16 December 2016
EMA/CHMP/788305/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Minutes of the meeting on 07-10 November 2016

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

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 document 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 document is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

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

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1. Introduction

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

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified as included in the pre-meeting list of participants and restrictions. See (current) November 2016 CHMP minutes for the list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session held 07-10 November 2016.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Committee noted that the Croatian alternate member Katarina Vučić was moved to the member position due to resignation of Ines Baotic. The Committee noted the new alternate member Selma Arapovic Dzakula from Croatia.

1.2. Adoption of agenda

CHMP agenda for 07-10 November 2016

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 10-13 October2016.

The CHMP adopted the minutes.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Cavoley - pegfilgrastim - EMEA/H/C/004342

STADA Arzneimittel AG; treatment of neutropenia

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 09 November 2016 at time 11:00

Similar biological application (Article 10(4) of Directive No 2001/83/EC), Duplicate of Efgratin

List of Outstanding Issues adopted on 13.10.2016, 21.07.2016. List of Questions adopted on 01.04.2016.

An oral explanation was held on Wednesday 09 November 2016 at time 11:00.

Post-meeting note: The company withdrew the application on 16 November 2016.

2.1.2. Efgratin - pegfilgrastim - EMEA/H/C/004023

Gedeon Richter Plc.; treatment of neutropenia

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 09 November 2016 at time 11:00

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 13.10.2016, 21.07.2016. List of Questions adopted on 01.04.2016.
An oral explanation was held on Wednesday 09 November 2016 at time 11:00.
Post-meeting note: The company withdrew the application on 16 November 2016.

2.1.3. Fiasp - insulin aspart - EMEA/H/C/004046

Novo Nordisk A/S; treatment of diabetes mellitus in adults

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 09 November 2016 at time 14:00

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

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.04.2016.

The CHMP agreed that no oral explanation was required at this time.

See 3.1.3

2.1.4. Kepnetic - aceneuramic acid - Orphan - EMEA/H/C/004176

Ultragenyx UK Limited; treatment of Hereditary Inclusion Body Myopathy (HIBM)

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday 08 November 2016 at time 14:00

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.01.2016.

An oral explanation was held on Tuesday 08 November 2016 at time 14:00.

Post meeting note: The company withdrew the application on 10 November 2016.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0020 & EMEA/H/C/002720/R/0022

MAH: PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Concepcion Prieto Yerro,

PRAC Rapporteur: Sabine Straus,

Scope: Oral explanation to be held on Tuesday 08 November 2016 at time 16:00

Type II variation

"Update of sections 4.4, 4.8, 5.1 and 5.3 of the SmPC in order to reflect the results from the submitted study TC124-GD-020-DMD object of the specific obligation (SOB 001) for the conditional marketing authorisation. The Package Leaflet and the RMP are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include some minor editorial changes throughout the Product information."
Oral explanation was held on 11 October 2016. Request for Supplementary Information adopted on 21.07.2016, 01.04.2016.

Renewal of Marketing Authorisation

Action: For adoption

Participation of patients' representatives

An oral explanation was held on Tuesday 08 November 2016 at time 16:00.

See 9.1.3

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Afstyla - lonoctocog alfa - EMEA/H/C/004075

CSL Behring GmbH; treatment of haemophilia A

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been

addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that lonoctocog alfa is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The CHMP noted the letter of recommendation dated 08.11.2016.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

3.1.2. Darunavir Mylan - darunavir - EMEA/H/C/004068

MYLAN S.A.S; treatment of HIV-1

Scope: Opinion

Action: For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Prezista

List of Outstanding Issues adopted on 15.09.2016, 26.05.2016. List of Questions adopted on 17.12.2015.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

3.1.3. Fiasp - insulin aspart - EMEA/H/C/004046

Novo Nordisk A/S; treatment of diabetes mellitus in adults

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 09 November 2016 at time 14:00

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

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.04.2016.

The CHMP agreed that no oral explanation was required at this time.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by majority (22 votes out of 27) together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The divergent position (Johann Lodewijk Hillege, Aranzazu Sancho-Lopez, Sol Ruiz, Nikola Moravcova, David Lyons) was appended to the opinion.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

See 2.1.3

3.1.4. Lusduna - insulin glargine - EMEA/H/C/004101

Merck Sharp & Dohme Limited; treatment of diabetes mellitus

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

3.1.5. Movymia - teriparatide - EMEA/H/C/004368

STADA Arzneimittel AG; treatment of osteoporosis

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC), Duplicate of Terrosa

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 10.11.2016.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

3.1.6. Suliqua - insulin glargine / lixisenatide - EMEA/H/C/004243

sanofi-aventis groupe; treatment of type 2 diabetes mellitus

Scope: Opinion

Action: For adoption

Fixed combination application (Article 10b of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 13.10.2016. List of Questions adopted on 21.07.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

3.1.7. Tadalafil Generics - tadalafil - EMEA/H/C/004297

MYLAN S.A.S; treatment of pulmonary arterial hypertension (PAH)

Scope: Opinion

Action: For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Adcirca, Cialis

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 26.05.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing

authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

3.1.8. Terrosa - teriparatide - EMEA/H/C/003916

Gedeon Richter Plc.; treatment of osteoporosis

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 10.11.2016.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

3.1.9. Vemlidy - tenofovir alafenamide - EMEA/H/C/004169

Gilead Sciences International Ltd; treatment of chronic hepatitis B

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 23.06.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

3.1.10. Zinplava - bezlotoxumab - EMEA/H/C/004136

Merck Sharp & Dohme Limited; indicated for the prevention of Clostridium difficile infection (CDI) recurrence

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 01.04.2016.

The CHMP noted the report from the SAG. The experts advised that the patients at high risk of CDI recurrence would be considered the appropriate target population for this product. Although some limitations of the clinical trial were identified the SAG considered the results as clinically relevant. The observed higher failure rate (clinical cure) in the bezlotoxumab group in subjects with higher baseline endogenous antibody B level could not be explained by the experts and no clear advice could be given by the group.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted the final positive opinion by consensus recommending the granting of a marketing authorisation via written procedure on 22 November 2016. The CHMP assessment report and translation timetable were also adopted.

Furthermore, the CHMP considered that bezlotoxumab is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

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

3.2.1. - anamorelin - EMEA/H/C/003847

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 25.02.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.2. - daptomycin - EMEA/H/C/004310

treatment of complicated skin and soft-tissue infections

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.06.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.3. - brodalumab - EMEA/H/C/003959

moderate to severe plaque psoriasis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 01.04.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a 2nd list of outstanding issues with a specific timetable.

The CHMP adopted the BWP report.

3.2.4. - sodium zirconium cyclosilicate - EMEA/H/C/004029

for the treatment of hyperkalaemia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.5. - methotrexate - EMEA/H/C/003756

treatment of rheumatological and dermatological diseases

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.6. - pentosan polysulfate sodium - Orphan - EMEA/H/C/004246

bene-Arzneimittel GmbH; treatment of Interstitial Cystitis

Scope: Day 180 list of outstanding issue, list of Questions to the ad'hoc expert group

Action: For adoption

List of Questions adopted on 23.06.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee agreed to consult an ad-hoc expert group.

The Committee adopted a list of outstanding issues with a specific timetable.

The Committee adopted a draft list of Questions to the ad-hoc expert group.

3.2.7. - rolapitant - EMEA/H/C/004196

prevention of nausea and vomiting

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.07.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues

The Committee adopted a list of outstanding issues with a specific timetable.

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

3.3.1. - cladribine - EMEA/H/C/004230

treatment of highly active relapsing-remitting multiple sclerosis (MS)

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.2. - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004250

treatment of HIV-1 infection

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.3. - sarilumab - EMEA/H/C/004254

treatment of active rheumatoid arthritis

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application,

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP adopted the BWP report.

3.3.4. - etirinotecan pegol - EMEA/H/C/003874

treatment of breast cancer with brain metastases

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

The CHMP agreed to revert back to a normal assessment timetable.

3.3.5. - edoxaban - EMEA/H/C/004339

prevention of stroke; embolism and treatment of venous thromboembolism

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.6. - adalimumab - EMEA/H/C/004279

treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP adopted the BWP report.

3.3.7. - telotristat ethyl - Orphan - EMEA/H/C/003937

Ipsen Pharma; treatment of carcinoid syndrome

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

3.4.1. - trientine tetrahydrochloride - Orphan - EMEA/H/C/004005

GMP-Orphan SA; Wilson's disease

Scope: Response from PKWP on CHMP questions, request for an extension to the clock stop to respond to the list of outstanding issues adopted on 13.10.2016.

Action: For adoption

List of Outstanding Issues adopted on 13.10.2016. List of Questions adopted on 28.04.2016.

The CHMP adopted the PKWP response on the CHMP questions and agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted on 13.10.2016 with a specific timetable.

3.4.2. - eryaspase - Orphan - EMEA/H/C/004055

ERYTECH Pharma S.A.; treatment of leukaemia

Scope: Request for an extension to the clock stop to respond to the Day 180 List of Outstanding Issues adopted on 15.09.2016.

Action: For adoption

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 28.01.2016.

The CHMP discussed the request by the applicant for an extension to the clock stop taking into

account the proposed progress plans for addressing the list of outstanding issue and agreed not to grant the extension as the longer clock stop was not considered sufficiently justified.

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

treatment of vulvovaginal atrophy

Scope: Request for an extension to the clock stop to respond to the Day 180 List of Outstanding Issues adopted on 13.10.2016.

Action: For adoption

List of Outstanding Issues adopted on 13.10.2016. List of Questions adopted on 26.05.2016.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 180 List of Outstanding Issues adopted on 13.10.2016.

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

No items

3.6. Initial applications in the decision-making phase

3.6.1. Cystadrops - mercaptamine - Orphan - EMEA/H/C/003769

Orphan Europe S.A.R.L.; treatment of cystinosis

Scope: Letter from the European Commission on the opinion adopted on 13.10.2016

Action: For information

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

Opinion: 13.10.2016; List of Outstanding Issues adopted on 19.11.2015, 22.10.2015, 25.06.2015. List of Questions adopted on 22.01.2015.

The CHMP noted the letter from the European Commission. A response will be sent by the EMA.

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. Ruconest - conestat alfa - EMEA/H/C/001223/X/0034

Pharming Group N.V

Rapporteur: Nithyanandan Nagercoil

Scope: “Addition of a new pharmaceutical form "powder and solvent for solution for injection" with self-administration kit.”

Action: For adoption

List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 26.05.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

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

No items

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

4.3.1. Nexium Control - esomeprazole - EMEA/H/C/002618/X/0016

Pfizer Consumer Healthcare Ltd

Rapporteur: Romaldas Mačiulaitis, Co-Rapporteur: Robert James Hemmings, PRAC
Rapporteur: Simona Kudeliene

Scope: “Extension application to introduce a new pharmaceutical form (Gastro-resistant capsule, hard)”

Action: For adoption

The Committee discussed the issues identified in this application, mainly relating to quality aspects and pharmacokinetics.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

4.3.2. Pergoveris - follitropin alfa / lutropin alfa - EMEA/H/C/000714/X/0047

Merck Serono Europe Limited

Rapporteur: Nithyanandan Nagercoil

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with 3 strengths of (300 IU + 150 IU)/ 0.48 ml, (450 IU + 225 IU)/ 0.72 ml and (900 IU + 450 IU)/ 1.44 ml."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion related to the expression of strength.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP also agreed to consult the QRD group.

4.3.3. Revestive - teduglutide - Orphan - EMEA/H/C/002345/X/0029

Shire Pharmaceuticals Ireland Ltd

Rapporteur: Sinan B. Sarac

Scope: "Extension application to add a new strength of 1.25mg (paediatric formulation)."

Action: For adoption

The Committee discussed the issues identified in this application, which related to the quality part of the dossier.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

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

4.4.1. Repatha - evolocumab - EMEA/H/C/003766/X/0002

Amgen Europe B.V.

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Kimmo Jaakkola

Scope: "To add a new strength of 420 mg (120 mg/mL) for evolocumab solution for injection in cartridge, for subcutaneous (SC) administration by an automated mini-doser device."

Request for an extension to the clock stop to respond to the Day 180 List of Outstanding Issues adopted on 26.05.2016.

Action: For adoption

List of Outstanding Issues 26.05.2016, List of Questions adopted on 25.02.2016.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the Day 180 List of Outstanding Issues adopted on 26.05.2016, with a specific timetable.

4.4.2. Xtandi - enzalutamide - EMEA/H/C/002639/X/0029

Astellas Pharma Europe B.V.

Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia

Scope: “To add new pharmaceutical form and strenghts (film-coated tablets 40 mg and 80 mg) to the currently approved presentations for Xtandi.” Request for clock stop extension to respond to the List of questions adopted on 21.07.2016.

Action: For adoption

List of questions adopted on 21.07.2016

The CHMP agreed to the request by the applicant for clock stop to respond to the list of questions adopted on 21.07.2016 with a specific timetable.

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

No items

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

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

5.1.1. Ameluz - 5-aminolevulinic acid - EMEA/H/C/002204/II/0024

Biofrontera Bioscience GmbH

Rapporteur: Harald Enzmann, Co-Rapporteur: Patrick Salmon, PRAC Rapporteur: Martin Huber

Scope: “Extension of Indication from "Treatment of actinic keratosis of mild to moderate severity on the face and scalp (Olsen grade 1 to 2; see section 5.1) and of field cancerization" to the following:
"Treatment of actinic keratosis of mild to moderate severity on the face and scalp (Olsen grade 1 to 2; see section 5.1) and of field cancerization in adults including the elderly.
Treatment of non-aggressive basal cell carcinoma (primary superficial or nodular basal cell carcinoma or mixed types of both, with good or intermediate prognosis) on the face, scalp, neck, trunk and extremities in adults including the elderly."
Consequently, sections 4.1, 4.2, 4.4, 4.6, 4.8 and 5.1 of the SmPC are updated. Editorial changes have been proposed in sections 2, 4.5, 4.7, 5.2, 6.5 and 9 of the SmPC. 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.”

Action: For adoption

The Committee discussed the issues identified in this application, which were related to the wording of indication and the place in therapy.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.2. Arzerra - ofatumumab - Orphan - EMEA/H/C/001131/II/0045/G

Novartis Europharm Ltd

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Doris Stenver

Scope: "Extension of Indication to include the combination of Arzerra with fludarabine and cyclophosphamide or in combination with bendamustine for the treatment of adult patients with relapsed CLL.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet and the RMP (v.13) are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

The CHMP adopted the BWP report.

The CHMP adopted the CHMP assessment report on similarity

5.1.3. Benepali - etanercept - EMEA/H/C/004007/II/0019/G

Samsung Bioepis UK Limited (SBUK)

Rapporteur: Andrea Laslop, PRAC Rapporteur: Rafe Suvarna

Scope: "Extension of indication to include two new indications for the treatment of juvenile idiopathic arthritis and paediatric plaque psoriasis already approved for the reference medicinal product (Enbrel) for Benepali.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. Annex II, the Package Leaflet and Labelling are updated in accordance. The RMP (version 4.2) is also updated accordingly. Furthermore, the PI is brought in line with the latest QRD template version 10."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to the RMP.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.4. Caprelsa - vandetanib - EMEA/H/C/002315/II/0016

Genzyme Europe BV

Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard

Scope: "Extension of Indication to include paediatric indication population for Caprelsa. As a consequence, sections 4.1, 4.2, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated in update the safety information. The Package Leaflet is updated in accordance."

Further, the MAH requested one additional year of market protection for a new indication.

Action: For adoption

Request for Supplementary Information adopted on 13.10.2016, 23.06.2016, 01.04.2016, 19.11.2015.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The CHMP agreed by consensus to the request for an additional 1 year of market protection.

The summary of opinion was circulated for information.

The CHMP adopted the CHMP assessment report on similarity.

5.1.5. Humira - adalimumab - EMEA/H/C/000481/II/0154

AbbVie Ltd.

Rapporteur: Kristina Dunder

Scope: "Extension of Indication to include the treatment of adolescents from 12 years of age with hidradenitis suppurativa for Humira; as a consequence, sections 4.1, 4.2, 5.1 and 5.2, of the SmPC are updated. The Package Leaflet and the RMP (version 12.1.1) are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 21.07.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.6. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0011

Merck Sharp & Dohme Limited

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

Scope: "Extension of Indication to extend the existing indication for Keytruda 50mg to include previously untreated patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) whose tumors express PD-L1. 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. An updated RMP version 4.0 was provided as part of the application.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion focused on the wording of the indication and the acceptance of an additional 1 year of market protection.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.7. Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0049

Pfizer Limited

Rapporteur: Greg Markey, Co-Rapporteur: Karsten Bruins Slot, PRAC Rapporteur: Rafe Suvarna

Scope: "Extension of Indication to include a wider paediatric population starting from 6 weeks of age for Nimenrix. As a consequence, sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and the RMP are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 15.09.2016, 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.8. Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0131

Gilead Sciences International Ltd

Rapporteur: Greg Markey, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Julie Williams

Scope: "Extension of Indication to include treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years for Truvada.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated.
The Package Leaflet and the Risk Management plan (v.13) are updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to safety.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.9. Vimpat - lacosamide - EMEA/H/C/000863/II/0060/G

UCB Pharma S.A.

Rapporteur: Filip Josephson, Co-Rapporteur: Luca Pani, PRAC Rapporteur: Qun-Ying Yue

Scope: "C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one.

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 MAH took the opportunity to update the Product Information (PI) in line with the latest QRD template."

Action: For adoption

Request for Supplementary Information adopted on 15.09.2016, 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.10. Vimpat - lacosamide - EMEA/H/C/000863/II/0065/G

UCB Pharma S.A.

Rapporteur: Filip Josephson, Co-Rapporteur: Luca Pani, PRAC Rapporteur: Qun-Ying Yue

Scope: "This is a group of variations including extension of Indication to include monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary

generalisation in children from 4 to less than 16 years old with epilepsy. For the treatment initiation pack it is proposed to extend only adjunctive treatment to adolescents weighting more than 50 kg (not suitable for monotherapy and children and adolescents weighting less than 50 kg). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to bring Annex IIIA in line with the latest QRD template version 10 and to introduce combined SmPC for film coated tablets. Moreover, updated RMP version 12 has been submitted.
Furthermore, only for syrup presentation, in addition sections 6.3 and 6.5 of the SmPC are updated."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to safety and extrapolation of data.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.11. Tafinlar / Mekinist - dabrafenib trametinib - EMEA/H/C/WS0996

Novartis Europharm Ltd

Lead Rapporteur: Filip Josephson, Lead Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include the combination treatment with trametinib and dabrafenib of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600 mutation. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the Mekinist and Tafinlar SmPC are updated. The Package Leaflet and RMP are updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to align the SmPCs of Mekinist and Tafinlar. Furthermore, the Product Information is brought in line with the latest QRD template version 10."

Action: For adoption

The Committee discussed the issues identified in this application. The main discussion related to the design and robustness of the results of the clinical study. The Committee furthermore discussed the need for randomised controlled data.

The Committee adopted a request for supplementary information with a specific timetable.

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

5.2.1. 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: "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."

Request by the MAH for an extension to the clock stop to respond to the request for supplementary information adopted on 15.09.2016.

Action: For adoption

The CHMP agreed to the request by the MAH for an extension to the clock stop to respond to the request for supplementary information adopted on 15.09.2016.

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

No items

6. Ancillary medicinal substances in medical devices

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

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. – Ciclosporin - Orphan - EMEA/H/C/04411

Santen Oy; Treatment of severe vernal keratoconjunctivitis in children and adolescents aged 4 to 18 years old

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

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

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

Note: Products requesting eligibility under PRIME scheme are listed in the Annex G.

The CHMP noted the list of applications received.

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

Note: Recommendation for PRIME are listed in the Annex G.

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 7 recommendations for eligibility to PRIME: 1 was granted and 6 were denied. The individual outcomes are listed in PRIME Monthly Report on EMA website.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Colobreathe - colistimethate sodium - EMEA/H/C/001225/II/0023

MAH: Laboratories UK Limited

Rapporteur: Greg Markey,

Scope: Update on procedure

Action: For information

Request for Supplementary Information adopted on 12.05.2016, 03.03.2016

The CHMP noted the update on the procedure.

9.1.2. Helicobacter Test INFAI - 13C-urea - EMEA/H/C/000140/II/0019

MAH: INFAI GmbH

Scope: "Update of the SmPC section 4.2, 4.3, 5.1 and 6.5 in order to add information on use of Refex test meal prior to the Helicobacter Test INFAI administration. The Package leaflet has been updated accordingly. Additionally, the MAH has taken the opportunity to align the PI with the latest QRD template version 9.1."

Letter from the applicant dated 25 October 2016 requesting the re-examination of the CHMP Opinion adopted 13 October 2016, appointment of Re-examination Rapporteur

Action: For adoption

Opinion adopted on 13.10.2016. Request for Supplementary Information adopted on 15.09.2016, 21.07.2016, 23.06.2016, 01.04.2016, 28.01.2016.

The CHMP noted the tentative timetable and appointed a re-examination rapporteur.

9.1.3. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0020 & EMEA/H/C/002720/R/0022

MAH: PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Concepcion Prieto Yerro,

PRAC Rapporteur: Sabine Straus,

Scope: Oral explanation to be held on 08 November 2016 at time 16:00

Type II variation

"Update of sections 4.4, 4.8, 5.1 and 5.3 of the SmPC in order to reflect the results from the submitted study TC124-GD-020-DMD object of the specific obligation (SOB 001) for the conditional marketing authorisation. The Package Leaflet and the RMP are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include some minor editorial changes throughout the Product information."
Oral explanation was held on 11 October 2016. Request for Supplementary Information adopted on 21.07.2016, 01.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

Annual Renewal of Marketing Authorisation

Action: For adoption

Participation of patients' representatives

An oral explanation was held on Tuesday 08 November 2016 at time 16:00. The oral

explanation focused on the benefit/risk ratio and the clinical study designs of an efficacy and a pharmacology study.

The CHMP adopted an opinion by majority (24 positive out of 31 votes) recommending the renewal of the conditional marketing authorisation.

The Icelandic member agreed with the CHMP recommendation and the Norwegian member did not agree.

The divergent position (Aranzazu Sancho-Lopez, Fatima Ventura, Johann Lodewijk Hillege, Karsten Bruins Slot, Koenraad Norga, Nikola Moravcova, Ondrej Slanar, Sol Ruiz) was appended to the opinion.

The CHMP noted the communication to be published on EMA website.

See 2.3.1

Post-meeting note: the final documents were adopted via written procedure on 23 November 2016.

9.1.4. Tyverb - lapatinib - EMEA/H/C/000795/II/0048/G

Novartis Europharm Ltd

Rapporteur: Filip Josephson, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "1) C.I.4 (type II): Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to add a warning on QTc prolongation and update safety information following the submission of study report EGF114271 (A Phase IV placebo controlled single sequence crossover study to evaluate the effect of repeat oral doses of lapatinib on cardiac repolarization in patients with advanced cancer). The Package Leaflet is updated accordingly.
2) C.I.4 (type II): Update of section 4.8 of the SmPC in order to further elaborate on the undesirable effect 'serious cutaneous reactions' based on the review of the Novartis safety database. The Package Leaflet is updated accordingly"

Action: For adoption

The CHMP discussed different aspects of updating the SmPC on QTc prolongation.

The Committee adopted a request for supplementary information with a specific timetable.

10. Referral procedures

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

10.1.1. Direct-acting antivirals (DAAV) indicated for the treatment of hepatitis C (interferon free): Daklinza - daclatasvir; Exviera - dasabuvir ; Viekirax - ombitasvir, paritaprevir, ritonavir ; Olysio – simeprevir; Sovaldi - sofosbuvir sofosbuvir, Harvoni - ledipasvir – EMEA/H/A-20/1438

Applicant: Bristol-Myers Squibb Pharma EEIG (Daklinza); AbbVie Ltd (Exviera, Viekirax); Janssen-Cilag International N.V. (Olysio); Gilead Sciences International Ltd (Harvoni, Sovaldi)

CHMP Rapporteurs: Rapporteur: Filip Josephson, Co-Rapporteur: Robert James Hemmings (Daklinza), Rapporteur: Filip Josephson, Co-Rapporteur: Johann Lodewijk Hillege (Exviera, Viekirax), Rapporteur: Arantxa Sancho-Lopez, Co-Rapporteur: Daniela Melchiorri (Olysio); Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs (Sovaldi), Rapporteur: Filip Josephson, Co-Rapporteur: Joseph Emmerich (Harvoni)

PRAC Rapporteur: Margarida Guimarães; PRAC Co-rapporteur: Dolores Montero Corominas

Scope: Minutes of the SAG HIV/Viral diseases meeting

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

Action: For information

The CHMP noted the minutes from the SAG.

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

10.2.1. Desloratadine-containing products - desloratadine - EMEA/H/A-5(3)/1431

Rapporteur: Koen Norga, Co-Rapporteur: Andrea Laslop,

Scope: LoOI/Opinion

Prescription status of desloratadine-containing products

Action: For adoption

The CHMP discussed the data and criteria for prescription status and considered that it would be appropriate to consult the SWP at this stage.

CHMP discussion: November 2016 CHMP

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 07.02.2017

Comments: 16.02.2017

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 16.02.2017

CHMP discussion/opinion: February 2017 CHMP

Post-meeting note: the CHMP adopted the list of questions to SWP via written procedure on

07.12.2016.

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

No items

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

10.4.1. Paracomb 500mg/150mg film coated tablets - Paracetamol/Ibuprofen 500 mg/150 mg Paracetamol and Ibuprofen - EMEA/H/1447

Vale Pharmaceutical Ltd

RMS: UK, CMS: AT, BE, DE, FR, HR, IE, LU, NL, PT, ES

Decentralised Procedure numbers: UK/H/6034-5/001/DC, UK/H/6176/001/DC

Scope: Start of procedure and appointment of Rapporteurs

Disagreement regarding justification for a fixed dose combination, the demonstration of an additional benefit and of an acceptable safety profile

Action: For adoption

The CHMP appointed Nithyanandan Nagercoil as Rapporteur (interest level 3) and Romaldas Maciulaitis as Co-Rapporteur (interest level 2).

The CHMP adopted a list of questions to the applicant with a specific timetable.

Submission of responses: 12.01.2017

Re-start of the procedure: 26.01.2017

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 08.02.2017

Comments: 13.02.2017

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 16.02.2017

CHMP list of outstanding issues/CHMP opinion: February 2017 CHMP

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

10.5.1. Haldol and associated names - haloperidol - EMEA/H/A-30/1393

Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić,

Scope: Amended timetable

Action: For adoption

List of outstanding issues adopted 13.10.2016, 01.04.2016, 26.03.2015. List of Questions adopted on 26.06.2014

The CHMP adopted an amended timetable.

CHMP list of outstanding issues 3: 13.10.2016

Submission of responses: 12.01.2017

Re-start of the procedure: 26.01.2017

Joint assessment report circulated to CHMP: 08.02.2017

Comments: 13.02.2017

Updated joint assessment report circulated to CHMP: 16.02.2017

CHMP opinion: February 2017 CHMP

10.5.2. Haldol decanoate and associated names – haloperidol - EMEA/H/A-30/1405

Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić,

Scope: Amended timetable

Action: For adoption

List of outstanding issues adopted 13.10.2016, 01.04.2016, 26.03.2015. List of Questions adopted on 26.06.2014

The CHMP adopted an amended timetable.

CHMP list of outstanding issues 3: 13.10.2016

Submission of responses: 12.01.2017

Re-start of the procedure: 26.01.2017

Joint assessment report circulated to CHMP: 08.02.2017

Comments: 13.02.2017

Updated joint assessment report circulated to CHMP: 16.02.2017

CHMP opinion: February 2017 CHMP

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

10.6.1. Vancomycin containing products – (vancomycin) - EMEA/H/A-31/1440

Rapporteur: Concepcion Prieto-Yerro, Co-rapporteur: Alar Irs

Scope: LoOI/Opinion

Action: For adoption

Review of the benefit-risk balance following notification by the Spanish Agency of Medicines and Medical Devices of a referral under Article 31 of Directive 2001/83/EC.

Lists of Questions adopted on 21.07.2016, 01.04.2016.

The main discussion at the CHMP focused on the dosing regimen, but also other parts of the SmPC.

The CHMP adopted a list of questions to the MAH as well as to the IDWP, PKWP, MSWG and the PDCO with a specific timetable.

Submission of responses: 12.01.2017

Re-start of the procedure: 26.01.2017

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 08.02.2017

Comments: 13.02.2017

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 16.02.2017

CHMP List of outstanding issues/opinion: February 2017 CHMP

10.6.2. Symbioflor 2, Escherichia Coli bacteria (cells and autolysate) - EMEA/H/A-31/1441

Symbiopharm GmbH,

Rapporteur: Harald Enzmann, Co-rapporteur: Milena Stain;

Scope: List of experts to Ad-hoc expert meeting to be held 01.12.2016, updated timetable

Article 31 triggered by the BfArM in Germany in March 2016 requesting the review of the benefit-risk balance for Symbioflor 2 and associated names following concerns that the effectiveness of the medicine(s) has not been adequately demonstrated.

Action: For adoption

The CHMP adopted an updated timetable.

CHMP list of outstanding issues: September 2016 CHMP

Ad-hoc expert meeting: 01.12.2016

Submission of responses: 12.01.2017

Re-start of the procedure: 26.01.2017

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 08.02.2017

Comments: 13.02.2017

Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 16.02.2017

CHMP opinion: February 2017 CHMP

10.6.3. Gadolinium-containing contrast agents (GdCA): gadoversetamide – OPTIMARK (CAP) Gadobenate dimeglumine; gadobutrol; gadodiamide; gadopentetic acid dimeglumine, gadoteric acid (intra articular formulation); gadoteric acid (intrvenous and intravascular formulations); gadoteridol; gadoxetic acid disodium (NAP)

Lead Rapporteur: Rafe Suvarna,

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

Action: For adoption

The CHMP adopted the assessments of the annual cumulative reviews.

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

November 2016 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

The CHMP noted the 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

The CHMP noted the minutes.

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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Co-opted membership of the CHMP

The mandate of Robert J. Hemmings as Co-opted member of the CHMP expires in February 2017

Scope: Agreement on the expertise required for 5th Co-opted membership

Action: For discussion

In light of the expiry of the mandate of Robert J Hemmings in February 2017, the CHMP should agree on the expertise required. Proposals for the additional expertise required for the 5th co-opted member should be submitted by 7 December 2016. The agreement of expertise will take place at the December 2016 CHMP Plenary.

14.1.2. Multinational assessment team concept: the next phase – broadening the concept to the post-authorisation phase

The CHMP noted the updated proposal to broaden the concept to the post-authorisation phase. Building on the positive feedback from the NCAs involved in the MNATs in pre-authorisation, a request was made by some CHMP members in Q4 2015 to extend the MNAT concept to post-authorisation activities for human medicinal products. The EMA presented a framework for this next phase which caters for all possible post-authorisation scenarios and is setting up ground for both human and veterinary medicinal products. Implementation will be undertaken in a phased approach. In a first phase it will be limited to existing MNAT pre-authorisation (Co)-Rapporteurships for human and veterinary medicines and will include extension of indication (and, additionally for veterinary medicines, addition of non-food target species) and line extension applications. The proposal will be adopted by the Management Board at the December 2016 meeting. The CHMP welcomed the information.

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 24-27 October 2016

Action: For information

The CHMP noted the information.

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for November 2016

Action: For adoption

The CHMP adopted the list.

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 3-4 November 2016
Action: For information

The CHMP noted the minutes.

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 21-22 November 2016

Action: For information

The CHMP noted the report.

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at November 2016 PDCO

Action: For information

The CHMP noted the information.

Report from the PDCO meeting held on 9-11 November 2016

Action: For information

The CHMP noted the report.

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 3-4 November 2016
Action: For information

The CHMP noted the report.

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 7-9 November 2016

Action: For information

The CHMP noted the report.

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

14.3.1. Scientific Advice Working Party (SAWP)

Chair: Robert J. Hemmings

Scope: Report from the SAWP meeting held on 24-27 October 2016. Table of conclusions
Action: For information
Scientific advice letters: See Annex G
Disclosure of information related to scientific advice letters cannot be released at present time

as these contain commercially confidential information.

Scope: SA new initiative: Biosimilar Pilot
Action: For adoption
It was proposed to use the existing Scientific Advice procedure to allow a suitably in-depth review of quality and in-vitro data to further advise on the next steps of the development programme. It is foreseen to run the pilot until the completion of 6 SAs. The pilot will be open to all types of biosimilars. The pilot will start next year. The CHMP agreed to the new initiative.

Scope: Call for interest for nomination of a replacement SAWP member and his alternate following retirement of Dr Jens Ersbøll. The required area of expertise is oncology.
Action: For information
The letters of candidacy together with the CV of both member and alternate, as per the SAWP Mandate requirements [see Article 2(10)], should be sent, deadline 7 December 2016.

Scope: SAWP Chair election. The candidates should submit their brief résumés in support of their candidature deadline 7 December 2016.
Action: For information
The CHMP noted the call for nominations.

Scope: Scientific guidance on Post-Authorisation Efficacy Study (PAES)
(EMA/PDCO/CAT/CMDh/PRAC/CHMP/261500/2015)
Action: For adoption
The CHMP adopted the final scientific guidance on Post-Authorisation Efficacy Study (PAES). The guidance is intended to provide scientific guidance for MAHs and for Competent Authorities on PAES in the context of EU regulatory decision-making with regard to: the general need for such studies, general methodological considerations, specific situations and study conduct. It is not restricted to the situations falling within the scope of the Delegated Regulation (EU) No 357/2014. The guidance is not intended to replace or reproduce methods available in textbooks on various study designs but to highlight regulators' particular considerations and the potential role of mentioned study designs for the PAES setting. For the specific scenarios where PAES may be considered, additional clarifications are given together with study designs which may be considered useful.

14.3.2. Biosimilar Medicinal Product Working Party (BMWP)

Revision of the Guideline on non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight-heparins
EMEA/CHMP/BMWP/118264/2007 Rev. 1
Action: For adoption for 3-month public consultation
The CHMP discussed the revised guideline and agreed that no further public consultation was required. The CHMP adopted the final Guideline. The guideline lays down the general requirements for demonstration of the similar nature of two biological products in terms of safety and efficacy.
The product specific guideline complements the above guideline and presents the current view of the CHMP on the non-clinical and clinical requirements for demonstration of comparability of two LMWH-containing medicinal products.

14.3.3. Biostatistics Working Party (BSWP)

Scope: Nomination of new core member following resignation of David Jonathan Wright

Action: For adoption

The CHMP appointed Anja Schiel (NO) as core member.

14.4. Cooperation within the EU regulatory network

None

14.5. Cooperation with International Regulators

None

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

None

14.7. CHMP work plan

None

14.8. Planning and reporting

None

14.9. Others

None

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: Updated guideline to be published for 3-month public consultation

Action: For adoption

The CHMP adopted the guideline for 3-month public consultation. Furthermore a timetable was proposed and members were invited to comment on press release and public communication.

The revised guideline is open for public consultation until 28 February 2017. Comments should be sent to FIH-rev@ema.europa.eu using the template. EMA will make available all comments received, both on the concept paper and the revised guideline, after the final guideline is released. The aim is to publish a final revised guideline for the conduct of first-in-human clinical trials in the first half of 2017.

15.1.2. Workshop on update of TB Guideline to be held on 25 November 2016

Scope: the European Medicines Agency is organising a workshop on Development of antimycobacterial medicinal products which will take place on 25th November 2016, 9:00 – 16:00 UK time. The workshop will bring together experts and stakeholders from the academic, regulatory and industrial sectors to discuss key issues and new developments in the field of development of antimycobacterial medicinal products. The presentations and discussions will support the finalisation of the newly drafted Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to Mycobacterium tuberculosis.

You can follow the workshop through the broadcast.

Action: For information

The CHMP noted the information.

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 7 – 10 November 2016 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Tomas Salmonson	Chair	Sweden	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Milena Stain	Alternate	Austria	No interests declared	
Bart Van der Schueren	Member	Belgium	No interests declared	
Mila Vlaskovska	Member	Bulgaria	No interests declared	
Katarina Vučić	Member	Croatia	No interests declared	
Panayiotis Triantafyllis	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czech Republic	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Hanne Lomholt Larsen	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Tuomo Lapveteläinen	Alternate	Finland	No interests declared	
Pierre Demolis	Member	France	No interests declared	
Joseph Emmerich	Alternate	France	No interests declared	
Harald Enzmann	Member (Vice-Chair)	Germany	No interests declared	
Martina Weise	Alternate	Germany	No restrictions applicable to this meeting	
Dimitrios Kouvelas	Member	Greece	No interests declared	
Agnes Gyurasics	Member	Hungary	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Kolbeinn Gudmundsson	Member	Iceland	No interests declared	
David Lyons	Member	Ireland	No restrictions applicable to this meeting	
Patrick Salmon	Alternate	Ireland	No interests declared	
Daniela Melchiorri	Member	Italy	No restrictions applicable to this meeting	
Natalja Karpova	Alternate	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No restrictions applicable to this meeting	
Jacqueline Genoux-Hames	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Karsten Bruins Slot	Member	Norway	No interests declared	
Bjorg Bolstad	Alternate	Norway	No restrictions applicable to this meeting	
Piotr Fiedor	Member	Poland	No interests declared	
Aldona Paluchowska	Alternate	Poland	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Nela Vilceanu	Member	Romania	No interests declared	
Nikola Moravcova	Member	Slovakia	No interest declared	
Jana Schweigertova	Alternate	Slovakia	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Stanislav Primožič	Member	Slovenia	No interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Concepcion Prieto Yerro	Member	Spain	No interests declared	
Arantxa Sancho-Lopez	Alternate	Spain	No restrictions applicable to this meeting	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Greg Markey	Member	United Kingdom	No interests declared	
Nithyanandan Nagercoil	Alternate	United Kingdom	No restrictions applicable to this meeting	
Robert James Hemmings	Co-opted member	United Kingdom	No restrictions applicable to this meeting	
Koenraad Norga	Co-opted member	Belgium	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Mette Madsen	Expert - in person*	Denmark	No interests declared	
Petr Vrbata	Expert - in person*	Czech Republic	No restrictions applicable to this meeting	
Ana Alonso Gutierrez	Expert - in person*	Spain	No interests declared	
Eleftheria Nikolaidi	Expert - in person*	Greece	No interests declared	
Mair Powell	Expert - via telephone*	United Kingdom	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Elizabeth Vroom	Expert - in person*	Patient representative	No interests declared	
Dimitrios Athanasiou	Observer, in person	Patient representative	No interests declared	
Macarena Rodriguez Mendizabal	Expert - in person*	Spain	No interests declared	
Bernard Mooney	Observer, in person	Patient representative	No interests declared	
Francois Houyez	Observer, in person	Patient representative	No restrictions applicable to this meeting	
Giuseppe Rosano	Expert - via telephone*	Italy	No interests declared	
Giancarlo Zito	Expert - via telephone*	Italy	No interests declared	
Svetlana Lorenzano	Expert - via telephone*	Italy	No restrictions applicable to this meeting	
Violeta Stoyanova-Beninska	Expert - in person*	Netherlands	No interests declared	
Valérie Lescrainier	Expert - in person*	Belgium	No interests declared	
Tanja Zahlner	Expert - via telephone*	Austria	No interests declared	
Thomas Lang	Expert - via telephone*	Austria	No interests declared	
Sabine Mayrhofer	Expert - in person*	Germany	No interests declared	
Christoph Unkrig	Expert - via telephone*	Germany	No interests declared	
Darius Matusevicius	Expert - via telephone*	Sweden	No restrictions applicable to this meeting	
Eva Gil Berglund	Expert - via telephone*	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Frans Opdam	Expert - via telephone*	Netherlands	No interests declared	
Barbara Spruce	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Giuseppe Capovilla	Expert - via telephone*	Italy	No interests declared	
Miranda Vroenhove	Expert - via telephone*	Belgium	No interests declared	
Representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.

17. 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)*

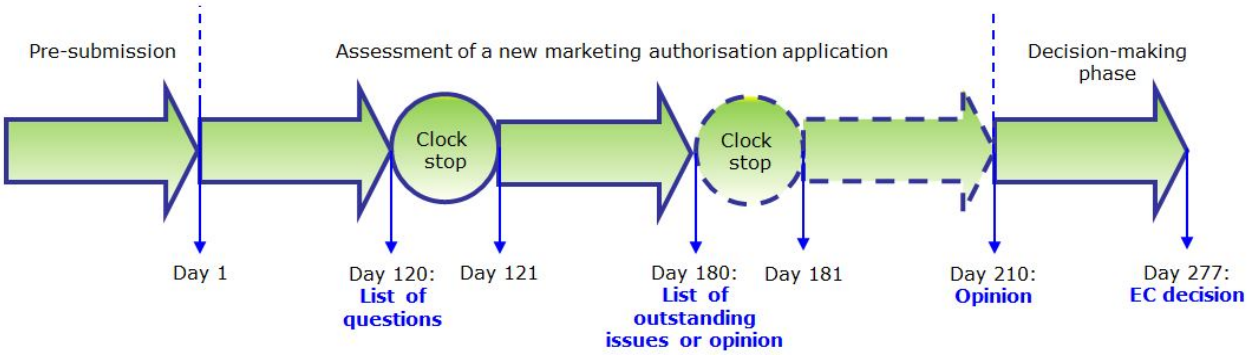
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

16 December 2016
EMA/CHMP/682759/2016 Corr[1]

ANNEX TO NOVEMBER 2016 CHMP Minutes

PRE SUBMISSION AND POST AUTHORISATIONS ISSUES

[1] Correction in section B.3.

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A. PRE SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for November 2016: **For adoption**	Adopted.

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

Final Outcome of Rapporteurship allocation for November 2016: **For adoption**	Adopted.

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Disclosure of information related to pre-submission of initial applications cannot be released at 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

Atriance - nelarabine - EMEA/H/C/000752/S/0034, Orphan MAH: Novartis Europharm Ltd, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Torbjorn Callreus	Positive Opinion adopted by consensus. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation. Marketing Authorisation remains under exceptional circumstances.
Imvanex - modified vaccinia Ankara virus - EMEA/H/C/002596/S/0022 MAH: Bavarian Nordic A/S, Rapporteur: Greg Markey, PRAC Rapporteur: Rafe Suvarna	Positive Opinion adopted by consensus. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation. Marketing Authorisation remains under exceptional circumstances.
Lojuxta - lomitapide - EMEA/H/C/002578/S/0023 MAH: Aegerion Pharmaceuticals Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 10.11.2016.	Request for Supplementary Information adopted with a specific timetable.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Bronchitol - mannitol - EMEA/H/C/001252/R/0028, Orphan MAH: Pharmaxis Pharmaceuticals Limited, Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Joseph Emmerich, PRAC	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Committee concluded that the renewal can be granted with unlimited validity. The Icelandic and

Rapporteur: Julie Williams	Norwegian CHMP Members were in agreement with the CHMP recommendation.
Capecitabine Accord - capecitabine - EMEA/H/C/002386/R/0021 MAH: Accord Healthcare Ltd, Generic, Generic of Xeloda, Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Committee concluded that the renewal can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Capecitabine Teva - capecitabine - EMEA/H/C/002362/R/0025 MAH: Teva B.V., Generic, Generic of Xeloda, Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Committee concluded that the renewal can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nimenrix - meningococcal group a, c, w135 and y conjugate vaccine - EMEA/H/C/002226/R/0059 MAH: Pfizer Limited, Rapporteur: Greg Markey, Co-Rapporteur: Karsten Bruins Slot, PRAC Rapporteur: Rafe Suvarna Request for Supplementary Information adopted on 10.11.2016.	Request for Supplementary Information adopted with a specific timetable.
Riluzole Zentiva - riluzole - EMEA/H/C/002622/R/0021 MAH: Aventis Pharma S.A., Rapporteur: Greg Markey, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Julie Williams	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Committee concluded that the renewal can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Sancuso - granisetron - EMEA/H/C/002296/R/0047 MAH: Kyowa Kirin Limited, Rapporteur: Romaldas Mačiulaitis, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Jolanta Gulbinovic	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Committee concluded that the renewal can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vepacel - prepandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture) - EMEA/H/C/002089/R/0015 MAH: Nanotherapeutics Bohumil Sro, Rapporteur: Bart Van der Schueren, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Jean-Michel Dogné	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Committee concluded that the renewal can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.2.3. Renewals of Conditional Marketing Authorisations

Caprelsa - vandetanib - EMEA/H/C/002315/R/0023 MAH: Genzyme Europe BV, Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard Request for Supplementary Information adopted on 10.11.2016.	Request for Supplementary Information adopted with a specific timetable.
Cometriq - cabozantinib - EMEA/H/C/002640/R/0022, Orphan MAH: Ipsen Pharma, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this Conditional Marketing Authorisation can be granted. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Sirturo - bedaquiline - EMEA/H/C/002614/R/0017, Orphan MAH: Janssen-Cilag International NV, Rapporteur: Filip Josephson, Co-Rapporteur: Karsten Bruins Slot, PRAC Rapporteur: Qun-Ying Yue	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this Conditional Marketing Authorisation can be granted. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Translarna - ataluren - EMEA/H/C/002720/R/0022, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus Request for Supplementary Information adopted on 28.04.2016. Oral explanation held on 08.11.2016	See main agenda 9.1.3.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 24-27 October 2016 PRAC:	
Cobicistat-containing products: cobicistat – **Tybost** EMEA/H/C/002572; cobicistat, atazanavir sulfate, CHMP Rapporteur: Robert James Hemmings **Evotaz** EMEA/H/C/003904; cobicistat, darunavir, CHMP Rapporteur: Bruno Sepodes **Rezolsta** EMEA/H/C/002819; cobicistat elvitegravir, emtricitabine, tenofovir alafenamide , CHMP Rapporteur: Johann Lodewijk Hillege	Adopted.

Genvoya EMEA/H/C/004042; cobicistat elvitegravir, emtricitabine, tenofovir disoproxil fumarate , CHMP Rapporteur: Robert James Hemmings **Stribild** EMEA/H/C/002574; elvitegravir, cobicistat, emtricitabine, tenofovir , CHMP Rapporteur: Robert James Hemmings PRAC Rapporteur: Rafe Suvarna. Signal of drug interaction with corticosyeroids leading to adrenal suppression • PRAC recommendation on a variation: **For adoption**	
Olanzapine – **ZYPADHERA** EMEA/H/C/000890**;** **ZYPREXA** EMEA/H/C/000115**;** **ZYPREXA VELOTAB** EMEA/H/C/000287; CHMP Rapporteur: Outi Mäki-Ikola PRAC Rapporteur: Kimmo Jaakkola - Signal of restless leg syndrome (RLS) • PRAC recommendation on a variation: **For adoption**	Adopted.
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its October 2016 meeting:	
EMEA/H/C/PSUSA/00001353/201604 (febuxostat) CAPS: **Adenuric** (EMEA/H/C/000777) (febuxostat), MAH: Menarini International Operations Luxembourg S.A., Rapporteur: Andrea Laslop, PRAC Rapporteur: Jan Neuhauser, "21/04/2015 - 20/04/2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Update of section 4.8 of the SmPC to add blood creatine phosphokinase increase with a frequency rare. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00001471/201603 (fosaprepitant) CAPS: **Ivemend** (EMEA/H/C/000743) (fosaprepitant), MAH: Merck Sharp & Dohme Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "26 March 2015 to 25 March 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to include information on anaphylactic reactions and shock. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

EMEA/H/C/PSUSA/00002023/201603 (methylnaltrexone bromide) CAPS: **Relistor** (EMEA/H/C/000870) (methylnaltrexone bromide), MAH: PharmaSwiss Ceska Republika s.r.o, Rapporteur: Harald Enzmann, PRAC Rapporteur: Valerie Strassmann, "28 May 2015 to 27 March 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.3, 4.4 and 4.8 of the SmPC to better reflect the safety concern gastrointestinal perforation and to add a warning on Opioid withdrawal syndrome. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00003152/201603 (zonisamide) CAPS: **Zonegran** (EMEA/H/C/000577) (zonisamide), MAH: Eisai Ltd, Rapporteur: Patrick Salmon, PRAC Rapporteur: Almath Spooner, "01/04/2015 to 31/03/2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following changes: Based on the PRAC review of data on safety and efficacy, the PRAC considers by consensus that the risk-benefit balance of medicinal products containing zonisamide remains unchanged but recommends that the terms of the marketing authorisation should be varied as follows: Update of sections 4.4 and 4.8 of the SmPC to add angle closure glaucoma with a frequency very rare and to add a warning on acute myopia and secondary angle closure glaucoma. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010052/201603 (vortioxetine) CAPS: **Brintellix** (EMEA/H/C/002717) (vortioxetine), MAH: H. Lundbeck A/S, Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Laurence de Fays, "30-SEP-2015 to 29-MAR-2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.8 of the SmPC to add the adverse reaction hyponatraemia with a frequency not known. The package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

EMEA/H/C/PSUSA/00010263/201604 (umeclidinium bromide) CAPS: **Incruse** (EMEA/H/C/002809) (umeclidinium bromide), MAH: Glaxo Group Ltd, Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Carmela Macchiarulo, "25/04/2015 - 20/04/2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reactions glaucoma, vision blurred, urinary retention, dysuria, with a frequency not known. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010272/201603 (insulin degludec / liraglutide) CAPS: **Xultophy** (EMEA/H/C/002647) (insulin degludec / liraglutide), MAH: Novo Nordisk A/S, Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst, "01 Oct 2015 - 31 March 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reactions 'increased lipase' and 'increased amylase' with a frequency "common". The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010319/201604 (nintedanib (respiratory indication)) CAPS: **OFEV** (EMEA/H/C/003821) (nintedanib), MAH: Boehringer Ingelheim International GmbH, Rapporteur: David Lyons, PRAC Rapporteur: Nikica Mirošević Skvrce, "16 Oct 20 15 to 15 Apr 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to amend the current warning on hepatic function to add that administration of nintedanib was also associated with drug-induced liver injury. In addition update of section 4.8 of the SmPC to add 'drug-induced liver injury' as a new adverse drug reaction with a 'not known' frequency. The Package leaflet is updated accordingly.

B.4. EPARs / WPARs

Cystadrops - mercaptamine - EMEA/H/C/003769, Orphan Applicant: Orphan Europe S.A.R.L., treatment of cystinosis, Known active substance (Article 8(3) of Directive No 2001/83/EC)	adopted.
Emtricitabine/Tenofovir disoproxil Krka -	adopted.

emtricitabine / tenofovir disoproxil - EMEA/H/C/004215 Applicant: KRKA, d.d., Novo mesto, treatment of HIV-1 infection, Generic, Generic of Truvada, Generic application (Article 10(1) of Directive No 2001/83/EC)	
Emtricitabine/Tenofovir disoproxil Mylan - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050 Applicant: MYLAN S.A.S, treatment of HIV, Generic, Generic of Truvada, Generic application (Article 10(1) of Directive No 2001/83/EC)	adopted
Ocaliva - obeticholic acid - EMEA/H/C/004093, Orphan Applicant: Intercept Pharma Ltd, treatment of primary biliary cirrhosis, New active substance (Article 8(3) of Directive No 2001/83/EC)	adopted.
Rekovelle - follitropin delta - EMEA/H/C/003994 Applicant: Ferring Pharmaceuticals A/S, indicated for controlled ovarian stimulation, New active substance (Article 8(3) of Directive No 2001/83/EC)	adopted.
SomaKit TOC - edotreotide - EMEA/H/C/004140, Orphan Applicant: Advanced Accelerator Applications, Diagnosis of gastro-entero-pancreatic neuroendocrine tumours, Well-established use application (Article 10a of Directive No 2001/83/EC)	adopted.
Tenofovir disoproxil Mylan - tenofovir disoproxil - EMEA/H/C/004049 Applicant: MYLAN S.A.S, treatment of HIV-1 infection and hepatitis B infection, Generic, Generic of Viread, Generic application (Article 10(1) of Directive No 2001/83/EC)	adopted.
Venclyxto - venetoclax - EMEA/H/C/004106, Orphan Applicant: AbbVie Ltd., treatment of adult patients with chronic lymphocytic leukaemia (CLL), New active substance (Article 8(3) of Directive No 2001/83/EC)	adopted.
Ertapenem Hospira - Ertapenem Sodium - (EMEA/H/C/004080) Applicant: Hospira UK Limited, treatment of bacterial infections and prophylaxis of surgical site infection following elective colorectal surgery,	adopted.

Generic application (Article 10(1) of Directive No 2001/83/EC) **WPAR**	

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Constella - linaclotide - EMEA/H/C/002490/II/0028 MAH: Allergan Pharmaceuticals International Ltd, Rapporteur: Harald Enzmann Opinion adopted on 27.10.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Dacogen - decitabine - EMEA/H/C/002221/II/0028/G, Orphan MAH: Janssen-Cilag International NV, Rapporteur: Pierre Demolis Opinion adopted on 27.10.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Empliciti - elotuzumab - EMEA/H/C/003967/II/0001/G MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van HennikIA -A.6 - to add the ATC Code following granting by WHO in the SmPC and bring the labelling in line with the latest QRD template (V10.0). Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Esbriet - pirfenidone - EMEA/H/C/002154/II/0039, Orphan MAH: Roche Registration Limited, Rapporteur: Greg Markey, Request for Supplementary Information adopted on 27.10.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Eylea - aflibercept - EMEA/H/C/002392/II/0028 MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016, 14.04.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Flixabi - infliximab - EMEA/H/C/004020/II/0003 MAH: Samsung Bioepis UK Limited (SBUK), Rapporteur: Jan Mueller-Berghaus, Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 29.09.2016.	
Foclivia - influenza virus surface antigens (inactivated) of strain A/Vietnam/1194/2004 (H5N1) - EMEA/H/C/001208/II/0023/G MAH: Seqirus S.r.l, Rapporteur: Daniela Melchiorri Request for Supplementary Information adopted on 27.10.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0070 MAH: CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Idelvion - albutrepenonacog alfa - EMEA/H/C/003955/II/0001/G, Orphan MAH: CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kalydeco - ivacaftor - EMEA/H/C/002494/II/0046, Orphan MAH: Vertex Pharmaceuticals (Europe) Ltd., Rapporteur: Concepcion Prieto Yerro, Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016, 12.05.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kanuma - sebelipase alfa - EMEA/H/C/004004/II/0006/G, Orphan MAH: Alexion Europe SAS, Rapporteur: Bart Van der Schueren Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together a specific timetable.
Memantine LEK - memantine hydrochloride - EMEA/H/C/002630/II/0007/G MAH: Pharmathen S.A., Generic, Generic of Ebixa, Rapporteur: Martina Weise Opinion adopted on 27.10.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
NexoBrid - concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0027/G, Orphan MAH: MediWound Germany GmbH, Rapporteur: Harald Enzmann Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 29.09.2016.	
NovoSeven - eptacog alfa / eptacog alfa (activated) - EMEA/H/C/000074/II/0093 MAH: Novo Nordisk A/S, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Orencia - abatacept - EMEA/H/C/000701/II/0103/G MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 06.10.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Pheburane - sodium phenylbutyrate - EMEA/H/C/002500/II/0014 MAH: Lucane Pharma, Rapporteur: David Lyons Request for Supplementary Information adopted on 10.11.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Prialt - ziconotide - EMEA/H/C/000551/II/0050 MAH: Eisai Ltd, Rapporteur: Koenraad NorgaOpinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Rapilysin - reteplase - EMEA/H/C/000105/II/0062 MAH: Actavis Group PTC ehf, Rapporteur: Harald Enzmann Request for Supplementary Information adopted on 20.10.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable:
Ratiograstim - filgrastim - EMEA/H/C/000825/II/0052 MAH: ratiopharm GmbH, Rapporteur: Outi Mäki-Ikola Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Senshio - ospemifene - EMEA/H/C/002780/II/0010 MAH: Shionogi Limited, Rapporteur: Paula Boudewina van Hennik Request for Supplementary Information adopted on 10.11.2016, 04.08.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable:
Stelara - ustekinumab - EMEA/H/C/000958/II/0051/G MAH: Janssen-Cilag International NV, Rapporteur:	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable:

Greg Markey Request for Supplementary Information adopted on 20.10.2016.	
Tevagrastim - filgrastim - EMEA/H/C/000827/II/0061 MAH: TEVA GmbH, Duplicate, Duplicate of Biograstim, Rapporteur: Outi Mäki-Ikola Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vimizim - elosulfase alfa - EMEA/H/C/002779/II/0015, Orphan MAH: BioMarin Europe Ltd, Rapporteur: Johann Lodewijk Hillege, Opinion adopted on 28.10.2016.	Positive Opinion adopted by consensus on 28.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0018/G MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise Opinion adopted on 27.10.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Voncento - human coagulation factor VIII / human von willebrand factor - EMEA/H/C/002493/II/0021/G MAH: CSL Behring GmbH, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Zaltrap - aflibercept - EMEA/H/C/002532/II/0025/G MAH: Sanofi-Aventis Groupe, Rapporteur: Filip Josephson Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 04.08.2016, 19.05.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS0950 **Leganto-EMEA/H/C/002380/WS0950/0021** **Neupro-EMEA/H/C/000626/WS0950/0071** MAH: UCB Manufacturing Ireland Ltd., Lead Rapporteur: Bruno Sepodes Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 04.08.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS0954 **Filgrastim** **Hexal-EMEA/H/C/000918/WS0954/0033** **Zarzio-EMEA/H/C/000917/WS0954/0034** MAH: SANDOZ GmbH, Lead Rapporteur: Greg	The Committee adopted a Request for Supplementary information together with the following timetable:

Markey Request for Supplementary Information adopted on 10.11.2016.	
Hexacima-EMEA/H/C/002702/WS0964/0051/G **Hexaxim-EMEA/H/W/002495/WS0964/0058/G** **Hexyon-EMEA/H/C/002796/WS0964/0054/G** MAH: Sanofi Pasteur SA, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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

Ambirix - hepatitis A (inactivated) and hepatitis B(rDNA) (HAB) vaccine (adsorbed) - EMEA/H/C/000426/II/0077 MAH: GSK Biologicals SA, Rapporteur: Robert James Hemmings, “Update of section 6.6 of the SmPC in order to update the re-suspension instructions, based on user testing results. 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 9.1, to include some corrections and to align the wording across combined hepatitis A and hepatitis B vaccines (i.e. Twinrix Adult, Twinrix Paediatric and Ambirix).” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bydureon - exenatide - EMEA/H/C/002020/II/0038 MAH: AstraZeneca AB, Rapporteur: Kristina Dunder, , “Submission of the final results of study 2993LAR-105 to examine the effects of exenatide once weekly on glucose control and safety in subjects with type II diabetes mellitus managed with diet modification and exercise and/or oral anti-diabetic medications.” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted,	The Committee adopted a Request for Supplementary information together with a

adsorbed) - EMEA/H/C/000721/II/0080 MAH: GSK Biologicals SA, Rapporteur: Bart Van der Schueren, "Submission of final Study report for study HPV-060. Study HPV-060 is an extension of the study HPV-014 (EXT 014 Y5-10). Study HPV-014 with 4 years post-vaccination data was submitted as a commitment in November 2009 (EMEA/H/C/721/FU2 20.5) The purpose of this variation is to fulfil the Post-Authorization Measure (PAM) (MEA-082) with the long term follow up (10 years post-vaccination) data from study HPV-060. GlaxoSmithKline Biologicals (GSK Biologicals) considers that there is no need to change the SmPC at this stage." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	specific timetable.
Effentora - fentanyl - EMEA/H/C/000833/II/0044 MAH: Teva B.V., Rapporteur: Martina Weise, "Update of sections 4.4, 4.6 and 4.8 as applicable of the SmPC in order to add a warning on adrenal insufficiency, androgen deficiency and Neonatal withdrawal syndrome following a request from FDA to introduce a class label safety warning. The PL was 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 and to apply a combined SmPC" Request for Supplementary Information adopted on 10.11.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Fycompa - perampanel - EMEA/H/C/002434/II/0030 MAH: Eisai Europe Ltd., Rapporteur: Robert James Hemmings, "Update of sections 5.1 and 5.2 of the SmPC to reflect the results from study E2007-G000-235." Opinion adopted on 20.10.2016. Request for Supplementary Information adopted on 28.07.2016, 16.06.2016.	Positive Opinion adopted by consensus on 20.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Giotrif - afatinib - EMEA/H/C/002280/II/0020 MAH: Boehringer Ingelheim International GmbH, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to include a table comparing adverse drug reactions (with	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

frequency very common) observed in the global, randomised, open-label, Phase IIb trial (LUX-Lung 7) with afatinib and gefitinib and update of section 5.1 of the SmPC in order to add the results of the primary analysis of this study." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	
Glivec - imatinib - EMEA/H/C/000406/II/0106 MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, "Update of section 4.8 of the SmPC to add the new ADR 'musculoskeletal pain upon treatment discontinuation' with a frequency of very common. The Package Leaflet has been updated accordingly. Further, the MAH has taken the opportunity to merge the SmPCs of the different strengths of the same pharmaceutical form i.e. 50 mg and 100 mg hard capsules, and 100 mg and 400 mg film coated tablets, respectively, and to align the annexes with version 10 of the QRD template." Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Harvoni - sofosbuvir / ledipasvir - EMEA/H/C/003850/II/0035 MAH: Gilead Sciences International Ltd, Rapporteur: Filip Josephson, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to add emerging clinical data available from studies SOLAR-1 and SOLAR-2." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Invirase - saquinavir - EMEA/H/C/000113/II/0120 MAH: Roche Registration Limited, Rapporteur: Milena Stain, "Update of sections 4.4 and 4.5 of the SmPC in order to add a warning regarding the co-administration of Invirase/ritonavir with cobicistat and other pharmaco-enhancers and to correct an error in the fold increase in exposure of maraviroc in the interaction table. 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, to correct minor typographical errors and to amend Annex A." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 15.09.2016.	
Invokana - canagliflozin - EMEA/H/C/002649/II/0020 MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, PRAC Rapporteur: Valerie Strassmann, "To revise RMP (v. 6.0) in order to update the following information: Article 20 procedure on Diabetic Ketoacidosis (DKA) including updates to reflect discussions with PRAC on renal impairment/renal failure; hypersensitivity and DKA, update the information related to revisions to proposed dates for completion of clinical studies and to include additional studies requested as part of the Article 20 DKA review procedure. Additionally, the MAH included in the response document the outcome of variation EMEA/H/C/002649/II/23 or Invokana and EMEA/H/C/002656/II/19 for Vokanamet concerning the completion of study DIA 1055 (a PK/PD study in children >10 years to < 18 years of age. The MAH included also with the response document the outcome of the Article 31 referral (EMEA/H/A-31/1432) procedure regarding metformin-containing products." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Jevtana - cabazitaxel - EMEA/H/C/002018/II/0035 MAH: Sanofi-Aventis Groupe, Rapporteur: Pierre Demolis, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to add information on study TED12689 a phase 1-2 dose finding, safety and efficacy study of cabazitaxel in pediatric patients with refractory solid tumors including tumors of the central nervous system." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable:
Kentera - oxybutynin - EMEA/H/C/000532/II/0041 MAH: Nicobrand Limited, Rapporteur: Bart Van der Schueren, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to implement the adopted wording from the final PRAC recommendation on the signal on psychiatric disorders. Updates to the agreed PRAC wording are also made in sections 4.2 and 4.4 to further clarify the dose adjustment in the elderly	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

population and in section 4.8 to clarify the text on adverse reactions considered associated with anticholinergic therapy. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the SmPC (Annex I), Labelling (Annexe IIIA) and Package leaflet (Annexe IIIB) in accordance with EDQM standards terms." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	
Lynparza - olaparib - EMEA/H/C/003726/II/0009/G, Orphan MAH: AstraZeneca AB, Rapporteur: Pierre Demolis, PRAC Rapporteur: Carmela Macchiarulo"Update section 4.2 and section 5.2 of the SmPC to reflect that Lynparza can be administered to patients with mild hepatic impairment with no dose adjustment based on the results of study D0816C00005 (MEA 005). In addition section 4.4 is updated to reflect that co administration with moderate CYP3A inducers is not recommended based on the addendum to the Simcyp modelling report. The risk management plan (version 13) has also been updated to reflect the study results. The requested group of variations proposed amendments to the Summary of Product Characteristics and to the Risk Management Plan (RMP)." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Nucala - mepolizumab - EMEA/H/C/003860/II/0005 MAH: GlaxoSmithKline Trading Services, Rapporteur: Nithyanandan Nagercoil, "Update of sections 4.4 and 4.8 of the SmPC in order to include "anaphylaxis" as an adverse reaction. The Package Leaflet is updated accordingly. Minor amendments to section 6.6 of the SmPC and to the Instructions for use and handling, reconstitution, and administration for the HCP are also introduced. 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 (Product Information) in line with the latest QRD template version 10." Opinion adopted on 27.10.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Portrazza - necitumumab - EMEA/H/C/003886/II/0002 MAH: Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Submission of study I4X-MC-JFCL, investigating necitumumab in combination with paclitaxel and carboplatin chemotherapy versus paclitaxel and carboplatin chemotherapy alone as the first line therapy in patients with Stage IV metastatic squamous non-small cell lung cancer (NSCLC). This variation leads to amendments of the Product Information: sections 4.4 and 5.1 of the SmPC were updated to reflect the findings of the study submitted. The update is being reflected in the PL." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Rotarix - human rotavirus, live attenuated - EMEA/H/C/000639/II/0089 MAH: GlaxoSmithKline Biologicals S.A., Rapporteur: Bart Van der Schueren, "Update of section 5.1 to introduce effectiveness data following completion of ecological observational study EPI-ROTA-025 VE AU DB (114910) - An ecological study to assess impact of rotavirus vaccination on hospitalisations for rotavirus gastroenteritis (RV GE) in children <5 years of age in Australia. In addition, the marketing authorisation holder took the opportunity to introduce clarifications in the SmPC." Request for Supplementary Information adopted on 27.10.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Twinrix Adult - hepatitis A (inactivated) and hepatitis B(rDNA) (HAB) vaccine (adsorbed) - EMEA/H/C/000112/II/0110 MAH: GSK Biologicals SA, Rapporteur: Robert James Hemmings, "Update of section 6.6 of the SmPC in order to update the re-suspension instructions based on user testing results. 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 9.1, to include some corrections, to align the wording across combined hepatitis A and B vaccines (i.e. Twinrix Adult, Twinrix Paediatric and Ambirix) and to combine the SmPC of the vial and pre-filled syringe presentations."	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	
Twinrix Paediatric - hepatitis A (inactivated) and hepatitis B(rDNA) (HAB) vaccine (adsorbed) - EMEA/H/C/000129/II/0111 MAH: GSK Biologicals SA, Duplicate, Duplicate of Twinrix Adult, Rapporteur: Robert James Hemmings, "Update of section 6.6 of the SmPC in order to update the re-suspension instructions based on user testing results. 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 9.1, to include some corrections, to align the wording across combined hepatitis A and B vaccines (i.e. Twinrix Adult, Twinrix Paediatric and Ambirix) and to combine the SmPC of the vial and pre-filled syringe presentations." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0016 MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, PRAC Rapporteur: Menno van der Elst, "To revise RMP (v. 6.0) in order to update the following information: Article 20 procedure on Diabetic Ketoacidosis (DKA) including updates to reflect discussions with PRAC on renal impairment/renal failure; hypersensitivity and DKA, update the information related to revisions to proposed dates for completion of clinical studies and to include additional studies requested as part of the Article 20 DKA review procedure. Additionally, the MAH included in the response document the outcome of variation EMEA/H/C/002649/II/23 or Invokana and EMEA/H/C/002656/II/19 for Vokanamet concerning the completion of study DIA 1055 (a PK/PD study in children >10 years to < 18 years of age. The MAH included also with the response document the outcome of the Article 31 referral (EMEA/H/A-31/1432) procedure regarding metformin-containing products." Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 15.09.2016.	
Votrient - pazopanib - EMEA/H/C/001141/II/0039 MAH: Novartis Europharm Ltd, Rapporteur: Sinan B. Sarac, "Update of section 4.8 to add the adverse reaction Polycythaemia with the frequency uncommon. This variation, based on cumulative review of all cases, is provided following the PRAC request on the signal assessment report EPITT no 18660. The Package Leaflet is updated accordingly." Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Xeplion - paliperidone - EMEA/H/C/002105/II/0030 MAH: Janssen-Cilag International NV, Rapporteur: Kristina Dunder, "Update of section 4.8 of the Xeplion SmPC in order to reflect safety information after assessment of study R092670-SCA-3004 and the PP3M (TREVICTA, once 3-monthly paliperidone palmitate injection) studies R092670-PSY1005, R092670-PSY-3011 and R092670-PSY-3012; the Package Leaflet has been updated accordingly. Additional changes are proposed in order to align the Xeplion Product information with the TREVICTA Product Information (for which XEPLION is the reference medicinal product) following the assessment of the PP3M studies (ref. to TREVICTA procedure EMEA/H/C/004066/X/0007/G)." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Zoely - nomegestrol / estradiol - EMEA/H/C/001213/II/0037 MAH: Teva B.V., Rapporteur: Joseph Emmerich, "Update of section 4.2 of the SmPC concerning reduced efficacy with regard to concomitant medications and section 4.5 of the SmPC concerning hepatic metabolism and HIV/HCV interactions. The Package Leaflet has been updated accordingly." Request for Supplementary Information adopted on 10.11.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Zoely - nomegestrol / estradiol - EMEA/H/C/001213/II/0038 MAH: Teva B.V., Rapporteur: Joseph Emmerich, "Update of sections 4.4 and 4.5 of the SmPC concerning Hepatitis C and the risk of elevated	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

ALT due to treatment with the HCV combination regimen ombitasvir/paritaprevir/ritonavir co-administered with ethinylestradiol-containing products. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the SmPC and Package Leaflet." Request for Supplementary Information adopted on 10.11.2016.	
Zydelig - idelalisib - EMEA/H/C/003843/II/0025 MAH: Gilead Sciences International Ltd, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC to reflect the results of the final report for a study of mechanisms of resistance to idelalisib in patients with chronic lymphocytic leukemia (CLL). This submission fulfils the post-authorisation measure (PAM) 013 for Zydelig." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS0919 **Exviera-EMEA/H/C/003837/WS0919/0015** **Viekirax-EMEA/H/C/003839/WS0919/0015** MAH: AbbVie Ltd., Lead Rapporteur: Filip Josephson, "Update of sections 4.2 and 5.2 of the SmPC in order to reflect the findings of study M14-226 in patients with HCV infection and several renal impairment or End Stage Renal Disease." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016, 01.04.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS0998 **OFEV-EMEA/H/C/003821/WS0998/0011** **Vargatef-EMEA/H/C/002569/WS0998/0013** MAH: Boehringer Ingelheim International GmbH, Lead Rapporteur: Sinan B. Sarac, "Update of section 4.8 of the SmPC in order to include 'thrombocytopenia' as new ADR with a 'common' frequency for Vargated and an 'uncommon' frequency for Ofev. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to introduce minor corrections to the English, Croatian and Slovak Annexes for Vargated and to the Slovak Annexes	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

for Ofev and to bring the Product Information in line with the latest QRD template version 10." Opinion adopted on 10.11.2016.	
WS1004 **Ultibro Breezhaler-EMEA/H/C/002679/WS1004/0012** **Ulunar Breezhaler-EMEA/H/C/003875/WS1004/0012** **Xoterna Breezhaler-EMEA/H/C/003755/WS1004/0014** MAH: Novartis Europharm Ltd, Lead Rapporteur: Hanne Lomholt Larsen, "Update of section 5.1 of the summary of product characteristics (SmPC) to reflect the final results of study CQVA149A2318 "A 52-week treatment, multi-center, randomised, double-blind, double dummy, parallel-group, active controlled study to compare the effect of QVA149 (indacaterol maleate/glycopyrronium bromide) with salmeterol/fluticasone (salm/flut) on the rate of exacerbations in subjects with moderate to very severe COPD". In addition, the MAH took this opportunity to more accurately reflect the mean pre-dose values at week 64 from clinical study CQVA149A2304 report, included in the original marketing authorisation application." Opinion adopted on 27.10.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1010 **Descovy-EMEA/H/C/004094/WS1010/0006** **Genvoya-EMEA/H/C/004042/WS1010/0017** **Odefsey-EMEA/H/C/004156/WS1010/0004** MAH: Gilead Sciences International Ltd, Lead Rapporteur: Robert James Hemmings, "Update of section 5.2 of the SmPC in order to provide the final results from Study GS-US-320-1615 "A Phase 1, Open-Label, Parallel-Group, Single Dose Study to Evaluate the Pharmacokinetics of Tenofovir Alafenamide (TAF) in Subjects with Normal Hepatic Function and Subjects with Severe Hepatic Impairment". In addition, the Worksharing applicant (WSA)	The Committee adopted a Request for Supplementary information together with a specific timetable:

took the opportunity to update section 4.2 of the SmPC for Descovy to allow dosing in patients with severe hepatic impairment. The information from the CSR for Study GS-US-320-1615 does lead to the addition or deletion of a safety concern in the corresponding RMPs." Request for Supplementary Information adopted on 10.11.2016.	

B.5.3. CHMP-PRAC assessed procedures

Aldara - imiquimod - EMEA/H/C/000179/II/0067 MAH: Meda AB, Rapporteur: Nithyanandan Nagercoil, PRAC Rapporteur: Rafe Suvarna, "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 RMP is updated accordingly (version 3.2)." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016, 26.05.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Amyvid - florbetapir (18F) - EMEA/H/C/002422/II/0022 MAH: Eli Lilly Nederland B.V., Rapporteur: Harald Enzmann, PRAC Rapporteur: Valerie Strassmann, "Update of sections 4.4 and 5.1 of the SmPC in order to introduce quantitative read as an adjunct to visual read of florbetapir (18F) PET scans. In addition, the Marketing authorisation holder (MAH) took the opportunity bring the PI in line with the latest QRD template version 10.0. The updated RMP version 2.0 has been submitted" Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable:
Evarrest - human fibrinogen / human thrombin - EMEA/H/C/002515/II/0027/G MAH: Omrix Biopharmaceuticals N. V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski"Group of variations consisting of: 1) Submission of the final results for study BIOS-13-005 updating the efficacy and safety information 2) Submission of the final results for study BIOS-13-004 updating the efficacy and safety	The Committee adopted a Request for Supplementary information together with a specific timetable.

information 3) Submission of the final results for study 400-12-002 updating the efficacy and safety information 4) Submission of the final results for study 400-12-005 updating the safety information 5) Update of section 5.1 of the SmPC to include further information on main existing efficacy studies Sections 4.8, 5.1 of the SmPC are affected by this group of variations. In addition, the Product Information has been updated in accordance with the QRD template, version 10 and Guideline on core SmPC for plasma-derived fibrin/sealant/haemostatic products (EMA/CHMP/BPWP/598816/2010 rev.1). Section 4.2 has been updated regarding the paediatric information for children under the aged of 1 month, according to the EMA waiver. A revised RMP (version 3) is also introduced, including consequential and routine changes." Request for Supplementary Information adopted on 10.11.2016.	
Exjade - deferasirox - EMEA/H/C/000670/II/0052, Orphan MAH: Novartis Europharm Ltd, Rapporteur: Pierre Demolis, Co-Rapporteur: Luca Pani, PRAC Rapporteur: Claire Ferard, "Update of sections 4.4 and 5.1 of the SmPC to include final results of study ICL670F2201: 'a randomized, open-label, multicentre, two-arm phase II study to evaluate the safety of deferasirox film-coated tablet (FCT) formulation and deferasirox dispersable tablet (DT) formulation in patients with transfusion dependent thalassemia or myelodysplastic syndrome (MDS) at very low, low or intermediate risk requiring chelation therapy due to iron overload' and consequent warnings (in order to fulfil ANX 047). The MAH took the opportunity to update Annex II and the RMP (version 14) are updated accordingly." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Feraccru - iron - EMEA/H/C/002733/II/0002/G MAH: Shield TX (UK) Ltd, Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Adam Przybylkowski"Submission of two final study reports for in vitro studies conducted as part of post-authorisation measures MEA 001 and MEA	The Committee adopted a Request for Supplementary information together with a specific timetable.

002 : - One drug-drug interaction study to investigate drug interactions with Feraccru - One drug-drug interaction study to identify UGT isoenzyme(s) that are responsible for metabolism of ferric maltol. Consequential changes have been made to the RMP to reflect the completion of the studies." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	
Firdapse - amifampridine - EMEA/H/C/001032/II/0043, Orphan MAH: BioMarin Europe Ltd, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, "Update of sections 4.4 and 5.3 of the SmPC respectively in order to delete the statements that amifampridine has not been fully tested in carcinogenicity models and to provide the findings from the carcinogenicity reports required for the completion of SOB 004. The RMP (v.9) is proposed to be updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to request the removal of the requirement to complete carcinogenicity testing in an appropriate model in section E of the Annex II." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Iclusig - ponatinib - EMEA/H/C/002695/II/0032/G, Orphan MAH: Incyte Biosciences UK Ltd, Rapporteur: Greg Markey, PRAC Rapporteur: Rafe Suvarna"Update of sections 4.2, 4.4, 4.8, 5.1 of the SmPC based on data from the ongoing Study AP24534-07-101 with a median duration of follow-up of approximately 48 months for the CP-CML patients and 3.6 months for the advanced phase Ph+ leukemia patients, as well as 48-month follow-up data from the ongoing Study AP24534-10-201 (PACE). The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the SmPC and to align the annexes with the latest QRD template v.10. An updated RMP version 14.1 was provided as part of the application in order to: - include the 48-month follow up data from the phase 2 study (PACE); - address the commitments made in the	The Committee adopted a Request for Supplementary information together with a specific timetable:

framework of the PSUR 4 assessment. In addition, the MAH took the opportunity to update the RMP to include two additional potential risks that have been identified in the post-marketing setting: - posterior reversible encephalopathy syndrome (PRES), for which data were included in the PSUR 5 (PSUSA/00010128/201512); - class effect of hepatitis B reactivation (EPITT ref. No. 18405 - SDA 013 and EMEA/H/C/002695/IA/TBC)." Request for Supplementary Information adopted on 10.11.2016, 21.07.2016.	
Imbruvica - ibrutinib - EMEA/H/C/003791/II/0025, Orphan MAH: Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams, "Update of the SmPC section 4.4 to remove the warning and precaution regarding the effect of Ibrutinib on the QT interval and section 5.1 to provide additional information regarding the pharmacodynamic effect of Ibrutinib on QT/QTc intervals and cardiac electrophysiology. No changes to the Annex III Package Leaflet are proposed." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Imbruvica - ibrutinib - EMEA/H/C/003791/II/0027/G, Orphan MAH: Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams"1. C.I.4 - Update of sections 4.8 in order to include Stevens-Johnson Syndrome (SJS) and Onychoclasis as post-marketing adverse drug reactions (ADRs). In addition the applicant has taken the opportunity to make minor editorial amendments to the SmPC, including an editorial amendment to section 4.8 to mark the existing ADR terms of tumor lysis syndrome (added in variation EMEA/H/C/003791/II/0004), erythema, angioedema, and urticaria (added in variation EMEA/H/C/003791/0008/G) with an "a" referring to the existing ADR table footnote that indicates that they originated from spontaneous post-marketing reports. 2. C.I.4 – Update of section 4.4 to include Hypertension as one of the risk factors for atrial fibrillation/flutter. The Package Leaflet is updated accordingly.	The Committee adopted a Request for Supplementary information together with a specific timetable.

Updated version 6.2 of the RMP has been submitted." Request for Supplementary Information adopted on 10.11.2016.	
Jetrea - ocriplasmin - EMEA/H/C/002381/II/0026 MAH: ThromboGenics NV, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, "Update of sections 4.4, 4.8 and 5.1 of the SmPC to reflect new long-term safety and efficacy data based on the final CSR for study TG-MV-014 in fulfilment of the post-authorisation measure MEA 002. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the annexes, to align the annexes with the latest QRD templates (v9.1 and 10) and to update the contact details of the local representative in Spain in the Package Leaflet. An updated RMP version 7 was included as part of the application." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 13.10.2016, 26.05.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Jevtana - cabazitaxel - EMEA/H/C/002018/II/0034 MAH: Sanofi-Aventis Groupe, Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add information from completed study EFC11785 (Randomized, open-label multicenter study comparing cabazitaxel at 20 mg/m2 and at 25 mg/m2 every 3 weeks in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing regimen). In addition, the MAH is proposing to modify the wording in section 4.1 of the indication from "hormone refractory" to "castration resistant" prostate cancer to reflect current terminology of the disease in the clinical practice. The RMP is updated accordingly and in accordance with the request from the latest PSUR procedure (EMEA/C/H/002018/PSUSA/000476/201506)" Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Kalydeco - ivacaftor - EMEA/H/C/002494/II/0049, Orphan MAH: Vertex Pharmaceuticals (Europe) Ltd., Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Dolores Montero Corominas,	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

"Submission of the final Clinical Study Report (CSR) for Study VX11-770-109 (Study 109) to fulfil the RMP commitment to address the following safety concerns: hepatotoxicity, cataracts, cardiac arrhythmias, use in children between 2 to 5 years old, long-term safety. An updated RMP (v5.1 updated from v4.9) is included in this submission to include the final data from Study 109." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	
Kyprolis - carfilzomib - EMEA/H/C/003790/II/0007/G, Orphan MAH: Amgen Europe B.V., Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Nikica Mirošević Skvrce"Update of sections 4.2 and 5.2 of the SmPC to revise the guidance on use in patients with renal and hepatic impairment with the submission of studies CFZ001 and CFZ002. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make editorial changes to the Product information, which includes a correction of a typographical omission in section 4.4 to specify that levels given are per mL of reconstituted product. The RMP (v.7) has been updated accordingly." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Levetiracetam Hospira - levetiracetam - EMEA/H/C/002783/II/0012 MAH: Hospira UK Limited, Generic, Generic of Keppra, Rapporteur: Juris Pokrotnieks, PRAC Rapporteur: Laurence de Fays, "Update of the section 4.4 and 4.8 of the SmPC to add warnings on acute kidney injury and on blood dyscrasias and to reflect rhabdomyolysis, blood creatine phosphokinase increased, acute kidney injury, encephalopathy as rare adverse drug reactions. The Package Leaflet was updated accordingly. These changes are in line with the PSUSA outcome for the originator product." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Odomzo - sonidegib - EMEA/H/C/002839/II/0005 MAH: Novartis Europharm Ltd, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Julie Williams, "To submit the results from the pivotal	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

registration study CLDE225A2201 and related analyses (correlative analysis of Gli1 data and molecular analysis in tumor material) with the aim to resolve two post-authorisation measures (PAES) listed in the Annex II.D of the Marketing Authorisation. Sections 4.8 and 5.1 of the SmPC and the Annex II are updated accordingly. Also the RMP is updated (version 4.0) to reflect the most recent 30-month data." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 13.10.2016.	
Opdivo - nivolumab - EMEA/H/C/003985/II/0018 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the safety information for toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), myositis, myocarditis and rhabdomyolysis based on findings from routine pharmacovigilance activities. The Package Leaflet is updated accordingly. In addition, the RMP is updated to version 4.5 to reflect this new safety information." Request for Supplementary Information adopted on 10.11.2016, 13.10.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Senshio - ospemifene - EMEA/H/C/002780/II/0012/G MAH: Shionogi Limited, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Julie WilliamsUpdate of section 4.5 of the SmPC in order to add the CYP3A4 in the drug interaction studies as a result of the submission of study E1508I0242. The following post authorisation measure is fulfilled: PAM 8: The Applicant is requested to investigate the CYP induction potential of ospemifene at clinically relevant intestinal concentrations to exclude potential CYP3A4 induction in the intestine. No CYP induction is expected for ospemifene and M-1 at clinically relevant systemic concentrations. -Update of section 5.2 of the SmPC in order to update the elimination section of the SmPC as a result of the submission of study E1508I0242 to fulfil the following post authorisation measures: PAM 13: The applicant committed to evaluate and the conversion of the Z-enantiomer of ospemifene	The Committee adopted a Request for Supplementary information together with a specific timetable.

to its E-enantiomer post marketing. PAM 14: The applicant committed to evaluate the metabolism and excretion of ospemifene and its metabolites using the commercial ospemifene 60 mg under fed conditions in a postauthorization study. -Update of section 5.2 of the SmPC in order to update the distribution section as a result of the submission of study OSP-PF-046-N and OSP-PF-047-N to fulfil the following post authorisation measures: PAM 6: The in vitro plasma protein binding data of M-1 in the non-clinical species will be provided post-authorisation for interspecies comparison between non-clinical species and humans. However the protocol should be adapted; the Applicant is requested to investigate a concentration range, e.g. 50 to 200 ng/mL for M1. PAM 7: The blood-to-plasma ratio data for ospemifene in monkey and rat and the blood-to plasma ratio for M-1 in rat, monkey and human will be provided post-authorisation. However the protocol should be adapted; the Applicant is requested to investigate a concentration range, e.g. 500 to 1200 ng/mL for ospemifene and 50 to 200 ng/mL for M 1. -Update of section 5.2 of the SmPC in order to update the biotransformation section as a result of the submission of study OSP-PF-041-N to fulfil the following post authorisation measure: PAM 9: The Applicant will provide BSEP transporter studies post-marketing. As a consequence, an updated RMP version 1.2 is provided accordingly." Request for Supplementary Information adopted on 10.11.2016.	
Sivextro - tedizolid phosphate - EMEA/H/C/002846/II/0009 MAH: Merck Sharp & Dohme Limited, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Dolores Montero Corominas, "Update of sections 4.4, 4.5 and 5.2 of the SmPC based on the completed Drug-Drug Interaction study MK-1986-004. The Package Leaflet has been updated accordingly. In addition the MAH took the opportunity to implement editorial changes in the annexes and to update the annexes in line with the latest QRD template version 10. The application included a revised RMP version 2.0 thereby removing the missing information for potential risks for drug-drug interactions mediated	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

by CYP3A4, as well as: - Addressing the identified risk for drug-drug interactions mediated via inhibition of Breast Cancer Resistance Protein (BCRP). - Adding updates made to timelines for ongoing and planned studies for long term safety and Asian population experience." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016, 26.05.2016.	
Stivarga - regorafenib - EMEA/H/C/002573/II/0019 MAH: Bayer Pharma AG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "The Marketing authorisation holder (MAH) took the opportunity to update Annex II to remove condition relating to the ceased COAST trial (15983). In addition, section 5.1 of the SmPC has been updated in order to remove the information on KRAS mutation status and regorafenib efficacy." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with the following timetable:
Tagrisso - osimertinib - EMEA/H/C/004124/II/0004 MAH: AstraZeneca AB, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Sabine Straus, "Update of section 5.2 of the SmPC to reflect the results of study 20 which was performed to assess the absolute bioavailability and to evaluate the PK parameters of Tagrisso in plasma following a single oral dose and a radio-labelled intravenous (IV) microdose of[14C] Tagrisso in healthy male subjects. In addition, the MAH took the opportunity to make a minor correction in SmPC section 6.5 and the Package Leaflet, where blister strips have been amended to blisters. Further, the MAH provided an updated RMP version 5.0 as part of the application." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	The Committee adopted a Request for Supplementary information together with the following timetable:
Translarna - ataluren - EMEA/H/C/002720/II/0016/G, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus"Update of section 4.4 to remove precautions for use relating to the co-administration of ataluren with substrates or inducers of UGT1A9 and section 4.5 of the SmPC to remove statements relating to the potential effect	The Committee adopted a Request for Supplementary information together with a specific timetable.

of co-administration of ataluren with inducers or substrates of UGT1A9 and to add results from studies PTC124-GD-026-HV and PTC124-GD-027-HV (MEA 011 and MEA 012). The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes to the SmPC. Moreover, the updated RMP version 4.2 has been submitted." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016, 23.06.2016, 28.04.2016, 28.01.2016.	
Translarna - ataluren - EMEA/H/C/002720/II/0020, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus, "Update of sections 4.4, 4.6, 4.7, 4.8, and 5.1 of the SmPC and Annex II in order to reflect the result from the submitted study TC124-GD-020-DMD object of SOB 001. The Package Leaflet and the RMP are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include some minor editorial changes throughout the Product information." Request for Supplementary Information adopted on 13.10.2016, 21.07.2016, 23.06.2016, 01.04.2016. SAG meeting held on 29.09.2016, 16.06.2016.	See main agenda 9.1.3.
Translarna - ataluren - EMEA/H/C/002720/II/0026, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus, "Update of sections 4.4 and 4.5 of the SmPC to remove the interaction with inhibitors of breast cancer resistant protein (BCRP) based on the results of a drug-drug interaction study of the co-administration of ataluren and inhibitors of BCRP. The package leaflet and the RMP (version 6.2) are updated accordingly." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tysabri - natalizumab - EMEA/H/C/000603/II/0095 MAH: Biogen Idec Ltd, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section sections 4.2, 4.3, 4.8, 5.1 and 5.2 of the SmPC based on	The Committee adopted a Request for Supplementary information together with a specific timetable.

the results of paediatric studies 101MS028 and 101MS328, in accordance with paediatric investigation plan (EMEA-001095-PIP-12). An updated RMP version 21 was provided as part of the application." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016, 23.06.2016.	
Tyverb - lapatinib - EMEA/H/C/000795/II/0048/G MAH: Novartis Europharm Ltd, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga"1) C.I.4 (type II): Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to add a warning on QTc prolongation and update safety information following the submission of study report EGF114271 (A Phase IV placebo controlled single sequence crossover study to evaluate the effect of repeat oral doses of lapatinib on cardiac repolarization in patients with advanced cancer). The Package Leaflet is updated accordingly. 2) C.I.4 (type II): Update of section 4.8 of the SmPC in order to further elaborate on the undesirable effect 'serious cutaneous reactions' based on the review of the Novartis safety database. 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. Moreover, the MAH took the opportunity to update Annex II to delete an Annex II condition which has been fulfilled with procedure ANX. 28.2. The RMP (version 32) is updated accordingly to the scopes presented above and also to introduce template-related changes, study milestones updates, and to upgrade 'food effect' to an important identified risk (from procedure EMEA/H/C/000795/II/0024)." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Vectibix - panitumumab - EMEA/H/C/000741/II/0079 MAH: Amgen Europe B.V., Rapporteur: Robert James Hemmings, PRAC Rapporteur: Julie Williams, "Update of section 4.6 of the SmPC in order to remove the references to the Pregnancy Surveillance Program (PSP) and Lactation Surveillance Programs (LSP). The Package Leaflet is updated accordingly.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

The RMP was also submitted in order to remove references to PSP and LSP. In addition, the Marketing authorisation holder (MAH) took the opportunity to make further administrative updates to the RMP." Opinion adopted on 10.11.2016.	
Vectibix - panitumumab - EMEA/H/C/000741/II/0080 MAH: Amgen Europe B.V., Rapporteur: Robert James Hemmings, PRAC Rapporteur: Julie Williams, "Update of Annex II in order to provide the results of biomarker analyses from the Vectibix clinical programme including Study 20080763 (according to Supplementary Statistical Analysis Plan dated 20 September 2013), Study 20070820 and Study 20060447. The data submitted are in fulfilment of Annex II obligation ANX017. The Risk Management Plan (version 21.0) has been updated accordingly. The requested variation proposed amendments to Annex II and the Risk Management Plan." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Voncento - human coagulation factor VIII / human von willebrand factor - EMEA/H/C/002493/II/0017/G MAH: CSL Behring GmbH, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus"C.I.4 (type II): Update of section 4.8 of the SmPC in order to update the frequencies of undesirable effects to reflect the final clinical study data from study CSLCT-BIO-08-53 in haemophilia A paediatric patients. The Package Leaflet is updated accordingly. The submission of the final CSR CSLCT-BIO-08-53 also leads to changes to the RMP (ver. 6.1) in order update the Company Core Safety Information (CCSI). C.I.11.z (type IB): Submission of a revised RMP in order to remove the commitment to conduct a post-marketing study for haemophilia A patients (CSLCT-BIO-12-78) for Voncento as consequence of new data from study CSLCT-BIO-08-53. In addition, the Marketing authorisation holder (MAH) took the opportunity to combine different strengths in the SmPC and Package Leaflet." Request for Supplementary Information adopted on 10.11.2016, 01.04.2016, 19.11.2015.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Zykadia - ceritinib - EMEA/H/C/003819/II/0006/G	The Committee adopted a Request for Supplementary information together with a

MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Ulla Wändel Liminga“Update of section 4.5 of the SmPC based on the final results of the clinical pharmacology study LDK378A2113 and results of a sub-group evaluating the impact of gastric PH-elevating agents on the steady-state PK, efficacy, and safety of ceritinib in ALK-positive NSCLC patients. The provision of the final CSR for study CLDK378A2113 addresses the post-authorisation measure (PAM) MEA 003. In addition, the MAH is proposing a change to the due date for the provision of the final study report for study CLDK378A2110 (PAM, MEA 001). An updated RMP version 3.0 was included as part of the application.” Request for Supplementary Information adopted on 10.11.2016, 21.07.2016, 26.05.2016.	specific timetable.
WS0926 **Jardiance-EMEA/H/C/002677/WS0926/0017** **Synjardy-EMEA/H/C/003770/WS0926/0016** MAH: Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Dolores Montero Corominas, “Update of sections 4.8 and 5.1 of the SmPC in order to include data from the study 1275.9. In addition, the Worksharing applicant (WSA) took the opportunity to remove optional sentence ‘Medicinal product subject to medical prescription’ from the Labelling. Moreover, the updated RMP version 8.1 (for Jardiance) and version 6.1 (for Synjardy) have been agreed, as part of this procedure. Furthermore, the WSA took the opportunity to bring the Labelling in line with the latest QRD template version 10. In addition, only for Synjardy, the WSA took the opportunity to make a minor editorial correction in section 4.8 of the SmPC in line with the outcome of EMEA/H/C/PSUSA/00010388/201510 procedure.” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS0993 **Adcirca-EMEA/H/C/001021/WS0993/0025** **Cialis-EMEA/H/C/000436/WS0993/0085** MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Concepcion Prieto Yerro, Lead PRAC Rapporteur: Dolores Montero Corominas, “Update of section	The Committee adopted a Request for Supplementary information together with a specific timetable.

4.4 of the SmPC in order to add a new warning on the risk of non-arteritic anterior ischemic optic neuropathy (NAION) based on the final results of study H6D-MC- LVHQ (category 3 study). In addition the Worksharing applicant (WSA) took the opportunity to update the RMP (version 8.0) accordingly." Request for Supplementary Information adopted on 10.11.2016, 15.09.2016.	
WS1031 **ANORO-EMEA/H/C/002751/WS1031/0013** **Laventair-EMEA/H/C/003754/WS1031/0014** MAH: Glaxo Group Ltd, Lead Rapporteur: Nithyanandan Nagercoil, Lead PRAC Rapporteur: Carmela Macchiarulo, "Update of section 4.8 of the SmPC in order to add the adverse reactions "vision blurred", "intraocular pressure increased" and "paradoxical bronchospasm" and to change the frequency of the adverse reaction "glaucoma" from "not known" to "rare". The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) 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. The risk management plan is submitted to reflect the changes proposed for the SmPC and also includes revision requested as part of the outcome of previous PSURs." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **Abilify - aripiprazole -** **EMEA/H/C/000471/II/0122** MAH: Otsuka Pharmaceutical Europe Ltd, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Leonor Chambel, , "Submission of the final Clinical Study Report of non-interventional, non-imposed PASS study 31-13-300 ("ABILIFY® for the Adolescent Bipolar I Mania Indication Tool Effectiveness Evaluation Survey") to fulfil a post-authorisation measure (MEA 068.2); the Annex II has been updated to delete additional risk minimisation measures based on the study results and to delete PASS study 31-13-300 included by	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

mistake during variation IB/112/G. Moreover, the updated RMP version 10 has been submitted as part of this application." Opinion adopted on 10.11.2016.	
PRAC Led **Adempas - riociguat - EMEA/H/C/002737/II/0014, Orphan** MAH: Bayer Pharma AG, PRAC Rapporteur: Julie Williams, , "Submission of a revised RMP in order to add Off-label use in patients with idiopathic pulmonary pneumonia, with or without pulmonary hypertension as an important identified risk." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
PRAC Led **Exjade - deferasirox - EMEA/H/C/000670/II/0050, Orphan** MAH: Novartis Europharm Ltd, Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard, , "Submission of the final study report from the additional pharmacovigilance activity in the RMP (category 3, MEA): study CICL670A2301 "International sentinel site surveillance of patients with transfusional hemosiderosis treated with Exjade in actual practice setting". This submission also serves to comply with Article 46 submission of the Regulation (EC) No 1901/2203 on medicinal products for paediatric use." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Humira - adalimumab - EMEA/H/C/000481/II/0159** MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, , "Submission of study P06-134: "A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of Humira in Subjects with Moderately to Severely Active Crohn's Disease" in fulfilment fo MEA 056.9. The study includes also some paediatric patients and fulfils article 46 paediatric obligations." Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
PRAC Led **Multaq - dronedarone - EMEA/H/C/001043/II/0035** MAH: sanofi-aventis groupe, Rapporteur: Johann	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, , “To update the Risk Management Plan and Annex II.D (Conditions or restrictions with regard to the safe and effective use of the medicinal product) of the Marketing Authorization.” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	
PRAC Led **Nevanac - nepafenac - EMEA/H/C/000818/II/0033** MAH: Alcon Laboratories (UK) Ltd, Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Eva A. Segovia, , “Submission of the final study Report for the Drug Utilisation Study, "Evaluation of the Use of Nepafenac in Selected European Populations" (category 3)-EU PAS register number ENCEPP/SDPP/5278 to quantify and describe off-label use of nepafenac in order to fulfil MEA12. This PAM was requested during EMEA/H/C/818/RMP/011.” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 21.07.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Trobalt - retigabine - EMEA/H/C/001245/II/0045** MAH: Glaxo Group Ltd, PRAC Rapporteur: Doris Stenver, , “Submission of a revised RMP (version 18) in order to remove a postauthorisation study (PASS) RTG116158, an open label study evaluating the effects of ezogabine/retigabine added to existing anti-epileptic drug(s) on urinary voiding function in subjects with partial onset seizures. In addition, routines change have also been introduced.” Request for Supplementary Information adopted on 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
PRAC Led **Victrelis - boceprevir - EMEA/H/C/002332/II/0039** MAH: Merck Sharp & Dohme Limited, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Claire Ferard, , “Submission of the final report for the cat 3 Observational Post-Authorization Safety Study of Victrelis among Chronic Hepatitis C patients (P08518). The updated RMP version 10.1 is agreed.” Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 15.09.2016.	
PRAC Led **Zytiga - abiraterone - EMEA/H/C/002321/II/0045** MAH: Janssen-Cilag International NV, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, “To update the RMP to modify the Planned dates for assessment in the Risk Minimisation Measures for all the Important Identified and Potential Risks as well as the Missing information.” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS0968** **Ebymect-EMEA/H/C/004162/WS0968/0012** **Edistride-EMEA/H/C/004161/WS0968/0009** **Forxiga-EMEA/H/C/002322/WS0968/0028** **Xigduo-EMEA/H/C/002672/WS0968/0023** MAH: AstraZeneca AB, Lead PRAC Rapporteur: Qun-Ying Yue, , “To provide a revised RMP in order to implement the recommendations given in the Article 20 assessment report dated 18th February (EMA/PRAC/50218/2016). The changes introduced are the following: - The inclusion of atypical DKA as an identified Risk. - Upgrade of a DUS from category 4 to 3 'required additional pharmacovigilance activities to address specific safety concerns or to measure effectiveness of risk minimisation measures'. - Addition of a description of an ongoing mechanistic study. This is a short description as it is an ongoing post-doctorate research project and no protocol will be reviewed. - Addition of a description of a DKA epidemiological study assessing the incidence of DKA to the RMP.” Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1005** **Ultibro Breezhaler-EMEA/H/C/002679/WS1005/0013** **Ulunar Breezhaler-EMEA/H/C/003875/WS1005/00**	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

13 **Xoterna Breezhaler-EMEA/H/C/003755/WS1005/0015** MAH: Novartis Europharm Ltd, Lead Rapporteur: Hanne Lomholt Larsen, Lead PRAC Rapporteur: Torbjorn Callreus, , "Update of section 4.8 of the Summary of Product Characteristics (SmPC) to add dysphonia and to bring up to date the list of adverse drug reactions and frequencies following a MAH's comprehensive review of all safety data. Section 4.4 of the SmPC was updated with regards the warning on paradoxical bronchospasm accordingly The Package Leaflet (PL) is updated accordingly. The MAH also took this opportunity to update the Product Information as per the latest QRD template. A new Risk Management Plan (RMP) version (version 2.0) has been submitted. The requested worksharing procedure proposed amendments to the SmPC, Annex II, Labelling and PL and to the Risk Management Plan (RMP)." Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	
PRAC Led **WS1012 IDflu-EMEA/H/C/000966/WS1012/0047 Intanza-EMEA/H/C/000957/WS1012/0050** MAH: Sanofi Pasteur SA, Duplicate, Duplicate of Intanza, Lead Rapporteur: Aranzazu Sancho-Lopez, Lead PRAC Rapporteur: Dolores Montero Corominas, , "Update of the RMP (v 12.0) to include information on the enhanced safety surveillance for NH 2016-2017 flu" Opinion adopted on 10.11.2016. Request for Supplementary Information adopted on 15.09.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

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

WS0984 Azilect-EMEA/H/C/000574/WS0984/0073 Rasagiline ratiopharm-EMEA/H/C/003957/WS0984/0	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

007 MAH: Teva B.V., Lead Rapporteur: Bruno Sepodes Request for Supplementary Information adopted on 27.10.2016.	
WS0985/G **Azilect-EMEA/H/C/000574/WS0985/0074/G** **Rasagiline ratiopharm-EMEA/H/C/003957/WS0985/0008/G** MAH: Teva B.V., Lead Rapporteur: Bruno Sepodes Opinion adopted on 27.10.2016.	Positive Opinion adopted by consensus on 27.10.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1009 **Cervarix-EMEA/H/C/000721/WS1009/0084** **Fendrix-EMEA/H/C/000550/WS1009/0054** MAH: GSK Biologicals SA, Lead Rapporteur: Bart Van der Schueren Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1024 **Humalog-EMEA/H/C/000088/WS1024/0147** **Liprolog-EMEA/H/C/000393/WS1024/0111** MAH: Eli Lilly Nederland B.V., Informed Consent of Humalog, Lead Rapporteur: Robert James Hemmings Request for Supplementary Information adopted on 20.10.2016.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
WS1035/G **Epclusa-EMEA/H/C/004210/WS1035/0002/G** **Harvoni-EMEA/H/C/003850/WS1035/0036/G** **Sovaldi-EMEA/H/C/002798/WS1035/0034/G** MAH: Gilead Sciences International Ltd, Lead Rapporteur: Filip Josephson Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1036 **Helixate NexGen-EMEA/H/C/000276/WS1036/0181** **KOGENATE Bayer-EMEA/H/C/000275/WS1036/0188** MAH: Bayer Pharma AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.11.2016.	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1054 **Humalog-EMEA/H/C/000088/WS1054/014**	Positive Opinion adopted by consensus on 10.11.2016. The Icelandic and Norwegian CHMP

9 **Liprolog-EMEA/H/C/000393/WS1054/0113** MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Robert James Hemmings, “To update sections 1, 2.2, 4.2, 4.4, 5.1, 6.6 of the SmPC with minor amendments, e.g. to change “u/ml” to “units/ml”. The package leaflet and labelling were updated accordingly and minor editorial changes were also included in annex II. In addition a newly formatted user manual for insulin lispro KwikPen 100 units/ml was introduced. The new format aims to present the information related to the operating the pen in a simpler manner and to reduce the repetition of information as compared to the previous version.” Opinion adopted on 10.11.2016.	Members were in agreement with the CHMP recommendation.

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

WS0988/G **Helixate NexGen-EMEA/H/C/000276/WS0988/0176/G** **KOGENATE Bayer-EMEA/H/C/000275/WS0988/0183/G** MAH: Bayer Pharma AG, Duplicate, Duplicate of KOGENATE Bayer, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 15.09.2016. Withdrawal request submitted on 08.11.2016.	The MAH withdrew the procedure on 08.11.2016.

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

B.5.11. Worksharing variations according to Article 20 of Commission Regulation (EC) No 1234/2008 (listing intended submissions of type II variations for CAPs and NAPS with the outcome regarding the Lead Rapporteur)

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

- adalimumab - EMEA/H/C/004319 treatment of rheumatoid arthritis, axial spondyloarthritis, psoriasis, hidradenitis suppurativa (HS), Crohn’s disease, ulcerative colitis and uveitis.
- darunavir - EMEA/H/C/004273 treatment of HIV-1 infection, Generic, Generic of Prezista
- dupilumab - EMEA/H/C/004390

treatment of moderate-to-severe atopic dermatitis	
- umeclidinium - EMEA/H/C/004654 treatment of chronic obstructive pulmonary disease (COPD)	
- 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	
- cenegermin - EMEA/H/C/004209 treatment of neurotrophic keratitis	**Accelerated review**
- ciclosporin - EMEA/H/C/004229 for the treatment of moderate dry eye disease in adults	
- rucaparib - EMEA/H/C/004272, Orphan Applicant: Clovis Oncology UK Ltd, treatment of ovarian cancer	
- tadalafil - EMEA/H/C/004666 Treatment of erectile dysfunction in adult males	
- pegfilgrastim - EMEA/H/C/004413 treatment of neutropenia	

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

Kuvan - sapropterin - EMEA/H/C/000943/X/0047, Orphan MAH: BioMarin International Limited, Rapporteur: Patrick Salmon, , “Extension application to introduce a new pharmaceutical form associated with new strength (100mg and 500 mg powder for oral solution)”	
Tasigna - nilotinib - EMEA/H/C/000798/X/0088/G, Orphan MAH: Novartis Europharm Ltd, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Harald Enzmann, PRAC Rapporteur: Doris Stenver“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 which were 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. As a consequence, sections
An updated RMP version 18.0 was provided as part of the application.
Extension application to add a new strength of 50mg hard capsules. The MAH proposes to merge the SmPCs for the 50 mg and 200 mg strengths."

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

Brilique - ticagrelor -
EMEA/H/C/001241/X/0034
MAH: AstraZeneca AB, Rapporteur: Johann Lodewijk Hillege, "To add new pharmaceutical form (orodispersible tablets 90 mg) to the currently approved presentations for Brilique."
List of Questions adopted on 15.09.2016.

- tivozanib hydrochloride monohydrate -
EMEA/H/C/004131, Orphan
Applicant: EUSA PHARMA, treatment of adult patients with advanced renal cell carcinoma (RCC),
List of Questions adopted on 21.07.2016.

Humira - adalimumab -
EMEA/H/C/000481/X/0157
MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, "Extension application to add a new strength of 80 mg (80 mg/0.8 ml) for adalimumab solution for injection in single-use pre-filled syringe, for subcutaneous injection."
List of Questions adopted on 13.10.2016.

- meningococcal group B vaccine (recombinant, component, adsorbed) -
EMEA/H/C/004051
prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B,
List of Questions adopted on 15.09.2016.

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

Increlex - mecasermin -
EMEA/H/C/000704/S/0041, Orphan
MAH: Ipsen Pharma, Rapporteur: Outi Mäki-Ikola,
PRAC Rapporteur: Kirsti Villikka

Obizur - susoctocog alfa -
EMEA/H/C/002792/S/0006
MAH: Baxalta Innovations GmbH, Rapporteur:

Nithyanandan Nagercoil, PRAC Rapporteur: Brigitte Keller-Stanislawski

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

alli - orlistat - EMEA/H/C/000854/R/0054
MAH: Glaxo Group Ltd, Informed Consent of Xenical, Rapporteur: Greg Markey, Co-Rapporteur: Dimitrios Kouvelas, PRAC Rapporteur: Rafe Suvarna

Atriance - nelarabine - EMEA/H/C/000752/R/0037, Orphan
MAH: Novartis Europharm Ltd, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Torbjorn Callreus

Bretaris Genuair - aclidinium - EMEA/H/C/002706/R/0031
MAH: AstraZeneca AB, Duplicate, Duplicate of Eklira Genuair, Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Piotr Fiedor, PRAC Rapporteur: Julie Williams

Deltyba - delamanid - EMEA/H/C/002552/R/0017, Orphan
MAH: Otsuka Novel Products GmbH, Rapporteur: Greg Markey, PRAC Rapporteur: Rafe Suvarna

Eklira Genuair - aclidinium - EMEA/H/C/002211/R/0031
MAH: AstraZeneca AB, Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Piotr Fiedor, PRAC Rapporteur: Julie Williams

Flebogamma DIF - human normal immunoglobulin - EMEA/H/C/000781/R/0048
MAH: Instituto Grifols, S.A., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Increlex - mecasermin - EMEA/H/C/000704/R/0042, Orphan
MAH: Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka

Jakavi - ruxolitinib - EMEA/H/C/002464/R/0032
MAH: Novartis Europharm Ltd, Rapporteur: Filip Josephson, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Ulla Wändel Liminga

Pixuvri - pixantrone -

EMEA/H/C/002055/R/0034
MAH: CTI Life Sciences Limited, Rapporteur: Greg Markey, PRAC Rapporteur: Rafe Suvarna

Rasilez - aliskiren -
EMEA/H/C/000780/R/0112
MAH: Novartis Europharm Ltd, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Carmela Macchiarulo

Zinforo - ceftaroline fosamil -
EMEA/H/C/002252/R/0031
MAH: AstraZeneca AB, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams

Zoledronic acid medac - zoledronic acid -
EMEA/H/C/002359/R/0018
MAH: medac Gesellschaft fur klinische Spezialpraparate mbH, Generic, Generic of Zometa, Rapporteur: Alar Irs, PRAC Rapporteur: Doris Stenver

Zykadia - ceritinib -
EMEA/H/C/003819/R/0009
MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Ulla Wändel Liminga

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

Faslodex - fulvestrant -
EMEA/H/C/000540/II/0057
MAH: AstraZeneca UK Ltd, Rapporteur: Filip Josephson, Co-Rapporteur: Tuomo Lapveteläinen, PRAC Rapporteur: Ulla Wändel Liminga,
“Extension of Indication to include o include the treatment of postmenopausal women with locally advanced or metastatic breast cancer who have not received prior endocrine therapy for Faslodex. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated in order to update the safety and pharmacodynamics information. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce clarifications in the SmPC.”

Pegasys - peginterferon alfa-2a -
EMEA/H/C/000395/II/0091
MAH: Roche Registration Limited, Rapporteur:

Filip Josephson, PRAC Rapporteur: Qun-Ying Yue, "Extension of Indication to include paediatric patients from 3 to less than 18 years of age with Chronic Hepatitis B in the immune-active phase for Pegasys.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add efficacy and safety information from study YV25718. The Package Leaflet is updated in accordance.
An updated EU RMP (version 8.0) is included in this application."

Sovaldi - sofosbuvir - EMEA/H/C/002798/II/0036

MAH: Gilead Sciences International Ltd, Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Rafe Suvarna, "Extension of indication to add treatment of chronic hepatitis C in adolescents aged 12 to <18 years.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add information on posology, warnings, safety, efficacy and pharmacokinetics.
The Package Leaflet and Risk Management Plan (RMP version 5.0) are updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.
Furthermore, the Product Information is brought in line with the latest QRD template version 10."

Stivarga - regorafenib - EMEA/H/C/002573/II/0020

MAH: Bayer Pharma AG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "Extension of indication of Stivarga to include treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with one systemic therapy.
As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the EU SmPC are updated. The package leaflet and RMP (version 5.0) have been updated accordingly.
Furthermore, the PI is brought in line with the latest QRD template version 10.0."

Victoza - liraglutide - EMEA/H/C/001026/II/0042

MAH: Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, "Extension of Indication to include a new indication/population in Section 4.1 of the SmPC

for Victoza.
As a consequence, sections 4.2, 4.4, 4.7, 4.8, 5.1 and 6.5 of the SmPC are updated to add warnings and update the safety information based on the findings of the LEADER (EX2211-3748) clinical study results, which constitutes the data set for the application. The Package Leaflet and Labelling (sections 17 and 18) are updated in accordance. Updates to the liraglutide RMP based on the LEADER study results are also proposed: RMP Version 27 of was submitted with the application, showing the proposed RMP changes."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Azarga - brinzolamide / timolol - EMEA/H/C/000960/II/0035/G
MAH: Alcon Laboratories (UK) Ltd, Rapporteur: Hanne Lomholt Larsen

Bexsero - meningococcal group B vaccine (rDNA, component, adsorbed) - EMEA/H/C/002333/II/0048
MAH: GSK Vaccines S.r.l, Rapporteur: Kristina Dunder

Biopoin - epoetin theta - EMEA/H/C/001036/II/0036/G
MAH: TEVA GmbH, Rapporteur: Pierre Demolis

Eporatio - epoetin theta - EMEA/H/C/001033/II/0035/G
MAH: ratiopharm GmbH, Rapporteur: Pierre Demolis

Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0093
MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege

Gardasil 9 - human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0013
MAH: Sanofi Pasteur MSD, Rapporteur: Kristina Dunder

HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0033/G
MAH: Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus

Kalydeco - ivacaftor - EMEA/H/C/002494/II/0053/G, Orphan

MAH: Vertex Pharmaceuticals (Europe) Ltd.,
Rapporteur: Concepcion Prieto Yerro

Levemir - insulin detemir -
EMEA/H/C/000528/II/0083
MAH: Novo Nordisk A/S, Rapporteur: Hanne
Lomholt Larsen

Mosquirix - plasmodium falciparum and
hepatitis B vaccine (recombinant,
adjuvanted) - EMEA/H/W/002300/II/0017
MAH: GSK Biologicals SA, Rapporteur: Jan
Mueller-Berghaus

NovoRapid - insulin aspart -
EMEA/H/C/000258/II/0115
MAH: Novo Nordisk A/S, Rapporteur: Kristina
Dunder

Opdivo - nivolumab -
EMEA/H/C/003985/II/0026
MAH: Bristol-Myers Squibb Pharma EEIG,
Rapporteur: Aranzazu Sancho-Lopez

Revestive - teduglutide -
EMEA/H/C/002345/II/0035, Orphan
MAH: Shire Pharmaceuticals Ireland Ltd,
Rapporteur: Sinan B. Sarac

Umbipro (TM) - chlorhexidine -
EMEA/H/W/003799/II/0002/G
MAH: GlaxoSmithKline Trading Services,
Rapporteur: Patrick Salmon

Xofigo - radium-223 -
EMEA/H/C/002653/II/0022/G
MAH: Bayer Pharma AG, Rapporteur: Harald
Enzmann

Zevalin - ibritumomab tiuxetan -
EMEA/H/C/000547/II/0046/G
MAH: Spectrum Pharmaceuticals B.V.,
Rapporteur: Sinan B. Sarac

WS1022/G
Neulasta-EMEA/H/C/000420/WS1022/009
1/G
Ristempa-EMEA/H/C/003910/WS1022/000
8/G
MAH: Amgen Europe B.V., Lead Rapporteur:
Robert James Hemmings

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

Abasaglar - insulin glargine -

EMEA/H/C/002835/II/0010/G

MAH: Eli Lilly Regional Operations GmbH, Rapporteur: Robert James Hemmings“C.I.Z (Type II): Update of section 4.4 and 4.6 of the SmPC of the cartridge presentations (EU/1/44/94/001-4,9) to only recommend the use of cartridges in Lilly reusable pens and to remove the suggestion to withdraw insulin from a syringe.
C.I.2 (Type IB): Update of section 4.2 of the SmPC in order to align the wording on switching from 3000 U/ml to 100 U/ml with the reference product, Lantus.
The Package Leaflet is updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to replace U/ml by units/ml, to amend the details of the Polish affiliate, to correct the image of the KwikPen and to bring the PI in line with the latest QRD template version 10.0.”

Adempas - riociguat -
EMEA/H/C/002737/II/0018/G, Orphan

MAH: Bayer Pharma AG, Rapporteur: Johann Lodewijk Hillege“C.I.13 Submission of the final clinical study report of study 12166: A multicentre, non-randomized, non-blinded, non-controlled study to investigate the impact of multiple doses of riociguat on safety, tolerability, pharmacokinetics and pharmacodynamics in patients with pulmonary hypertension in a 12 week 3 times a day individual dose titration scheme.
C.I.13 Submission of the final clinical study report of study 16097: An open-label phase IIIb study of riociguat in patients with in-operable chronic thromboembolic pulmonary hypertension (CTEPH) or recurrent or persisting pulmonary hypertension after surgical treatment who are not satisfactorily treated and cannot participate in any other CTEPH trial.”

Adempas - riociguat -
EMEA/H/C/002737/II/0019, Orphan

MAH: Bayer Pharma AG, Rapporteur: Johann Lodewijk Hillege, “Update of section 4.5 of the SmPC in order to add information about interactions of riociguat when administered concomitantly with combined oral contraceptives containing levonorgestrel and ethinyl estradiol to healthy female subjects.
In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the Product Information in line with the latest QRD template

version 10.0."

Aerinaze - desloratadine / pseudoephedrine sulphate - EMEA/H/C/000772/II/0033

MAH: Merck Sharp & Dohme Limited, Rapporteur: Koenraad Norga, "Update of sections 4.4 and 4.8 of the SmPC to include information on acute generalised exanthematous pustulosis (AGEP). In addition, the MAH takes the opportunity to correct minor typographical errors in the SmPC and Package Leaflet and to align the annexes with the revised QRD template v10."

Avastin - bevacizumab - EMEA/H/C/000582/II/0093

MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac, "Update of sections 4.2 Posology and method of administration, 4.8 Undesirable effects, 5.1 Pharmacodynamic properties and 5.2 Pharmacokinetic properties of the SmPC in order to include the paediatric results from the HERBY (BO25041) study. Study BO25041 (HERBY) is an open-label, randomized, multicenter, comparator Phase II study of the addition of bevacizumab to adjuvant chemoradiation with temozolomide (TMZ) followed by adjuvant TMZ in pediatric patients from ≥ 3 years to < 18 years of age with newly diagnosed, localized, supratentorial or infratentorial cerebellar or peduncular high-grade glioma.
The package leaflet (PIL) is updated accordingly."

Blincyto - blinatumomab - EMEA/H/C/003731/II/0009, Orphan

MAH: Amgen Europe B.V., Rapporteur: Pierre Demolis, "Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update the safety information with the data from the study 103311. This study is fulfilling the specific obligation for the conditional MA. The SO is removed from annex II. The Package Leaflet is updated accordingly.
The MAH takes this opportunity to amend the format of the preparation instructions to improve clarity. The content is not impacted."

Cerdelga - eliglustat - EMEA/H/C/003724/II/0010, Orphan

MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, , "Update of section 5.1. of the SmPC in order to update the safety and efficacy of eliglustat from studies in the GD1 patient population (studies ENGAGE & EDGE).
In addition, the Marketing authorisation holder

(MAH) took the opportunity to update the list of local representatives in the Package Leaflet for Bulgaria and Romania."

Cinryze - c1-esterase inhibitor, human - EMEA/H/C/001207/II/0048

MAH: Shire Services BVBA, Rapporteur: Jan Mueller-Berghaus, "To replace Unit (U) by International Unit (IU) in labelling for harmonization with the registration dossier Module 3 information"

Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0094

MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update the safety information on paediatric study after its assessment in procedure EMEA/H/C/000370/P46/063. The Package Leaflet is updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for Bulgaria, Romania and France in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.0."

HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0032

MAH: Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.2 and 4.8 of the SmPC in order to add information on infusion site leakage. 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."

Invokana - canagliflozin - EMEA/H/C/002649/II/0026

MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the safety information: the term 'and fatal' is added when describing the Diabetic Ketoacidosis cases that have been reported. The Package Leaflet is updated accordingly: term 'rare but serious, sometimes life-threatening and fatal' is added when describing Diabetic Ketoacidosis.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of

local representatives in the Package Leaflet."

Iressa - gefitinib -
EMEA/H/C/001016/II/0027
MAH: AstraZeneca AB, Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to update information on mechanisms of resistance to Iressa in patients with EGFR mutation positive Non-Small Cell Lung Cancer (NSCLC) as proposed during assessment of LEG 21.
In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce some editorial changes in the SmPC"

Kisplyx - lenvatinib -
EMEA/H/C/004224/II/0001
MAH: Eisai Europe Ltd., Rapporteur: Bart Van der Schueren, "Update of sections 4.2, 4.4 and 4.8 of the SmPC to add warnings on "haemorrhage" and "non-gastrointestinal fistula" in line with what was aproved for Lenvima. The package leaflet is updated accordingly. In addition, the format of the EU authorisation numbers is corrected throughout the product information."

Kuvan - sapropterin -
EMEA/H/C/000943/II/0046, Orphan
MAH: BioMarin International Limited, Rapporteur: Patrick Salmon, "Update of section 4.5 to delete the statement that no interaction studies have been performed and section 5.2 to reflect the relevant results of in vitro pharmacokinetic drug interactions studies BMN162-14-021, 022, 023, BMN162-15-036 and 101.
In addition, the MAH took the opportunity of this procedure to improve the wording of section 4.2 and implement minor administrative changes in the SmPC."

Kyprolis - carfilzomib -
EMEA/H/C/003790/II/0010, Orphan
MAH: Amgen Europe B.V., Rapporteur: Aranzazu Sancho-Lopez, "Update of section 4.5 of the SmPC in order to inform the prescriber that no Drug Drug Interaction (DDI) studies were conducted at the higher dose (56mg/m2)."

M-M-RVAXPRO - measles, mumps and rubella vaccine (live) -
EMEA/H/C/000604/II/0080
MAH: Sanofi Pasteur MSD SNC, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.8 of the

SmPC in order to add acute haemorrhagic oedema of infancy and Henoch-Schönlein purpura with a frequency rare in the tabulated list of adverse reactions. In addition, the MAH took the opportunity to make some editorial changes in the product information."

Mosquirix - plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0015

MAH: GSK Biologicals SA, Rapporteur: Jan Mueller-Berghaus, "The SOH submitted the final study report of study Malaria-066, a non-interventional ancillary study to Malaria-055 to evaluate the genetic polymorphism of the circumsporozoite (CS) protein of P. falciparum found in infants and children who developed clinical malaria in Malaria-055 study or with prevalent parasitaemia at cross-sectional survey. The SOH did not propose any changes to the product information."

NovoThirteen - catridecacog - EMEA/H/C/002284/II/0018

MAH: Novo Nordisk A/S, Rapporteur: Joseph Emmerich, "Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to consolidate the outcome of the clinical development programme (studies F13CD-3720 and F13CD-3835) submitted in procedures P46/014 and P46/016.
Briefly, section 4.4 was updated to reflect that on-demand treatment was used in the extension study F13CD-3720, section 4.8 was updated to reflect the data on number of patients/paediatric patients and exposures, in section 5.1 the bleeding rate was updated, in section 5.2 minor amendments were made to the half-life of NovoThirteen.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update Annex II with minor administrative amendments in line with QRD template 9.1 and Annex III in line with QRD template version 10.0."

Odefsey - emtricitabine / rilpivirine / tenofovir alafenamide - EMEA/H/C/004156/II/0008/G

MAH: Gilead Sciences International Ltd, Rapporteur: Robert James Hemmings"Update of sections 4.8, 5.1 and 5.2 of the SmPC with 48 weeks data from Study GS-US-366-1216 and Study GS-US-366-1160 in fulfilment of MEA 001 and MEA 002 respectively.

Study GS-US-366-1216 is a Phase 3b, Randomized, Double-Blind Switch Study to Evaluate the Safety and Efficacy of Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) Fixed Dose Combination (FDC) in HIV-1 Positive Subjects who are Virologically Suppressed on Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF)
Study GS-US-366-1160 is a Phase 3b, Randomized, Double-Blind Study to Evaluate Switching from a Regimen Consisting of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) FDC in Virologically-Suppressed, HIV-1 Infected Subjects.
The Marketing Authorisation Holder took the opportunity to make minor administrative corrections in the SmPC, Annex II, Labelling and Package Leaflet"

Olysio - simeprevir - EMEA/H/C/002777/II/0027/G

MAH: Janssen-Cilag International NV, Rapporteur: Aranzazu Sancho-Lopez"Update of sections 4.4 and 4.5 of the SmPC in order to update Pharmacokinetics data of drug-drug interactions following the submission of final clinical study reports for phase 2 stuides: TMC435HPC2017 and TMC435HPC3016."

Opdivo - nivolumab - EMEA/H/C/003985/II/0023

MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aranzazu Sancho-Lopez, "Update of sections 4.8 and 5.1 of the SmPC in order to update the safety and pharmacological information with the 24 months data from the completed NSCLC studies CA209017 and CA209057."

Prialt - ziconotide - EMEA/H/C/000551/II/0052

MAH: Eisai Ltd, Rapporteur: Koenraad Norga, "Update of sections 4.4, 4.6 and 4.8 of the SmPC in order to update the safety information following receipt of final PRAC PSUR assessment report (Procedure no.: EMEA/H/C/PSUSA/00003142/201512). The Package Leaflet sections 2 and 4 are updated accordingly."

ProQuad - measles, mumps, rubella and varicella vaccine (live) - EMEA/H/C/000622/II/0114

MAH: Sanofi Pasteur MSD SNC, Rapporteur: Jan Mueller-Berghaus, Procedure Manager: Gaelle Bec, EPL: Manuela Mura, "Update of section 4.8 of the SmPC in order to add acute haemorrhagic oedema of infancy with a frequency rare in the tabulated list of adverse reactions."

Revestive - teduglutide - EMEA/H/C/002345/II/0034, Orphan

MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Sinan B. Sarac, "Submission of the Clinical Study Report of study TED-C10-004 ('A Randomized, Double-blind, Multiple-dose, Placebo controlled, Parallel-group, Single-center Study to Assess the Effects of Teduglutide on Postprandial Gallbladder Motility and Biliary Luminal Diameters in Healthy Volunteers') that was not submitted to the EMA by the previous MAH NPS Pharmaceuticals."

Revestive - teduglutide - EMEA/H/C/002345/II/0036/G, Orphan

MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Sinan B. Sarac"Submission of the 7 non- clinical study reports (study 8248957, 8248958, TED-P10-007, P10-005, XGW00009, V7674M-SHP633 and 19498) that was not submitted to the EMA by the previous MAH NPS Pharmaceuticals."

Sutent - sunitinib - EMEA/H/C/000687/II/0064

MAH: Pfizer Limited, Rapporteur: Daniela Melchiorri, "Update of section 4.1 of the SmPC in order to remove statement 'Experience with SUTENT as first-line treatment is limited (see section 5.1)' based on the final CSR of study A6181202 in fulfilment of MEA 037.2."

Tivicay - dolutegravir - EMEA/H/C/002753/II/0027

MAH: ViiV Healthcare UK Limited, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC for the 50mg film-coated tablets to add the ADRs arthralgia and myalgia with a frequency of uncommon. The Package Leaflet has been updated accordingly. In addition, the MAH has taken the opportunity to make minor corrections in section 5.1 of the SmPC and to update the contact details of the local representative in Norway in the

Package Leaflet."

Travatan - travoprost - EMEA/H/C/000390/II/0053

MAH: Alcon Laboratories (UK) Ltd, Rapporteur: Concepcion Prieto Yerro, "Following the submission of final CSR for study C-01-79 and a review of supporting clinical studies and post-marketing data, update to SmPC section 4.8 is proposed. The package leaflet is updated accordingly.
In addition, MAH took the opportunity to update number of the Spanish representative in the PL."

Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0035

MAH: ViiV Healthcare UK Limited, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC to include Week 48 data from the Phase IIIb clinical study ING117172 (ARIA) to support the use of Triumeq in HIV-infected antiretroviral (ART)-naïve women."

Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0036

MAH: ViiV Healthcare UK Limited, Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC to include Week 24 (primary analysis) and Week 48 data from the Phase IIIb clinical study 201147 (STRIIVING), to support the use of Triumeq in HIV-infected antiretroviral (ART)-experienced adults."

Triumeq - dolutegravir / abacavir / lamivudine - EMEA/H/C/002754/II/0037

MAH: ViiV Healthcare UK Limited, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC to add the ADR myalgia with a frequency of common, and to update the source of observed ADRs with the combination of dolutegravir + abacavir/lamivudine, based on post-marketing experience with dolutegravir."

Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0023

MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, , "Update of section 4.4 of the SmPC in order to update the safety information: the term 'and fatal' is added when describing the Diabetic Ketoacidosis cases that have been reported. The Package Leaflet is updated accordingly: term 'rare but serious, sometimes life-threatening and fatal' is added when

describing Diabetic Ketoacidosis.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet."

Xagrid - anagrelide -
EMEA/H/C/000480/II/0074, Orphan
MAH: Shire Pharmaceutical Contracts Ltd., Rapporteur: Pierre Demolis, "Submission of the final Clinical Study Report of the study SPD422-403, a phase IIIb, randomised, open-label study conducted as a specific obligation to compare the safety, efficacy, and tolerability of anagrelide hydrochloride versus hydroxyurea in high-risk essential thrombocythaemia patients. No changes to the approved product information have been requested as a consequence of this study report."

Xagrid - anagrelide -
EMEA/H/C/000480/II/0075, Orphan
MAH: Shire Pharmaceutical Contracts Ltd., Rapporteur: Pierre Demolis, "Update of sections 4.4, 4.5 and 5.1 of the SmPC in order to change the terminology of myeloproliferative disorders to neoplasms, add text regarding platelet count rebound above baseline following dosage interruption, incorporate a section in drug interactions on Cyp 1A2 inducers and update information on the mode of action. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, correct typographical errors and bring the PI in line with the latest QRD template. No changes were proposed to the RMP."

Xyrem - sodium oxybate -
EMEA/H/C/000593/II/0063/G
MAH: UCB Pharma Ltd., Rapporteur: Bruno Sepodes"Update of section 4.4 to update the warning on neuropsychiatric events and update of section 4.8 to include increased appetite, homicidal ideation, aggression, irritability and dyskinesia as undesirable effects with an unknown frequency. The Package Leaflet is updated accordingly."

WS1041
CONTROLOC
Control-EMEA/H/C/001097/WS1041/0025
PANTOLOC
Control-EMEA/H/C/001100/WS1041/0029

PANTOZOL
Control-EMEA/H/C/001013/WS1041/0027
SOMAC
Control-EMEA/H/C/001098/WS1041/0026
MAH: Takeda GmbH, Lead Rapporteur: Greg Markey, “Update of sections 4.3, 4.4, 4.5, 4.6 and 4.8 of the SmPC to reflect that co-administration with HIV protease inhibitors in contraindicated (not only atazanavir), to include a warning about the reduction of the absorption of vitamin B12, and a warning about the increased risk of bone fractures and hypomagnesemia, to include drug interactions with HIV protease inhibitors in section 4.5 of the SmPC, to include that animal studies have shown excretion of pantoprazole in breast milk, and to include fracture of wrist, hip and spine as undesirable effects with unknown frequency. The package leaflet is updated accordingly.”

WS1055
Ebymect-EMEA/H/C/004162/WS1055/0016
Edistride-EMEA/H/C/004161/WS1055/0012
Forxiga-EMEA/H/C/002322/WS1055/0031
Qtern-EMEA/H/C/004057/WS1055/0004
Xigduo-EMEA/H/C/002672/WS1055/0027
MAH: AstraZeneca AB, Lead Rapporteur: Kristina Dunder, “Update of section 4.8 of the SmPC in order to update the safety information related to rash. The Package Leaflet is updated accordingly. Additional editorial changes were made in sections 5.1, 5.2 of the SmPC to Qtern.”

WS1056
Ebymect-EMEA/H/C/004162/WS1056/0015
Edistride-EMEA/H/C/004161/WS1056/0011
Forxiga-EMEA/H/C/002322/WS1056/0030
Qtern-EMEA/H/C/004057/WS1056/0003
Xigduo-EMEA/H/C/002672/WS1056/0026
MAH: AstraZeneca AB, Lead Rapporteur: Kristina Dunder, “Update of sections 4.5 to add information on the interaction between 1,5-anhydroglucitol assay (monitoring glycaemic control method) and the SGLT2 inhibitors.
In addition, the Worksharing applicant (WSA) 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. Combined SmPCs are introduced in line with the EMA Policy on combined Summaries of Product Characteristics (SmPCs) (EMA/333423/2015).”

WS1062

Descovy-EMEA/H/C/004094/WS1062/0011

Genvoya-EMEA/H/C/004042/WS1062/0023

Odefsey-EMEA/H/C/004156/WS1062/0009

MAH: Gilead Sciences International Ltd, Lead Rapporteur: Robert James Hemmings, “Update of sections 4.8 and 5.1 of the SmPC in order to provide information about Studies GS-US-292-0104 and GS-US- 292-0111.
In addition, the Worksharing applicant (WSA) took the opportunity to make minor administrative corrections to the Product Information of Genvoya, Descovy and Odefsey and linguistic amendments in Slovakian, Swedish, Polish, Latvian, Czech and Portuguese.”

WS1066

Adcirca-EMEA/H/C/001021/WS1066/0026

Cialis-EMEA/H/C/000436/WS1066/0086

MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Concepcion Prieto Yerro, “Update of sections 4.2 and 5.1 of the SmPC in order to reflect the results of study H6D-MC-LVJJ, a randomized, double-blind, placebo-controlled phase 3 trial of tadalafil in the treatment of Duchenne Muscular Dystrophy (DMD), to fulfil Adcirca P46 019.1 and Cialis P46 045.1.”

WS1079

Exviera-EMEA/H/C/003837/WS1079/0023

Viekirax-EMEA/H/C/003839/WS1079/0028

MAH: AbbVie Ltd., Lead Rapporteur: Filip Josephson, “Update of section 4.5 to include information on the drug-drug interaction with mTOR inhibitors sirolimus and everolimus. The Package Leaflet is updated accordingly.”

B.6.10. CHMP-PRAC assessed procedures

Cinqaero - reslizumab - EMEA/H/C/003912/II/0005/G

MAH: Teva Pharmaceuticals Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Brigitte Keller-Stanislawski“Update of section 4.2 of the SmPC in order to include a revised dosing regimen as a result of the new 25mg vial presentation. Consequential B.II.e.5c variation to change the pack size of the finished product and update sections 6.5 and 6.6 of the SmPC.
The Annex II, Package Leaflet, Labelling and Risk

Management Plan v. 2.0 are updated accordingly."

Cometriq - cabozantinib - EMEA/H/C/002640/II/0024, Orphan

MAH: Ipsen Pharma, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "Submission of the final study report of the non-clinical study (XL184-NC-036) to assess the carcinogenicity potential in rat. Update of section 5.3 of the SmPC to reflect the results of this study. In addition, the risk management plan (RMP) is being updated accordingly."

Fampyra - fampridine - EMEA/H/C/002097/II/0036/G

MAH: Biogen Idec Ltd, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus"This is a grouped variation proposing updates:

- to the SmPC sections 4.2, 5.1, Annex II and Package Leaflet based on the clinical study Enhance,

- to the SmPC section 4.6 based on the data from pregnancy registry.

- Further changes to the PI, section 4.2 and 5.2 of the SmPC have been introduced based on the Core Data Sheet (CDS) and PRAC review of the Fampyra PSUR 03.

The RMP (version 11) has been 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.

With this application the MAH requests to switch the marketing authorisation from conditional to standard."

Kalydeco - ivacaftor - EMEA/H/C/002494/II/0054, Orphan

MAH: Vertex Pharmaceuticals (Europe) Ltd., Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Dolores Montero Corominas, "Submission of the final clinical study report (CSR) for Study VX12-770-112 (Study 770-112), to fulfil a Risk Management Plan commitment. Study 112 was a rollover study to evaluate the long-term safety and efficacy of IVA treatment in subjects ≥6 years of age with cystic fibrosis (CF) and a non-G551D mutation in the CFTR gene. The RMP has been amended consequently with final results

of Study 770-112 (ver. 5.4)."

Keytruda - pembrolizumab - EMEA/H/C/003820/II/0018/G

MAH: Merck Sharp & Dohme Limited, Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Sabine Straus, "Update of section 5.1 of the SmPC to reflect the data from the post-authorisation efficacy studies (PAES) in melanoma; studies P001, P002 and P006. Annex II has been revised to reflect that these three final CSRs have been submitted.
An updated RMP version 6.0 was provided as part of the application. The following summarizes the changes to the updated RMP:
•The final analyses were completed for melanoma studies P001/002/006 and removed as PAES commitments from the RMP;
•Melanoma studies P001/002/006 and the validation report for anti-MK-3475 neutralizing antibody assay were included as Completed Pharmacovigilance Activities;
•The MAH proposed the removal of 'Long-term safety' as missing information in the list of ongoing safety concerns."

Lonsurf - trifluridine / tipiracil - EMEA/H/C/003897/II/0002/G

MAH: Les Laboratoires Servier, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Ulla Wändel Liminga"1) C.I.4 (type II) - Update of sections 4.2, 4.4 and 5.2 of the SmPC following availability of the final clinical study report TO-TAS-102-106. This is a study to evaluate the safety, tolerability, and pharmacokinetics of TAS-102 in patients with advanced solid tumours and varying degrees of hepatic impairment (requested in MEA 002). As a consequence of TO-TAS-102-106 study results. The RMP (ver. 5.0) is updated to remove the missing information "Use in patients with moderate to severe hepatic impairment", and to add "Hyperbilirubinaemia in patients with baseline moderate to severe hepatic impairment" as important potential risk.
2) C.I.4 (type II) - Update of sections 4.5 and 5.2 of the SmPC following availability of the results of the in vitro CYP induction study of TPI using the appropriate concentration of TPI (requested in a REC). Section SVII.4 of the RMP is updated accordingly.
3) C.I.4 (type II) - Update of section 4.2 of the SmPC in order to correct inconsistencies in the

dose calculation according to BSA. The package leaflet is updated to add 'interstitial lung disease' in the serious side effects part of section 4.
In addition, the MAH took the opportunity to update Annex IIIA in accordance with the latest QRD template."

Odomzo - sonidegib - EMEA/H/C/002839/II/0007

MAH: Novartis Europharm Ltd, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Julie Williams, "To provide the final study report from the nonclinical Study No. 1070056: A study to perform an evaluation of a subset of tissues from the 6-month rat study using Ki-67 immunohistochemistry and to quantify cell proliferation."

Odomzo - sonidegib - EMEA/H/C/002839/II/0008/G

MAH: Novartis Europharm Ltd, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Julie Williams"C.I.13 (Type II): To provide the final study report from the Clinical Pharmacology Study CLDE225A2120: A relative bioavailability study to evaluate timing of meal relative to dose and fast conditions and effect of light meal (low fat meal), which is a category 3 study in the Odomzo Risk Management Plan (RMP).

C.I.11.z (Type IB): to change the Clinical Study Report due date for a category 3 study in version 5.0 of the EU RMP: The CSR submission date for study X2116 is changed from Q1 2017 to Q4 2018.

C.I.11.z (Type IB): to change the Clinical Study Report due date for a category 3 study in version 5.0 of the EU RMP: The study CLDE225A2404 timelines and the CSR submission date for study CLDE225A2404 are changed from Q4 2024 to Q1 2025."

Opdivo - nivolumab - EMEA/H/C/003985/II/0024

MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 5.1 of the SmPC in order to reflect the final overall survival and response data, including duration of response with longer follow-up, following completion of PAES CA209037 (Randomized, Open-Label, Phase 3 Trial of

nivolumab vs Investigator's Choice in Advanced (Unresectable or Metastatic) Melanoma Patients Progressing Post Anti-CTLA-4 Therapy) and its addendum on predictability of efficacy with biomarkers.
This application fulfils ANX 001 and 003.1. Annex II has been updated accordingly.
RMP version 5.5 has been submitted within this application."

Prolia - denosumab - EMEA/H/C/001120/II/0065

MAH: Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of a revised RMP (version 18) in order to update the following information: "important potential risk of hypercalcemia following treatment discontinuation in patients with growing skeletons to: "important potential risk: hypercalcemia following treatment discontinuation in patients with growing skeletons and the adult population. This RMP update is based on Amgen's updated safety assessment conducted earlier this year. The applicant is also taking this opportunity to request removal of the important potential risk of fracture healing complications as recommended by PRAC rapporteur at the end of Prolia procedure EMEA/H/C/PSUSA/00000954/201509 and also to propose addition of study 20090601 as a category 4 study pharmacovigilance activity."

Tresiba - insulin degludec - EMEA/H/C/002498/II/0024/G

MAH: Novo Nordisk A/S, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue"Grouping of two variations to update sections 4.2 and 5.1 of the SmPC in order to include updated information on the use of Tresiba in terms of transfer from other basal insulin regimens and the effects of Tresiba on hypoglycaemia.

The Package Leaflet and Labelling are proposed to be updated accordingly.

An updated RMP (version 7.0) is being submitted.

The proposed changes reflect the findings from two studies submitted:
NN1250-3995 (SWITCH 1) and NN1250-3998 (SWITCH 2), comparing the safety and efficacy of Tresiba and insulin glargine U-100, mainly to document the hypoglycaemia profile in type 1

diabetes and type 2 diabetes, respectively.

In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0.

Finally, minor changes have been made to the SmPC section 4.2 and the corresponding section of the Package Leaflet to clarify the correct use of Tresiba."

Xadago - safinamide - EMEA/H/C/002396/II/0014

MAH: Zambon SpA, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Almath Spooner, "Submission of study VDD4193 (Safinamide: In Vitro Metabolic Stability in Human Cryopreserved Hepatocytes, by Fatty Acid Amide Hydrolase enzyme (FAAH), Recombinant Human N-Acylethanolamine Acid Amidase (NAAA) and Recombinant Human Acid Ceramidase (ASAHl)) conducted in order to identify specific substances blocking the amidases (inhibitors of amidases) involved in the metabolism of safinamide. The study fulfils the MEA 001.2."

Xgeva - denosumab - EMEA/H/C/002173/II/0051

MAH: Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of a revised Risk Management Plan (RMP) (version 23) in order to update the following information: a newly categorised important potential risk of hypercalcemia following treatment discontinuation in patients other than those with growing skeletons. This RMP update is based on Amgen's updated safety assessment conducted earlier this year. The applicant is also taking the opportunity to include minor changes for correction and/or to add clarification."

Zykadia - ceritinib - EMEA/H/C/003819/II/0010

MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Ulla Wändel Liminga, "Provision of an update for study A2303, listed in SOB004. Sections 4.8 and 5.1 of the SmPC are proposed to be updated to reflect the safety and efficacy findings of the study. The Package Leaflet and Labelling are updated accordingly.

Annex II and the Risk Management Plan are also

proposed to be updated to reflect the potential fulfilment the only outstanding specific obligation and the efficacy and safety results of Study A2303, respectively."

WS1047
Kalydeco-EMEA/H/C/002494/WS1047/0055
Orkambi-EMEA/H/C/003954/WS1047/0016
MAH: Vertex Pharmaceuticals (Europe) Ltd., Lead Rapporteur: Concepcion Prieto Yerro, Lead PRAC Rapporteur: Dolores Montero Corominas, "Submission of final clinical study report (CSR) for Study VX12-770-115 (Study 770-115), an ocular safety study of ivacaftor-treated paediatric patients 11 years of age or younger with Cystic Fibrosis (CF) as a follow up of Kalydeco MEA 023 and Orkambi MEA 004.
The RMPs are being updated accordingly (ver. 5.3 for Kalydeco and ver. 2.6 for Orkambi)."

WS1075
Epclusa-EMEA/H/C/004210/WS1075/0006
Harvoni-EMEA/H/C/003850/WS1075/0043
Sovaldi-EMEA/H/C/002798/WS1075/0037
MAH: Gilead Sciences International Ltd, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Margarida Guimarães, "Submission of the final non-clinical study report PC-334-2035 assessing the potential for a pharmacokinetic interaction via transporter or enzyme based inhibition when sofosbuvir and other Direct Acting Antivirals (DAAs) are used concomitantly with amiodarone
The RMPs (Epclusa – RMP version 1.0, Harvoni – RMP version 2.0, Sovaldi – RMP version 5.0) have been updated accordingly."

B.6.11. PRAC assessed procedures

PRAC Led
Eperzan - albiglutide -
EMEA/H/C/002735/II/0029/G
MAH: GlaxoSmithKline Trading Services, PRAC Rapporteur: Julie Williams, "II: C.I.11.b - Update of the RMP to amend Study 201805 (category 3 study): "Observational Study of the Risk of Common Malignant Neoplasms and Malignant Neoplasms of Special Interest (Thyroid and Pancreatic Cancer) in Subjects Prescribed Albiglutide Compared to Those Prescribed Other Antidiabetic Agents", in order to use a different

database to study the risk of neoplasms in association with albiglutide exposure
II: C.I.11.b – Update of the RMP to add a new category 3 study as an additional pharmacovigilance activity – Study 207351: "Observational Study to Assess Maternal and Fetal Outcomes following exposure to Albiglutide during Pregnancy""

PRAC Led

Humira - adalimumab - EMEA/H/C/000481/II/0162

MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, , "Submission of the final national report for the Swedish biologics registry ARTIS (Anti-Rheumatic Treatment in Sweden) after ending AbbVie's support by end 2015. This fulfils MEA 066.5. No changes to the product information have been proposed."

PRAC Led

Ozurdex - dexamethasone - EMEA/H/C/001140/II/0025

MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, , "In line with the RMP commitment, submission of the final report for the Post-Authorisation Safety Study 206207-025 (A Prospective Observational Study to Evaluate Long-Term Safety in Real-World Clinical Practice.)"

PRAC Led

Revolade - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/II/0039

MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, , "Submission of final report of the Drug Utilization Study REVIEU (CETB115B2406) in fulfilment of MEA 21.1."

PRAC Led

Revolade - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/II/0040

MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, , "Submission of the final data from the nested eltrombopag HCV-TARGET cohort study. An updated RMP version 44.0 has also been submitted."

PRAC Led

Viread - tenofovir disoproxil -
EMEA/H/C/000419/II/0173
MAH: Gilead Sciences International Ltd, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Claire Ferard, , “Submission of final long-term safety and efficacy data (480 weeks) from two completed Phase 3 studies in HBeAg-negative and HBeAg-positive patients with chronic hepatitis B (CHB), Studies GS-US-174-0102 and GS-US-174-0103.”

PRAC Led
WS1059
Prezista-EMEA/H/C/000707/WS1059/0084
Rezolsta-EMEA/H/C/002819/WS1059/0015
MAH: Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, , “Submission of an updated RMP version 3.1 in order to propose the deletion of the cat 3 study TMC114HIV3015 in HIV-1 infected pregnant women and replace the commitment by the assessment of the pharmacokinetics data in HIV-1 pregnant women.”

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

WS1029
M-M-RVAXPRO-EMEA/H/C/000604/WS1029/0078
ProQuad-EMEA/H/C/000622/WS1029/0112
MAH: Sanofi Pasteur MSD SNC, Lead Rapporteur: Jan Mueller-Berghaus

WS1048/G
Infanrix hexa-EMEA/H/C/000296/WS1048/0212/G
MAH: GSK Biologicals SA, Lead Rapporteur: Bart Van der Schueren,

WS1064
Comtess-EMEA/H/C/000170/WS1064/0054
Entacapone Orion-EMEA/H/C/002440/WS1064/0013
MAH: Orion Corporation, Lead Rapporteur: Outi Mäki-Ikola

WS1065

Entresto-EMEA/H/C/004062/WS1065/0010
Neparvis-EMEA/H/C/004343/WS1065/0008
MAH: Novartis Europharm Ltd, Lead Rapporteur: Johann Lodewijk Hillege

WS1071
Hexacima-EMEA/H/C/002702/WS1071/0054
Hexaxim-EMEA/H/W/002495/WS1071/0061
Hexyon-EMEA/H/C/002796/WS1071/0058
MAH: Sanofi Pasteur SA, Lead Rapporteur: Jan Mueller-Berghaus

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

B.7.1. Line listing for Variation Type I and Variation Type II (MMD only) post authorisation procedures from the beginning of the year.

B.7.2. Line listing overview of all applications under the centralised procedure (MMD only). line listing - products - authorised, under evaluation, suspended.xls

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

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

E.1. PMF Certification Dossiers:Annual Update

E.1.1. Variations:

E.1.2. 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):

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

Qualification of Biomarkers:

HTA:

PASS procedure:

G.2. Ongoing procedures

G.3. PRIME

Disclosure of some information related to PRIME cannot be released at present time as these contain commercially confidential information.

G.3.1. List of procedures concluding at 07-10 November 2016 CHMP plenary:

Oncology		
1.	ATMP; Treatment of mesothelioma	The CHMP denied eligibility to PRIME and adopted the critical summary report.
	Critical Limb Ischemia (CLI) in subjects with Diabetes Mellitus (DM)	The CHMP denied eligibility to PRIME and adopted the critical summary report.
	ATMP; Adjunct therapy for Adult Heart Failure patients undergoing CABG at risk of Incomplete revascularization	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Neurology		
	Tics associated with Tourette syndrome	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Psychiatry		
	Allopregnanolone (SAGE-547 Injection); Treatment of Postpartum depression	The CHMP granted eligibility to PRIME and adopted the critical summary report.
Gastroenterology-Hepatology		
	Treatment of patients with non-alcoholic steatohepatitis	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Dermatology		
	Treatment of sytemic sclerosis	The CHMP denied eligibility to PRIME and adopted the critical summary report.

G.3.2. List of procedures starting in October 2016 for December 2016 CHMP adoption of outcomes

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