11 September 2017
EMA/CHMP/479458/2017 Corr[1]
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 11-14 September 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

11 September 2017, 13:00 – 20:00, room 2A

12 September 2017, 08:30 – 20:00, room 2A

13 September 2017, 08:30 – 20:00, room 2A

14 September 2017, 08:30 – 16:00, room 2A

Health and safety information

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

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also 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).

[1] correction in section 3.1

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 11-14 September 2017. See September 2017 CHMP minutes (to be published post October 2017 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 11-14 September 2017

1.3. Adoption of the minutes

CHMP minutes for 17-20 July 2017.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - prasterone - EMEA/H/C/004138

treatment of vulvovaginal atrophy

Scope: Oral explanation

Action: Oral explanation to be held on 13 September 2017 at time 16:00

List of Outstanding Issues adopted on 22.06.2017, 26.01.2017, 13.10.2016. List of Questions adopted on 26.05.2016.

2.1.2. - ocrelizumab - EMEA/H/C/004043

treatment of multiple sclerosis

Scope: Oral explanation to be held on 13 September 2017 at time 09:00. Report from SAG Neurology.

Action: For adoption

List of Outstanding Issues adopted on 23.03.2017. List of Questions adopted on 15.09.2016.

See 3.1

2.1.3. - sirukumab - EMEA/H/C/004165

treatment of rheumatoid arthritis

Scope: Oral explanation

Action: Oral explanation to be held on 14 September 2017 at time 09:00

List of Outstanding Issues adopted on 22.06.2017. List of Questions adopted on 26.01.2017.

2.2. Re-examination procedure oral explanations

2.2.1. Human IGG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech - human IgG1 monoclonal antibody specific for human interleukin-1 alpha - EMEA/H/C/004388

XBiotech Germany GmbH; treatment of metastatic colorectal cancer

Scope: Oral explanation to be held on 12 September 2017 at time 11:00

Action: For adoption

Opinion adopted on 18.05.2017

See 3.5

2.2.2. Masipro - masitinib - Orphan - EMEA/H/C/004159

AB Science; treatment of mastocytosis

Scope: Oral explanation to be held on 12 September 2017 at time 09:00

Action: For adoption

Opinion adopted on 18.05.2017.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Raxone - idebenone - Orphan - EMEA/H/C/003834/II/0003

Santhera Pharmaceuticals (Deutschland) GmbH

Rapporteur: John Joseph Borg, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Carmela Macchiarulo

Scope: Oral explanation to be held on 13 September 2017 at time 14:00

Action: For adoption

Participation of patients' representatives

Request for Supplementary Information adopted on 18.05.2017, 23.02.2017, 15.09.2016.

See 5.1

2.4. Referral procedure oral explanations

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - adalimumab - EMEA/H/C/004319

treatment of rheumatoid arthritis, axial spondyloarthritis, psoriasis, hidradenitis suppurativa (HS), Crohn's disease, ulcerative colitis and uveitis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 23.03.2017.

3.1.2. - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004781

treatment of adult patients with chronic obstructive pulmonary disease (COPD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 21.04.2017.

3.1.3. - guselkumab - EMEA/H/C/004271

treatment of plaque psoriasis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 21.04.2017.

3.1.4. - imatinib - EMEA/H/C/004748

treatment of newly diagnosed and chronic Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML), gastrointestinal stromal tumours (GIST), unresectable dermatofibrosarcoma protuberans (DFSP) and recurrent and/or metastatic DFSP

Scope: Opinion

Action: For adoption

3.1.5. - miglustat - EMEA/H/C/004366

treatment of Gaucher disease

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.06.2017. List of Questions adopted on 15.12.2016.

3.1.6. - naloxone - EMEA/H/C/004325

intended for emergency use for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 23.03.2017.

3.1.7. - ocrelizumab - EMEA/H/C/004043

treatment of multiple sclerosis

Scope: Opinion/ Oral explanation. Report from SAG Neurology.

Action: For adoption

List of Outstanding Issues adopted on 23.03.2017. List of Questions adopted on 15.09.2016.

See 2.1

3.1.8. - trastuzumab - EMEA/H/C/004323

treatment of breast cancer and metastatic gastric cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 26.01.2017.

3.1.9. - ritonavir - EMEA/H/C/004549

treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 21.04.2017.

3.1.10. - padeliporfin - EMEA/H/C/004182

treatment of prostate cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017, 21.04.2017, 15.12.2016. List of Questions adopted on 26.05.2016.

3.1.11. - fluticasone furoate / umeclidinium / vilanterol - EMEA/H/C/004363

treatment of adult patients with chronic obstructive pulmonary disease (COPD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 21.04.2017.

3.1.12. - human fibrinogen/human thrombin - EMEA/H/C/004446

treatment of haemostasis

Scope: Opinion

Action: For adoption

List of Questions adopted on 21.04.2017.

3.1.13. - niraparib - Orphan - EMEA/H/C/004249

Tesaro UK Limited; Treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.06.2017. List of Questions adopted on 23.02.2017.

3.1.14. - buprenorphine / naloxone - EMEA/H/C/004407

treatment for opioid drug dependence

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 23.02.2017.

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

3.2.1. - anagrelide - EMEA/H/C/004585

reduction of elevated platelet counts in at risk essential thrombocythaemia patients

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

3.2.2. - paclitaxel - Orphan - EMEA/H/C/004154

Oasmia Pharmaceutical AB; treatment of ovarian cancer

Scope: day 180 list of outstanding issue, letter from the applicant dated 4 September 2017 requesting an extension of clock stop to respond to the Day 180 list of outstanding issue.

Action: For adoption

List of Outstanding Issues adopted on 18.05.2017. List of Questions adopted on 23.06.2016.

3.2.3. - plitidepsin - Orphan - EMEA/H/C/004354

Pharma Mar, S.A.; treatment of multiple myeloma

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.02.2017.

3.2.4. - benralizumab - EMEA/H/C/004433

treatment of severe asthma with an eosinophilic phenotype

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

3.2.5. - darunavir - EMEA/H/C/004273

treatment of HIV-1 infection

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.03.2017.

3.2.6. - darunavir - EMEA/H/C/004891

treatment of HIV-1 infection

Scope: Day 180 list of outstanding issue

Action: For adoption

3.2.7. - fulvestrant - EMEA/H/C/004649

treatment of breast cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

3.2.8. - bevacizumab - EMEA/H/C/004360

treatment of breast cancer, non-small cell lung cancer, renal cell cancer, advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

3.2.9. - velmanase alfa - Orphan - EMEA/H/C/003922

Chiesi Farmaceutici S.p.A.; indicated for long-term enzyme replacement therapy in patients with alpha-mannosidosis

Scope: Day 180 list of outstanding issue, letter from the applicant dated 5 September 2017 requesting an extension of clock stop to respond to the Day 180 list of outstanding issue.

Action: For adoption

List of Questions adopted on 26.01.2017.

3.2.10. - letermovir - Orphan - EMEA/H/C/004536

Accelerated assessment

Merck Sharp & Dohme Limited; prophylaxis of cytomegalovirus (CMV) reactivation and disease

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 18.07.2017.

3.2.11. - bevacizumab - EMEA/H/C/004728

treatment of metastatic breast cancer, unresectable advanced, metastatic or recurrent non-small cell lung cancer, unresectable advanced metastatic or recurrent non-squamous non-small cell lung cancer, advanced and/or metastatic renal cell cancer, advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

3.2.12. - semaglutide - EMEA/H/C/004174

to improve glycaemic control in adults with type 2 diabetes and to prevent cardiovascular events

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

3.2.13. - d-biotin - EMEA/H/C/004153

treatment of progressive multiple sclerosis (primary or secondary)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 15.12.2016.

3.2.14. - ciclosporin - EMEA/H/C/004229

for the treatment of moderate dry eye disease in adults

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.03.2017.

3.2.15. - rucaparib - Orphan - EMEA/H/C/004272

Clovis Oncology UK Ltd; treatment of ovarian cancer

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.03.2017.

3.2.16. - human herpesvirus 3 - EMEA/H/C/004336

prevention of herpes zoster (HZ) and HZ-related complications

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.04.2017.

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

3.3.1. - viable t-cells - Orphan - ATMP - EMEA/H/C/002397

Kiadis Pharma Netherlands B.V.; adjunctive treatment in haematopoietic stem cell transplantation (HSCT) for a malignant disease

Scope: Day 120 list of questions

Action: For information

3.3.2. - doxorubicin hydrochloride - EMEA/H/C/004110

treatment of breast and ovarian cancer

Scope: Day 120 list of questions, letter from the applicant dated 7 September 2017 requesting an extension of clock stop to respond to Day 120 list of questions, similarity assessment

Action: For adoption

3.3.3. - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004274

treatment of HIV-1 infection

Scope: Day 120 list of questions

Action: For adoption

3.3.4. - adalimumab - EMEA/H/C/004429

treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - adalimumab - EMEA/H/C/004320

treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis

Scope: Day 120 list of questions

Action: For adoption

3.3.6. - budesonide - Orphan - EMEA/H/C/004655

Accelerated assessment

Dr. Falk Pharma GmbH; treatment of eosinophilic esophagitis (EoE)

Scope: Day 120 list of questions

Action: For adoption

3.3.7. - melatonin - PUMA - EMEA/H/C/004425

treatment of insomnia in children with Autism Spectrum Disorders and neurogenetic diseases

Scope: Day 120 list of questions

Action: For adoption

3.3.8. - vestronidase alfa - Orphan - EMEA/H/C/004438

Ultragenyx Germany GmbH; indicated for the treatment of Mucopolysaccharidosis VII (MPS VII; Sly syndrome) for patients of all ages

Scope: Day 120 list of questions

Action: For adoption

3.3.9. - pegfilgrastim - EMEA/H/C/003961

treatment of neutropenia

Scope: Day 120 list of questions

Action: For adoption

3.3.10. - prasugrel - EMEA/H/C/004644

prevention of atherothrombotic events

Scope: Day 120 list of questions

Action: For adoption

3.3.11. - infliximab - EMEA/H/C/004647

treatment of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, psoriasis and ulcerative colitis

Scope: Day 120 list of questions

Action: For adoption

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

3.4.1. - rurioctocog alfa pegol - EMEA/H/C/004195

treatment of haemophilia A

Scope: CHMP list of questions to BPWP/BWP

Action: For adoption

List of Outstanding Issues adopted on 21.04.2017, 15.12.2016. List of Questions adopted on 21.07.2016.

3.4.2. - naldemedine - EMEA/H/C/004256

treatment of opioid-induced constipation (OIC) in adult patients

Scope: Letter from the applicant dated 8 September 2017 requesting an extension of clock stop to respond to Day 120 list of questions adopted on 20.07.2017

Action: For adoption

List of Questions adopted on 20.07.2017.

3.4.3. - pegfilgrastim - EMEA/H/C/004413

treatment of neutropenia

Scope: Letter from the applicant dated 23 August 2017 requesting an extension of clock stop to respond to Day 120 list of questions adopted on 23.03.2017

Action: For adoption

List of Questions adopted on 23.03.2017.

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

3.5.1. Adlumiz - anamorelin - EMEA/H/C/003847

Helsinn Birex Pharmaceuticals Ltd; treatment of anorexia, cachexia or unintended weight loss in adult patients with non-small cell lung cancer (NSCLC)

Scope: Opinion

Action: For adoption

List of experts for the SAG planned on 04.09.2017 adopted by written procedure on 30 August 2017.

Opinion adopted on 18.05.2017

3.5.2. Fanaptum - iloperidone - EMEA/H/C/004149

Vanda Pharmaceuticals Ltd.; treatment of schizophrenia

Scope: Appointment of re-examination Rapporteurs

Action: For adoption

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

Opinion adopted on 20.07.2017, Oral explanation 17.05.2016, List of Outstanding Issues adopted on 18.05.2017, 23.02.2017. List of Questions adopted on 28.04.2016.

3.5.3. Human IGG1 monoclonal antibody specific for human interleukin-1 alpha XBiotech - human IgG1 monoclonal antibody specific for human interleukin-1 alpha - EMEA/H/C/004388

XBiotech Germany GmbH; treatment of metastatic colorectal cancer

Scope: Re-examination of Opinion /Oral explanation to be held on 12 September 2017 at time 11:00

Action: For adoption

Opinion adopted on 18.05.2017

See 2.2

3.5.4. Masipro - masitinib - Orphan - EMEA/H/C/004159

AB Science; treatment of mastocytosis

Scope: Oral explanation/Opinion

Action: For adoption
List of experts for the SAG planned on 04.09.2017 adopted by written procedure on 30 August 2017.

Opinion adopted on 18.05.2017.

See 2.2

3.5.5. Onzeald - etirinotecan pegol - EMEA/H/C/003874

Nektar Therapeutics UK Limited; treatment of breast cancer with brain metastases

Scope: Appointment of re-examination Rapporteurs

Action: For adoption

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

Opinion adopted on 20.07.2017, Oral explanation 16.05.2017, List of Outstanding Issues adopted on 18.05.2017, 23.03.2017. List of Questions adopted on 10.11.2016.

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

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

4.1.1. Benlysta - belimumab - EMEA/H/C/002015/X/0046/G

Glaxo Group Ltd

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (200 mg) and a new route of administration (subcutaneous use) grouped with a type II variation (C.I.4) to include changes in the Product Information."

Action: For adoption

List of Outstanding Issues adopted on 22.06.2017. List of Questions adopted on 23.02.2017.

4.1.2. ellaOne - ulipristal acetate - EMEA/H/C/001027/X/0045

Laboratoire HRA Pharma

Rapporteur: Paula Boudewina van Hennik

Scope: "Addition of a new pharmaceutical form (film-coated tablets) to the existing strength 30 mg."

Action: For adoption

List of Questions adopted on 22.06.2017.

4.1.3. Exjade - deferasirox - EMEA/H/C/000670/X/0054

Novartis Europharm Ltd

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ghania Chamouni

Scope: "Extension application for a new pharmaceutical form (Exjade 90, 180 and 360 mg granules)."

Action: For adoption

List of Outstanding Issues adopted on 22.06.2017. List of Questions adopted on 23.02.2017.

4.1.4. Tasigna - nilotinib - Orphan - EMEA/H/C/000798/X/0088/G

Novartis Europharm Ltd

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Harald Enzmann, PRAC Rapporteur: Doris Stenver

Scope: "Extension of Indication to include treatment of paediatric patients with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase (Ph+ CML-CP), or with Ph+ CML-CP resistant or intolerant to prior therapy including imatinib, based on results from two clinical studies in paediatric patients conducted in accordance with the approved Tasigna Paediatric Investigation Plan (PIP), the Phase I PK study CAMN107A2120 and the Phase II safety and efficacy study CAMN107A2203. An updated RMP version 18.0 was provided as part of the application.
Extension application to add a new strength of 50mg hard capsules.
In addition, the applicant proposes to merge the SmPCs for the 50 mg and 200 mg strengths."

Action: For adoption

List of Outstanding Issues adopted on 20.07.2017. List of Questions adopted on 23.03.2017.

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

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

4.3.1. Lynparza - olaparib - Orphan - EMEA/H/C/003726/X/0016/G

AstraZeneca AB

Rapporteur: Alexandre Moreau, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Carmela Macchiarulo

Scope: Extension application to add a new pharmaceutical form associated with a new strength (100mg and 150 mg film-coated tablets) including an extension of the indication to treat patients with platinum-sensitive relapsed ovarian tumours. The extension application is grouped with a type II variation to align the PI for the currently authorised capsule licence with the safety updates proposed for the tablet formulation.

Action: For adoption

4.3.2. Nuwiq - simoctocog alfa - EMEA/H/C/002813/X/0020

Octapharma AB

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to add new strengths of 2500 IU, 3000 IU, 4000 IU for Nuwiq, powder and solvent for solution for injection. The RMP (version 5.4) is updated accordingly ."

Action: For adoption

4.3.3. Sprycel - dasatinib - EMEA/H/C/000709/X/0056/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Doris Stenver

Scope: "Extension application to introduce a new pharmaceutical form (powder for oral suspension) associated with a new strength (10 mg/ml)

2. C.I.6.a(type II) to include the treatment of children and adolescents aged 1 year to 18 years with Ph+ chronic phase CML for Sprycel. Sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add the new indication and its relevant posology, to add a warning on effects on growth and development in the paediatric population and to update the safety information. The Package Leaflet is updated in accordance."

Action: For adoption

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

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

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

5.1.1. Bydureon - exenatide - EMEA/H/C/002020/II/0045

AstraZeneca AB

Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue

Scope: "Extension of Indication to include treatment in combination with basal insulin for Bydureon; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated based on the study D5553C00002 (Duration 7 study) which evaluated safety and efficacy of exenatide once weekly therapy added to titrated basal insulin in patients with type 2 diabetes who have inadequate glycemic control on basal insulin with or without metformin. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor corrections in sections 4.8 and 5.1 of the SmPC. Furthermore, the updated RMP version 26 has been submitted."

Action: For adoption

5.1.2. Firazyr - icatibant - Orphan - EMEA/H/C/000899/II/0034/G

Shire Orphan Therapies GmbH

Rapporteur: Kristina Dunder, Co-Rapporteur: Nithyanandan Nagercoil, PRAC Rapporteur: Qun-Ying Yue

Scope: "A type II variation (C.I.6) to modify the existing marketing authorization to include a recommendation for use in children (study HGT-FIR-086) following completion of the PIP (EMEA-000408-PIP01-08-M05)
In addition, it is proposed to reflect the conduct of a juvenile toxicity study (JE049-0172) in SmPC section 5.3 in order to fulfill article 37 of regulation 1901/2006. Study JE049-0172 has previously been assessed by EMA.

Section 5.2. of the SmPC has been updated to reflect the effect on age (elderly), gender and race on PK of icatibant."

Action: For adoption

Request for Supplementary Information adopted on 18.05.2017, 15.12.2016.

5.1.3. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0027

Merck Sharp & Dohme Limited

Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to include 1st line treatment of metastatic non-squamous non-small cell lung cancer (NSCLC) in combination with platinum-pemetrexed chemotherapy based on the results from study KEYNOTE-021 (cohort G); a Phase 1/2, open-label trial of pembrolizumab in combination with chemotherapy or immunotherapy in patients with locally advanced or metastatic NSCLC.
As a consequence sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC have been updated and the Package Leaflet has been updated accordingly.
An updated RMP version 9.0 was provided as part of the application."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2017.

5.1.4. Nplate - romiplostim - Orphan - EMEA/H/C/000942/II/0060/G

Amgen Europe B.V.

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Eva A. Segovia

Scope: "C.I.6.a - Extension of Indication to include paediatric population for Nplate: to register Nplate for the use in the paediatric chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients: 1 year of age and older.

As a consequence Product information has been updated accordingly.

The RMP version 18 has also been submitted.
Furthermore, the PI is brought in line with the latest QRD templare version 10.

B.II.e.5.c – To add a low-dose romiplostim 125 microgram vial presentation for powder for solution for injection (4 vials pack).

B.II.e.5.a.1 – To add a 1 vial pack size of a low-dose romiplostim 125 microgram presentation."

Action: For adoption

Request for Supplementary Information adopted on 23.03.2017.

5.1.5. Raxone - idebenone - Orphan - EMEA/H/C/003834/II/0003

Santhera Pharmaceuticals (Deutschland) GmbH

Rapporteur: John Joseph Borg, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Carmela Macchiarulo

Scope: "Extension of indication to include treatment of patients with Duchenne muscular dystrophy in whom respiratory function has started to decline and who are currently not taking concomitant glucocorticoids. Raxone can be used in patients previously treated with glucocorticoids or in patients in whom glucocorticoid treatment is not desired, not tolerated or is contraindicated."

Action: For adoption/Oral explanation

Participation of patients' representatives

Request for Supplementary Information adopted on 18.05.2017, 23.02.2017, 15.09.2016.

See 2.3

5.1.6. Repatha - evolocumab - EMEA/H/C/003766/II/0017/G

Amgen Europe B.V.

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of Indication to include reduction of atherosclerotic cardiovascular disease risk in adults with high cardiovascular risk for Repatha based on the results from Study 20110118 (a category 3 PV activity in the Risk Management Plan, MEA 004); 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.

In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update section 5.1 of the SmPC to include important mechanistic information for healthcare professionals based on Study 20120153 (a category 3 PV activity, MEA 006).
Submission of an updated RMP version 2.0 in order to add two category 3 studies in the RMP (Study 20160250 and Study 20150338), as well as to update the milestones of five category 3 studies (20110110, 20110271, 20120138, 20130286, 20130295)"

Action: For adoption

5.1.7. Stribild - elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil - EMEA/H/C/002574/II/0079

Gilead Sciences International Limited

Rapporteur: Robert James Hemmings, Co-Rapporteur: Joseph Emmerich, PRAC Rapporteur: Julie Williams

Scope: "Extension of Indication to include the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years and weighing ≥ 35 kg; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated based on pharmacokinetics, safety and efficacy data through 48 weeks of treatment with Stribild in Study GS-US-236-0112.

The Package Leaflet and Risk Management Plan (v.12) are updated in accordance.

The requested variation proposed amendments to the Summary of Product Characteristics, Package Leaflet and Risk Management Plan (RMP).

In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor linguistic amendments"

Action: For adoption

Request for Supplementary Information adopted on 18.05.2017.

5.1.8. Taltz - ixekizumab - EMEA/H/C/003943/II/0009

Eli Lilly Nederland B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include alone or in combination with conventional disease-modifying anti-rheumatic drug (cDMARD), the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARD therapies. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, and 5.2 of the SmPC are updated to reflect the new safety and efficacy information. The Package Leaflet and RMP have been updated accordingly.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.9. Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0135

Gilead Sciences International Limited

Rapporteur: Greg Markey, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Julie Williams

Scope: "Extension of Indication to include pre-exposure prophylaxis of HIV in adolescents aged 12 to < 18 years at high risk; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated based on extrapolation of data for emtricitabine, tenofovir disoproxil fumarate, and Truvada in HIV-infected and uninfected subjects.

The Package Leaflet and Risk Management Plan (v.15) are updated in accordance.

The requested variation proposed amendments to the Summary of Product Characteristics, Package Leaflet and Risk Management Plan (RMP).

In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor linguistic amendments"

Action: For adoption

Request for Supplementary Information adopted on 18.05.2017.

5.1.10. Yervoy - ipilimumab - EMEA/H/C/002213/II/0044

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus

Scope: "Extension of indication to include the treatment of advanced (unresectable or metastatic) melanoma in children and adolescents 12 years of age and older for Yervoy. As a consequence sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and the RMP (version 15) are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 22.06.2017.

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

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

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

6.2. Update of Ancillary medicinal substances in medical devices

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)

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. – fexinidazole - Art. 58 - H0002320

treatment of both, the first-stage (hemo-lymphatic) and second-stage (meningo-encephalitic) of human African trypanosomiasis due to T.b. gambiense in adults and children ≥ 6 years old and weighing 20 kg or more.

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.1.2. – cytarabine, daunorubicin - H0004282

treatment of adults with high-risk Acute Myeloid Leukaemia (AML) as defined by therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.2. Priority Medicines (PRIME)

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

8.2.1. List of applications received

Action: For information

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Aranesp - darbepoetin alfa - EMEA/H/C/000332/II/0143

Amgen Europe B.V.

Rapporteur: Martina Weise

Scope: CHMP request for PRAC advice on the "signal procedure (EMEA/H/C000332/SDA/090) and addresses the potential need for additional risk minimisation measures and an amendment of the RMP and Annex IID a formal request for PRAC advice is considered necessary for the assessment and conclusions on this variation procedure"

Action: For information

9.1.2. Cotellic - cobimetinib -EMEA/H/C/003960

Roche Registration Limited

CHMP Rapp: Filip Jospehson, PRAC Rapp: Sabine Straus

Scope: A non-interventional Study to investigate the Effectiveness, Safety and Utilisation of cobimetinib and vemurafenib in Patients with and without Brain Metastasis with BRAF V600 mutant melanoma under real world Conditions - (covenis).

Action: For discussion

9.1.3. Deltyba - delamanid - EMEA/H/C/002552/II/0021, Orphan

MAH: Otsuka Novel Products GmbH

Rapporteur: Greg Markey

Scope: "Update of sections 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC to reflect the results of the final study report of 242-09-213 (A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Trial to Evaluate the Safety and Efficacy of Delamanid (OPC-67683) Administered Orally as 200 mg Total Daily Dose for Six Months in Patients With Pulmonary Sputum Culture-positive, Multidrug-resistant Tuberculosis), submitted to fulfill SOB-01. The Package leaflet is updated accordingly."

Action: For discussion

9.1.4. Ibrance - palbociclib - EMEA/H/C/003853

MAH: Pfizer Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Torbjorn Callreus

Scope: Discuss the rationale supporting the indication of Ibrance in combination with an aromatase inhibitor irrespective of the line of therapy

Action: For discussion

9.1.5. Opdivo - nivolumab - EMEA/H/C/003985/II/0036/G

MAH: Bristol-Myers Squibb Pharma EEIG

Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "C.I.4 (Type II) - Update of sections 4.2, 5.1, 5.2 and 6.6 of the SmPC in order to introduce new dosing regimens and schedule.

C.I.4 (Type II) - Update of sections 4.2, 5.1, 5.2 and 6.6 of the SmPC in order to introduce change the infusion time from 60 minutes to 30 minutes

These changes are based on interim results from study CA209153; this is a phase IIIb/IV safety trial of nivolumab in subjects with advanced or metastatic non-small cell Lung cancer who have progressed during or after receiving at least one prior systemic regimen;
The Package Leaflet is updated accordingly.
The RMP version 10.0 has also been submitted."

Action: For discussion

9.1.6. Prolia - denosumab - EMEA/H/C/001120/II/0068

MAH: Amgen Europe B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga

Scope: List of experts at ad hoc expert group meeting and CHMP list of questions to the ad hoc expert group

Action: For adoption

Request for Supplementary Information adopted on 22.06.2017.

9.1.7. Neulasta – pegfilgrastim - EMEA/H/C/000420/0093/G

MAH: Amgen Europe B.V.

Rapporteur: Robert James Hemmings, PRAC Rapporteur: Patrick Batty

Scope: "B.IV.1.a.3 (type II) – To add a new device which may have a significant impact on the delivery of the product: the on-body injector (Onpro kit) to be used with Neulasta, 6mg solution for injection, pre-filled syringe
- B.II.e.5.c (type II) – To change the fill volume from 0.6 to 0.64 mL for Neulasta, 6 mg, solution for injection pre-filled syringe co-packed with the new on-body injector (Onpro kit)
In addition the MAH took the opportunity to introduce editorial changes to module 3.2.P.2.4

Container Closure System
Update of sections 3, 4.2, 5.1, 6.4, 6.5, 6.6 and 8 of the SmPC. The Labelling, Package Leaflet and the RMP (version 4.2) are updated accordingly. In addition the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to include some editorial changes and correct some typos throughout the product information, and to bring the product information in line with the latest QRD template version 10."

Action: For discussion

Request for Supplementary Information adopted on 22.06.2017.

9.1.8. Tarceva - erlotinib - EMEA/H/C/000618/II/0052

Roche Registration Limited

Rapporteur: Sinan B. Sarac

Scope: Letter from the applicant requesting extension of clock stop to respond to Request for supplementary information adopted on 20.07.2017

"Update of section 4.4 of the SmPC in order to include recommendations on Epidermal Growth Factor Receptor (EGFR) mutation status testing, to be in line with current technical and scientific progress.
In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes and to bring the PI in line with the latest QRD template version 10. Moreover, the MAH took the opportunity to make minor correction of section 4.2 of the SmPC. Furthermore, the Annex II has been corrected, as requested by the EMA, to include Educational Material as an additional risk minimisation measure, which has been already in place in the RMP."

Action: For adoption

Request for Supplementary Information adopted on 20.07.2017.

10. Referral procedures

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

10.1.1. Zinbryta - Daclizumab - EMEA/ H/A-20/1456

Biogen Idec Ltd

Rapporteurs for the Article 20 referral: PRAC Rapporteur: Eva Segovia; PRAC Co-rapporteur: Marcia Sofia Sanches de Castro Lopes Silva,

Rapporteurs for Zinbryta: CHMP Rapporteur: Bruno Sepodes, CHMP Co-rapporteur: Greg Markey

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004 based on

pharmacovigilance data

List of question to the SAG

Action: For adoption

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

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

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

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

10.5.1. Scandonest and associated names – mepivacaine - EMEA/H/A-30/1455

Septodont group of companies and associated companies

Rapporteur: Romaldas Maciulaitis, Co-rapporteur: Fatima Ventura,

Scope: Start of procedure and timetable

Action: For adoption

Harmonisation exercise for Scandonest and associated names. Summary of Product Characteristics and Module 3 harmonisation was triggered by the MAH.

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

10.6.1. Human coagulation (plasma-derived) factor VIII: human coagulation factor VIII (antihemophilic factor A) (NAP); human coagulation factor VIII (inhibitor bypassing fraction) (NAP); human coagulation factor VIII, human von Willebrand factor - Voncento (CAP) Recombinant factor VIII: antihemophilic factor (recombinant) (NAP); efmoroctocog alfa – Elocta (CAP); moroctocog alfa – Refacto AF (CAP) octocog alfa – Advate (CAP), Helixate Nexgen (CAP), Iblias (CAP), Kogenate (CAP), Kovaltry (CAP); turoctocog alfa – Novoeight (CAP); simoctocog alfa – Nuwiq (CAP); susoctocog alfa – Obizur (CAP) - EMEA/H/A-31/1448

Baxter AG (Advate), Bayer Pharma AG (Helixate Nexgen, Iblias, Kogenate, Kovaltry), CSL Behring GmbH (Voncento), Novo Nordisk A/S (NovoEight), Octapharma AB (Nuwiq), Pfizer Limited (Refacto AF), Swedish Orphan Biovitrum AB (publ) (Elocta), Baxalta Innovations GmbH (Obizur), various

PRAC led referral - PRAC Rapporteur: Jan Neuhauser; PRAC Co-rapporteur: Ghania Chamouni

Scope: Opinion

Action: For adoption

Re-examination procedure under Article 32 of Directive 2001/83/EC of the review of the benefit-risk balance of factor VIII following notification by Germany of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data.

10.6.2. Gadolinium-containing contrast agents (GdCA): gadobutrol (NAP); gadodiamide (NAP); gadopentetic acid (NAP); gadoteric acid (NAP); gadoteridol (NAP); gadoxetic acid (NAP) - EMEA/H/A-31/1097

Lead Rapporteur: Patrick Batty

Scope: Annual cumulative reviews on NSF cases submission as a post-authorisation measure resulting from the 2010 Article 20 and Article 31 referral procedures for gadolinium-containing contrast agents, timetable

Action: For adoption

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

10.7.1. Alcover 750 mg, 1250 mg, 1750 mg Granulat im Beutel – Sodium oxybate – EMEA/H/A-29(4)/1451

D&A Pharma

Rapporteur: Andrea Laslop, Co-Rapporteur: Fatima Ventura,

Scope: List of questions to the SAG, list of experts

Action: For adoption

Decentralised Procedure number: AT/H/0552/01-03/DC, notification by the Austrian Agency dated 22 December 2016 notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC.

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

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

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

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

11. Pharmacovigilance issue

11.1. Early Notification System

September 2017 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

Disclosure of information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Disclosure of information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Disclosure of information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

13.2. Innovation Task Force briefing meetings

Disclosure of information related to briefing meetings taking place with applicants cannot be released at present time as deemed to contain commercially confidential information

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

13.4. Nanomedicines activities

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

Area of expertise of co-opted member

The mandate of co-opted member (expertise in Quality and safety of biological medicinal products, including biotechnology derived medicines, cell therapies and gene therapies) will expire on 13 November 2017.

Proposed timeline for appointment of the co-opted member:

Confirmation of areas of expertise: September 2017

Call for nomination for expert: September/October 2017

Election of co-opted member: November 2017

Action: For discussion

CHMP/CAT joint membership

The Advanced Therapies Regulation ((EC) 1394/2007) requires that 5 members or co-opted members of the Committee for Medicinal Products for Human Use (CHMP) together with an alternate, either proposed by the Member state of the member or identified by the co-opted member, are appointed by the CHMP to the Committee for Advanced Therapies (CAT). The Member States, who are not represented through the members appointed by the CHMP, nominate then one member and alternate to the CAT.

Action: For discussion

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on 29 August – 1 September 2017

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for September 2017

Action: For adoption

Comments on post consultation on 'Guideline on good pharmacovigilance practices (GVP), Module XV – Safety communication (Rev 1)' should be sent **by 18 September 2017**

Action: For information

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 6-8 September 2017
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 11-12 July 2017

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2017 PDCO

Action: For information

Report from the PDCO meeting held on 15-18 August 2017

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 5-7 September 2017
Action: For information

14.2.6. Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 17-19 July 2017

Action: For information

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

14.3.1. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 29 August – 1 September 2017. Table of conclusions

Action: For information

Scientific advice letters: Disclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

14.3.2. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl,

Election of PGWP Vice-Chair, the term of the current Vice-Chair ending September 2017

Action: For adoption

14.3.3. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Election of PKWP Vice-Chair, the term of the current Vice-Chair ending September 2017

Action: For adoption

14.3.4. Infectious Disease Working Party (IDWP)

Chair: TBC

Election of IDWP Vice-Chair, the term of the current Vice-Chair ended in July 2017

Action: For adoption

Call for nominations for Chair position: Nominations together with a brief resume in support of their candidature should be sent

Action: For information

14.3.5. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Nomination of new observer Petr Vrbata (CZ) to the CNSWP

Action: For adoption

14.3.6. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00 Rev. 2)

Action: For adoption for 6-months public consultation

14.3.7. Oncology Working Party (ONCWP)

Chair: Pierre Demolis/Paolo Foggi

Guideline on the evaluation of anticancer medicinal products in man (EMA/CHMP/205/95 Rev.5)

Action: For adoption

14.3.8. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

Nomination of new member to the BMWP

Action: For adoption

Election of BMWP Vice-Chair, the term of the current Vice Chair ended in July 2017

Action: For adoption

14.3.9. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

Nomination of Bill Vestergaard (DK) and Camilla Ærtebjerg (DK) as observers to the SWP

Action: For adoption

14.3.10. Extrapolation Working Group (EWG)

Reflection paper on the use of extrapolation in the development of medicines for paediatrics

CHMP: Robert James Hemmings

Action: For discussion

14.4. Cooperation within the EU regulatory network

14.5. Cooperation with International Regulators

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee

14.7. CHMP work plan

14.7.1. CHMP 2018 Work Plan: proposed list of topics

Action: For information

14.8. Planning and reporting

14.8.1. New marketing authorisation applications for 2017 with and without appointed rapporteurs

Action: For information

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. Revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products'

CHMP Rapporteur: Harald Enzmann

Scope: Overview of comments of the revised guideline

Action: For information

Revised guideline adopted at the July 2017 plenary.

16. 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)*

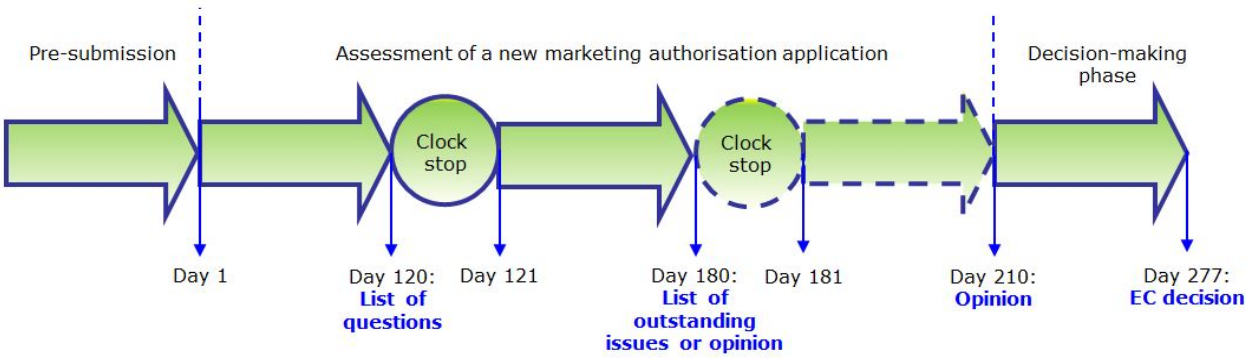
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 September 2017
EMA/CHMP/479459/2017

Annex to 11-14 September 2017 CHMP Agenda

Pre submission and post authorisations issues

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A. PRE SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for September 2017: **For adoption**

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

Final Outcome of Rapporteurship allocation for September 2017: **For adoption**

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

Firdapse - amifampridine - EMEA/H/C/001032/S/0049, Orphan
MAH: BioMarin Europe Ltd, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams
Request for Supplementary Information adopted on 22.06.2017.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/R/0031, Orphan
MAH: MediWound Germany GmbH, Rapporteur: Harald Enzmann, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Valerie Strassmann
Request for Supplementary Information adopted on 22.06.2017.

Pradaxa - dabigatran etexilate - EMEA/H/C/000829/R/0105
MAH: Boehringer Ingelheim International GmbH,

Rapporteur: Hanne Lomholt Larsen,
Co-Rapporteur: Joseph Emmerich, PRAC
Rapporteur: Torbjorn Callreus

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Adasuve - loxapine -
EMEA/H/C/002400/R/0024
MAH: Ferrer Internacional s.a., Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Luca Pani, PRAC Rapporteur: Sabine Straus

Glubrava - pioglitazone / metformin hydrochloride -
EMEA/H/C/000893/R/0054
MAH: Takeda Pharma A/S, Informed Consent of Competact, Rapporteur: Patrick Salmon, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Almath Spooner
Request for Supplementary Information adopted on 22.06.2017.

Jetrea - ocriplasmin -
EMEA/H/C/002381/R/0033
MAH: ThromboGenics NV, Rapporteur: Greg Markey, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Julie Williams

Selincro - nalmefene -
EMEA/H/C/002583/R/0022
MAH: H. Lundbeck A/S, Rapporteur: Harald Enzmann, Co-Rapporteur: Patrick Salmon, PRAC Rapporteur: Martin Huber

B.2.3. Renewals of Conditional Marketing Authorisations

Adcetris - brentuximab vedotin -
EMEA/H/C/002455/R/0051, Orphan
MAH: Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus
Request for Supplementary Information adopted on 20.07.2017.

Ocaliva - obeticholic acid -
EMEA/H/C/004093/R/0002, Orphan
MAH: Intercept Pharma Ltd, Rapporteur: Jorge Camarero Jiménez, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Sabine Straus

Venclyxto - venetoclax -
EMEA/H/C/004106/R/0005, Orphan

MAH: AbbVie Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Patrick Batty
Request for Supplementary Information adopted on 20.07.2017.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 29 August – 1 September 2017 PRAC:

Signal of dystonia
Pramipexole -
Mirapexin - pramipexole -
EMEA/H/C/000134
Boehringer Ingelheim International
Rapporteur: Hanne Lomholt Larsen,
Co-Rapporteur: Outi Mäki-Ikola, PRAC
Rapporteur: Doris Stenver,

Sifrol - pramipexole -
EMEA/H/C/000133
Boehringer Ingelheim International
Rapporteur: Hanne Lomholt Larsen,
Co-Rapporteur: Outi Mäki-Ikola, PRAC
Rapporteur: Doris Stenver,

Oprymea - pramipexole -
EMEA/H/C/00941
KRKA, d.d., Novo mesto
Rapporteur: Hanne Lomholt Larsen, PRAC
Rapporteur: Doris Stenver,

Pramipexole Teva - pramipexole -
EMEA/H/C/00940
Teva B.V.
Rapporteur: Filip Josephson, Co-Rapporteur: Hanne Lomholt Larsen, PRAC Rapporteur: Qun-Ying Yue,

Pramipexole Accord - pramipexole -
EMEA/H/C/00291
Accord Healthcare Limited
Rapporteur: Svein Rune Andersen,
Co-Rapporteur: Hanne Lomholt Larsen, PRAC
Rapporteur: Doris Stenver,

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its 29 August – 1 September 2017 PRAC meeting:

Pyramax - pyronaridine / artesunate - EMEA/H/W/002319/PSUV/0016 (without RMP)
MAH: Shin Poong Pharmaceutical Co., Ltd., PRAC Rapporteur: Caroline Laborde, “16 August 2016 – 15 February 2017”

EMEA/H/C/PSUSA/00000057/201612
(adalimumab (except for biosimilars))
CAPS:
Humira (EMEA/H/C/000481) (adalimumab), MAH: AbbVie Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, “DLP 31/12/2016, 3 years”

EMEA/H/C/PSUSA/00000985/201701
(dexamethasone (centrally authorised product indicated in uveitis and macular oedema))
CAPS:
Ozurdex (EMEA/H/C/001140) (dexamethasone), MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, “28 Jan 2016 – 27 Jan 2017”

EMEA/H/C/PSUSA/00001152/201611
(docetaxel)
CAPS:
Docetaxel Winthrop (EMEA/H/C/000808) (docetaxel), MAH: Aventis Pharma S.A., Rapporteur: Alexandre Moreau
Taxotere (EMEA/H/C/000073) (docetaxel), MAH: Aventis Pharma S.A., Rapporteur: Alexandre Moreau
NAPS:
TAXOTAN - MEDICOPHARM AG
, PRAC Rapporteur: Ghania Chamouni, “01-Dec-2013 – 30-Nov-2016”

EMEA/H/C/PSUSA/00002875/201701
(gimeracil / oteracil monopotassium / tegafur)
CAPS:
Teysuno (EMEA/H/C/001242) (tegafur / gimeracil / oteracil), MAH: Nordic Group B.V., Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, “25 Jan 2016 – 24 Jan 2017”

EMEA/H/C/PSUSA/00002973/201612
(tipranavir)
CAPS:
Aptivus (EMEA/H/C/000631) (tipranavir), MAH: Boehringer Ingelheim International

GmbH, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Caroline Laborde, “01 January 2014 to 3 I December 2016”

EMEA/H/C/PSUSA/00010275/201701
(peginterferon beta-1A)
CAPS:
Plegridy (EMEA/H/C/002827) (peginterferon beta-1a), MAH: Biogen Idec Ltd, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Julie Williams, “19 Jul 2016 to 18 Jan 2017”

EMEA/H/C/PSUSA/00010303/201701
(idelalisib)
CAPS:
Zydelig (EMEA/H/C/003843) (idelalisib), MAH: Gilead Sciences International Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Patrick Batty, “23 Jul 2016 - 22 Jan 2017”

EMEA/H/C/PSUSA/00010363/201701
(dasabuvir)
CAPS:
Exviera (EMEA/H/C/003837) (dasabuvir), MAH: AbbVie Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Dolores Montero Corominas, “15 July 2016 – 14 January 2017”

EMEA/H/C/PSUSA/00010367/201701
(ombitasvir / paritaprevir / ritonavir)
CAPS:
Viekirax (EMEA/H/C/003839) (ombitasvir / paritaprevir / ritonavir), MAH: AbbVie Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Dolores Montero Corominas, “15 July 2016 – 14 January 2017”

EMEA/H/C/PSUSA/00010448/201701
(carfilzomib)
CAPS:
Kyprolis (EMEA/H/C/003790) (carfilzomib), MAH: Amgen Europe B.V., Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Nikica Mirošević Skvrce, “20 July 2016 to 19 January 2017”

EMEA/H/C/PSUSA/00010094/201702
(florbetaben (18f))
CAPS:
Neuraceq (EMEA/H/C/002553) (florbetaben (18F)), MAH: Piramal Imaging Limited, Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Patrick Batty, , “21 August 2016 -

20 February 2017”

B.4. EPARs / WPARs

Entecavir Mylan - entecavir -
EMEA/H/C/004377
Applicant: Mylan S.A.S, treatment of chronic hepatitis B virus infection, Generic, Generic of Baraclude Generic application (Article 10(1) of Directive No 2001/83/EC)

Fulphila - pegfilgrastim -
EMEA/H/C/004262
Applicant: Mylan S.A.S, treatment of neutropenia, Similar biological application (Article 10(4) of Directive No 2001/83/EC)
WPAR

Ogivri - trastuzumab -
EMEA/H/C/004346
Applicant: Mylan S.A.S, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC), Similar biological application (Article 10(4) of Directive No 2001/83/EC)
WPAR

Xermelo - telotristat ethyl -
EMEA/H/C/003937, Orphan
Applicant: Ipsen Pharma, treatment of carcinoid syndrome, New active substance (Article 8(3) of Directive No 2001/83/EC)

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

Advate - octocog alfa - **EMEA/H/C/000520/II/0085** MAH: Baxter AG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 20.07.2017.	Weekly start timetable.
BeneFIX - nonacog alfa - **EMEA/H/C/000139/II/0146** MAH: Pfizer Limited, Rapporteur: Jan Mueller-Berghaus	Weekly start timetable.

Benepali - etanercept - EMEA/H/C/004007/II/0026 MAH: Samsung Bioepis UK Limited, Rapporteur: Andrea Laslop	Weekly start timetable.
Betaferon - interferon beta-1b - EMEA/H/C/000081/II/0114 MAH: Bayer AG, Rapporteur: Greg Markey Request for Supplementary Information adopted on 15.06.2017.	Weekly start timetable.
Cosentyx - secukinumab - EMEA/H/C/003729/II/0026 MAH: Novartis Europharm Ltd, Rapporteur: Tuomo Lapveteläinen	Weekly start timetable.
Cystadane - betaine anhydrous - EMEA/H/C/000678/II/0029 MAH: Orphan Europe SARL, Rapporteur: Harald Enzmann	Weekly start timetable.
Darunavir Mylan - darunavir - EMEA/H/C/004068/II/0001/G MAH: Mylan S.A.S, Generic, Generic of Prezista, Rapporteur: John Joseph Borg Request for Supplementary Information adopted on 05.05.2017.	Weekly start timetable.
Deltyba - delamanid - EMEA/H/C/002552/II/0020/G, Orphan MAH: Otsuka Novel Products GmbH, Rapporteur: Greg Markey	Weekly start timetable.
Elocta - efmoroctocog alfa - EMEA/H/C/003964/II/0016/G MAH: Swedish Orphan Biovitrum AB (publ), Rapporteur: Jan Mueller-Berghaus	Weekly start timetable.
Extavia - interferon beta-1b - EMEA/H/C/000933/II/0084 MAH: Novartis Europharm Ltd, Informed Consent of Betaferon, Rapporteur: Greg Markey Request for Supplementary Information adopted on 15.06.2017.	Weekly start timetable.
Foscan - temoporfin - EMEA/H/C/000318/II/0042 MAH: biolitec Pharma Ltd, Rapporteur: Paula Boudewina van Hennik	Weekly start timetable.
Ganfort - bimatoprost / timolol - EMEA/H/C/000668/II/0027/G MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Hanne Lomholt Larsen Request for Supplementary Information adopted	Weekly start timetable.

on 09.06.2017.	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0074/G MAH: CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 22.06.2017, 23.02.2017.	
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0086 MAH: CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	Weekly start timetable.
Imvanex - modified vaccinia Ankara virus - EMEA/H/C/002596/II/0027 MAH: Bavarian Nordic A/S, Rapporteur: Greg Markey Request for Supplementary Information adopted on 22.06.2017.	Weekly start timetable.
Kadcyla - trastuzumab emtansine - EMEA/H/C/002389/II/0034 MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 29.06.2017.	Weekly start timetable.
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0030 MAH: Merck Sharp & Dohme Limited, Rapporteur: Daniela Melchiorri Request for Supplementary Information adopted on 06.07.2017.	Weekly start timetable.
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0031/G MAH: Merck Sharp & Dohme Limited, Rapporteur: Daniela Melchiorri Request for Supplementary Information adopted on 13.07.2017.	Weekly start timetable.
Myozyme - alglucosidase alfa - EMEA/H/C/000636/II/0063/G MAH: Genzyme Europe BV, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 20.07.2017.	Weekly start timetable.
Opdivo - nivolumab - EMEA/H/C/003985/II/0037/G MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jorge Camarero Jiménez	Weekly start timetable.

Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/II/0052/G MAH: Merck Serono Europe Limited, Rapporteur: Nithyanandan Nagercoil	Weekly start timetable.
Perjeta - pertuzumab - EMEA/H/C/002547/II/0030 MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 29.06.2017.	Weekly start timetable.
Praluent - alirocumab - EMEA/H/C/003882/II/0021/G MAH: sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege Request for Supplementary Information adopted on 18.05.2017.	Weekly start timetable.
Soliris - eculizumab - EMEA/H/C/000791/II/0100, Orphan MAH: Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez	Weekly start timetable.
Suliqua - insulin glargine / lixisenatide - EMEA/H/C/004243/II/0003/G MAH: sanofi-aventis groupe, Rapporteur: Kristina Dunder	Weekly start timetable.
Uptravi - selexipag - EMEA/H/C/003774/II/0010 MAH: Actelion Registration Limited, Rapporteur: Martina Weise	Weekly start timetable.
Voncento - human coagulation factor VIII/ human von willebrand factor - EMEA/H/C/002493/II/0030/G MAH: CSL Behring GmbH, Rapporteur: Paula Boudewina van Hennik	Weekly start timetable.
WS1084/G **Ganfort-EMEA/H/C/000668/WS1084/0028/G** **Lumigan-EMEA/H/C/000391/WS1084/0053/G** MAH: Allergan Pharmaceuticals Ireland, Lead Rapporteur: Hanne Lomholt Larsen	Weekly start timetable.
WS1177/G **Neulasta-EMEA/H/C/000420/WS1177/0097/G** **Ristempa-EMEA/H/C/003910/WS1177/0012/G** MAH: Amgen Europe B.V., Lead Rapporteur:	Weekly start timetable.

Robert James Hemmings	
WS1226 **Humalog-EMEA/H/C/000088/WS1226/0158** **Liprolog-EMEA/H/C/000393/WS1226/0121** MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Robert James Hemmings	Weekly start timetable.

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

Aranesp - darbepoetin alfa - EMEA/H/C/000332/II/0143 MAH: Amgen Europe B.V., Rapporteur: Martina Weise, "Update of section of section 4.8 the SmPC in order to add a warning on injection site bruise and haemorrhage with frequency unknown and to provide additional instructions on the use of the device in the PL following signal procedure EMEA/H/C000332/SDA/090 on cases of incorrect device use / device malfunction"	See also 9.1 in main agenda
Cinryze - C1-esterase inhibitor, human - EMEA/H/C/001207/II/0048 MAH: Shire Services BVBA, Rapporteur: Jan Mueller-Berghaus, Request for Supplementary Information adopted on 18.05.2017, 26.01.2017.	
Deltyba - delamanid - EMEA/H/C/002552/II/0021, Orphan MAH: Otsuka Novel Products GmbH, Rapporteur: Greg Markey, "Update of sections 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC to reflect the results of the final study report of 242-09-213 (A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Trial to Evaluate the Safety and Efficacy of Delamanid (OPC-67683) Administered Orally as 200 mg Total Daily Dose for Six Months in Patients With Pulmonary Sputum Culture-positive, Multidrug-resistant Tuberculosis), submitted to fulfill SOB-01. The Package leaflet is updated accordingly."	Weekly start timetable.
Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0034 MAH: Merck Sharp & Dohme Limited, Rapporteur: Paula Boudewina van Hennik, "Update of section 4.5 of the SmPC to add information pertaining to potential hCG	Weekly start timetable.

cross-reactivity resulting in a false positive pregnancy test. In addition, the MAH is taking the opportunity to implement changes in the annexes in line with the QRD templates (versions 9.1 and 10) and to propose combined versions of the SmPCs and Package Leaflets for the different strengths." Request for Supplementary Information adopted on 20.07.2017, 18.05.2017.	
Emend - aprepitant - EMEA/H/C/000527/II/0055 MAH: Merck Sharp & Dohme Limited, Rapporteur: Filip Josephson, "Update of sections 4.2 of the SmPC in order to replace the nomogram for the paediatric formulation provided in ml/kg with purely weight-based dosing instructions (in mg/kg) This is based on data that were already submitted as part of the paediatric application X/49. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0." Request for Supplementary Information adopted on 20.07.2017.	
Epclusa - sofosbuvir / velpatasvir - EMEA/H/C/004210/II/0012 MAH: Gilead Sciences International Limited, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to add non-clinical safety findings based on a 6-month carcinogenicity study conducted with velpatasvir in transgenic mice"	Weekly start timetable.
Eperzan - albiglutide - EMEA/H/C/002735/II/0031 MAH: GlaxoSmithKline Trading Services Limited, Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add angioedema with frequency 'rare' and to include a warning concerning hypersensitivity reactions in general. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder took the opportunity to implement minor editorial amendments throughout the Product Information." Request for Supplementary Information adopted on 22.06.2017, 21.04.2017.	Weekly start timetable.

Esbriet - pirfenidone - EMEA/H/C/002154/II/0043, Orphan MAH: Roche Registration Limited, Rapporteur: Greg Markey, "Update of sections 4.2 and 5.2 of the SmPC in order to update the existing safety information with revised recommendations for patients with moderate renal impairment based on the totality of data from clinical studies; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 29.06.2017.	Weekly start timetable.
Eviplera - emtricitabine / rilpivirine / tenofovir disoproxil - EMEA/H/C/002312/II/0082 MAH: Gilead Sciences International Limited, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC with Drug-Drug Interaction information for Eviplera based on the results from Study TMC435-TiDP16-C114; this is a Phase I, 2-panel, open-label, randomized, cross-over trial in healthy subjects to investigate the pharmacokinetic interaction between TMC435 and antiretroviral agents, TMC278 and tenofovir disoproxil fumarate (TDF), at steady-state. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor administrative changes in the SmPC and to update the list of local representatives in the Package Leaflet for Estonia, Latvia and Lithuania. Minor linguistic amendments (MLAs) have been implemented to the translations of the product information annexes: CS, DE, ES, FR, IS, IT, NL, NO, PT, SE and SK." Request for Supplementary Information adopted on 15.06.2017.	Weekly start timetable.
Forsteo - teriparatide - EMEA/H/C/000425/II/0046 MAH: Eli Lilly Nederland B.V., Rapporteur: Greg Markey, "Update of section 5.1 of the SmPC of the SmPC based on the results of study B3D-EW-GHDW (VERO), a phase 4 multi-centre, prospective, randomized, parallel, double-blind, double-dummy, active controlled study comparing the effect of teriparatide for injection versus risedronate on the incidence of fractures and low bone mass. In addition, the Marketing	Weekly start timetable.

authorisation holder (MAH) took the opportunity to correct the formatting throughout the Product Information and to bring Annex II in line with the latest QRD template version 10." Request for Supplementary Information adopted on 20.07.2017.	
Glivec - imatinib - EMEA/H/C/000406/II/0108 MAH: Novartis Europharm Ltd, Rapporteur: Jorge Camarero Jiménez, "Submission of the final CSR for study STI571A2405 - the International Study for Chronic Myeloid Leukemia (CML) in childhood and adolescents (I-CML-Ped Study). The provision of the study report addresses the post-authorisation measure MEA 162.8." Request for Supplementary Information adopted on 22.06.2017, 21.04.2017.	Weekly start timetable.
Imnovid - pomalidomide - EMEA/H/C/002682/II/0025, Orphan MAH: Celgene Europe Limited, Rapporteur: Robert James Hemmings, "Submission of a biomarker analysis report following a recommendation from CHMP in MAA procedure (EMEA/H/C/2682/0000) to present the biomarker analysis report based on clinical studies CC-4047-MM-008 and CC-4047-MM-010." Request for Supplementary Information adopted on 06.07.2017.	Weekly start timetable.
Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0103 MAH: Boehringer Ingelheim International GmbH, Rapporteur: Hanne Lomholt Larsen, "Update of sections 4.2, 4.4 and 5.1 to reflect the final study results of the phase IV study 1160.204 (The RE-CIRCUIT Trial), " A Randomised Evaluation of dabigatran etexilate Compared to warfar/n inpulmonaRy vein ablation: assessment of an uninterrupted periproCedUralant/coagulation sTrategy"" Request for Supplementary Information adopted on 20.07.2017.	
ReFacto AF - moroctocog alfa - EMEA/H/C/000232/II/0140 MAH: Pfizer Limited, Rapporteur: Hanne Lomholt Larsen, "Submission of the report 'The Immunogenicity of ReFacto AF in UK PUPs Who Started Treatment from 2010' prepared by the United Kingdom Haemophilia Centre Doctors'	Weekly start timetable.

Organisation (UKHCDO). This report is being submitted in the context of a post-approval commitment, MEA 115.1 ('The MAH commits to submit the CSR for "A Postauthorization Safety Surveillance Registry or ReFacto AF in Previously Untreated Patients (PUPs) in Usual Care Settings – study number 4435" and to initiate the registry'), as supporting evidence of the ongoing safety evaluation of ReFacto AF in PUPs with haemophilia A and with a specific focus on the development of inhibitors."	
Revatio - sildenafil - EMEA/H/C/000638/II/0077 MAH: Pfizer Limited, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.6 of the SmPC in order to revise the statement concerning the detection of sildenafil and its active metabolite in human mik and the potential for impact on the breastfed infact. The Package Leaflet and Labelling are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0."	Weekly start timetable.
Revestive - teduglutide - EMEA/H/C/002345/II/0037, Orphan MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Sinan B. Sarac, "Update of section 4.2 of the SmPC in order to amend the recommendation that treatment effect should be evaluated after 12 months (instead of the current recommended 6 months) based on literature references." Request for Supplementary Information adopted on 18.05.2017, 23.02.2017.	
Stelara - ustekinumab - EMEA/H/C/000958/II/0058 MAH: Janssen-Cilag International NV, Rapporteur: Greg Markey, "Update of section 4.8 of the SmPC in order to include Lower Respiratory Tract Infection as an Adverse Drug Reaction based on a comprehensive evaluation of safety information from the STELARA clinical studies database and post-marketing database, as well as available literature. The Package Leaflet is updated accordingly."	Weekly start timetable.
Strensiq - asfotase alfa - EMEA/H/C/003794/II/0019/G, Orphan	Weekly start timetable.

MAH: Alexion Europe SAS, Rapporteur: Greg Markey, “Update of section 5.1 of the SmPC in order to update information following final results from studies ENB-006-09 [A Randomized, Open-Label, Multicenter, Multinational, Dose-Ranging, Historical Control Study of the Safety,Efficacy, Pharmacokinetics, and Pharmacodynamics of Asfotase Alfa (Human Recombinant Tissue-Nonspecific Alkaline Phosphatase Fusion Protein) in Children with Hypophosphatasia (HPP)] (and its extension ENB-008-10 [Extension Study of Protocol ENB-006-09 Evaluating the Long-Term Safety and Efficacy of Asfotase Alfa (Human Recombinant Tissue-Nonspecific Alkaline Phosphatase Fusion Protein) in Children with Hypophosphatasia (HPP)]) and ENB-009-10 [A Randomized, Open-Label, Multicenter, Multinational, Dose-Ranging, Concurrent Control Study of the Safety, Efficacy, and Pharmacokinetics of ENB-0040 (Human Recombinant Tissue-Nonspecific Alkaline Phosphatase Fusion Protein) in Adolescents and Adults with Hypophosphatasia (HPP)] listed as an obligation in the Annex II (ANX002). In addition, the Marketing authorisation holder (MAH) took the opportunity to propose editorial changes for section 4.5 to better clarify the information provided.”	
Stribild - elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil - EMEA/H/C/002574/II/0083 MAH: Gilead Sciences International Limited, Rapporteur: Robert James Hemmings, “Update of sections 4.5 of the SmPC in order to add drug-drug interaction data from Study GS-US-292-1316; this is a Phase 1, Open-Label, Fixed Sequence Study Evaluating the Pharmacokinetics and Drug Interaction Potential Between Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Single-Table Regimen and Sertraline in Healthy Subjects. In addition, the Marketing authorisation holder (MAH) took the opportunity make administrative amendments to section 4.8 of the SmPC.”	Weekly start timetable.
Tecfidera - dimethyl fumarate - EMEA/H/C/002601/II/0041 MAH: Biogen Idec Ltd, Rapporteur: Martina	Weekly start timetable.

Weise, “Update of sections 4.4 and 4.8 of the SmPC in order to add anaphylactic reaction as a warning and as an adverse reaction with unknown frequency, based on post-marketing experience. The Package Leaflet is updated accordingly. In addition, the Biogen Idec Ltd took the opportunity to bring the PI in line with the latest QRD template version 10.”	
Tecfidera - dimethyl fumarate - EMEA/H/C/002601/II/0042 MAH: Biogen Idec Ltd, Rapporteur: Martina Weise, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the safety and efficacy information in the paediatric population based on the clinical study results from study 109MS202, listed as a category 3 study in the RMP; this is an open-label, multicentre, multidose study designed to assess the effect of Tecfidera on magnetic resonance imaging lesions and pharmacokinetics, safety and tolerability in paediatric population with relapsing-remitting multiple sclerosis. There are no updates proposed in the package leaflet or RMP.”	Weekly start timetable.
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0043/G MAH: Biogen Idec Ltd, Rapporteur: Martina Weise, “Submission of non-clinical study report for study PD-15-73: haemotoxicity study of dimethyl fumarate (DMF) and monomethyl fumarate (MMF) on T lymphocyte colony forming progenitor stem cells (T CFC) and T-cells derived from mononuclear cells (MNCs) of bone marrow and peripheral blood of humans and Cynomolgus monkeys. This submission is linked to a category 3 study in the RMP. Submission of non-clinical study report for study P00012-15-05: 3-Month repeated-dose oral (nasogastric) toxicity and toxicokinetic study of dimethyl fumarate (DMF) and hydroxyurea (HU) in cynomolgus monkeys. This submission is linked to a category 3 study in the RMP.”	Weekly start timetable.
TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0044 MAH: Biogen Idec Ltd, Rapporteur: Martina Weise, “Submission of the final report from study 109MS407: an interventional PASS listed as a	Weekly start timetable.

category 4 study in the RMP: a multicentre, open-label, single-arm study to evaluate gastrointestinal tolerability in subjects with relapsing-remitting multiple sclerosis receiving dimethyl fumarate (TOLERATE)."	
Toviaz - fesoterodine - EMEA/H/C/000723/II/0049 MAH: Pfizer Limited, Rapporteur: Concepcion Prieto Yerro, "Update of the SmPC sections 4.6 and 5.3 with revised information from reproductive toxicity studies in mice. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.0."	Weekly start timetable.
Translarna - ataluren - EMEA/H/C/002720/II/0036, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, "Update of section 4.5 of the SmPC in order to include information regarding the effects of ataluren on the pharmacokinetics of sensitive probe substrate of organic anion transporter 3 (OAT3)) following results from study PTC124-GD-037-HV (MEA015). In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce some editorial changes in the PI."	Weekly start timetable.
Trevicta - paliperidone - EMEA/H/C/004066/II/0011 MAH: Janssen-Cilag International NV, Informed Consent of Xeplion, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to update the safety information after assessment of study R092670-SCA-3004 (A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder). The Package Leaflet has been updated accordingly"	Weekly start timetable.
Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0138/G MAH: Gilead Sciences International Limited, Rapporteur: Greg Markey, "Submission of the final report from studies GS-US-276-0101 and GS-US-276-0105, listed as a category 3 studies in the RMP. GS-US-276-0101 - This is a A Prospective, Observational Study of Pregnancy Outcomes among Women Exposed to Truvada for PrEP Indication Nested in the Antiretroviral Pregnancy	Weekly start timetable.

Registry GS-US-276-0105 – This is a A Prospective, Observational, Drug Utilization Study of Subjects Taking Truvada for Pre-exposure Prophylaxis in the USA." Request for Supplementary Information adopted on 09.06.2017.	
Vargatef - nintedanib - EMEA/H/C/002569/II/0017 MAH: Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to add 'weight decreased' as a new adverse drug reaction based on a safety review of clinical trials and post-marketing data. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement a minor correction in the English product information, minor corrections to the Croatian, Danish, Dutch and Finnish translations and to bring section 4 of the Package Leaflet in line with QRD template version 10."	Weekly start timetable.
Vargatef - nintedanib - EMEA/H/C/002569/II/0018 MAH: Boehringer Ingelheim International GmbH, Rapporteur: Sinan B. Sarac, "Update of section 4.4 of the SmPC to amend the current warning on hepatic function to include that drug liver induced injury was associated with nintendanib administration, to include female sex as a factor of increased risk of liver enzyme elevations, update of section 4.8 of the SmPC to add 'drug-induced liver injury' (DILI) as new ADR and update of section 5.2 of the SmPC to amend the current information related to the mean exposure to nintedanib by race, based on a review of clinical trials and post-marketing data on DILI and on the exposure safety relationship between nintedanib plasma exposure and liver enzyme elevations, as requested by the PRAC as part of PSUSA/00010318/201611. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make some minor changes to section 4.4 and 4.8 of the SmPC."	Weekly start timetable.
Venclyxto - venetoclax - EMEA/H/C/004106/II/0003, Orphan MAH: AbbVie Limited, Rapporteur: Filip Josephson, "Submission of the final report from study R&D 16/1398: Assessment of Cytochrome	Weekly start timetable.

P450 mRNA Induction by A-1195425 in Cultured Human Hepatocytes to evaluate CYP1A2 and CYP2B6 induction response which is included as a Post Authorisation Measure (Category 3) in RMP 2.0." Request for Supplementary Information adopted on 15.06.2017.	
Xeljanz - tofacitinib - EMEA/H/C/004214/II/0003 MAH: Pfizer Limited, Rapporteur: Robert James Hemmings, "Submission of 2 transported inhibition studies evaluating tofacitinib for its potential to inhibit organic anion transporter (OAT) 1, OAT3 and to interact with Human MRP2 Efflux (ABC) Transporter in fulfilment of the Recommendation dated 26 January 2017."	Weekly start timetable.
Xeplion - paliperidone - EMEA/H/C/002105/II/0035 MAH: Janssen-Cilag International NV, Rapporteur: Kristina Dunder, "Update of section 4.2 of the SmPC in order to add a dosage conversion table to provide guidance for healthcare professionals when switching patients from paliperidone ER tablets to paliperidone palmitate long acting injection (PP1M). The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 20.07.2017.	
XGEVA - denosumab - EMEA/H/C/002173/II/0054 MAH: Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of an updated RMP version 25 in order to remove cataracts from the list of potential risks associated with denosumab therapy based on the results of study 20080560 (Multicentre, randomized, double blind, placebo-controlled study in men with nonmetastatic prostate cancer receiving androgen deprivation therapy cataract development and progression study using a slit-lamp-based evaluation system (Lens Opacities Classification System III (LOCS III))." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 09.06.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Xultophy - insulin degludec / liraglutide - EMEA/H/C/002647/II/0021 MAH: Novo Nordisk A/S, Rapporteur: Kristina	Weekly start timetable.

Dunder, “Update of section 5.1 of the SmPC in order to reflect data for transfer from insulin glargine U100 to Xultophy as compared to a basal-bolus regimen. The update is based on data from the clinical trial NN9068-4185: ”A clinical trial comparing efficacy and safety of insulin degludec/liraglutide (IDegLira) versus basal-bolus therapy in subjects with type 2 diabetes mellitus”. The MAH has taken the opportunity to make minor editorial and formatting changes throughout the Annexes.”	
Xyrem - sodium oxybate - EMEA/H/C/000593/II/0067/G MAH: UCB Pharma Limited, Rapporteur: Bruno Sepodes, “Update of section 4.8 of the SmPC in order to add the adverse reactions “increased libido” and “seborrhea” with an unknown frequency. Update of section 4.6 of the SmPC in order to amend the information about breast-feeding. The Package Leaflet is updated accordingly.”	Weekly start timetable.
Yondelis - trabectedin - EMEA/H/C/000773/II/0051, Orphan MAH: Pharma Mar, S.A., Rapporteur: Sinan B. Sarac, “Update of sections 4.2, 4.4 and 5.2 of the SmPC in order to update the safety information following submission of study report ET743-OVC-1004 “An Open-Label, Multicenter, Pharmacokinetic Study of Trabected in in Subjects with Advanced Malignancies and Hepatic Dysfunction” listed in the RMP. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes in the SmPC.” Request for Supplementary Information adopted on 22.06.2017, 21.04.2017.	Weekly start timetable.
Zyclara - imiquimod - EMEA/H/C/002387/II/0013 MAH: Meda AB, Rapporteur: Nithyanandan Nagercoil, “Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to add data on the clinical experience gained with study X-03016-3284 (LEIDA 2) and a meta-analysis of X-03016-3271 and X-03016-3284. The MAH took the opportunity to update the details of local representatives in the PIL.”	

Request for Supplementary Information adopted on 22.06.2017.	
Zykadia - ceritinib - EMEA/H/C/003819/II/0016 MAH: Novartis Europharm Ltd, Rapporteur: Jorge Camarero Jiménez, "Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to include amendments to the posology in hepatically impaired patients and update the safety information, respectively. The updates are based on the results from the hepatic function Study CLDK378A2110 which evaluated the PK, safety and tolerability of a single oral dose of ceritinib in subjects with varying degrees of impaired hepatic function and results from physiology-based pharmacokinetic (PBPK) modeling at steady-state. Submission of the Report for Study A2110 fulfils MEA 001 for Zykadia."	
WS1137 **Lyrica-EMEA/H/C/000546/WS1137/0087** **Pregabalin** **Pfizer-EMEA/H/C/003880/WS1137/0017** MAH: Pfizer Limited, Lead Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.8 and 5.1 of the SmPC in order to reflect final results from paediatric study A0081041: "A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Efficacy and Safety of Pregabalin as Adjunctive Therapy in Children 4-16 Years of Age with Partial Onset Seizures"." Request for Supplementary Information adopted on 08.05.2017.	Weekly start timetable.
WS1203/G **Docetaxel** **Winthrop-EMEA/H/C/000808/WS1203/0053/G** **Taxotere-EMEA/H/C/000073/WS1203/0128/G** MAH: Aventis Pharma S.A., Lead Rapporteur: Alexandre Moreau, "1) C.I.4 (type II) Update of sections 4.4 and 4.8 of the SmPC to add information about ventricular arrhythmia including ventricular tachycardia based on review of the MAH's global pharmacovigilance database and scientific literature. The Package Leaflet is updated accordingly. 2) C.I.4 (type II) Update of section 4.8 of the	Weekly start timetable.

SmPC on the 10-year follow-up data for studies TAX316 and GEICAM 9805 studies in order to clarify the persisting events in the follow-up periods."	
WS1205 **Descovy-EMEA/H/C/004094/WS1205/0020** **Genvoya-EMEA/H/C/004042/WS1205/0034** **Odefsey-EMEA/H/C/004156/WS1205/0018** MAH: Gilead Sciences International Limited, Lead Rapporteur: Robert James Hemmings, "Update of section 4.5 of the SmPC in order to provide the final study report for the in vitro study AD-120-2045; this is a non-clinical study on the Effect of Xanthine Oxidase Inhibitors on Metabolism of Tenofovir alafenamide fumarate in Primary Human Hepatocytes. This study is listed in their respective Risk Management Plans (RMPs) as an additional pharmacovigilance activity (Category 3) (Genvoya: MEA 006; Descovy: MEA 004; Odefsey: MEA 007). The requested worksharing procedure proposed amendments to the Summary of Product Characteristics."	Weekly start timetable.
WS1218 **Brimica Genuair-EMEA/H/C/003969/WS1218/0015** **Duaklir Genuair-EMEA/H/C/003745/WS1218/0015** MAH: AstraZeneca AB, Lead Rapporteur: Nithyanandan Nagercoil, "Update of section 5.1 of the SmPC in order to update information following results from study M-40464-33 (A Multiple Dose, Randomised, Double-Blind, Placebo Controlled, Parallel Clinical Trial to Assess the Effect of Aclidinium Bromide/Formoterol Fumarate Fixed-Dose Combination on Lung Hyperinflation, Exercise Capacity and Physical Activity in Patients with Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD))"	Weekly start timetable.
WS1219 **Brimica**	Weekly start timetable.

Genuair-EMEA/H/C/003969/WS1219/0014 **Duaklir Genuair-EMEA/H/C/003745/WS1219/0014** MAH: AstraZeneca AB, Lead Rapporteur: Nithyanandan Nagercoil, “Update of section 5.2 of the SmPC in order to update information based on results from study KRP-AB1102F-302 [KRP-AB1102F Phase II Clinical Pharmacology Study - An Investigation into the Pharmacokinetics upon Repeated Administration of KRP-AB1102F to COPD Patients as Subjects]. In addition, the Worksharing applicant (WSA) took the opportunity to update footnotes of the table in section 4.8 as requested during PSUR procedure EMEA/H/C/PSUSA/00010307/201511 and to amend annex II following request from procedure EMEA/H/C/PSA/S/0017.”	
WS1225/G **Exviera-EMEA/H/C/003837/WS1225/0031/G** **Viekirax-EMEA/H/C/003839/WS1225/0035/G** MAH: AbbVie Limited, Lead Rapporteur: Filip Josephson, “Submission of the final reports for two phase IIIb studies (studies M14-226 and M15-461) listed as category 3 studies in the RMP. These are open-label studies evaluating the safety and efficacy of ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin in hepatitis C virus infected patients with several renal impairment or end-stage renal disease with or without compensated cirrhosis.”	Weekly start timetable.
WS1234/G **Genvoya-EMEA/H/C/004042/WS1234/0036/G** **Stribild-EMEA/H/C/002574/WS1234/0084/G** **Tybost-EMEA/H/C/002572/WS1234/0038/G** MAH: Gilead Sciences International Limited, Lead Rapporteur: Robert James Hemmings, “Update of sections 4.4 and 4.5 of the SmPC based on data from the following Pharamacology Studies (GS-US-216-1008 and GS-US-216-4032). Study GS-US-216-1008 is a Phase 1, randomized, fixed-sequence, open -label,	Weekly start timetable.

single_and multiple -dose, multiple-cohort, single-center study that evaluated the drug interaction potential between darunavir (DRV)+COBI, atazanavir (ATV)+COBI, or Genvoya and the 3 hydroxy-3-methylglutaryl-coenzyme A (HMG CoA) reductase inhibitors rosuvastatin and/or atorvastatin. Study GS-US-216-4032 is an open-label, single -center, multiple-cohort, fixed_sequence, Phase 1 study that evaluated the effect of DRV+COBI or ATV+COBI on the pharmacokinetic (PK) of a representative hormonal contraceptive medication, drospirenone/ethinyl estradiol. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to make administrative changes to the PI of all three products and update the list of local representatives for Estonia, Latvia and Lithuania for Tybost and Stribild. Minor linguistic amendments were made to the Product Information."	

B.5.3. CHMP-PRAC assessed procedures

Abasaglar - insulin glargine - EMEA/H/C/002835/II/0014 MAH: Eli Lilly Regional Operations GmbH, Rapporteur: Robert James Hemmings, PRAC Rapporteur: Carmela Macchiarulo, "Submission of the final report from study I4L-MC-ABER(ABER). This is a Prospective, Randomized, Open-Label Comparison of a Long-Acting Basal Insulin Analog LY2963016 to LANTUS® in Adult Patients with Type 2 Diabetes Mellitus: the ELEMENT 5 Study. This study was conducted in non European countries. This study replaces the cancelled studies that were planned to be conducted in China and other countries and that were described in the RMP. An updated RMP version 1.6 is submitted accordingly." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 09.06.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Adcetris - brentuximab vedotin - EMEA/H/C/002455/II/0049, Orphan	Weekly start timetable.

MAH: Takeda Pharma A/S, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, “Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC with data from study C25002; a phase 1/2 study of brentuximab vedotln (SGN-35) in paediatric patients with relapsed or refractory systemic anaplastic large cell lymphoma or hodgkin lymphoma (listed in the agreed PIP covering the conditions of Hodgkin lymphoma and anaplastic large cell lymphoma for ADCETRIS (EMEA-000980-PIP01-10-M04)).
An updated RMP version 11.0 was provided as part of the application.”
Request for Supplementary Information adopted on 01.09.2017.

Adenuric - febuxostat - EMEA/H/C/000777/II/0047

MAH: Menarini International Operations Luxembourg S.A., Rapporteur: Andrea Laslop, PRAC Rapporteur: Jan Neuhauser, “Update of sections 4.4 and 4.5 of the SmPC in order to reflect the results of preclinical study MRPO-2015-PKM-005 “Pharmacokinetic of azathioprine in the rat after one-week daily oral treatment at three different dosages and with the concomitant oral administration of febuxostat or allopurinol" and clinical study REP-POPPK-MRP-2015-PKM-005 “Population Pharmacokinetic analysis from study titled Pharmacokinetic of azathioprine in the rat after one-week daily oral treatment at three different dosages and with the concomitant oral administration of febuxostat or allopurinol”, investigating the drug-drug interaction with azathioprine when co-administered with febuxostat.

The RMP version 6.0 has also been submitted.

In addition, the MAH took the opportunity to correct the typing errors and to bring the PI in line with the latest QRD template version 10.”

CABOMETYX - cabozantinib - EMEA/H/C/004163/II/0002/G

MAH: Ipsen Pharma, Rapporteur: Robert James Hemmings, PRAC Rapporteur: Sabine Straus, “1) C.I.4 (type II)
Update of section 5.1 of the SmPC to reflect the final study results from clinical study XL184-308: A Phase 3, Randomized, Controlled Study of Cabozantinib (XL184) vs Everolimus in Subjects

with Metastatic Renal Cell Carcinoma that has Progressed after Prior VEGFR Tyrosine Kinase Inhibitor Therapy, to fulfil the condition to the marketing authorisation listed as a PAES in the Annex II. The RMP version 2.0 has also been submitted. 2) C.I.4 (type II) Update of section 5.3 of the SmPC to reflect the final study results from non-clinical study XL184-NC-036: 104-Week Oral Gavage Carcinogenicity and Toxicokinetic Study with Cabozantinib (XL184) in Rats. The RMP version 2.0 has also been submitted. 3) C.I.3.z (type IB) Update of section 4.5 of the SmPC to implement the wording agreed by the PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/10180/201603."	
Cerdelga - eliglustat - EMEA/H/C/003724/II/0013, Orphan MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Dolores Montero Corominas, "Update of section 4.8. of the SmPC in order to amend the safety information based on the analysis of Adverse Events from the following clinical trials: GZGD00304 (Phase 2), GZGD02507 (ENGAGE), GZGD02607 (ENCORE) and GZGD03109 (EDGE) to address post-authorisation MEA011.1 which is included in the current approved Risk Management Plan. Update of the labelling in order to reflect the instructions on use for the sleeve of the intermediate packaging of the single blister. The RMP version 4.0 has also been submitted." Opinion adopted on 01.09.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0085 MAH: GlaxoSmithkline Biologicals SA, Rapporteur: Bart Van der Schueren, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jean-Michel Dogné, "Submission of Study EPI-HPV-069, a meta-analysis assessing the risk of three autoimmune diseases following vaccination with Cervarix: autoimmune thyroiditis (AIT), Guillain-Barre Syndrome (GBS) and Inflammatory Bowel Disease (IBD). The	

EPI-HPV-069 study is a post-licensure commitment to the EMA (PASS register number EUPAS13332). As part of this submission, an updated RMP (version 18) is provided, including changes related to the EPI-HPV-069 meta-analysis submitted and minor updates related to other studies." Request for Supplementary Information adopted on 18.05.2017, 15.12.2016.	
Cimzia - certolizumab pegol - EMEA/H/C/001037/II/0060 MAH: UCB Pharma S.A., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.6 of the SmPC in order to update the information on pregnancy and lactation based on two pharmacokinetics studies evaluation the transfer of Cimzia into breastmilk and via the placenta (UP0016 and UP0017). The Package Leaflet is updated accordingly. The RMP version 12 has also been submitted." Request for Supplementary Information adopted on 22.06.2017.	
Eperzan - albiglutide - EMEA/H/C/002735/II/0033 MAH: GlaxoSmithKline Trading Services Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Julie Williams, "Update of the Package Leaflet in order to amend the layout and content of the Instructions for Use (IFU). In addition, the RMP version 8 has also been submitted to implement additional pharmacovigilance and risk minimisation activities addressing the safety concern of "medication errors/device issue potentially leading to lack of efficacy or inadequate diabetes control"." Opinion adopted on 01.09.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
IBRANCE - palbociclib - EMEA/H/C/003853/II/0007 MAH: Pfizer Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Torbjorn Callreus, "Update of sections 4.2, 4.4 and 5.2 of the SmPC to reflect the results of studies A5481013 and A5481014. The mentioned studies provide information of the impact of hepatic impairment (Study A5481013) on the PK of a single oral dose of 75 mg palbociclib and the impact of renal impairment (Study A5481014) on the PK of a single oral dose of 125 mg palbociclib both	

administered under fed conditions to subjects with varying degrees of hepatic function or renal function. The RMP (version 1.4) is proposed to be amended to reflect the completion of these studies."	
Increlex - mecasermin - EMEA/H/C/000704/II/0044/G, Orphan MAH: Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Update of section 4.4 of the SmPC in order to update the warning regarding antibody response to injected IGF-1. Submission of an updated RMP version 9 , including the educational materials, to update the instructions for antibody testing and improve wording and advices." Request for Supplementary Information adopted on 22.06.2017, 23.02.2017.	
Mozobil - plerixafor - EMEA/H/C/001030/II/0032, Orphan MAH: Genzyme Europe BV, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "Update of sections 4.2 and 5.2 of the SmPC in order to reflect the results of the completed study MSC12830 (MOZ11809), entitled "A Phase 4, Multicenter, Randomized, Comparator Trial Evaluating the Standard Weight-Based Dose (0.24 mg/kg) Compared to a Fixed Dose (20 mg) of Plerixafor Injection in Combination with G-CSF to Mobilize and Collect ≥5 x 106 CD34+ cells/kg in ≤4 Days and to Evaluate the Difference in Total Systemic Exposure in Patients with Non-Hodgkin's Lymphoma Weighing ≤70 kg" listed as a category 3 study in the RMP. The Package Leaflet is updated accordingly. The RMP version 9.0 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." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 06.07.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/II/0017 MAH: Orexigen Therapeutics Ireland Limited, Rapporteur: Hanne Lomholt Larsen, PRAC	

Rapporteur: Martin Huber, “Submission of the final report from phase I study NaltrexBuprop-1001 (TQT) to evaluate the potential effect of Naltrexone and Bupropion extended-release combination on cardiac repolarization in healthy subjects and updated RMP to include study NaltrexBuprop-1001 but also studies recently completed (NB-CVOT, NaltrexBuprop-4001, NaltrexBuprop-1004 and NB-404). The MAH also took the opportunity to include throughout the RMP references to the PASS protocols currently under discussion at the PRAC.” Request for Supplementary Information adopted on 22.06.2017.	
Nulojix - belatacept - EMEA/H/C/002098/II/0045 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, “Update of sections 4.4 and 4.8 of the SmPC in order to add a warning and update the safety information on the risk of venous thrombosis of the renal allograft when anti-thymocyte globulin (ATG) and belatacept are coadministered (at the same or nearly the same time) in patients with other predisposing risk factors for thrombosis. The update is based on a review of the potential increased risk for allograft thrombosis with belatacept given in close temporal relation to Thymoglobulin, as requested during assessment of PSUR 8 (EMEA/H/C/PSUSA/00000311/201606). In addition, the MAH took the opportunity update section 6.6 “Special precautions for disposal and other handling” of the SmPC and the “Information for healthcare professionals (HCPs)”in the Package Leaflet (PL) with additional safety instructions for the co-administration of Belatacept. Submission of this variation application fulfils LEG 021 for Nulojix. Consistently with the above, RMP version 14 has also been submitted, including addition of the potential risk of venous thrombosis of the allograft when ATG and belatacept are coadministered in patients with other	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

predisposing risk factors for thrombosis and a number of administrative changes."
Opinion adopted on 01.09.2017.

Nuwiq - simoctocog alfa - EMEA/H/C/002813/II/0017/G

MAH: Octapharma AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, "C.I.4: Update of sections 4.2, 4.8 and 5.1 of the SmPC to reflect available data from Previously Untreated Patients (PUP) from GENA-05 (interim report) study. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the Product Information throughout to bring it in line with the Core summary of product characteristics for human plasma-derived and recombinant coagulation factor VIII products (EMA/CHMP/BPWP/1619/1999 rev. 2) and with the QRD version 10 (affects labelling only). Moreover the MAH is combining the SmPC for all strengths and updating Annex A with detailed information on the packaging.

C.I.11: Submission of an updated RMP version 8.0 in order to align the content in a single harmonised worldwide version for simoctocog alfa (rFVIII)."
Request for Supplementary Information adopted on 22.06.2017, 21.04.2017.

Olumiant - baricitinib - EMEA/H/C/004085/II/0002

MAH: Eli Lilly Nederland B.V., Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Patrick Batty, "Update of sections 4.5 and 5.2 of the SmPC, based on the final study report of in vitro study to investigate the inhibitory effect of baricitinib on the organic anion transporter 2 (OAT2) in fulfilment of PAM (MEA 001). The updated RMP version 3.0 has been submitted as part of this application."

Opdivo - nivolumab - EMEA/H/C/003985/II/0032

MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Variations that affect the PI
Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to add administration guidance

and update the safety information based on final results from study…(include study CA209067 listed as a imposed PAES in the Annex II; this is an interventional randomized, double-blind study in subjects treated with nivolumab monotherapy, ipilimumab monotherapy and nivolumab combined with ipilimumab; The Package Leaflet is updated accordingly. The RMP version 5.8 has also been submitted. This submission fulfils ANX 016 and Annex II is updated accordingly In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial and formatting revisions in the PI." Request for Supplementary Information adopted on 18.05.2017.	
Opdivo - nivolumab - EMEA/H/C/003985/II/0038 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 4.8 of the SmPC with longer follow-up for subjects proceeding to allogeneic transplant following nivolumab treatment, of section 5.1 of the SmPC with efficacy data from longer follow-up based on final results from study CA209205 listed as a PAES in the Annex II; this is a Phase 2, non-comparative, multi-cohort, single-arm, open-label study of nivolumab (BMS-936558) in cHL subjects after failure of ASCT Annex II is updated to remove the commitment. Version 7.5 of the RMP has been submitted."	
Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/II/0021 MAH: Vertex Pharmaceuticals (Europe) Ltd., Rapporteur: Nithyanandan Nagercoil, PRAC Rapporteur: Almath Spooner, "Update of section 4.8 of the SmPC in order to add information on respiratory events based on final results from study Study VX14-809-106 (Study 106), a Phase 3b, open-label study to evaluate safety and tolerability of lumacaftor and ivacaftor combination therapy in subjects 12 years and older with Cystic Fibrosis and advanced lung disease, homozygous for the F508del-CFTR Mutation. Efficacy was evaluated as a secondary objective. This study report is being submitted to fulfil MEA 002.	

An updated RMP (version 3.2) has also been submitted." Request for Supplementary Information adopted on 22.06.2017.	
Praxbind - idarucizumab - EMEA/H/C/003986/II/0007 MAH: Boehringer Ingelheim International GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to reflect the final results from a study 1321.3 titled "A Phase III, case series clinical study of the reversal of the anticoagulant effects of dabigatran by intravenous administration of 5.0 g idarucizumab (BI 655075) in patients treated with dabigatran etexilate who have uncontrolled bleeding or require emergency surgery or procedures. RE-VERSE-AD (A study of the RE-VERSal Effects of Idarucizumab on Active Dabigatran) trial" listed as a category 3 study in the RMP (MEA 001). The RMP version 3.0 has also been submitted. In addition, the Marketing authorisation holder took the opportunity to update the immunogenicity section in 5.1 of SmPC and to bring the PI in line with the latest QRD template version 10." Request for Supplementary Information adopted on 20.07.2017.	
Prolia - denosumab - EMEA/H/C/001120/II/0069 MAH: Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.8 of the SmPC and PL in order to remove cataracts from the list of adverse reaction associated with denosumab therapy based on final data from study 20080560, a category 3 study in the RMP (multicentre, randomized, double blind, placebo-controlled study in men with non-metastatic prostate cancer receiving androgen deprivation therapy cataract development and progression study using a slit-lamp-based evaluation system (Lens Opacities Classification System III (LOCS III).) In addition, the RMP has been updated to remove the important potential risk 'cataract in men with prostate cancer receiving androgen deprivation therapy'." Opinion adopted on 01.09.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 09.06.2017.	
Remicade - infliximab - EMEA/H/C/000240/II/0204 MAH: Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final registry report from the C0168T71 study (a review and analysis of birth outcomes from Swedish, Danish and Finish medical birth registers) and an evaluation of pregnancy data from multiple sources. Section 4.6 of the SmPC, relevant section of the PL and the RMP version 13.2 has been updated to reflect the study results. The MAH has also taken the opportunity to bring the product in line with the QRD template and update the local representative section of the PL." Request for Supplementary Information adopted on 22.06.2017, 23.03.2017.	
Reyataz - atazanavir / atazanavir sulfate - EMEA/H/C/000494/II/0111 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Caroline Laborde, "Update of sections 4.4 and 4.8 of the SmPC to add a warning on chronic kidney disease observed in HIV infected patients during treatment with atazanavir (with or without ritonavir). This update is based on a review of the MAH safety database, a cohort study of patients with laboratory values from a large US administrative claims database and a review of published scientific literature. The Package Leaflet is updated accordingly. The RMP version 12.0 has also been submitted." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 09.06.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Soliris - eculizumab - EMEA/H/C/000791/II/0098, Orphan MAH: Alexion Europe SAS, Rapporteur: Jorge Camarero Jiménez, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.6 and 5.3 of the SmPC in order to update the safety information related to pregnancy, lactation and fertility following the review of data in PSUR 13 and 14. Annex II and the Package Leaflet are updated accordingly. The RMP version 17 has also been submitted with	

updated information on pregnancy and lactation and fertility."	
Spedra - avanafil - EMEA/H/C/002581/II/0027/G MAH: Menarini International Operations Luxembourg S.A., Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Dolores Montero Corominas, "Update of section 4.4. to reflect the results of clinical study TA-402 "A Double-Blind, Randomized, Placebo-Controlled, Single-Dose, Parallel Study to Assess the Effects of Avanafil on Multiple Parameters of Vision, including, but Not Limited to Visual Acuity, Intraocular Pressure, Pupillometry, and Color Vision Discrimination, in Healthy Male Subjects). Update of section 4.6. of the SmPC in order to reflect the results of clinical study TA-401 "A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Clinical Trial of the Effect of Avanafil on Spermatogenesis in Healthy Adult Males and Adult Males with Mild Erectile Dysfunction". The Package Leaflet is updated accordingly. The RMP version 5.1has also been submitted. In addition, the MAH took the opportunity to make an editorial correction on the approved SmPc by adding the missing adverse reaction epistaxis from the tabulated list of adverse reactions reported in section 4.8. Additionally, the MAH took the opportunity of this variation to align the information included in Section 3 "How to take Spedra" in the Package Leaflet to section 4.2 "Posology" in the SmPC. Some additional minor amendments, due to translation mistakes are proposed for the French Product Information."	
Tresiba - insulin degludec - EMEA/H/C/002498/II/0028 MAH: Novo Nordisk A/S, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, "Update of section 5.1 of the SmPC based on new clinical data from a cardiovascular outcome trial EX1250-4080 (DEVOTE) conducted for Tresiba. DEVOTE was a randomised, double-blind and event-driven clinical trial with a median duration of 2 years comparing the cardiovascular safety of Tresiba versus insulin glargine (100 units/mL) in patients with type 2 diabetes mellitus at high risk	Weekly start timetable.

of cardiovascular events.
The RMP version 8 has also been submitted, with updates consequent to the data in support of the application."
Request for Supplementary Information adopted on 01.09.2017.

Wakix - pitolisant - EMEA/H/C/002616/II/0004/G, Orphan

MAH: BIOPROJET PHARMA, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Kirsti Villikka, "Update of sections 4.4, 4.5, 4.6 and 5.2 of the SmPC based on the final CSR of study P15-02 (to assess the mass balance recovery, metabolite profile and metabolite identification of 14C-pitolisant at steady state conditions, in healthy CYP2D6 phenotyped subjects), P14-07 (to evaluate pharmacokinetic interaction of pitolisant with sodium oxybate and modafinil in healthy male volunteers) and P15-15 (to evaluate pharmacokinetic interaction of pitolisant with CYP3A4 substrates (midazolam), CYP2B6 substrates (bupropion), UGT2B7 inhibotors (probenecide)) in fulfilment of PAM (MEA 02, 03 and 04). The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial change in section 4.8 of the SmPC. Moreover, updated RMP version 5.0 has been submitted as part of this application."
Request for Supplementary Information adopted on 22.06.2017, 23.03.2017.

Xarelto - rivaroxaban - EMEA/H/C/000944/II/0052/G

MAH: Bayer AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, "Group of variations consisting of:
1) C.1.4. To add the authorised indications "Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults" to Xarelto 10 mg based on Einstein Choice trial (A randomised phase III clinical study to evaluate efficacy and safety of Reduced-dosed rivaroxaban and standard-dosed rivaroxaban versus ASA in the long-term prevention of recurrent symptomatic venous thromboembolism in patients with symptomatic deep-vein thrombosis and/or pulmonary embolism) in section 4.1 of the SmPC 10 mg.
Consequently:

- Changes in sections 4.2, 4.8 and 5.1 for Xarelto 10mg, 15mg and 20 mg are made in order to update the posology, efficacy and safety information.
- Annex III is updated to include Xarelto 10 mg into Patient alert card to support management of bleeding when the 10 mg is treated for long-term prevention of recurrent VTE
- RMP (version 10) is updated
2) B.II.e.5.a.1- to add a new pack size of 14 film coated tablets in blister (PP/alu) for Xarelto 10 mg
3) B.II.e.5.a.1- to add a new pack size of 28 film coated tablets in blister (PP/alu) for Xarelto 10 mg
4) B.II.e.5.a.1- to add a new pack size of 98 film coated tablets in blister (PP/alu) for Xarelto 10 mg
5) B.II.e.1.b.1 to change immediate packaging of the finished product for 10 mg film coated tablets to introduce HDPE bottle with screw cap including new presentation (pack containing 100 film coated tablets for 10 mg strength)
6) C.1.4 To add information on interactions with SSRIs and SNRIs in section 4.5 and a related warning in section 4.4 of the SmPC based on post-hoc analyses to investigate bleeding risk for rivaroxaban in patients with and without use of SSRI or SNRIs from the pivotal studies.
In addition, MedDRA terminology is updated in the adverse drug reactions table in section 4.8 of the SmPC
7) C.1.11.z To delete from the summary of safety concerns: “Patients undergoing major orthopaedic surgery other than elective hip or knee replacement surgery” and “Remedial pro-coagulant therapy for excessive haemorrhage”. Part II - Modules SVIII: Summary of the safety concerns, Part III, Section 1 Safety Concerns and overview of planned pharmacovigilance action were amended accordingly. In addition, Part II, Safety Specification, module SIV, Populations not studied in clinical trials: “Patients undergoing major orthopaedic surgery other than elective hip or knee replacement surgery” and “Remedial pro-coagulant therapy for excessive haemorrhage” was updated.

Request for Supplementary Information adopted on 20.07.2017, 18.05.2017.

Yervoy - ipilimumab - EMEA/H/C/002213/II/0042 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "Update of sections 4.4, 4.8 and 5.1 of the SmPC to reflect the final results of study CA184-169, a randomized double-blind phase III study of ipilimumab administered at 3 mg/kg versus at 10 mg/kg in subjects previously treated or untreated with unresectable or metastatic melanoma, in order to fulfil ANX 014.1. The MAH also provided with this variation application efficacy and safety data from study CA184-169 in two subgroups: female ≥ 50 years of age and with brain metastases in order to fulfil MEA 015.1. Annex II.D and the RMP (version 14.0) are updated accordingly. In addition the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to include some editorial changes and correct some typos throughout the product information, and to bring the product information in line with the latest QRD template version 10." Request for Supplementary Information adopted on 01.09.2017, 05.05.2017.	Weekly start timetable.
Yervoy - ipilimumab - EMEA/H/C/002213/II/0047/G MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "Update of section 4.4 to revised the current warning on concurrent administration with vemurafenib to enhance awareness on the potential of hypersensitivity reactions when ipilimumab is used sequentially with vemurafenib as requested by the PRAC following the assessment of PSUSA/00009200/201603. Update of sections 4.8 of the SmPC to amend the frequency of the adverse drug reaction 'Vogt-Konyanagi-Haranda syndrome' from 'not know' to 'very rare'. The RMP (version 16) has been updated accordingly.]In addition, the Marketing authorisation holder (MAH) took the opportunity to implement some editorial changes to sections 4.2 and 4.4 of the SmPC to update the dose modification information for hepatotoxicity management guidelines in line with National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

recommendations (version 4)." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 09.06.2017.	
WS1026 **Rasilez-EMEA/H/C/000780/WS1026/0110** **Rasilez** **HCT-EMEA/H/C/000964/WS1026/0080** MAH: Noden Pharma DAC, Lead Rapporteur: Daniela Melchiorri, Lead PRAC Rapporteur: Carmela Macchiarulo, "Update of section 5.1 of the SmPC in order to reflect the results of study SPP100F2301 (ATMOSPHERE) a multicenter, randomized, doubleblind, parallel group, active-controlled study to evaluate the efficacy and safety of both aliskiren monotherapy and aliskiren/enalapril combination therapy compared to enalapril monotherapy, on morbidity and mortality in patients with chronic heart failure (NYHA Class II - IV). The RMP (v 13) has also been updated to reflect the study results." Request for Supplementary Information adopted on 22.06.2017, 21.04.2017, 15.12.2016.	
WS1117/G **Stocrin-EMEA/H/C/000250/WS1117/0110/G** **Sustiva-EMEA/H/C/000249/WS1117/0139/G** MAH: Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, "C.I.4 (Type II) - Update of sections 4.4, 4.5 and 5.1 of the SmPC in order to add a warning and update the safety information on QTc prolongation based on the final results from study AI266959; this is an interventional study to determine the concentration-electrocardiographic effects of efavirenz in healthy subjects enriched for cyp2b6 polymorphisms; the Package Leaflet is updated accordingly. The RMP version 8 has also been submitted. C.I.4 (Type II) – Update of sections 4.4 and 4.8 to add catatonia as a Psychiatric symptom following an assessment of catatonia cases reported in the literature and via the United States (US) Food and Drug Administration Adverse Event Reporting System (FAERS)." Request for Supplementary Information adopted	Weekly start timetable.

on 01.09.2017, 06.07.2017, 06.04.2017.	
WS1158/G **Humalog-EMEA/H/C/000088/WS1158/0154/G** **Liprolog-EMEA/H/C/000393/WS1158/0117/G** MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Robert James Hemmings, Lead PRAC Rapporteur: Julie Williams Request for Supplementary Information adopted on 09.06.2017, 05.05.2017.	Weekly start timetable.
WS1168 **AZILECT-EMEA/H/C/000574/WS1168/0077** **Rasagiline ratiopharm-EMEA/H/C/003957/WS1168/0010** MAH: Teva B.V., Lead Rapporteur: Bruno Sepodes, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, “Update of sections 4.4, 4.7 and 4.8 to include a new warning on excessive daytime sleepiness and sudden sleep onset episodes, update of section 4.9 to remove ‘dysphoria’ as a symptom reported following overdose of rasagiline based on a CCDS update. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the Worksharing applicant (WSA) took the opportunity to make editorial changes throughout the PI, to correct the invented name for Rasagiline Ratiopharm in the Czech annexes and to bring the PI in line with the latest QRD template version 10.” Opinion adopted on 01.09.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1180 **Corlentor-EMEA/H/C/000598/WS1180/0047** **Ivabradine Anpharm-EMEA/H/C/004187/WS1180/0006** **Procoralan-EMEA/H/C/000597/WS1180/0046** MAH: Les Laboratoires Servier, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, “Update to the section 4.8 of the SmPC with new ADRs: Ventricular tachycardia, Ventricular fibrillation and Torsade de pointes. The PL is updated accordingly. The RMP version 6 has also been submitted. In	Weekly start timetable.

addition the MAH took the opportunity to align the PI with the latest QRD template 10.0." Request for Supplementary Information adopted on 01.09.2017.	
WS1182 **AMGEVITA-EMEA/H/C/004212/WS1182/0001** **SOLYMBIC-EMEA/H/C/004373/WS1182/0001** MAH: Amgen Europe B.V., Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final report from study/studies 20130258, an open-label, single-arm extension study to evaluate the long-term safety and efficacy of ABP 501 in subjects with moderate to severe rheumatoid arthritis, listed as a category 3 study in the RMP (MEA002). No changes of the PI are proposed; the RMP is updated accordingly (version 2.0)." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 06.07.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1211 **Januvia-EMEA/H/C/000722/WS1211/0059** **Ristaben-EMEA/H/C/001234/WS1211/0051** **TESAVEL-EMEA/H/C/000910/WS1211/0059** **Xelevia-EMEA/H/C/000762/WS1211/0063** MAH: Merck Sharp & Dohme Limited, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2, 4.4 and 5.2 of the SmPC in order to modify the information on dosing, an existing warning and administration instructions, respectively for use of sitagliptin in patients with type 2 diabetes mellitus and renal impairment. Consequently, the RMP version 8 has also been updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to update the list of local representatives in the Package Leaflet for Tesavel and to bring the PI in line with the latest QRD template version 10. Minor editorial changes are also introduced in the Product Information."	
WS1212/G **Efficib-EMEA/H/C/000896/WS1212/0085/G**	

Janumet-EMEA/H/C/000861/WS1212/0085/G **Ristfor-EMEA/H/C/001235/WS1212/0072/G** **Velmetia-EMEA/H/C/000862/WS1212/0088/G** MAH: Merck Sharp & Dohme Limited, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, "Update of sections 4.2, and 5.2 of the SmPC in order to modify the information on dosing, and administration instructions respectively for use of sitagliptin/metformin in patients with type 2 diabetes mellitus and moderate renal impairment. Consequently, the RMP version 8 has also been updated accordingly. Section 4.5 of the SmPC is also updated to include information on the concominant use of ranolazine, vandetanib, dolutegravir and cimetidine. In addition, the Worksharing applicant (WSA) took the opportunity to update the list of local representatives in the Package Leaflet for Efficib and to bring the PI in line with the latest QRD template version 10. Minor editorial changes are also introduced in the Product Information."	

B.5.4. PRAC assessed procedures

PRAC Led **Eliquis - apixaban - EMEA/H/C/002148/II/0043** MAH: Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of the final report from study (CV185-365) listed as a category 3 study in the RMP. This is a post authorisation safety study which evaluates the effectiveness of Eliquis (apixaban) risk minimisation tools in the European Economic Area countries. A RMP (version 17.0) has also been submitted to reflect the completion of the study CV185-365." Opinion adopted on 01.09.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Invokana - canagliflozin - EMEA/H/C/002649/II/0030** MAH: Janssen-Cilag International NV,	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

Rapporteur: Martina Weise, PRAC Rapporteur: Valerie Strassmann, PRAC-CHMP liaison: Martina Weise, “Submission of an updated RMP version 7.1 in order to include prior commitments made to PRAC during the PSUR/LEG procedural review of pancreatitis cases and the Article 20 referral procedure reviewing lower limb amputation in relation to the use of SGLT-2 inhibitors. In addition, the updated RMP reflects labelling changes that resulted from a variation to add information regarding fatal DKA cases to the existing DKA warning and the Article 31 procedure reviewing metformin-containing medicines.” Opinion adopted on 01.09.2017.	recommendation.
PRAC Led **Plenadren - hydrocortisone - EMEA/H/C/002185/II/0024, Orphan** MAH: Shire Services BVBA, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, PRAC-CHMP liaison: Kristina Dunder, “Submission of an updated RMP (version 3.1) in order to submit protocol amendments of SHP 617-400 (EU-AIR) study – A European multicentre, multi-country, post-authorisation, observation study (registry) of patients with chronic adrenal insufficiency (category 3). Additionally, the opportunity is being taken to implement a change agreed by the PRAC/CHMP as part of the assessment of MEA 005.3 in July 2016 and remove from the RMP reference to study SHP617-404 (SWE-DUS), a Category 3 study to monitor off-label use of Plenadren to evaluate physician prescribing patterns.” Request for Supplementary Information adopted on 01.09.2017, 05.05.2017.	Weekly start timetable.
PRAC Led **Viread - tenofovir disoproxil - EMEA/H/C/000419/II/0182** MAH: Gilead Sciences International Limited, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Caroline Laborde, PRAC-CHMP liaison: Joseph Emmerich, “Submission of the final report from Study GX-US-174-0172, listed as a category 3 study in the RMP. This is a 5-year observational (non-interventional) renal safety registry conducted to provide further safety data in HBV-infected patients with decompensated liver disease.”	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 01.09.2017.	
PRAC Led **Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0031** MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP version 7.1 in order to include prior commitments made to PRAC during the PSUR/LEG procedural review of pancreatitis cases and the Article 20 referral procedure reviewing lower limb amputation in relation to the use of SGLT-2 inhibitors. In addition, the updated RMP reflects labelling changes that resulted from a variation to add information regarding fatal DKA cases to the existing DKA warning and the Article 31 procedure reviewing metformin-containing medicines." Opinion adopted on 01.09.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Xeplion - paliperidone - EMEA/H/C/002105/II/0031** MAH: Janssen-Cilag International NV, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, PRAC-CHMP liaison: Filip Josephson, "Submission of final study report "Post-Authorization Safety Study Using European Union Databases to Assess the Risk of Cardiovascular and Cerebrovascular Adverse Events in Elderly Patients Treated with Paliperidone Palmitate, Paliperidone Prolonged-Release, and Other Antipsychotics". No changes in the PI are proposed." Request for Supplementary Information adopted on 22.06.2017, 23.02.2017.	
PRAC Led **Xyrem - sodium oxybate - EMEA/H/C/000593/II/0066** MAH: UCB Pharma Limited, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, PRAC-CHMP liaison: Bruno Sepodes, "Submission of the final report from study (C00302) listed as a category 3 study in the RMP. This is a post marketing non-interventional surveillance pharmacoepidemiology study (PMSS) to evaluate long-term safety, tolerability and compliance in administration of Xyrem (sodium oxybate) oral solution in patients who	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

receive treatment with this medication in regular clinical practice. In addition, the MAH submitted a revised risk management plan version 8.0." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 09.06.2017.	
PRAC Led **Yervoy - ipilimumab -** **EMEA/H/C/002213/II/0049** MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Submission of an updated RMP (version 17.1) in order to amend the study objectives and milestones for two studies: - study CA184332, a multi-site retrospective observational study of US patients with unresectable or metastatic melanoma receiving ipilimumab (Yervoy) as first line therapy in a community setting, a category 3 study in the RMP (MEA 029): to submit the final study report with 2-years of follow-up - study CA184338, a multi-site retrospective observational study of US patients with unresectable or metastatic melanoma receiving ipilimumab (Yervoy) as first line therapy, a category 3 study in the RMP (MEA 030): to submit the final study report with 4-years of follow-up." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 06.07.2017.	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1188** **Humalog-EMEA/H/C/000088/WS1188/0157** **Liprolog-EMEA/H/C/000393/WS1188/0120** MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Robert James Hemmings, Lead PRAC Rapporteur: Julie Williams, PRAC-CHMP liaison: Robert James Hemmings, "Submission of the final report of a non-interventional post-authorisation safety study EUPAS 13422. This study is aimed to evaluate the impact of additional risk minimisation measures on healthcare professionals and on patients' understanding and their behaviour regarding the risk of hypoglycaemia and/or hyperglycaemia due to medication errors associated with	Positive Opinion adopted by consensus on 01.09.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

administration of Humalog 200 U/ml KwikPen." Opinion adopted on 01.09.2017. Request for Supplementary Information adopted on 06.07.2017.	
PRAC Led **WS1197** **Actraphane-EMEA/H/C/000427/WS1197/0072** **Actrapid-EMEA/H/C/000424/WS1197/0066** **Insulatard-EMEA/H/C/000441/WS1197/0069** **Mixtard-EMEA/H/C/000428/WS1197/0073** **Protaphane-EMEA/H/C/000442/WS1197/0068** MAH: Novo Nordisk A/S, Lead Rapporteur: Hanne Lomholt Larsen, Lead PRAC Rapporteur: Doris Stenver, PRAC-CHMP liaison: Sinan B. Sarac, "Submission of an updated RMP version 3.0 according to GVP Module V, in order to remove three important potential risks (immunogenicity, allergic reactions and lack of efficacy) related to the new NN729 manufacturing process from the RMP, remove hypoglycaemia and anaphylactic reactions, remove peripheral neuropathy, refraction disorders, lipodystrophy, urticaria, rash, oedema and diabetic retinopathy and remove missing information concerning special populations. No changes are proposed to the product information." Request for Supplementary Information adopted on 01.09.2017.	Weekly start timetable.

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

WS0935/G **Filgrastim** **Hexal-EMEA/H/C/000918/WS0935/0035/G** **Zarzio-EMEA/H/C/000917/WS0935/0036/G**	Weekly start timetable.

MAH: Sandoz GmbH, Lead Rapporteur: Greg Markey	
WS1172 **Infanrix hexa-EMEA/H/C/000296/WS1172/0221** MAH: GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren	Weekly start timetable.
WS1184 **Eucreas-EMEA/H/C/000807/WS1184/0063** **Icandra-EMEA/H/C/001050/WS1184/0064** **Zomarist-EMEA/H/C/001049/WS1184/0064** MAH: Novartis Europharm Ltd, Lead Rapporteur: Kristina Dunder	Weekly start timetable.
WS1185/G **Hexacima-EMEA/H/C/002702/WS1185/0065/G** **Hexaxim-EMEA/H/W/002495/WS1185/0071/G** **Hexyon-EMEA/H/C/002796/WS1185/0069/G** MAH: Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus	Weekly start timetable.
WS1187/G **Kalydeco-EMEA/H/C/002494/WS1187/0061/G** **Orkambi-EMEA/H/C/003954/WS1187/0022/G** MAH: Vertex Pharmaceuticals (Europe) Ltd., Lead Rapporteur: Nithyanandan Nagercoil	Weekly start timetable.
WS1192 **Hexacima-EMEA/H/C/002702/WS1192/0066** **Hexaxim-EMEA/H/W/002495/WS1192/0072** **Hexyon-EMEA/H/C/002796/WS1192/0070** MAH: Sanofi Pasteur SA, Lead Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 20.07.2017.	
WS1194 **Infanrix hexa-EMEA/H/C/000296/WS1194/0222**	Weekly start timetable.

MAH: GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren	
WS1196/G **Ebymect-EMEA/H/C/004162/WS1196/0023/G** **Xigduo-EMEA/H/C/002672/WS1196/0034/G** MAH: AstraZeneca AB, Lead Rapporteur: Kristina Dunder	Weekly start timetable.
WS1201/G **Glyxambi-EMEA/H/C/003833/WS1201/0009/G** **Jentadueto-EMEA/H/C/002279/WS1201/0041/G** **Trajenta-EMEA/H/C/002110/WS1201/0031/G** MAH: Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege	Weekly start timetable.
WS1202/G **Efficib-EMEA/H/C/000896/WS1202/0084/G** **Janumet-EMEA/H/C/000861/WS1202/0084/G** **Januvia-EMEA/H/C/000722/WS1202/0058/G** **Ristaben-EMEA/H/C/001234/WS1202/0050/G** **Ristfor-EMEA/H/C/001235/WS1202/0071/G** **TESAVEL-EMEA/H/C/000910/WS1202/0058/G** **Velmetia-EMEA/H/C/000862/WS1202/0087/G** **Xelevia-EMEA/H/C/000762/WS1202/0062/G** MAH: Merck Sharp & Dohme Limited, Lead Rapporteur: Johann Lodewijk Hillege	Weekly start timetable.
WS1204/G **Herceptin-EMEA/H/C/000278/WS1204/0134/G** **Kadcyla-EMEA/H/C/002389/WS1204/0037/G** MAH: Roche Registration Limited, Lead Rapporteur: Jan Mueller-Berghaus	Weekly start timetable.
WS1213 **Lyrica-EMEA/H/C/000546/WS1213/0090** **Pregabalin** **Pfizer-EMEA/H/C/003880/WS1213/0020**	Weekly start timetable.

MAH: Pfizer Limited, Lead Rapporteur: Johann Lodewijk Hillege	
WS1214 **Aflunov-EMEA/H/C/002094/WS1214/0039** **Foclivia-EMEA/H/C/001208/WS1214/0033** MAH: Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri	Weekly start timetable.
WS1216 **IntronA-EMEA/H/C/000281/WS1216/0112** **PegIntron-EMEA/H/C/000280/WS1216/0131** **ViraferonPeg-EMEA/H/C/000329/WS1216/0124** MAH: Merck Sharp & Dohme Limited, Lead Rapporteur: Koenraad Norga	Weekly start timetable.
WS1224 **Relvar Ellipta-EMEA/H/C/002673/WS1224/0031** **Revinty Ellipta-EMEA/H/C/002745/WS1224/0027** MAH: Glaxo Group Ltd, Lead Rapporteur: Concepcion Prieto Yerro “To update sections 4.4 and 4.8 of the SmPC and sections 2 and 4 of the package leaflet for Relvar Ellipta/Revinty Ellipta in accordance with the wording proposed in the CMDh/PRAC recommendation following the release of the CMDh/PRAC recommendation on signals regarding `Blurred Vision' and `Central Serous Chorioretinopathy' as a class risk effect of corticosteroids from their meeting in April 2017.”	Weekly start timetable.
WS1235/G **Incresync-EMEA/H/C/002178/WS1235/0020/G** **Vipdomet-EMEA/H/C/002654/WS1235/0022/G** **Vipidia-EMEA/H/C/002182/WS1235/0017/G** MAH: Takeda Pharma A/S, Lead Rapporteur: Johann Lodewijk Hillege	Weekly start timetable.

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

Advate - octocog alfa - EMEA/H/C/000520/II/0087/G MAH: Baxter AG, Rapporteur: Jan	The MAH withdrew the procedure on 24.08.2017.

Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski Withdrawal request submitted on 24.08.2017.	
MACI - matrix applied characterised autologous cultured chondrocytes - EMEA/H/C/002522/II/0015/G, ATMP MAH: Vericel Denmark ApS, Rapporteur: Christiane Niederlaender Withdrawal request submitted on 05.09.2017.	The MAH withdrew the procedure on 05.09.2017.
Sebivo - telbivudine - EMEA/H/C/000713/II/0047 MAH: Novartis Europharm Ltd, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Caroline Laborde Withdrawal request submitted on 01.09.2017.	The MAH withdrew the procedure on 01.09.2017.
WS1179 **Invega-EMEA/H/C/000746/WS1179/0055** **Trevicta-EMEA/H/C/004066/WS1179/0010** **Xeplion-EMEA/H/C/002105/WS1179/0034** MAH: Janssen-Cilag International NV, Lead Rapporteur: Kristina Dunder, "Update of section 4.6 (Fertility, pregnancy and lactation) of the SmPC in order to add new information concerning a retrospective observational cohort study with risperidone and risk of congenital malformations. Nationally approved products are also affected by this variation." Request for Supplementary Information adopted on 20.07.2017. Withdrawal request submitted on 05.09.2017.	The MAH withdrew the procedure on 05.09.2017.

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

Tarceva - erlotinib - EMEA/H/C/000618/II/0052 MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac, "Update of section 4.4 of the SmPC in order to include recommendations on Epidermal Growth Factor Receptor (EGFR) mutation status testing, to be in line with current technical and scientific progress. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes and to bring the PI in line with the latest QRD template version 10. Moreover, the MAH took the opportunity to make minor correction of section 4.2 of the SmPC. Furthermore, the Annex II has been corrected, as	Request for clock stop extension.

requested by the EMA, to include Educational Material as an additional risk minimisation measure, which has been already in place in the RMP."
Request for Supplementary Information adopted on 20.07.2017.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

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

- trastuzumab - EMEA/H/C/002575
, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)
List of Questions adopted on 23.02.2017.

- ertugliflozin / metformin hydrochloride - EMEA/H/C/004314
, treatment of type 2 diabetes mellitus
List of Questions adopted on 22.06.2017.

- ertugliflozin - EMEA/H/C/004315
, type 2 diabetes mellitus
List of Questions adopted on 22.06.2017.

- ertugliflozin / sitagliptin - EMEA/H/C/004313
, type 2 diabetes mellitus
List of Questions adopted on 22.06.2017.

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

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/0027
MAH: Genzyme Europe BV

Sirturo - bedaquiline - EMEA/H/C/002614/R/0024, Orphan
MAH: Janssen-Cilag International NV

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

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Atripla - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/000797/II/0125/G
MAH: Bristol-Myers Squibb and Gilead Sciences Ltd.,

Cerezyme - imiglucerase - EMEA/H/C/000157/II/0105
MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege,

- daptomycin - EMEA/H/C/004310/II/0003
MAH: Hospira UK Limited, Generic, Generic of Cubicin, Rapporteur: Kolbeinn Gudmundsson,

Elaprase - idursulfase - EMEA/H/C/000700/II/0071/G
MAH: Shire Human Genetic Therapies AB, Rapporteur: Greg Markey,

Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0037/G
MAH: Merck Sharp & Dohme Limited, Rapporteur: Paula Boudewina van Hennik,

Natpar - parathyroid hormone - EMEA/H/C/003861/II/0004/G, Orphan
MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Bart Van der Schueren,

Opatanol - olopatadine - EMEA/H/C/000407/II/0035/G
MAH: Novartis Europharm Ltd, Rapporteur: Patrick Salmon,

Strensiq - asfotase alfa - EMEA/H/C/003794/II/0023, Orphan
MAH: Alexion Europe SAS, Rapporteur: Greg Markey,

Trulicity - dulaglutide - EMEA/H/C/002825/II/0021
MAH: Eli Lilly Nederland B.V., Rapporteur: Greg Markey,

Vaniqa - eflornithine -

EMEA/H/C/000325/II/0051
MAH: Almirall S.A, Rapporteur: Patrick Salmon,

Vyndaqel - tafamidis -
EMEA/H/C/002294/II/0041/G, Orphan
MAH: Pfizer Limited, Rapporteur: Joseph Emmerich,

Xadago - safinamide -
EMEA/H/C/002396/II/0020
MAH: Zambon S.p.A., Rapporteur: Johann Lodewijk Hillege,

WS1206/G
Exelon-EMEA/H/C/000169/WS1206/0114/G
Prometax-EMEA/H/C/000255/WS1206/0114/G
MAH: Novartis Europharm Ltd, Lead Rapporteur: Alexandre Moreau

WS1254/G
Hirobriz Breezhaler-EMEA/H/C/001211/WS1254/0042/G
Onbrez Breezhaler-EMEA/H/C/001114/WS1254/0041/G
Oslif Breezhaler-EMEA/H/C/001210/WS1254/0041/G
Ultibro Breezhaler-EMEA/H/C/002679/WS1254/0017/G
Ulunar Breezhaler-EMEA/H/C/003875/WS1254/0017/G
Xoterna Breezhaler-EMEA/H/C/003755/WS1254/0020/G
MAH: Novartis Europharm Ltd, Lead Rapporteur: Hanne Lomholt Larsen

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

Abilify - aripiprazole -
EMEA/H/C/000471/II/0127
MAH: Otsuka Pharmaceutical Europe Ltd, Rapporteur: Bruno Sepodes“Update of sections 4.4 and 4.8 of the SmPC with further information about the risk of impulse control disorders, and section 4.8 of the SmPC to include the new ADRs

‘impulse control disorders’, ‘binge eating’ and ’compulsive shopping’ and to delete the ADR ‘hyperglycaemia’. The Package Leaflet has been updated accordingly. Further, the MAH has implemented minor editorial changes in section 6.1 of the SmPC, section 6 of the Package leaflet and module 3.2.P.1 to include lactose as one of the components of the excipient vanilla flavour. In addition, the MAH takes the opportunity to align the annexes with the product information of Abilify Maintena and the latest QRD template.”

Abilify Maintena - aripiprazole - EMEA/H/C/002755/II/0023

MAH: Otsuka Pharmaceutical Europe Ltd, Rapporteur: Bruno Sepodes“Update of sections 4.4 and 4.8 of the SmPC with further information about the risk of impulse control disorders, and section 4.8 of the SmPC to include the new ADRs ‘impulse control disorders’, ‘binge eating’ and ’compulsive shopping’. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to add a unique identifier (barcode) in the labelling, to implement minor editorial changes and align the annexes with the latest QRD template.”

Eliquis - apixaban - EMEA/H/C/002148/II/0047

MAH: Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Johann Lodewijk Hillege“Update of section 4.5 of the SmPC to include clarithromycin as one of the active substances which are not considered strong inhibitors of both CYP3A4 and P-gp and which are expected to increase apixaban plasma concentration to a lesser extent based on the final results from study CV185547. The final study report of study CV185547 (an open-label, non-randomised, single-sequence, crossover study in healthy subjects to determine the effect of multiple-dose clarithromycin on the single-dose pharmacokinetics of apixaban) is also submitted. In addition, the MAH took the opportunity to make some corrections in the SmPC and to update the labelling in line with the latest QRD template version 10.0.”

Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0038

MAH: Merck Sharp & Dohme Limited, Rapporteur: Paula Boudewina van Hennik, “Update of section 5.1 of the SmPC to include

updated information regarding congenital malformations reported in infants born after a frozen_thawed embryo transfer (FTET) cycle."

Enbrel - etanercept - EMEA/H/C/000262/II/0213

MAH: Pfizer Limited, Rapporteur: Robert James Hemmings,"Update of section 4.8 of the SmPC to update the frequency category of 7 ADRs currently listed and to split one ADR into 2, following a re-analyse of the frequencies of all listed ADRs as proposed by the MAH as part of Enbrel LEG 0168. For the ADR 'interstitial lung disease and 'autoimmune hepatitis' the description of these ADRs has also been amended as a consequence. The Marketing authorisation holder (MAH) also took the opportunity to reformat the ADR listing in section 4.8 of the SmPC. Section 4.4 of the SmPC and the Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to combine the 25 mg and 50 mg pre-filled syringe (PFS) SmPCs and Package Leaflets."

Gazyvaro - obinutuzumab - EMEA/H/C/002799/II/0020, Orphan

MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac, "Update of section 4.4 of the SmPC in order to update the safety information on delayed hypersensitivity reactions based on drug safety report (DSR) number 1072198. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the SmPC and package leaflet."

Praluent - alirocumab - EMEA/H/C/003882/II/0029

MAH: sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege,"Submission of the final report from study R727-CL-1032 (study title: A Phase 2, Open-Label Extension of Study R727-CL-1003 to Evaluate the Long-Term Safety and Efficacy of REGN727 Administered by Subcutaneous Injection in Patients with Heterozygous Familial Hypercholesterolemia), listed as a category 3 study in the RMP (MEA013)."

Spinraza - nusinersen - EMEA/H/C/004312/II/0002/G, Orphan

MAH: Biogen Idec Ltd, Rapporteur: Bruno Sepodes,"Update of sections 4.8 and 5.1 of the SmPC to reflect efficacy and immunogenicity data from the final clinical study reports for study CS4

and CS12 and the final update to the CS2-12 longitudinal analysis."

Toujeo - insulin glargine - EMEA/H/C/000309/II/0100

MAH: Sanofi-Aventis Deutschland GmbH, Duplicate, Duplicate of Lantus, Rapporteur: Johann Lodewijk Hillege,"Update of sections 4.2, 4.4 and 6.6 of the SmPC in order to add a warning on the risk for medication error associated with pre-filled pens and cartridges presentations following the evaluation of a signal (EPITT 18893) .The Package Leaflet is updated accordingly."

Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0047

MAH: ViiV Healthcare UK Limited, Rapporteur: Kristina Dunder,"Update of section 4.5 of the SmPC with new transporter data available for abacavir and lamivudine. In addition, the MAH took the opportunity to implement some minor editorial changes in the SmPC."

Visudyne - verteporfin - EMEA/H/C/000305/II/0095

MAH: Novartis Europharm Ltd, Rapporteur: Alexandre Moreau,"Update of sections 4.4 and 4.8 of the SmPC in order to add a warning to update the safety information to reflect current knowledge about the product based on new data from spontaneous reports on localised (skin) necrosis at the injection site following extravasation; the Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10."

Xalkori - crizotinib - EMEA/H/C/002489/II/0051

MAH: Pfizer Limited, Rapporteur: Alexandre Moreau, "Update of section 4.5 and 5.2 of the SmPC based on the results from the crizotinib-itraconazole drug-drug interaction (DDI) substudy of Study A8081001 (to determine the effect of the coadministration of a strong cytochrome P450 (CYP) 3A inhibitior, itraconazole, on the multiple-dose plasma pharmacokinetic of crizotinib) and the assessment of potential DDIs between crizotinib and weak and moderate CYP3A inhibitors.

The labelling is also updated in line with the QRD template."

Zelboraf - vemurafenib - EMEA/H/C/002409/II/0043

MAH: Roche Registration Limited, Rapporteur: Filip Josephson,"Update of section 4.8 of the SmPC in order to update the safety information following results from pooled safety analysis of the final results from pivotal phase II (NP22657 BRIM-2) and pivotal phase III (NO25026 BRIM-3) trials. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to review the SmPC and Package Leaflet in order to improve clarity and consistency across sections."

WS1251

Eviplera-EMEA/H/C/002312/WS1251/0086

Odefsey-EMEA/H/C/004156/WS1251/0019

MAH: Gilead Sciences International Limited, Lead Rapporteur: Johann Lodewijk Hillege"Updates to the Summary of Product Characteristics (SmPC) sections 4.2, 4.4 , 4.6, 5.1 and 5.2 for Eviplera and Odefsey with data from Study TMC114HIV3015, a Category 4 additional pharmacovigilance activity in the pharmacovigilance plan for both the Eviplera and Odefsey. This is a single-arm, open-label study to assess the pharmacokinetics of Darunavir and Ritonavir, Darunavir and Cobicistat, Etravirine, and Rilpivirine in HIV-1 infected pregnant women results for the Rilpivirine arm. The Labelling and Package Leaflet are updated accordingly.
In addition, the Worksharing Applicant (WSA) has taken the opportunity to introduce some minor administrative amendments and to implement some minor linguistic amendments (MLAs) to the translations of the product information annexes."

WS1267

Docetaxel

Winthrop-EMEA/H/C/000808/WS1267/0054

Taxotere-EMEA/H/C/000073/WS1267/0129

MAH: Aventis Pharma S.A., Lead Rapporteur: Alexandre Moreau"Update of sections 4.4 and 4.8 of the SmPC in order to add a warning of

enterocolitis in patients with neutropenia and to update the safety information on enterocolitis to reflect fatal outcomes based on the review of the MAH global pharmacovigilance data base, worldwide scientific literature and main pharmacovigilance textbooks; the Package Leaflet is updated accordingly.

In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10."

B.6.10. CHMP-PRAC assessed procedures

Defitelio - defibrotide - EMEA/H/C/002393/II/0027, Orphan

MAH: Gentium S.r.l., Rapporteur: Nithyanandan Nagercoil, "Submission of an updated RMP version 4.0 in order to re-classify the imposed non-interventional PASS listed as a category 2 study in the RMP (specific obligation) to a study listed as a category 3 in the RMP (required additional pharmacovigilance activities). This study is an observational registry (DF-VOD2013-03-REG) which aims to record safety and outcome data in patients diagnosed with severe VOD following HSCT treated or not with defitelio. The Annex II of the product information is updated accordingly."

emlidy - tenofovir alafenamide - EMEA/H/C/004169/II/0004

MAH: Gilead Sciences International Limited, Rapporteur: Robert James Hemmings, PRAC Rapporteur: Amelia Cupelli,"Update of sections 4.8 and 5.1 of the Vemlidy SmPC in order to provide 96 week data from Studies GS-US-320-0108 and GS-US-320-0110, listed as category 3 studies in the RMP;

GS-US-320-0108 is an ongoing Phase 3, randomized, double-blind, non-inferiority study evaluating the safety and efficacy of Vemlidy 25 mg compared with tenofovir disoproxil fumarate 300 mg in HBeAg-negative subjects with Chronic hepatitis B.

GS-US-320-0110 is a an ongoing Phase 3, randomized, double-blind, noninferiority study evaluating the safety and efficacy of Vemlidy versus tenofovir disoproxil fumarate for the treatment of HBeAg-positive subjects with

chronic hepatitis B; the Package Leaflet is updated accordingly.

The RMP version 2.0 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."

B.6.11. PRAC assessed procedures

PRAC Led

Multaq - dronedarone - EMEA/H/C/001043/II/0039/G

MAH: sanofi-aventis groupe, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege"C.I.13: Submission of the final report from study DRONE_C_05917 listed as a category 3 study in the RMP. This is a non-interventional epidemiological study aimed for the surveillance of serious liver injuries/diseases (SLD) with the use of dronedarone using multiple databases in the US, including the addendum on surveillance of interstitial lung disease (ILD). The RMP version 11.0 has also been submitted.

C.I.13: Submission of the final report from study DRONE_C_05911 listed as a category 3 study in the RMP. This is a non-interventional epidemiological study aimed to study the concomitant use of dronedarone and digoxin (or statins) and the risk of digitalis intoxication (or rhabdomyolysis and myopathy). The RMP version 11.0 has also been submitted."

PRAC Led

WS1221

Brimica Genuair-EMEA/H/C/003969/WS1221/0017

Duaklir Genuair-EMEA/H/C/003745/WS1221/0017

MAH: AstraZeneca AB, Lead Rapporteur: Nithyanandan Nagercoil, Lead PRAC Rapporteur: Julie Williams, PRAC-CHMP liaison: Robert James Hemmings "To provide an updated RMP, version 3, to promote "Hypersensitivity (anaphylactic responses, angioedema, and urticaria)" from Important Potential Risk to Important Identified Risk, remove "Use in non-Caucasian patients" as

Missing Information (with the completion of clinical studies in Asian patients), and include milestones and due dates for a cardiovascular PASS (D6560R00004) and a drug utilisation study (DUS2: D6560R00002)."

PRAC Led

WS1261

Enbrel-EMEA/H/C/000262/WS1261/0212

LIFMIOR-EMEA/H/C/004167/WS1261/0010

MAH: Pfizer Limited, Lead Rapporteur: Robert James Hemmings, Lead PRAC Rapporteur: Patrick Batty, PRAC-CHMP liaison: Robert James Hemmings"Submission of the final report for the Anti-Rheumatic Treatment in Sweden Registry-Etanercept Cohort Study listed as a category 3 study in the RMP. This non-interventional PASS aimed at providing an assessment of a number of pre-specified safety outcomes for Enbrel as used in the treatment of RA in Sweden, using data from the ARTIS system, in total and from 2006."

B.6.12. CHMP-CAT assessed procedures

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

WS1215

Infanrix hexa-EMEA/H/C/000296/WS1215/0224

MAH: GlaxoSmithkline Biologicals SA, Lead Rapporteur: Bart Van der Schueren

WS1230

Lixiana-EMEA/H/C/002629/WS1230/0014

Roteas-EMEA/H/C/004339/WS1230/0002

MAH: Daiichi Sankyo Europe GmbH, Lead Rapporteur: Concepcion Prieto Yerro

WS1240/G

Ambirix-EMEA/H/C/000426/WS1240/0087/G

Twinrix Adult-EMEA/H/C/000112/WS1240/0121/G

Twinrix
Paediatric-EMEA/H/C/000129/WS1240/0122/G
MAH: GlaxoSmithkline Biologicals SA, Lead Rapporteur: Robert James Hemmings

WS1253
Iblias-EMEA/H/C/004147/WS1253/0009
Kovaltry-EMEA/H/C/003825/WS1253/0012
MAH: Bayer AG, Lead Rapporteur: Kristina Dunder

Hexacima-EMEA/H/C/002702/WS1231/0069
Hexaxim-EMEA/H/W/002495/WS1231/0074
Hexyon-EMEA/H/C/002796/WS1231/0073
MAH: Sanofi Pasteur SA, Lead Rapporteur: Jan Mueller-Berghaus

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.

G.3.1. List of procedures concluding at 11-14 September 2017 CHMP plenary:

G.3.2. List of procedures starting in September 2017 for October 2017 CHMP adoption of outcomes

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