of SmPC to clarify the instructions on the start of therapy, according to current treatment guidelines for aspergillus and mucor diseases. Additionally, correction of an oversight is carried out in SmPC section 4.8 and PL section 4 of Cresemba 100mg capsules, to reinstate "odema peripheral" as "uncommon" adverse event, which was unintentionally omitted from the PI at the time of the initial MAA. Re-instatement of text about the potential interaction between isavuconazole and protease inhibitors other than indinavir and lopinavir/ritonavir, wrongly deleted from the interactions table in SmPC section 4.5 and PL

section 2 as part of a previous procedure, is also carried out."

Enbrel - etanercept - EMEA/H/C/000262/II/0234

Pfizer Europe MA EEIG, Rapporteur: Maria Concepcion Prieto Yerro, "Update of section 5.1 of the SmPC in order to update the efficacy and safety information based on the final results from study (B1801381); this is a multicenter open-label study which evaluated withdrawal and retreatment of etanercept in subjects with non-radiographic axial spondyloarthritis who achieved an adequate response following 24 weeks of treatment. In addition, the MAH took the opportunity to make some editorial changes and bring the PI in line with the latest QRD template version 10.1."

Ervebo - recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMEA/H/C/004554/II/0007/G

Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke, "C.I.4: To update section 5.1 of the SmPC with the description and final results from study V920-018; this is a phase 3 open-label trial conducted in Guinea to evaluate the safety and immunogenicity of Ervebo in vaccinated frontline workers 18 years of age and older that was implemented as Part B of the Phase 3 ring vaccination study V920-010. With this submission, REC 20 is fulfilled.

C.I.4: To update section 5.1 of the SmPC based on the result of the final study reports on the Correlate of Protection. With this submission, REC 16 is fulfilled.

C.I.4: To update section 5.1 of the SmPC, based on results from the integrated summary of immunogenicity (ISI). With this submission, RECs 15 and 22 are fulfilled.

C.I.13 - Submission of Non-Human Primates

(NHP) Correlate of Protection analysis report (non-clinical report). Analysis is based upon previous submitted NHP studies which are already part of the dossier.

The MAH takes the opportunity to implement changes in the Package Leaflet following the assessment of the User Acceptance Test, procedure EMEA/H/C/004554/REC/011. With the implementation of these changes to the PL, the MAH fulfils REC011). In addition, a minor editorial change has been included in section 4.4 of the SmPC and section 2 of the patient leaflet."

Eylea - aflibercept - EMEA/H/C/002392/II/0064

Bayer AG, Rapporteur: Alexandre Moreau, "C.1.4 to update section 5.1 of the SmPC based on the ALTAIR Study with additional long-term efficacy information on patients with wet AMD."

Eylea - aflibercept - EMEA/H/C/002392/II/0065

Bayer AG, Rapporteur: Alexandre Moreau, "C.I.4, Update of section 4.2 to modify the posology in wet AMD and of 5.1 to reflect the underlying data."

Fluad Tetra - influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0003

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, "Update of section 5.1 of the SmPC in order to introduce effectiveness information of Fluad (trivalent formulation) in the product information of Fluad Tetra based on the results from three retrospective observational studies "CORE 17-18 and 18-19", "HEOR 17-18" and "HEOR 18-19") and a randomised clinical trial "LTCF 16-17"."

Jevtana - cabazitaxel - EMEA/H/C/002018/II/0043/G

sanofi-aventis groupe, Rapporteur: Alexandre Moreau, "Update of sections 4.8 and 5.1 of the

SmPC with new clinical data from CARD study - a randomized, multicenter, Phase 4 study comparing cabazitaxel at 25 mg/m2 every 3 weeks in combination with prednisone versus alternate AR-targeted agent (abiraterone or enzalutamide) for the treatment of mCRPC patients previously treated with docetaxel and who failed a prior AR-targeted agent. Section 4.4 of the SmPC is also updated in accordance with the updated annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) regarding ethanol used as an excipient. The Package Leaflet is updated accordingly."	
Lyumjev - insulin lispro - EMEA/H/C/005037/II/0005 Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-Ikola, "Update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study I8B-MC-ITSA (submitted in accordance with Article 46 of regulation (EC) No 1901/2006). This study was conducted to evaluate the pharmacokinetics and glucodynamics of Lyumjev compared to Humalog in children, adolescents, and adults with Type 1 Diabetes Mellitus."	
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0049, Orphan MediWound Germany GmbH, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC based on interim results from study MW2010-03-02 (DETECT) listed as an obligation in the Annex II; this is a multicenter, multinational, randomized, controlled, assessor blinded, three-arm study performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to Gel Vehicle and compared to	

Standard of Care. The submitted Clinical Study Report includes data of Acute Phase and 12M Follow Up Period. The MAH also took the opportunity to submit integrated pooled analyses of efficacy and safety data obtained from phase 2 and phase 3 clinical studies to provide a comprehensive assessment of the safety and efficacy of NexoBrid. The Package Leaflet is updated accordingly."

NovoEight - turoctocog alfa - EMEA/H/C/002719/II/0035

Novo Nordisk A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 5.1 of the SmPC to include the results of the completed study PASS Guardian 5 NN70083553. The RMP has been updated accordingly."

Prolia - denosumab - EMEA/H/C/001120/II/0085/G

Amgen Europe B.V., Rapporteur: Kristina Dunder, "Updates to SmPC section 4.8 adding the adverse reactions "hypersensitivity vasculitis" with a frequency category of very rare and "drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome" with a frequency category of not known, and section 4.4 to introduce QRD traceability statement. The package leaflet has been updated accordingly."

Ranexa - ranolazine - EMEA/H/C/000805/II/0063

Menarini International Operations Luxembourg S.A., Rapporteur: Kristina Dunder, "C.I.4 Update of sections 4.8 of the SmPC in order to add "myoclonus" to the list of adverse drug reactions (ADRs) with frequency "rare" based on post-marketing data and update to section 4.9 based on review of the data regarding events of overdose. The Package Leaflet was updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring

the PI in line with the latest QRD template version 10.1, to correct linguistic mistakes in the SmPC and in some national translations of the Product Information."

Rekovelle - follitropin delta - EMEA/H/C/003994/II/0023

Ferring Pharmaceuticals A/S, Rapporteur: Jean-Michel Race, "Update of section 5.1 of the SmPC in order to add information on dose equivalence factor to follitropin alfa based on clinical data from literature. The MAH took the opportunity to amend section 4.4. of the SmPC with traceability information and to bring the PI in line with the latest QRD template version 10.1."

Shingrix - herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0036

GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "Submission of the final report from study Zoster-056, in order to fulfil the post-authorisation measure MEA/FSR 006. This is a cross-vaccination study in subjects who previously received placebo in studies Zoster-006 and Zoster-022."

Strensiq - asfotase alfa - EMEA/H/C/003794/II/0047, Orphan

Alexion Europe SAS, Rapporteur: Daniela Melchiorri, "Update of section 5.1. of the SmPC in order to to remove the Paediatric Investigation Plan (PIP) compliance statement as per Article 28(3) of Regulation (EC) No 1901/2006 and to request the 2-year extension of the market exclusivity of Strensiq as per Article 37 of Regulation (EC) No 1901/2006, following submission of the results and reports of all the PIP measures, including results of the Extrapolation Study AXN100107PIP ("Extrapolation of Efficacy to Asfotase Alfa Treatment in Paediatric Patients Ages 6 months to <3 years with Juvenile-Onset Hypophosphatasia")"

Taltz - ixekizumab -
EMEA/H/C/003943/II/0038/G

Eli Lilly Nederland B.V., Rapporteur: Kristina Dunder, "Clinical studies in adult plaque psoriasis:
Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long term data in the treatment of psoriasis: RHAZ, RHBA, RHBC (3 studies of the "UNCOVER" series) were the pivotal registration studies, with response data up to 60 weeks already included in the SmPC. The current update relates to the extension data available, covering a total of 5 years.
Section 5.1 of the SmPC has also been updated with information from study RHCR (known as "IXORA-R") which is a 24-week head-to-head comparison of Taltz vs guselkumab.

Clinical studies in adult psoriatic arthritis:
Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long term data in the treatment of psoriatic arthritis: RHAP and RHBE (also known as SPIRIT-P1 and P2) were pivotal registration studies, with response data at 24 weeks and up to 52 weeks (SPIRIT-P1) already included in the SmPC. The current update relates to extension data available covering a total of 3 years. Section 5.1 of the SmPC has also been updated with longer-term data from study RHCF ("SPIRIT-H2H" Taltz vs adalimumab). Response data of up to 24 weeks are already in the SmPC and the addition of 52 week data are being proposed."

Tivicay - dolutegravir -
EMEA/H/C/002753/II/0064

ViiV Healthcare B.V., Rapporteur: Filip Josephson, "Update of section 5.1 in order to add long-term efficacy and safety data, following the week 96 results from studies 204861 (GEMINI-1) and 205543 (GEMINI-2), listed as specific category 3 studies in the RMP. These are two identical pivotal ongoing, randomized, double-blind, parallel group, 148-week, phase III studies

to evaluate the efficacy, safety and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment naïve patients. In addition, the MAH took the opportunity to introduce minor editorial changes throughout the Product Information."

Votrient - pazopanib - EMEA/H/C/001141/II/0059

Novartis Europharm Limited, Rapporteur: Sinan B. Sarac, "To update sections 4.2, 4.8 and 5.1 of the SmPC to update the safety information based on results from studies 2012-001306-20 (ADVL0815 / PZP114411) and study 2013-003595-12 (ADVL1322 / VEG116731 / PZP034X2203) listed in the agreed PIP; these are a phase 1 clinical trial of single-agent pazopanib in children with a relapsed or refractory solid (including CNS) tumour, and a therapeutic-exploratory (phase 2) clinical trials of single-agent pazopanib in children (including adolescents) and young adults with a refractory tumour (in the latter no relevant anti-tumour activity was found)."

VPRIV - velaglucerase alfa - EMEA/H/C/001249/II/0048, Orphan

Shire Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC to include information on 1 additional patient with IgG anti-velaglucerase antibodies with neutralizing activity reported during extension Study HGT-GCB-044, and to include vomiting as an infusion-related reaction that has been reported in post-marketing experience. Further, the MAH is updating the instructions in sections 4.2 and 6.6 of the SmPC to state that a 0.2 µm filter and a 0.22 µm filter are both considered acceptable when administering the product. In addition, the MAH took the opportunity to implement some minor editorial changes in SmPC section 5.1 and a clarification that paediatric patients included in

the studies were 4 years of age and older. The Package Leaflet is updated accordingly.”	
WS1886/G **Aprovel-** **EMEA/H/C/000141/WS1886/0181/G** **CoAprovel-** **EMEA/H/C/000222/WS1886/0199/G** **Karvea-** **EMEA/H/C/000142/WS1886/0183/G** **Karvezide-** **EMEA/H/C/000221/WS1886/0199/G** sanofi-aventis groupe, Lead Rapporteur: Maria Concepcion Prieto Yerro, “Group of variations consisting of: C.I.4 - Update of section 4.4 and 4.8 of the SmPC to add information on hypoglycemia based on a review of available data including the MAH pharmacovigilance data base and a literature review. The Package leaflet is updated accordingly. C.I.4 - Update of 4.4 and 4.5 of the SmPC to add information on a drug -drug interaction with irbesartan and repaglinide based on a review of the available data including the MAH database and a literature review. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to implement the updated annex to the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use' to update the excipient sodium.”	
WS1898 **Efficib-EMEA/H/C/000896/WS1898/0095** **Janumet-** **EMEA/H/C/000861/WS1898/0095** **Ristfor-EMEA/H/C/001235/WS1898/0082** **Velmetia-** **EMEA/H/C/000862/WS1898/0098** Merck Sharp & Dohme B.V., Lead Rapporteur: Johann Lodewijk Hillege, “Update of the SmPC sections 4.2, 4.8, 5.1 and 5.2, to include data from the pooled analysis of paediatric studies P170 (sitagliptin/metformin) and P289	

(sitagliptin/metformin extended release). The package leaflet is revised accordingly, and update of the product information is performed to comply with QRD Version 10.1."

B.6.10. CHMP-PRAC assessed procedures

Erleada - apalutamide - EMEA/H/C/004452/II/0008

Janssen-Cilag International N.V., Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Tiphaine Vaillant, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study ARN-509-003 (SPARTAN) listed as a PAES in Annex II; this is a multicenter, randomised, double-blind, placebo-controlled, phase III study of ARN-509 in men with non-metastatic (M0) castration-resistant prostate cancer; the package leaflet and Annex II are updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package leaflet."

Ocrevus - ocrelizumab - EMEA/H/C/004043/II/0020

Roche Registration GmbH, Rapporteur: Kirstine Moll Harboe, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Submission of the final report for study 17-1133 listed as a Category 3 study in the RMP (MEA 006). This is a study to assess the effects of ocrelizumab on embryo-fetal and pre- and postnatal development in cynomolgus monkeys. The RMP ver. 5.0 has also been submitted."

OFEV - nintedanib - EMEA/H/C/003821/II/0038

Boehringer Ingelheim International GmbH, Rapporteur: Peter Kiely, PRAC Rapporteur: Nikica Mirošević Skvrce, "Update of sections 4.5, 4.6 and 5.2 of the SmPC in order to add drug-drug

interaction information with the oral contraceptive Microgynon, a combination of ethinylestradiol and levonorgestrel based on final) based on final results from clinical study №1199-0340. This was a phase I, open-label, 2-period cross-over, fixed-sequence design trial, investigated the effect of multiple oral doses of nintedanib on the single dose kinetics of a combination of ethinylestradiol and levonorgestrel (Microgynon). The Package Leaflet is updated accordingly. The RMP version 10 has also been submitted."

Oncaspar - pegaspargase - EMEA/H/C/003789/II/0036/G

Les Laboratoires Servier, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Annika Folin, "Group of 2 Type II variations to submit the study results of Study 12-266 A(12) an open label single arm phase II trial evaluating the efficacy and toxicity of treatment regimens including Oncaspar in adults (aged 18-60) with newly diagnosed Philadelphia chromosome-negative acute lymphoblastic leukaemia and Study CAALL-F01 a prospective multicentre cohort study evaluating Oncaspar used in the first-line treatment of children and adolescents with ALL along with multi-agent chemotherapy. Consequently Annex II is proposed to be updated to remove both PAES. Additionally, update of the product information to remove the need for additional monitoring and to implement editorial changes. The RMP (version 4.1) is updated accordingly."

Stelara - ustekinumab - EMEA/H/C/000958/II/0081/G

Janssen-Cilag International NV, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Update of section 4.2 of Stelara SmPC solution for injection presentations in order to change posology recommendations for patients with ulcerative colitis, and 5.1 of Stelara SmPC to update efficacy information based on 2-year results from study 3001 listed

as a category 3 study in the RMP; this is a Phase 3, randomized, double blind, placebo controlled, parallel-group, multicenter protocol to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis. Update of section 5.1 of the SmPC in order to update efficacy information based on 5-year results from study 3003 listed as a category 3 study in the RMP; this is a Phase 3, randomized, double blind, placebo controlled, parallel-group, multicenter trial to evaluate the safety and efficacy of ustekinumab maintenance therapy in adult patients with moderately to severely active Crohn's disease. The RMP version 18.1 has also been submitted."	
Tevagrastim - filgrastim - EMEA/H/C/000827/II/0077 TEVA GmbH, Duplicate, Duplicate of Biograstim (SRD), Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Submission of a variation to update the RMP to remove the additional pharmacovigilance activity "Cooperation with SCNIR (Severe Chronic Neutropenia International Registry) and analysis of corresponding Ratiograstim/Tevagrastim-SCNIR data"	
Vizimpro - dacomitinib - EMEA/H/C/004779/II/0003/G Pfizer Europe MA EEIG, Rapporteur: Blanca Garcia-Ochoa, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2 and 5.2 of the SmPC in order to revise the dosing recommendation for patients with hepatic impairment and include relevant pharmacokinetics data based on results of Study A7471058, evaluating the effect of severe hepatic impairment on the plasma PK, safety and tolerability after a single dose of dacomitinib. As a consequence, the MAH is proposing to remove the missing information "Safety in Patient with Severe Hepatic	

Impairment" from the list of safety concerns in the RMP. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1.

The MAH has also taken the opportunity to update the EU RMP to include PASS Study A7471064 "Single Arm Study to Evaluate the Safety of Dacomitinib for the First-Line Treatment of Participants in India with Metastatic NSCLC with Epidermal Growth Factor Receptor (EGFR)-Activating Mutations" as a "Category 3 required additional pharmacovigilance activity". A revised RMP v1.1 (clean and tracked) has been submitted."

B.6.11. PRAC assessed procedures

PRAC Led

Aclasta - zoledronic acid - EMEA/H/C/000595/II/0076

Novartis Europharm Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Provision of an updated RMP version 13.0.

Proposed changes:

1. Alignment with requirements of GVP Module V Rev.2 with consequential removal/reclassification of a number of important potential risks;
2. Consequential removal of education material for renal risk (renal dysfunction and use in patients with severe renal impairment);
3. Removal of 'post-dose symptoms' from the list of important identified risks (following the assessment of LEG 037 & variation II/74/G);
4. Update of the targeted questionnaire related to the ONJ risk (following the assessment of LEG 035);
5. Inclusion of the completed 5-year registry study ZOL446H2422 (following the assessment of variation II-69 & MEA 017.1).

The additional risk minimisation measures in the Annex II of the product information are proposed

to be updated accordingly."

PRAC Led

Circadin - melatonin -

EMEA/H/C/000695/II/0061

RAD Neurim Pharmaceuticals EEC SARL, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Risk Management Plan update to remove the following risks from the list of potential risks: "Drug interaction with levothyroxine" "Panic Attacks", "Potential interaction with warfarin", "Sperm motility decreased/Spermatozoa morphology abnormal" and "Withdrawal"."

PRAC Led

EMEND - aprepitant -

EMEA/H/C/000527/II/0063

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Filip Josephson, "update of the RMP to version 5.1 to remove all the safety concerns (important identified risks, important potential risks and missing information) and information
related to both 40 mg and 165 mg capsules strengths and the Postoperative Nausea and Vomiting indication (PONV), as well as to update data in the post-authorisation exposure (Part II: Module SV) and epidemiology
(Part II: Module SI) sections."

PRAC Led

Ivemend - fosaprepitant -

EMEA/H/C/000743/II/0043

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Annika Folin, PRAC-CHMP liaison: Filip Josephson, "update of the RMP for IVEMEND to version 5.1 to remove all the safety concerns (important identified risks, important potential risks and missing information), as well as to
update data in the post-authorisation exposure (Part II: Module SV) and epidemiology (Part II:

Module SI) sections.”

PRAC Led

Keppra - levetiracetam - EMEA/H/C/000277/II/0189

UCB Pharma S.A., Rapporteur: Koenraad Norga, PRAC Rapporteur: Laurence de Fays, PRAC-CHMP liaison: Karin Janssen van Doorn, “Submission of the final report of the PASS EUPAS26595 'Comparing the incidence of acute renal failure in patients with epilepsy exposed to levetiracetam versus other antiepileptics drugs'.”

PRAC Led

Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0044/G

Orexigen Therapeutics Ireland Limited, Rapporteur: Kirstine Moll Harboe, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, “Update of product information resulting from PRAC Assessment Report request in PSUSA/00010366/201909:
- Introduction of a warning concerning the interaction between Naltrexone/Bupropion and Digoxin in SmPC section 4.5 and related PL section.
- Update of SmPC section 4.8 and related PL section on drug-induced lupus erythematosus with Naltrexone/Bupropion and its individual substances.”

PRAC Led

Ratiograstim - filgrastim - EMEA/H/C/000825/II/0069

ratiopharm GmbH, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, “Submission of an updated RMP version 10.0 in order to remove the additional pharmacovigilance activity “Cooperation with SCNIR (Severe Chronic Neutropenia International Registry) and analysis of corresponding Ratiograstim/Tevagrastim-

SCNIR data."

PRAC Led

Tecentriq - atezolizumab -

EMEA/H/C/004143/II/0048

Roche Registration GmbH, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Marcia Sofia Sanches de Castro Lopes Silva, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the results of study WO41486 evaluating the effectiveness of the HCP brochure designed to mitigate important immune-related risks in patients receiving atezolizumab in the European Union. As a consequence, the MAH is updating section 4.4 of the SmPC, Annex II.D and the RMP. In addition the MAH is proposing a delay in the due date for the submission of the CSR for IMvigor210 to 31 August 2021."

PRAC Led

Xarelto - rivaroxaban -

EMEA/H/C/000944/II/0080

Bayer AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from a Survey on Prescribers' Guide/Patient Alert listed as a category 3 study in the RMP."

PRAC Led

WS1897

Mirapexin-

EMEA/H/C/000134/WS1897/0096

Sifrol-EMEA/H/C/000133/WS1897/0087

Boehringer Ingelheim International GmbH, Lead Rapporteur: Kirstine Moll Harboe, Lead PRAC Rapporteur: Anette Kirstine Stark, PRAC-CHMP liaison: Kirstine Moll Harboe, "RMP update to implement changes requested by PRAC in the context of the PSUSA procedure (EMEA/H/C/PSUSA/00002491/201904) of the PBRER with a DLP on 06 Apr 2019:
· to remove 'Cardiac failure' from the list of important identified risks;

· to amend the information with regard to the important identified risk 'Dopamine agonist withdrawal syndrome' (DAWS)."

PRAC Led
WS1919
Lyrica-EMEA/H/C/000546/WS1919/0109
Pregabalin Pfizer-
EMEA/H/C/003880/WS1919/0038
Upjohn EESV, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Liana Gross-Martirosyan, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Update to the Risk Management Plan to include results of recently completed PASS studies."

B.6.12. CHMP-CAT assessed procedures

Kymriah - tisagenlecleucel -
EMEA/H/C/004090/II/0026/G, Orphan,
ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Kymriah - tisagenlecleucel -
EMEA/H/C/004090/II/0027, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Zolgensma - onasemnogene abeparvovec -
EMEA/H/C/004750/II/0006, Orphan, ATMP
AveXis EU Limited, Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinator: Johann Lodewijk Hillege

B.6.13. CHMP-PRAC-CAT assessed procedures

Yescarta - axicabtagene ciloleucel -
EMEA/H/C/004480/II/0028, Orphan, ATMP
Kite Pharma EU B.V., Rapporteur: Jan Mueller-BerghausCHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark, "To update SmPC sections; 4.4 on CRS grading and neurologic adverse reactions; 4.8 on

safety profile summary; 5.1 on follow up analysis; to update the safety information based on updates from study KTE-C19-101, entitled "A Phase 1/2 Multicenter Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1)", the pivotal study for Yescarta. The updates include the Phase 2 safety management ZUMA-1 Cohort 4, which was intended to assess the impact of earlier interventions (tocilizumab and/or corticosteroids, in addition to prophylactic levetiracetam) on the rate and severity of CRS and neurologic events; and data from a 36-month analysis from ZUMA-1 Cohorts 1 and 2. The updated RMP version 3.1 has also been submitted."	

B.6.14. PRAC assessed ATMP procedures

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

WS1901 **Actraphane-EMEA/H/C/000427/WS1901/0086** **Actrapid-EMEA/H/C/000424/WS1901/0079** **Fiasp-EMEA/H/C/004046/WS1901/0024** **Insulatard-EMEA/H/C/000441/WS1901/0084** **Levemir-EMEA/H/C/000528/WS1901/0100** **Mixtard-EMEA/H/C/000428/WS1901/ 0087** **NovoMix-EMEA/H/C/000308/WS1901/0106** **NovoRapid-EMEA/H/C/000258/WS1901/0136** **Protaphane-EMEA/H/C/000442/WS1901/0083** **Ryzodeg-EMEA/H/C/002499/WS1901/0041** **Tresiba-EMEA/H/C/002498/WS1901/0048** **Xultophy-EMEA/H/C/002647/WS1901/0038**	

Novo Nordisk A/S, Lead Rapporteur: Kirstine Moll Harboe, "To implement the risk of cutaneous amyloidosis in section 4.4, 4.8 of the SmPC following a PRAC signal assessment (EPITT no. 19499). Sections 2 and 4 of the PL is updated accordingly and also changed to highlight to patients that the precautions they need to take (such as rotating the injection site) are important not only to help preventing cutaneous amyloidosis but also to help preventing lipodystrophy. Additionally, the annexes have been brought in line with the current QRD template (version 10.1)."	
WS1907/G Galvus-EMEA/H/C/000771/WS1907/ 0065/G Jalra-EMEA/H/C/001048/WS1907/0067/G Xiliarx-EMEA/H/C/001051/WS1907/ 0065/G Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder	
WS1910/G Filgrastim Hexal-EMEA/H/C/000918/WS1910/0058/G Zarzio-EMEA/H/C/000917/WS1910/0059/G Sandoz GmbH, Lead Rapporteur: Johann Lodewijk Hillege	
WS1916 Cegfila-EMEA/H/C/005312/WS1916/0005 Pelmeg-EMEA/H/C/004700/WS1916/0009 Mundipharma Corporation (Ireland) Limited, Lead Rapporteur: Koenraad Norga	
WS1925 Filgrastim Hexal-EMEA/H/C/000918/WS1925/0057 Zarzio-EMEA/H/C/000917/WS1925/0058 Sandoz GmbH, Lead Rapporteur: Johann Lodewijk Hillege	

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 - EMEA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

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

F.1. Parallel Distribution - Pursuant to Article 9 of Council Regulation (EC) No. 2743/98 of 14 December 1998, as amended

F.2. Request for scientific opinion on justification of exceptional circumstance and for imperative grounds of public health

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

G.2. Ongoing procedures

G.3. PRIME

Some information related to PRIME cannot be released at the present time as these contain commercially confidential information.

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)*

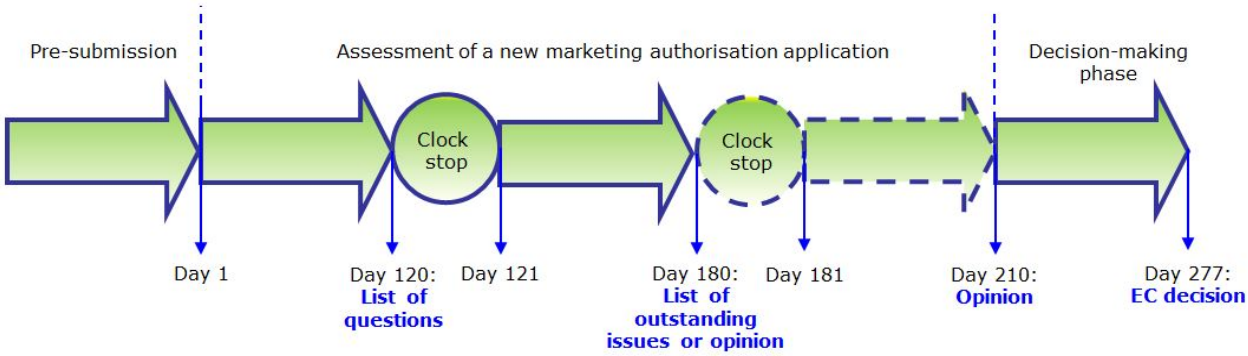
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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/